THE BROOKINGS INSTITUTION

USING COMPARATIVE EFFECTIVENESS RESEARCH TO IMPROVE THE HEALTH OF PRIORITY POPULATIONS

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Welcome and Introductory Remarks:

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Keynote Address:

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PANEL 1: SETTING RESEARCH PRIORITIES THAT IMPROVE CARE FOR VULNERABLE POPULATIONS

Moderator:

MARK MCCLELLAN
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Panelists:

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P R O C E E D I N G S

MS. CLANCY: (in progress) -- from the famous pathologist Rudolph Virchow, who once said that all diseases have two causes: one pathological and the other political.

And since we are now into social networking and all this kind of stuff, my Tweet for my comments would be, "Health care reform game change; chronic illness, disparities now." And that's where I think CER can make a huge difference.

As Mark indicated this is something that is very, very important to our improving quality and reducing disparities. So, it has been something that we have taken very seriously in our opportunities to invest in comparative effectiveness research and also, frankly, as a way to think about our investments in the use of health IT to improve quality and reduce disparities.

Now, every year we get to report to the Congress on how we're doing in terms of disparities in health care. Let me just say there's no shortage of opportunities for improvement. That would be the most positive thing I could say. We report both on quality and access. So for blacks, Asians, and Hispanics, at least two-thirds of measures of quality are not improving. That is to say the gap stayed the same or actually got larger.

For blacks, only about 20 percent of measures of disparities and quality of care improved; not eliminated, but improved. That is to say the gap decreased. For poor people, disparities are improving for almost half of the quality measures, which is good news. This is the first year we've seen this. We started reporting in 2003. And for Asians and American Indians and Alaskan Natives, approximately one-third of disparities in quality improved. I could go on and on. For those of you who love data it's all on our website at

ahrq.gov.

And what we know from a recent study by the Kaiser Family Foundation that I thought was particularly breathtaking, focusing on women's health care, is that at the state level quality and disparities are related but very distinct concepts. So, I've been thinking about it in very much similar ways to the way that Mark framed it for us, two sides of the same coin. If you want to actually have a big impact on quality you go where the opportunity is the largest and so forth. But it's very, very interesting because in there, the Kaiser report, high quality does not guarantee low disparities and vice versa.

So, for example, Massachusetts was among the best states involving the share of women who did not get a mammogram; about 16 percent. But the percentage of women of color without a dental checkup was about 80 percent higher than that of white women. In Oklahoma and I think West Virginia, white women and women of color both experience significant problems with access to care and in terms of quality of care, but the disparities were almost nonexistent. This is not the Everest of our ambitions in terms of reducing and ultimately eliminating disparities. But the overall point is that disparities exist in every state on almost all measures.

So, all of you know this. I know many people in this room and I'm thrilled to see you. How do we create a framework for comparative effectiveness research that captures, analyzes, and actually engages clinicians and their patients in these populations in the use of this research? Well, as Mark said -- and I like those slides, by the way. I might be borrowing those. Ours are much more boring looking. The American Recovery and Reinvestment Act, or ARRA, allocated $1.1 billion for comparative effectiveness research. In fact, at the Brookings conference last year, I do recall, this is just when CER was starting to get a little sensitive. And I remember that Senator Baucus proposed maybe we should just call it "Fred." He didn't care, he could see that the work was important, but anything that

we could do to kind of diffuse some of the concerns. But the focus on priority populations across the $1.1 billion has been very strong and consistent, and as I'm sure my colleague Richard Hodes from NIH would agree.

In fact, we estimate that about half of the $400 million allocated to the Office of the Secretary was invested in either specific research demonstrations or data infrastructure investments that specifically address the needs of priority populations. I know some of you are waiting to hear more about this. You'll be hearing lots and lots of announcements of initiatives funded over the summer, because we worked very, very hard and long to make sure that three pots of money were very tightly coordinated.

Just to give you a flavor for what some of this looks like at AHRQ, we've invested in research on delivery systems because one thing that emerged this past year was broad consensus and agreements that CER is not just about the clinical stuff, but it's also the care delivery intervention, which is a good thing. So, we are investing in research on various aspects of delivery systems and evaluations emphasizing care for priority populations, which includes people who are members of racial and ethnic minorities, but also people with multiple chronic conditions and so forth. We have a specific initiative that you'll hear about in the near future focused on improving care for people with multiple chronic illnesses. So, it's a very broad focus on priority populations.

Now, if you look at chronic illness care, in particular the question is how do we fix this? Now, where we've tended to see more improvements in quality of care, and even some very promising developments in terms of reducing disparities, is in hospitals, right? Now, the good news about hospitals is although they're chaotic, you've got a captive population. You can have campaigns and blast people by e-mail, signs on the wall, and so forth. Once you get outside the hospital walls it gets a lot more challenging in terms of keeping issues important, keeping it in front of people's face, and so forth. But the Internet

and other types of information and communications technology can be very, very helpful in that regard. And yet, we see something of a digital divide. Now, these days the digital divide I think about most of the time is with -- between us: people of my age and the digital natives. But if you actually look at some recent results from PEW, only about a third of people over 65 have used the Internet. About 75 percent of whites have used it compared with 59 percent of blacks. There's also significant differences associated with those -- for those who live in rural areas; presumably some broadband issues, as well as annual income.

So, we've got specific initiatives that we're funding this year designed to at least address the consequences of this divide. One is called iADAPT for Innovative Adaptation and Dissemination of Our Comparative Effectiveness Research Projects. And this will go out to about 25 research teams who are going to come up with and test new ways of presenting this research information. Because if there's one thing we know about CER is the ultimate success of this enterprise will not be judged in terms of peer reviewed publications. That's all important, more better research is really important. The clear guiding intent is that it has an impact on improving patient care. So, I really want to salute the three panels that you've put together here today.

Some of the specific actions I think we can take, and you'll hear about in more detail. One is including data sources for evidence-based studies and diverse populations. A second is following through on the Institute of Medicine's recommendations about collecting data at a fairly detailed level on patients, which I think is terrific. And what's really great news, some communities are starting to do this, right? Cincinnati has got 65 hospital leaders and trainers that they're actually making this part of everyday practice in the hospitals, just as one example. So, that's very, very exciting.

CER has also by ARRA, by AHRQ, and by the intent of the legislation as I

would read it is very participatory. And the intent is that there's broad input from multiple stakeholders. I can speak for AHRQ and say over the past five years we have found that fantastically useful. Newell is here and he's been one of the people who's helped us, but not because everyone's giving us point-to-point recommendations, but because they're having a dialogue with each other. So, I'm very optimistic and hopeful about other's who will be appointed to the new -- to the Board of the new Patient-Centered Outcomes Research Institute.

And one thing I'm incredibly excited about is at the National Institute -- I love saying that -- for Minority Health and Health Disparities where they've made some long standing investments in community based participatory research, the Office of Minority Health on behalf of the Secretary will be making additional supplemental investments. And I'm told that they are just totally overloaded with fantastic applications. That's all I can say about it or I'd have to shoot you all.

So, challenges moving ahead I think is not just to make this aspirational, but to actually create a framework and operational plan moving forward where we're making sure that we're getting input from and collaborating closely with those who live in the worlds where priority populations are served, that we've got that prospective as part of our daily work at all times. Clearly the opportunities are going to be discussed here this morning in terms of expanding infrastructure and capacity. I'm thrilled that we're making some investments that way this year in community health centers.

AHRQ will shortly announce prospective studies with a very strong focus on those populations traditionally underrepresented in research. We're going to continue to need innovative CER methods. And we've got to get a lot smarter faster about how do we get this information to people in such a way that good information is impossible to avoid. So, I know that these are all big passions of Mark and his colleagues at Brookings, as well as

many of my colleagues who will be presenting in the panels.

So, with that, I want to thank you for organizing this today and I know you've got a tight schedule, so I -- everyone's got to go boom. This is working with Mark. Thanks for your attention. (Applause)

MR. McCLELLAN: Carolyn, thank you very much for your remarks to help get us started. We deeply appreciate them. And you can bet that we'll be staying in touch with all of those efforts that are underway in terms of developing a framework and supporting prospective studies with underrepresented populations, overrepresented on improved methods, on effective communication. I know AHRQ is in the process of getting a citizen's forum up and running, too, as yet another way to have effective input. This really is a major priority now for the agencies. So, thank you very much for your leadership and the opportunity to work with you on these efforts.

And in terms of meeting these challenges, let's get right to that. Our first panel is going to be introduced by Richard Hodes, who is the director of the National Institute on Aging and was probably one of the people -- he didn't know it at the time -- that helped me get started on research early in my career through some NIA funding for issues related to comparative effectiveness, actually. Richard has been long involved in taking steps to not only improve the basic science around understanding the illnesses and health of older Americans and their wellbeing in the community, but also practical steps to identify and support effective interventions and their use. So, he's been a long-time leader in issues related to comparative effectiveness and particularly issues related to priority populations including older Americans and people with multiple chronic conditions and people of lower socioeconomic status and racial and ethnic minorities.

Richard, we're very pleased to have you today to introduce our first panel. Thank you.

MR. HODES: Thank you, Mark. As Mark noted, NIA had the privilege of supporting his career and career development until he exhausted, I think, all possible support mechanisms and decided he had to move along much to the benefit of the nation and the world. And I thank Mark for his opening remarks and for the introduction to this panel. The panel members who have come up to join me -- Garth Graham was not able to join us, so Jamila Rashid --

MR. McCLELLAN: Jamila Rashid is going to be here shortly.

MR. HODES: Okay. Lisa Iezzoni, why don't you come up?

MR. McCLELLAN: And Lisa is a professor of medicine at Harvard Medical School and at the Mongan Institute for Health Policy at Massachusetts General Hospital.

MR. HODES: And Nancy Roizen from Rainbow Babies and Children's Hospital. And Mark's request was that we introduce briefly the topics and expand upon them some as noted. These topics were discussed by the group in some teleconferencing and are reflected in revisions in the draft which you have. So I think there's a need to simply summarize them briefly and elaborate a bit, and then we'll give an opportunity for the rest of the panel members to elaborate as well providing most of the opportunity and time, therefore, for discussion.

So, the first and basic recommendation, developing common definitions of priority populations, is, of course, critical. If we're going to address these populations we need to find them. Now, in some cases this seems rather self-evident, the definitions of certain racial, ethnic populations. Those that are defined by age, are rather self-evident. But in other cases we'll see they are not quite so clear, so the spectrum of disabilities and their definitions, and in the cases of chronic diseases and co- or multi-morbidities are going to be particular challenges in identifying populations. They need to be identified so that we can evaluate their current status, the existence of disparities, and then target CER towards them.

The second bullet recommendation, setting research priorities as related to mission of agencies and departments, is clearly important and, again, I'll just elaborate a bit. In some cases the setting of priorities that are targeted at these priority populations will involve, in large part, inclusion to a degree that has not occurred before. That is there may be common interventions, common studies, common analyses that need to include populations which are more or less applicable to priority populations, but where the status and representation of those populations has been less complete in the past and the challenge is to be inclusive.

There will be other cases where because of known or emerging information about disparities among these priority populations, we'll be talking about targeting specific studies and potentially specific initiatives. So, these are two different areas, but both fall under the important categories of accounting for the populations who, as Mark pointed out, can profit -- will profit most by the successful application of CER.

Then in addressing the needs of priority populations it's important to note that the application of research is going to be directed at both patient and population level decisions. This is, I think to the gratification of all of us, a part of the definitions that have prevailed at the level of federal enterprise in CER including under ARRA; that is, it is broad. It's not simply one drug versus another or one device versus another, but it applies to means of analyzing and delivering health care at the population level, at the societal level. So, this is, for many research enterprises, a continuation of the theme that we've already seen, but it will have to continue to include both optimizing of care of the individual and ways in which to deliver the sum or integral of those individual decisions across populations.

Of interest, the notion of value of information analysis, and this is a clear one of importance, but also very challenging. So, some of the metrics that have been applied in the past have been around concepts, termed such things as "burden of illness," so

they have related to the importance and intervention as it addresses the problem at hand. This relates to the frequency of the problem, how many people or individuals are affected, by the severity of the condition as it affects quality of life, as well as financial burden, but importantly, in addition to defining the public health needs and priorities, an important parameter as well is that of scientific opportunity we deal with all the time. So, there will be cases in which there will be needs of high priority, but where scientific opportunities are more elusive or less immediate. And it needs to be emphasized this is not an excuse or rationale for not addressing those problems, but it points to the need for relating CER to basic and translational research. So those areas where the opportunities are still more distant for applying CER, this reflects a need to continue efforts at more basic and translational work and to make sure those are tied to CER. They will not all fall under the definition of CER, but CER will be based upon an intensity of basic research as well.

Gap filling, an important concept. We need to understand those areas which are priorities and of the priorities, which are already being addressed and which are not. And I think the recent exercise we had over the past year stimulated by ARRA, provides some excellent examples of the importance and the challenges and shortcomings of our ability to do this most rationally. So, if one finds the IOM report, which did an outstanding job in a remarkably short time of putting together a list of 100 priorities, they were forced, because of the timing, to do this without the luxury of an opportunity to do a careful portfolio analysis. And, in fact, if they had tried to do the portfolio analysis, speaking for NIH, despite our best and ongoing efforts, it would indeed have been quite difficult to be at a high level of confidence, certain of exactly what is happening. So, to be illustrative of the 100 conditions -- 100 topics that were judged to be the highest priority by IOM, when the National Institutes of Health went through and reviewed its current portfolio before the CER initiative, there were 88 of those 100 which were already being addressed to greater or

lesser degrees.

The approaches we took, I think, is an example of what can occur in response to omnibus or blanket, broad solicitations for CER applications under ARRA. We were able to address not only some of the 88, which are already actively supported by additions, and when then a few months ago we assessed to see what gaps remained, we found that over the 25, that is the top quartile of the IOM 100, there were three areas of research which were not being addressed, and so we're able to issue now a targeted funding opportunity. Had outstanding responses by investigators in those fields and are now in the process of reviewing those. So, we have to be committed to a better understanding of just what research is ongoing and monitoring that in real time. And as we succeed in some areas, continue there, but also make sure that efforts are directed at those initiatives where we are falling behind in terms of success and moving forward. So, gap filling is going to be important, but it's got to be done in the context of improved informatics and analysis of where we're making best efforts.

So, Mark, I hope within time constraints, I thought we'd stop there and move along to give each of the other members of the panel an opportunity to comment briefly and introduce themselves. Jamila, welcome.

MR. McCLELLAN: Jamila, thank you for being here. Jamila, for those of you who don't know her, is the associate director of the Office of Minority Health at HHS, where she oversees research programs. And because of a conflict with Garth Graham, she graciously agreed to be here on short notice. We really appreciate your joining us.

I'd like to start down at the end of the table and just go across the table to follow on Richard's excellent summary of the recommendations, and I'll start with Lisa for her views.

MS. IEZZONI: Okay. I had the brief about people with disabilities. There's

about 54 million Americans currently living with disabilities in the United States. That's about 20 percent of the population. I just want to make the point that disability rates are much higher in some of the vulnerable populations that we're talking about here today. Obviously the elderly, but also racial and ethnic minorities typically have higher rates of disability, especially African Americans and Native Americans have very high rates of disability.

Now, when I used the words "54 million," that's a lot of people. It's obvious that disability is an incredibly diverse concept. It ranges all the way from children with developmental disabilities to elderly people with Alzheimer's disease, to people in middle age with spinal cord injury. In terms of thinking about comparative effective research, the phrase "people with disabilities" really is not an actionable phrase. It really needs to be honed in, focused on, for us to be able to begin to, in a meaningful way, identify where the gaps are for comparative effectiveness research.

Now, another problem for doing research on people with disabilities is that information about disability is typically unavailable in the traditional data sources where people go to look for it for comparative effectiveness research. It may be kind of shocking to hear this, but even medical records may not very extensively document disabilities such as hearing loss, vision loss, if it's not actively being treated by the clinician. The National Center for Health Statistics surveys do collect pretty good information about disability, but the traditional discharge abstracts, the claims that are analyzed by so many investigators to look at service use, do not have any information on disability in them.

People with disabilities can require health care interventions on three levels which require comparative effectiveness research. The first is routine health services that everybody needs such as screening and preventive services, and care for episodic illnesses. The second is care for their underlying disabling condition such as arthritis, which is the leading cause of disability among adults in the United States. The third is care for co-

morbid conditions that occur, for example, people with disabilities can also get breast cancer and colon cancer.

Comparative effectiveness research studies for the first and third types of interventions have been conducted, you know, studies for breast cancer, studies for routine immunizations, but typically people with disabilities are explicitly excluded from the clinical trials that are used to create the scientific evidence base. Therefore, the research evidence may not, in fact, apply to certain people with disabilities.

It's important to note that some disabilities affect people fairly little in terms of their anatomic or physiologic functioning. For example, if somebody is born blind or born deaf, they may not react any differently to breast cancer treatments than other people. But for somebody who had poliomyelitis as a young person, they may, in fact, respond very differently to breast cancer treatments. And so for certain subsets of populations with disabilities, it's important to do specific analyses on them.

Finally, it's important to know, and I'm going to be a little bit political here, that it is important to do studies on interventions that our health care system currently may not pay for because, in fact, those may be the exact kind of interventions that are going to be most likely to improve the quality of life of people with disabilities. For example, the medical necessity provisions of Medicare and many private health insurers refuse payment for services that are viewed as convenience items or that are not actively improving or restoring function. We don't have much comparative effectiveness research on physical or occupational therapy that is meant for just simply maintaining function or preventing its physical declines. Wheelchair technologies with capabilities that are deemed not medically necessary need to have further research on them because, in fact, wheelchair technologies like that can significantly improve the quality of life for people with severe mobility problems.

Finally, home modifications could improve the ability of people with

disabilities to live independently in their communities and to participate independently in their daily lives, but home modifications also are not often paid for and may not be under the kind of purview of comparative effectiveness research because of that.

And so, that's -- my comments are about done, but that's where my focus is this morning, on disability.

MR. McCLELLAN: Lisa, thank you very much for your comments. And now I'd like to turn to Nancy Roizen.

MS. ROIZEN: Eight to one, the return on investing in the families and the education of young, disadvantaged children is 8-to-1. That is the conclusion of the University of Chicago Nobel Prize-winning economist Dr. James Heckman. In studies investing in the families and the education of young disadvantaged children, the return on the investment of $8 -- was $8 for every $1 of investment. This is in his article in the 2009 *Economics and Human Biology*, probably not very many of us read that, and in the 2006 *Science*. But maybe you read the January 2006 article in the *Wall Street Journal* by Dr. Heckman entitled, "Catch 'Em Young." He wrote, "There are many reasons why investing in disadvantaged young children has a high economic return. Early interventions for disadvantaged children promote schooling, raise the quality of the workforce, enhance the productivity of schools, reduce crime, teenage pregnancy, and welfare dependency. They raise earnings and promote social attachments." Or as he goes on to demonstrate, "The benefit/cost ratio is 8-to-1."

So, why are only 20 of the IOM's selected research priorities for CER related to pediatrics with maybe 25 more related to adults and children? But how many will actually go to children?

Maybe it's already been done. No, pediatric effectiveness research, even research in choosing the best intervention for children identified with a hearing loss at birth,

hasn't had much funding, which actually happens to be topic number one on our list. Actually, this is a perfect topic. Thanks to the 1998 work of Christie Yoshinaga-Itano, we know that if we intervened with amplification and education by six months of age, we take advantage of the sensitive period of brain development and these children will have language in the typical range instead of half their age. But we do not know what is the best intervention for each child, so I would give a big vote for number one.

Maybe children are not a priority group or a big enough group. Hardly. Twenty-four percent of Americans are children. Forty-three percent of children represent racial and ethnic minorities where there are huge shocking disparities in health and health care of children as described in the *Pediatrics* article in March 2010, with higher mortality from drowning, leukemia, congenital heart disease. And if you have Down's syndrome, you die 25 years earlier if you're a minority than if you're white. And 17 percent of children have a disability. They also have chronic diseases, so they represent four of the priority groups.

So, will children, where you get your biggest bang for your buck, get their due? Were they well represented on the 23-member IOM committee? I don't think so. Only 1 of the 17 physician members on the committee was a pediatrician. Thus the message that I mean to relay to you is, one, studies lumping adults and children cannot concentrate on the period zero to two years of age when the brain depends on early experiences to develop incredibly important sensory and language pathways or synapses that we then spend the rest of our life pruning away, or the zero to five period when Dr. Heckman has told us that the returns are great. This class, children, need to be considered separately so we can get the data, like what Lisa has said, that can make these disadvantaged kids taxpayers.

Two, there currently exists very limited clinical effectiveness research in children, but we should fix this problem and not perpetuate it. We need to fund clinical effectiveness research and the best and the brightest will come and do the work. And the

topics on clinical interventions, like topic number 10, which starts in the prenatal period, have the enormous potential to benefit society.

And three, if we start by making children, who are 24 percent of the population, a truly top priority and give them a disproportionate share, one, we can capture the minority priority group as 43 percent of children are minorities; two, we can capture the disability group as 17 percent of children have a disability; and three, we can change their trajectory so that as adults they can live better, have better health and education, have better occupational outcomes, and make our society more globally competitive with the Heckman 8-to-1 return on investment and help these kids be taxpayers.

MR. McCLELLAN: Thank you very much, Nancy. Clearly, you know a lot about the issue and feel very passionately about it.

And I'd like to turn to our next panelist who also has a long-time commitment to leadership on issues related to comparative effectiveness for vulnerable populations, and that's Jamila Rashid. And again, appreciate your stepping in on short notice, Jamila.

MS. RASHID: Good morning. Yes, very short notice as of yesterday evening. So, please bear with me if I ramble a bit, but I want to just say that you're going to hear a common theme here across my two previous speakers and myself, and there is a link as well between racial and ethnic disparities and disabilities as well as with children.

So, I just want to highlight a few things. One, I think it's not a mystery to most of you if not all of you that the racial and ethnic minority population is growing steadily and by 2050, it could likely be as high as 50 percent. And that sends a message to all of us that as we develop these initiatives and programs that we have to more and more take into consideration the special needs of these populations so that we can better assure that what we're doing will have a greater impact, because it impacts on the lives of all of us.

I think it's no mystery to many that racial and ethnic minorities are not only impacted by the fact that they are minority groups, but they also are impacted by many social determinants of health, many things that keep them from having the same equity in health that other populations have: poverty, low education, poor housing, environmental constraints, neighborhoods that are not adequately -- do not have the adequate infrastructure to meet their health needs, and so on. And these factors play a role in how and whether CER will actually work in these populations, and we have to take that into consideration.

In the Office of Minority Health we are working on CER. And we have looked at the IOM recommendations and we've identified those that we feel that we can use to make a difference in the lives and health of the populations that we serve. However, there are others that as we begin to work on this we're going to have to go back and try and see how do we address some of the other concerns and needs.

One of the issues that was raised earlier about persons with disabilities is also for racial and ethnic minorities and that is their lack of adequate inclusion in clinical trials and in research studies. And this was pointed out by the National Medical Association in one of the first -- I believe the first listening session that the council held, and that cannot go unnoticed or lost in the work that we do.

Another point that I want to make is that the need to make sure that we engage the populations because of their special needs, and they differ: American Indians are different from Hispanic-Latino and different from African Americans. And so what might be needed -- and that population could be different or slightly different from what is needed for African Americans. So, within the Office of Minority Health, we're using a full-scale engagement approach to how we do CER. We're also using a professional development approach where you take experts, those who are experts in CER, and involve them with

established academic researchers and community researchers to work together in a collaborative way as opposed to having someone do something to these populations. We want the populations to be a part of that and we think that research -- that should and could possibly be part of CER research -- actually studying how best to get communities and get populations to receive, accept, and use CER rather than just disseminate it and put it out there, but make it usable.

Another key point -- and I don't know if I'm running out of time or not -- I can see far without my glasses, but I can't see far with them.

MR. McCLELLAN: You're okay.

MS. RASHID: Okay -- is that we want to make sure that, as I said, that we provide education. When we start our activities we will spend time doing training, doing education, helping communities to understand what is CER and how will it help them. And then we want them to help us figure out what is the best way to get that information to you. What are the reading levels that you need that information at? How can we use social networking to help you get that information? I think this, in itself, is a body of research that we could better understand what do we know about how often when people receive materials in the mail or on the Internet. It actually impacts on whether they go to the doctor and it results in an acceptance and a change in their behavior around CER-related activities.

You're looking at me now, so I think that's my clue, right?

MR. McCLELLAN: It's okay. If you have anything else important to say, Jamila, please go ahead. I certainly don't want to make you nervous up here with all the beeps and the looks.

MS. RASHID: I'll just wrap up by saying that we know that there are certain health conditions, there are leading causes of health -- we're putting our focus on those within the Office of Minority Health. And we hope that we will be able to show that by

engaging the populations that we want to accept CER in what we do, that that in itself will be research that could be used to inform CER going forward.

MR. McCLELLAN: Jamila, thank you very much and, again, thanks for getting through the beeps and things to be able to participate here this morning.

I'd like to start off the discussion with a couple of follow-up questions on all of your comments and on fleshing out these draft recommendations, and I'd like to start with just the definitions here. The first recommendation in this set focuses on a common definition of priority populations and the implementation of that definition. And you heard from Carolyn that there are some efforts underway now to actually collect data as part of research studies on race, ethnicity, other important characteristics relating to identifying priority populations reliably, but there are a couple of challenges here.

One is that if you look across the different efforts to promote more effective development of evidence for these populations, there are some differences, maybe some would argue they're not huge differences, in what the definitions are. So, the economic stimulus legislation, the recent health care reform legislation, the IOM and OMB have had somewhat different definitions of vulnerable populations. And I'd like to start by asking if, first, any of you all have any comments about whether these issues are settled enough. And for practical purposes, at least, we can move forward clearly on conducting further studies in a way that will be comparable, and that rests on some common foundation of definitions. Or is there more work to do there?

And then second, any promising next steps for actually making sure that these populations can be reliably identified and data on them can be collected in practice, since that seems like a kind of prerequisite for being able to learn something about the affects of the treatments.

Any thoughts? You want to start, Lisa?

MS. IEZZONI: Yeah, sure. It's a huge issue for people with disabilities. First of all, disability is not a static concept. You know, people's functional status can change over time. You know, gender usually doesn't change and, you know, people's self-identified race and ethnicity can change in how people identify it. You know, the Census Bureau showed that when they looked at different ways of collecting information on race and ethnicity over time.

But I think one of the issues for disability is that the typical ways of kind of making data into bits, the International Classification of Diseases, 9th revision, Clinical Modification, ICD-9-CM, which is the classic scheme for classifying diagnoses just simply does not apply to disability. And the World Health Organization, which is the über organization that oversees ICD, has a functional status classification system. It's called the International Classification of Functioning Disability and Health. But for some reason, the United States just has not picked up on it and there certainly are problems with it. I can't say that it's a perfect classification scheme, but although ICD-9-CM codes appear in every discharge abstract, in every claim that's submitted by providers for reimbursement, there are no ICF codes, no functional status codes.

You also have the issue that some people may not want to self-identify their disabilities because they may be afraid of discrimination, they may be afraid of revealing things that they don't want other people to know about them, or, in fact, they may not feel themselves as having a disability even though they may have a condition such as deafness that, you know, may be viewed as a cultural linguistic condition rather than a disability whereas the rest of the world might.

And so I think for disability, maybe we should just say people with disabilities and leave it undefined so it's included as a category. But for operationalizing it and then moving on to make actual decisions about what exact type of research needs to be

done, we need to think both about collecting information and being more specific about the conditions that are included.

MS. ROIZEN: When I think about how are we going to define things, I have a couple of comments. One comment is, it wasn't clear to me where poverty fit in this equation. It seems like it should be in the equation someplace.

Secondly, in relation to disabilities, I agree with everything that Lisa has said. I think you have to break things down into specific disabilities and you have to look at what you're doing specifically about high-impact, low-frequency disabilities such as deafness and high frequency, we'll call it low-impact disabilities such as ADHD. And you need to -- you really need to break them down.

I think in relation to children that the issues are very different when you're a teenager, And the issue is -- what we're trying to look at is suicide or depression; or when you're zero to three and where you, as I have already pointed out, have the opportunity to get much more of an impact for your input, but that there are different ages. And I think the IOM list does identify different ages and it's important in children.

MS. RASHID: Yes. In terms of definition, we could look at groups of categories, you know, by race and ethnicity, by age, gender, geography. There are many different categories that could put someone in a priority grouping for CER, and that would be one way of doing it. Another thought that comes to mind for me is looking at criteria such as need and opportunity. What is the need? Is there a need there for CER to improve health and health care for a particular group of people, and what are those needs that exist? And we may want to look at that. And then is there an opportunity? An opportunity to intervene? An opportunity to identify strategies and ways of disseminating CER, and those sorts of criteria that could also come into play? But I do think there is some value in not necessarily have it drive decisions, but at least it should be examined and explored and taken into

consideration.

MR. HODES: I think consistent with what everyone has said there's certainly an importance to identifying the characteristics of individuals who we currently are assigning to priority populations. But I think even more important than identifying those populations with rubrics or titles or labels now, and using those then to define research in the future, is the establishment of a database, of an evidence base, that will allow what is likely to be a discovery of relevant priority populations and sub populations as we evolve. So, I think the real challenge, Mark, is in the database, be it in health care in general or in research, to identify a common database that will allow an assortment and assignment to groups and populations as research dictates and as needs dictate.

MR. McCLELLAN: And do you see a mechanism for doing that now that the comparative effectiveness research is really starting to take off and there is so much attention to getting the infrastructure right?

MR. HODES: Well, some CER is going to be carried out in randomized clinical trials where there's a great deal of flexibility in identifying what the minimum dataset will be. But a large component, as you alluded to, is going to be -- and as Carolyn mentioned as well -- is going to occur in observational studies, which are going to take huge advantage of health IT and health care reform. So, I think it's part of the -- in those large rubrics is really the place where we need to try to exert influence in establishing a common clinical database that will be accessible for this kind of research.

In addition to identifying populations where it's clear there are special needs, we are going to uncover, undoubtedly, in research cases in which variables of age or disability or race or ethnicity were not suspected to have any relevance, and they will, and we're going to have to redefine groups there.

But if I could just identify one example that occurred over the past few

years, there was a study carried out, supported at NIH, to look at comparative effectiveness for interventions to prevent diabetes in those who are at high risk for diabetes; high risk based on clinical diagnosis, short though of chemical definition of diabetes. The groups were assigned into three treatments: one was placebo; the other was an oral hypoglycemic, a drug; and the third was behavioral intervention.

At the time the study was put together there was a suggestion that because individuals at older age groups were likely to have more co-morbidities, might be harder to recruit, that there wouldn't be any effort to oversample. In fact, they might be restricted to younger adults without concomitant diseases, and that's when there was some advantage to NIH and its heterogeneity. So, the Aging Institute, in collaboration with NIDDK, worked to help assure there was recruitment over a wider age range, including older adults, and the results were not anticipated by any of us.

So, in young adults, oral hypoglycemic and the behavioral intervention, which was exercise and diet, were equally effective in reducing by approximately half the risk of diabetes. This was one of those trials that was stopped early, not because of adverse effects, but because it was deemed to be so positive that it was unethical to continue people in the placebo group.

In contrast, in the age group 65 and older, the drug, the oral hypoglycemic which was effective in young adults, had absolutely no effect. And an even more impressive and, fortunately, positive contrast, the behavioral intervention was more effective in older adults than anywhere else, producing a 71 percent reduction. And this group, by age, was at highest risk for diabetes. I don't think that anyone predicted the result or could have, but it's a point to emphasize what we've heard from all the panelists, the need for people being able to identify groups -- with age, it's relatively easy; with other groups it's going to be more difficult -- and then inclusion. If we don't include individuals in these various heterogeneous

groups, we'll never determine whether one or another intervention is better for a particular group or subgroup.

The extreme of this (inaudible), I'll quickly add, is personalized medicine, when we take full cognizance of the importance subgroups to be careful not to regard them as homogeneous within a group and eventually be able to look at individualization within these priority populations.

MR. McCLELLAN: Thanks, Richard. One more question and then I want all of you to be ready with your questions and comments. We're coming to you next.

This panel has been focusing on priority setting for priority populations and in the comments that you all have already made, in the report, there are a number of ideas for ways to approach the priority setting process that assures that the most important opportunities are directed. That said, I wanted to push you all a little bit further on ways in which the -- specific ways in which the priority setting process could be improved and what -- perhaps what some of those priorities might be. So, as the Patient-Centered Research Institute gets up and running, any one particular piece of advice you'd want to give them about priority setting based on the experiences we've had so far.

So, for example, Jamila talked about the possibility of having a more community-based process for defining priorities with the hope that that would not only make the priorities more relevant to the populations that we're focusing on here, but also help with communication and acceptance and that's something that AHRQ is starting to do now.

And another issue, I can tell you, in the IOM process, there was some discussion about just what was the scope of this health care-related comparative effectiveness research. Was it about traditional medical interventions? Or should it include, as Nancy rightly emphasized, should it include the fact that many of the interventions that make the biggest difference for especially younger children are not what you might think of

as traditional health care, or at least not simple traditional health care? So, a quick idea from each of you on making sure that the priority setting process going forward reflects the kinds of goals that this panel has stated.

MS. IEZZONI: I'm hoping you'll ask me last, Mark, because it's just so hard around disability because the population is so diverse, and Nancy made the compelling case about children who are born deaf, to intervene before six months of life. I mean, how could you argue with that not being a priority and trying to have a priority about how to make that happen?

But then at the other end, I also made the point that we need to emphasize research that might go beyond the boundaries of traditional health care to look at ways to improve quality of life for people with disabilities, looking at, for example, smart homes and technologies that allow people to live more independently in their homes. And so it's just, again, very, very hard for me with the brief of people with disabilities to get too specific because the population is just so diverse, and I'm sorry to wimp out on you that way.

MS. ROIZEN: I think that -- I mean, even though as you clearly have heard, I argue very strongly for children to be a top priority, if not a disproportionate priority. I also argue for balance. I think there needs to be -- everybody needs a chance. And my sort of vision of how you set your priorities is that you have, you know, the high impact and you have low impact and you have high frequency and you have low frequency and you have safety, and then you turn it the other way and you have safety and you have possible benefit. I mean, what possible benefit are we expecting or hoping for? And that we look at it in a multidimensional way and that people have to, when they're -- everything doesn't apply to every situation, but that when people are looking at priorities and applying for these grants that they have to at least address these different aspects, these different dimensions, and it should be sort of multidimensional.

MR. McCLELLAN: And in terms of scope, it sounds like pretty broad as long as there's a significant -- I mean, you're really focusing on the impact on health, right?

MS. IEZZONI: Well, I think quality of life, too. I mean, wouldn't you?

MS. ROIZEN: Quality of life and participation. That was the word that you have used. You know, do you have a job? Are you participating in your community? We have to do better in being competitive as a nation.

MR. McCLELLAN: And things like early education intervention's clearly falling within the scope.

MS. ROIZEN: Yes, absolutely. I mean, you know, the opportunities are just -- the earlier opportunities, the data is so -- the amount of money that you have to put in for later opportunities is a lot more for an effect than earlier opportunities, if you get it right. I mean, you might not -- if you get it right.

MS. RASHID: I worked in the National Immunization Program for about five years at CDC before doing some other things there, and we had some terms we used a lot, one being "low-hanging fruit," and trying to focus on pockets of need. And I think we have some low-hanging fruit within the list of CER priorities, IOM priorities, and then there's some that, of course, may not even be on the list. And so I think there is some value in looking at what are some of those interventions and less important ones on the list that should maybe be brought up to the top because they're opportunities for us to maybe show whether they're effective or not effective.

A lot of resources, for example, by some states and agencies are being used on community health workers, on patient navigators and those sorts of things, and so those are some areas that perhaps we should look at those types of interventions and see whether we should put some time and energy into really -- or raise them up to really tell once and for all, is there value in those or are there only value in them for certain types of

populations? That would be really valuable to this whole country to know that with these types of groups, yes, community health workers are very important and very effective, but with these others, use something else. Then we could better tailor the use of our resources if we understand that. Too often we kind of put that on the back burner because it's not sexy or whatever, it's not as science-based. But they may really -- it may be some real value in understanding once and for all what do we -- what can we get from that, if anything, and who should that be used with.

MR. McCLELLAN: Any further comments?

MR. HODES: I think we've heard excellent comments and I don't want to take any time needlessly repeating them. Just note that another challenge we're going to have is to do a better job of being aware in real time of what research is ongoing. Duplication in some areas can be useful, but I think there are a number of areas where research has been quite inefficient because of absence of realization of what is ongoing, what is being funded. Talk about low-hanging fruit, this is an easy thing we ought to do. We ought to make sure there's a centralized awareness and database of ongoing research studies.

And just know, we've had a fair bit of experience these past years in trying to use priority setting. Can't argue with the fact that public health needs and scientific opportunity are the two basic contributants, but in terms of public health needs, we're going to undoubtedly be facing some difficult decisions which involve rather subjective evaluations. And whether it was qualees or other measures which have been discussed over the years, there have been controversial assumptions that have weighed, for example, the relative value of life and quality of life and years of life at different stages in life. I think we would all like to avoid competition over which age, which condition, is somehow more of higher value than other, but I think there's going to be unavoidable challenges that we face.

MR. McCLELLAN: Good. Excellent comments. Let me ask you all to add to this discussion now. If anyone has a question or comment, please raise your hand. Wait for a microphone, which will be coming to you in the back first, here second. And again, be sure to identify who you are when you ask your question. Thanks.

MR. MILLMAN: I'm Mike Millman from the Health Resources and Services Administration, and I just wanted to mention that we were successful in getting some of the Secretary's $400 million, and I wanted to mention three projects that are incredibly relevant to the topic this morning, two projects and these are projects that are now solicitations out on the street soon to close. Two are in the area of pediatrics: one is focusing on pediatric emergency services and the other is focusing on pediatric office-based practice research systems. And in all of the cases I'm going to mention, the money we got was for infrastructure building, and a big sort of focus of that is going to be how do we use the movement to electronic health records and information exchange to be able to use for comparative effectiveness research.

The third project is I think very unique, and that's -- we're calling Community Health Applied Research Network, and we're going to be funding four research center nodes. These are community health center networks and other community providers that are going to link up with academic affiliates and one of those is going to be in the area of HIV/AIDs.

So, with the disability here -- the way we argued for this was kind of the Willie Sutton approach, you rob banks because that's where the money is. And we argued if you want to address underserved, vulnerable populations, whether you cut it in terms of economics or racial and ethnic minorities, you go to HRSA programs. And so I think we're in the beginnings of this, of trying to take advantage of some of the infrastructure building. We've already started the movement to electronic health records and an effort to try to figure

out how to do comparative effectiveness research, which I think is the other major issue. As we were constantly reminded during the sort of priority setting process, it's not just about doing research or health services research, but figuring how to do comparative effectiveness research which has a lot of methodological and data issues associated with it.

MR. McCLELLAN: Thanks for the comment. Any comments? Definitely appreciate the work on priority setting.

We had a couple up here, Jonathan and one over there.

MS. CARLIN: Hi, I'm Roberta Carlin from the American Association on Health and Disability. And the presentation was excellent, thank you.

I just have one comment that I think reflects the comments of the presenters about setting definitions for priority populations and in the draft document, combining disabilities and multiple chronic conditions, I would recommend that those be separated. They're really very different and as Lisa said and was followed by the other speakers, just defining disability for purpose of CER in research is complicated enough as it is and then to somehow attempt to integrate chronic health conditions I think is doing a disservice to both priority population areas.

So, thank you.

MS. McCLELLAN: Comments? Lisa? Lisa agrees.

MS. IEZZONI: Yeah, I agree with that.

MS. McCLELLAN: And it does get back to a point that Jamila made which is, look, if you take these priority populations together, we're really talking about something approaching a majority of the population. I mean, this is a big part of the overall population, the health opportunities. This is where the money is in terms of opportunities to improve health and have an impact. And that really does suggest a different -- a higher degree of attention to both the definitions and applying the definitions, collecting the data and research,

as Richard said. And, you know, I think that's going to be a pretty big challenge given the scope of the work here.

Do you all think we're up for it?

MS. RASHID: Yes.

MS. IEZZONI: We have to be.

MR. McCLELLAN: All right. I know Jonathan had a comment here.

MR. HARE: Jonathan Hare from Resilient Network Systems. First of all, great presentation. I have a question.

I've looked at a lot of the plan designs and study designs for comparative effectiveness research and it seems like the first step is de-identify the data so we can get the rights to use it. And when you do that, you basically lose the ability to correlate that data with other datasets, things like behavioral background, socioeconomic status, disability status, just about all sorts of stuff. And I look at the definition, you know, what are the definition of the priority populations? How would you query the database and sort of filter out the priority populations if you've eliminated any ability to sort of cross index with other sources? How do you eliminate confounding errors if you can't capture -- you have no ability to capture the data from these other sources?

And on a related topic, how do you then use this intelligence and make it actionable by linking it into care deliver? I think if you were to add up all the money spent on comparative effectiveness research, it's got to be a fraction of 1 percent of overall health care delivery. And if you're not able to integrate it back, once you've de-identified the data, you do some analytics, it's basically impossible to reach back out to the caregivers and the patient, add any value, and get sort of a feedback loop.

So, the question is for Richard and Mark, since Mark knows everything --

MR. McCLELLAN: I'm just the moderator.

MR. HARE: Has there been any progress in sort of a systematic way for capturing data from diverse sources, sort of not irreversibly de-identifying it, using it, and then linking it back into care delivery environments?

MR. McCLELLAN: Well, as the moderator, before putting the rest of the panel a little bit on the spot about this, just a reminder: I mean, those are good questions and we're going to come back to them in our next panel on infrastructure for conducting the research and then for our third panel on using the evidence that's developed, but these are issues that relate to priority setting, too, and they're important challenges and priorities will hopefully find a way to address them.

Any comments?

MS. RASHID: I have an easy comment. We'll send our folks that are going to do that to the next panel and they'll deal with it there, because it is a bit of a challenge.

MR. McCLELLAN: Lisa?

MS. IEZZONI: Yeah, I do have a comment and I'm not sure I'm going to be able to say this crisply, so I apologize, Mark, in advance.

I personally believe that the view of the person with a disability about their functional impairment has inherent validity, but a lot of physicians say, oh, no, that person's too subjective, they can objectively evaluate their disability, and so they insist on having a physician come in and evaluate the functional status of somebody. But, in fact, physicians often see patients at their worst. You know, they're sick, they come into the office because they're feeling poorly. They don't see them when they're out in the community, when they're living their daily life, and so they really do not have a good perception of exactly what the functional status of that person is.

And so I think whatever data systems are created need to be able to include the perspectives of the person with disability about their own functioning. And, in

fact, the small body of research that has looked at this has shown a lot of discordance between physicians and patients in terms of self-rating the patients of their disability and the physician's ratings. And again, as I said, I think patients have an inherent validity there. And so whatever data systems are designed need to maybe include both perspectives, but I think scientists need to increasingly respect that the view of the person with the disability needs to be, at the end of the day, the view that dominates.

MR. McCLELLAN: And indeed, with this greater emphasis on personalization, as Richard was saying, and more reliance on individuals for providing the data, seems like something that could be reflected in the priority setting.

MS. IEZZONI: Yeah, but it's going to require a mindset among our profession, change. Yeah.

MR. McCLELLAN: Richard?

MR. HODES: All good comments. In terms of subject reports, you know, I think there is some progress being made defining the right query instruments that are amenable to data-basing is important and there is some progress. But the basic challenge, I think, is always going to be there: trying to protect the rights to privacy with the value of having extensive information that is ultimately potentially identifiable as a fodder for research. And there would be certainly -- and Mark probably does know better than anybody else from experience here -- but there've been a number of approaches taken that will continue to be needed.

There's the use of enclaves and confidentiality agreement that under highly regulated circumstances allow limited access to data which is potentially identifiable, but with very stringent restriction to access to those data.

There is the format of informed consent, so I think -- you know, Joel will be talking about VA. There are opportunities there for large populations who may choose to

participate with rather global consent. Informed consent is a challenge here, but individuals who are willing to ease, if you will, constraints on personal identifiers in the interest of research, but there's never going to be a way, I think, to avoid the importance of respecting confidentiality in individuals and having the very most informed consent when that is being compromised in any way.

MR. McCLELLAN: And we are going to come back to these important methodologic issues in the later panels and the further work on this effort.

We're just about out of time. I know there are some more questions. I know there's one here and we'll see if we can get through that, and may not get to all of them here, but we'll have more time for discussion in the later panels.

MS. TURK: Thank you. I'm Peggy Turk from SUNY Upstate Medical University in Syracuse, and I'd like to thank the panel for the presentation and starting us off, I think, very nicely.

I have a question in regard to that dirty word called "cost," and that is that people have talked around it, have mentioned it briefly, and yet I am very much aware of issues of cost because of my practice, I'm a physician in physical medicine and rehabilitation in pediatrics. And what we see is that cost of care is really one of those limiting factors. And so it seems to me that that might make your list, Nancy, of what is the high and the low impact, and yet I know we don't talk very much about cost.

Lisa, I think you also mentioned some cost issues as well. But I wonder if the panel might make some comments recognizing of course we're looking for effectiveness of interventions, but would cost have any impact as well?

MR. McCLELLAN: I think cost is an important issue. What do you all think?

MS. IEZZONI: In disability, Peggy, I agree, cost is an important issue, but

it's also cost beyond the patient. It's cost to the families, to the caregivers, to the community. And so if we're going to go around cost for people with disabilities that we need to -- it's like putting the pebble in the pond, we need to look at the ripple effects.

MS. ROIZEN: Once again, I think that it's -- as you say, it's the elephant in the room, so to speak. And I think your comment to low-hanging fruit was a comment to cost. Let's get the easy, quick, cheap things done and I think it has to be in that multidimensional equation. And then we have to consider what is this going to mean for a whole life or a whole society if Suzie gets her cochlear implant and she can be sort of mainstreamed forever, is it worth the cost?

MR. McCLELLAN: It is the elephant in the room, and if it's the elephant in the room, it's better off acknowledging it in the process.

MS. RASHID: I know you're short on time, but I just want to echo Lisa's comments. There are other non-monetary costs that we have to factor in.

MR. McCLELLAN: Very important. And we are short on time. I know there's some more questions. We're going to try to hold them for the upcoming discussion, but right now I'd like to thank our first panel for doing a really good job of getting us started.

THE BROOKINGS INSTITUTION

USING COMPARATIVE EFFECTIVENESS RESEARCH TO IMPROVE THE HEALTH OF PRIORITY POPULATIONS

Washington, D.C.
Thursday, June 3, 2010

PARTICIPANTS:

PANEL 2: EXPANDING INFRASTRUCTURE AND CAPACITY FOR CONDUCTING CER IN PRIORITY POPULATIONS

Moderator:

MARK MCCLELLAN
Director, Engelberg Center for Health Care Reform

Panelists:

JOEL KUPERSMITH
Chief Research and Development Officer
Veterans Health Administration

RUTH BRANNON
Director, Division of Research Sciences, National Institute on Disability and Rehabilitation Research
U.S. Department of Education

NEWELL MCELWEE
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Merck & Co., Inc.

RUTH SHABER
Medical Director
Kaiser Permanente Care Management Institute

PHILIP WANG
Deputy Director
National Institute of Mental Health

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P R O C E E D I N G S

MR. McCLELLAN: And while they're transitioning off, I'm going to go ahead and start encouraging our next speakers to transition on as we get to our second panel. This is a panel on the topic of expanding infrastructure and capacity for conducting comparative effectiveness research in priority populations, and I'm going to introduce all of them as they make their way up to the stage.

The panel's recommendations are going to be presented by Dr. Joel Kupersmith, who's the chief research and development officer of the Veterans Health Administration; has a long background in research and policy related to better evidence generally and comparative effectiveness research in particular. He is going to be accompanied on this panel by Ruth Brannon, the director of the Division of Research Sciences at the National Institute on Disability and Rehabilitation Research in the U.S. Department of Education; and Newell McElwee, who's the executive director of U.S. Outcomes Research at Merck & Co.; and Ruth Shaber -- two Ruths on the panel, to make this interesting -- who's the medical director for Kaiser Permanente Care Management Institute; and Phillip Wong, the deputy deputy director of the National Institute of Mental Health. All of them have again a tremendous amount of experience on comparative factors research, particularly in priority populations.

And Joel, can I turn it over to you?

MR. KUPERSMITH: Okay. Thank you very much. It's very nice to be here among this excellent group of people and all of you. I'm going to review what is on two slides. First a disclaimer. These do not reflect the views, official views, of the Department of Veterans' Affairs or the Veterans Health Administration. And these two slides have the major bullets which I will go through elaborating on each and please consider the slides as a backdrop.

First recommendation, translate priority research questions into data needs and analytic questions. And I think that is a fairly apparent recommendation. I just want to mention, as is in the text, that the Patient-Centered Outcomes Research Institute of the Health Care Reform Bill does deal with this and has in it a translation table with data sources and methods, and these should be addressed in priority populations. That's on page 1632 in case you're interested.

If you look at the third recommendation, address gaps in data, infrastructure for conducting comparative effectiveness research in priority populations. And on this electronic health records and other

medical records as has been said in the first panel should collect data on priority populations and should collect much of the specific data on disabilities, on quality of life, and on all sorts of things that are not being adequately collected now. And these would include disability, certain aspects of aging, functional status, quality of life, social determinance of health and factors that influence it, like housing, food, home situation. And I think very much care giving. I think we have not done anywhere near enough research on care giving. I can tell you that the VA is taking a special interest in this. And these are after all the primary caregivers; we are not. It's the home caregivers who are the primary caregivers, and I think we need to figure out how to do much more research on those. And access to healthy behaviors is another issue.

Now, we have to measure outcomes of use to these priority populations, functional status quality of life and so forth. And if you look in the text of the document that was handed out, the AAA model of the Institute for Health Improvement, which is care, health, and cost. And these data should be aggregated in large databases.

Now, if you look at the second bullet, it has to do with the databases. Critically evaluate existing data sources that could support comparative effectiveness research in priority populations. And this is an aggregate of the medical research data. And we should have searchable inventories. We should have public and private databases. Both claims and clinically rich. And hopefully, we will move much more to clinically rich databases as electronic health records become more prominent. And they should include available data elements. Obviously, it should include how this data can be linked.

Just to say one thing about the identification which was raised in the last panel, this is something of great interest to us and an extremely difficult problem. First of all, it may not be possible to completely de-identify data. Certainly, when you're dealing with something like genetic information it is not possible to completely de-identify it if you include the genetic information. It is possible to de-identify and then have ways of going back and as Dr. Hodes said there are a number of ways that we can deal with the components of it.

But we, I think, are going to have to take perhaps a different view to this in general. And one thing that's interested us lately is looking at statistical de-identification. How likely is it that a particular piece of data will reveal anything about the patient? So these are things to think about. Well, these databases should describe existing cohorts of priority populations. As I said, ability to links, ranks, limitations, and so

forth. There would be indirect estimation methods to reach hard to reach demographics.

Now on the next slide, firstly, improved methods for conducting comparative effectiveness research with internal and external validity in priority populations. And this is in many ways a problem of small sample size. And there are a number of designs that have been approached, although we have nowhere near solved this problem from a research point of view. And if one designs adaptive designs, instrumental variables, sequential and selection design, risk base, allocation designs -- you can Google all of these and figure out what they are. And we need to develop new designs. We have a number of methodologists in the VA that are working on this. Have been working on it for many years. And I think it's an important question.

We need to establish networks of providers and list certain providers, and then we can also deal with designs that are related to cluster randomization, randomization of medical centers, practices, health systems, and so forth.

Okay. On the lower part of the slide you see design programs to increase the number of researchers from vulnerable populations. We have an issue, I think, with clinical research in general. We have not produced enough clinical researchers over the years and it's been discussed in academic medical centers ever since I can remember. But I think now with more money available for clinical research, I think this will change. But still we need to look at loan forgiveness and research career development awards, expanding them, and giving them special purpose. And also, we need to think of the early pipeline in this. We, when we get to the medical school level or in our case even later in the VA, we're too late often to develop many of the people we should be.

And I think a part of this is increasing cultural competency. And if you just -- to take an example, if you think about the epidemic that you've probably heard the most about in the last six months to a year, which is the obesity epidemic -- obesity in African-Americans, obesity in Hispanics, obesity in individuals with disabilities, obesity in the elderly, obesity in poor individuals, obesity in women, and, if it occurs, obesity in multiple kind of conditions -- all have different research questions and different approaches. With African-Americans, Hispanics, Asians, different diets. And in the case of Hispanics, genetic predisposition to diabetes. Healthy choices in the poor may be difficult, and there are metabolic syndromes, for example, in patients with spinal cord injuries. So we have to think of all of that.

Now, I'm going to take a minute to tell you about the VA. Just a few things about what we're doing. We have been doing comparative effectiveness research for 35 years. Now, we gave a conference about 8 months ago where we said we have been doing comparative effectiveness research for 30 years, but things happen in Washington and they move quickly sometimes. We've upped the number.

Our population consists of mainly priority populations: the disabled, poor, minorities, and the elderly. Seventy-six percent, the number -- 88 percent was the NIH number. Our number is 76 percent of the IOM featured 100 most important priority -- 100 priority topics. Seventy-six percent we have done research on over the last five years.

We are an embedded research system and large health care system: 8 million enrollees, 5.5 million visits a year, 1,400 sites of care. We have an electronic health record and we are a practice network on steroids.

The cooperative studies program is the centerpiece, and this includes -- and I just want to mention because I think this is important when you deal with this -- we have a statistical coordinating center, an epidemiology research center, a pharmacy center which, by the way, won the Baldrige Award this year -- only the second government entity ever to do so -- methodology center and economic center. So these are fixed structures and we have a very busy area. So these fixed structures are very busy.

Our proposals can be made by clinicians with no research experience. And then we have a group of experts looking at it to see the feasibility and so forth. And clinical relevance, clinical importance. We have a research career development award and we can use it to develop specific areas that we need, like disparities, like traumatic brain injury and post-traumatic stress disorder which are obviously topics of great interest to us.

We have vehicles for translation, although it's just as difficult in the VA -- maybe not quite just as difficult, but it's difficult to translate these things in the VA. Unless we translate them, they're not going to do us any good.

And just let me make one more comment. And I think this goes in line with a number of comments that were made on the last panel. And that is I think what we're talking about in many ways is a really big change in how we think of research and how we do research. For 30 years under the influence of people like Tom Chalmers many years ago and others, we thought of best research as being randomized

clinical trials of large groups of people, one group versus another. What we're dealing now with is the need to individualize research. Individualize in these priority populations. And it's a personalized medicine that goes beyond genomics. And we have to figure out how to do this. We haven't quite figured it out yet. And I think many of the things, the recommendations here, lead to that. But we have to think of -- if you take an example of a patient with a prosthetic, every individual patient is different.

So how do we do research on that? Our wheelchair center, we do have a center that does research on wheelchairs. Every individual is different, has different needs. So those are the kind of things we have to think of I think in framing this issue.

Thank you.

MR. McCLELLAN: Joel, thanks for those opening comments both in their scope and in terms of framing the challenges ahead for our panel. So I'm looking forward to getting some more answers and directions on this.

And I want to go down the line this way. Ruth, if you don't mind starting.

MS. BRANNON: I don't mind at all. And I want to start out by saying I'm going to do this in two ways: I have a number of observations and then I have recommendations. And some of my observations are more general and some are specific.

First observation has to do with awareness and inclusion. I think despite the 2003 AHRQ policy on the inclusion of priority populations and health services research, there are tremendous gaps. And Dr. Kupersmith just mentioned obesity, so I'm going to use that as an example. There are major initiatives coming out of the CDC on obesity. None of those involve people with disabilities. People with disabilities, particularly young people, and people with functional impairments have major obesity issues leading to significant health disparities.

I think there is sufficient -- insufficient awareness of the overlap of disability and other priority populations. As the 2007 National Health Care Disparities Report indicated, adults with basic and complex activity limitations were significantly more likely than persons with neither limitations to be unable to receive or to experience delay in receiving needed medical care, dental care, or prescription medicine. This is especially true for preventative care.

Individuals with disabilities and disability statuses, ethnic minorities, have significantly worse

health and functional status outcomes compared to individuals with disabilities who are not from ethnic minority populations. And Dr. Clancy actually proved my point. If you remember her presentation, she spoke specifically about ethnicity, gender, age-related disparities. She didn't mention disability. If you layer disability on top of every single one of those categories, the outcomes, the health outcomes are significantly worse. And this data is widely available now, but it's not an integrated dialogue which is really what I think is missing in this discussion.

It can be very difficult to identify individuals with disabilities and administrative datasets since diagnostic codes, as Dr. Iezzoni mentioned, are not necessarily proxies in any way for disability. There needs to be another way of identifying people with disabilities as we talk about creating these large datasets and linking the datasets. For individuals with disabilities doing research in health services or interventions, there's a particular issue of concern and that has to do with the external validity of research designs that target homogeneous populations when disability is not such and people with disabilities, whatever group, I mean, this is not one group. Whatever, however you define disability they're often left out of large-scale studies because the studies are controlling for difference and disability is different and very complex. So those are general observations.

So I have some recommendations. And the first one is not about data. The first one is about people, which is I think we need to fund the efforts to include disability topics and public health training, building on work initiated in particular by the work of the late Dr. Alan Myers from BU because people come out of health programs and they've never heard the word disability. And these people become the architects of the future. And if they don't know about disability, they're going to leave us out.

And the other issue for me and Dr. Iezzoni is a perfect example of this is, you know, she is very prominent in these kinds of settings because of her work and her efforts over the years, but we need to build the next generation of Dr. Iezzoni's and we need to have a lot more of them at the table as comparative effectiveness research is being discussed because they're few and far between. If you're not at the table, you're not part of the discussion of the problem, nor of the solution.

I think that we need to -- there are real issues about measurement and outcomes when you're doing comparative effective research. And I think that one specific thing we can do is support and adopt measures such as those being developed by the AHRQ disability working group to develop a

consensus on measurement of disabilities that would be applicable across multiple national existing data sources; that would allow comparison by race, ethnicity, and income; and that would be sensitive to sample size limitations.

In addition, we need to develop methods to identify disability in these administrative datasets using functional, as well as diagnostic information. One example of an effort in this regard was the CAPS, the consumer assessment of health performance disability module, which was sponsored by my agency, NIDRR, and AHRQ, which was responsible for CAPS. And taking into account that responses to functional questions may be mitigated by use of assistive devices and encourage the adoption of the ICF.

And I think we talked about payment, I've been in many ICF discussions. In the United States, failure to adopt the ICF is largely tied to reimbursement. Nobody pays you for using this functional measure. So we need to work at ways to incentive the government to work on requiring functional assessment if we're really going to look at disability. Because being disabled does not mean that you're unhealthy; it means that you're more vulnerable to health care needs.

I think another issue in doing comparative effectiveness research is we have learned as our agency has moved into more interventions research, that there is a severe limit to measures that could detect differences at the level of specificity required for doing interventions research. And so every step to do interventions research has been accompanied by major outcome measurement development issues. And so I think that's going to be an issue in disability and other outcome measures may or may not be specific to populations of people with disabilities.

We need to invest in knowledge translation efforts and ways to support that because doing the research and not having the funding and the commitment to translate it to practice is going to result in a lot more peer review journals, but not changes in our health care system.

And then I think the final thing I will say is there are a lot of silos in the disability community and research, you know. And the VA doesn't inform research, and the non-VA research at the NAIH may not inform research around the concept of longer term outcomes and return to community. And there have been some recent encouraging examples of change that I think could be models. And the one I'm thinking about in particular has to do with traumatic brain injury, which may end up being the only good thing to come out of the wars that we're in because there's a tremendous influx of funding in traumatic brain injury. And that has

led to cross-VA, cross-DOD, cross-NIH, and cross-NIDRR efforts to combine data, to develop common data elements, to build actually a data system for all of the information on traumatic brain injury treatments, and long-term outcomes are going to be merged and allow for a much broader analysis of outcomes.

So I think -- so I will summarize and say I think -- well, I think the final thing I should say is that in the disability world, and I think in patient care in general, is the end users need to be involved in the determination of relevance. It's been a strong part of the disability and the patient rights movement, but I think as you talk about how we're going to use the information that may come out of these efforts, we need to look at how it's going to be used downstream and by whom. Outcomes for whom? Outcomes for clinicians are one thing, but outcomes for the end users are something else. And those two ideas have been commented on. Dr. Margaret Steinman , who is a brilliant analyst of this has been talking about this for many years. And I think that we need to learn some lessons from that and think about for disability are you talking about that short-term health outcome or the longer return to community, return to participation, return to quality of life outcomes? And who is responsible for that and how far do we track that to get information about the effectiveness of that initial intervention? So.

MR. McCLELLAN: Ruth, thank you. That's covering a lot of ground in those comments. Thank you very much.

Newell?

MR. McELWEE: Well, thank you. It's been a real privilege to work with Brookings on this project. And I have to say I've really been impressed with the process that they've used. This has been sausage making at its best where most of you probably don't really want to know the ingredients that went into this, but it was e-mails in the middle of the night and voice mails and so forth, but they've produced a great document.

So our panel was asked to address expanding infrastructure and capacity for conducting CER in priority populations. And I just want to emphasize just a few points on this. A lot of my comments are based on experiences that I've had recently serving on an Institute of Medicine roundtable on health disparities and inequities. So I'm going to start with the workforce issues which are recommendation 2E in the document. So the IO roundtable has an excellent resource on diversity in the workforce, and it's workshop proceedings from 2003 entitled In the Nation's Compelling Interest. Another great resource in this

area is AAMC, which is an organization that has been tracking diversity among physicians since 1950. So they've got all these great graphs showing, you know, over time the percentage of various ethnic groups that are physicians.

So that's the good news. The bad news is that we know very little about diversity and the disparities in CER research communities. And establishing a baseline for this I think will be important for us to measure our progress. But this is going to be fraught with all sorts of difficulties. So I think we're going to need to do a lot more thinking about how we ensure diversity in the research community as opposed to the provider community.

The IOM report from 2003 also does a great job of addressing ways to get underrepresented minority college students into medical school and other training programs, things like overcoming financial barriers. You've heard a little bit about this already: admissions policies, accreditation programs for things like cultural competency. But that really doesn't address adequately the leaks in the pipeline that occur prior to college. Foundations such as the California Endowment, Gateway, and Stanford University have shown that pipeline programs actually work. The bigger question is whether they're sustainable when the foundation funding goes away. So again, there are no easy solutions to this, but I think it's something that we really need to address.

Should research on priority populations be done in specialized centers or should it be ubiquitous? This has been a change that a lot of people I think have sort of missed. On the IOM roundtable we had -- during all of the health care reform discussions we had Hill staffers come talk to us. And one of our first questions was where is the disparities in the reform legislation? And the answer was it's not specifically called out. It's included in everything that we're doing. So I think as we move forward we have to have both disparities included in everything we do and we have to have specialized centers doing disparities research. But I think that needs to be a more deliberate decision.

I just wanted to make a plug for an IOM workforce diversity workshop that we're planning for the fall. So if you just keep in tune with the IOM website you'll see that. And then finally, just one last comment on the workforce, is that I'm also in the business of hiring people that do research and disparities. And I have two positions open right now. (Laughter) So if any of you know anyone, please see me during the break.

All right. So the next area I want to talk about is gaps in data infrastructure, and this is recommendation 2C. I think many people, including myself prior to my IOM roundtable experience, underestimate the importance of social determinants of health. And you've heard that mentioned a number of times this morning. I think we need more and better research on social determinants, including some of the overlapping factors that have been mentioned already, such as poverty, which seems to be across the board in a lot of these priority populations. So as we build a new HIT infrastructure, it's going to be critical to build these variables into the system.

And I just want to give you two examples of social determinants that will help highlight the importance of this. One is, you know, something that a lot of people that do research on disparities talk about all the time, and that's the importance of geography. And the saying is if you tell me your ZIP code, I can tell you your life expectancy. So if you're a Native American woman living in South Dakota, your life expectancy is in the early 50s. I think it's 52 or something like that. If you're a white woman living in Bergen County, New Jersey, in northern New Jersey, which is where I live, your life expectancy is in the early 90s. I think it's 91. That is an enormous difference.

Another example has to do with -- so just imagine this scenario. So you're an African American that has diabetes and you've just met with your African-American doctor who completely understands the literature and the importance of diabetes self-management and tells you that you have to eat a lot of fruits and vegetables and you have to exercise. And as a patient you believe that this is true, but you live in inner-city Detroit where there are no major grocery stores, there is not a good way to buy fresh fruits and vegetables, and there's not a safe place to exercise. So just two examples of the importance of social determinants.

So finally, and the last point that I want to make just in terms of overall research strategy, I think that we can't lose sight of some of the earlier work that's done by the Office of Minority Health and by John Ruffins' group, who, as you heard this morning, is becoming a national institute, moving from an office to an institute. And they've developed a strategic framework using a model that I was not familiar with called a logic development model. And what they propose is a couple of different buckets of individual factors, environmental and community factors, and systems level factors. And it's this report.

So with that I will (inaudible).

MR. McCLELLAN: Newell, thanks for some comments and for the job positing. (Laughter) We'll move on to Ruth Shaber.

MS. SHABER: Hi, thank you. Thank you very much for including me on the panel. I really want to build on some of the themes that have already come up, but also to offer some, what I hope are practical solutions that we've explored and have a history of using at Kaiser Permanente. I think there are some specific solutions for helping to build infrastructure and increasing capacity that aren't specifically unique to priority populations, but obviously could be used for better understanding priority populations and comparative effectiveness.

As we all know, observational studies have tremendous weaknesses. Even at Kaiser Permanente where we are known for our huge electronic databases that predate our current electronic medical record, there are tremendous problems I doing observational studies. There's coding variations, lack of consistent definitions, there's errors in data entry, especially when you're relying on clinicians to do that data entry. Key data elements that you may really be relying on, such as extent of disabilities or functional status are embedded in text in the electronic medical record and aren't retrievable other than by doing word searches, pathology reports, or imaging reports that are there, but need to be searched in special ways that can't be retrieved for studies.

I think our goal is to learn from care delivery itself in real time as the care is being delivered so it can be fed back to physicians and the delivery system to move from what we've done I think very well in evidence-based medicine to move more towards evidence-based practice. And the elements that are allowing you to do the research need to be embedded in the delivery system in a way that does not inhibit or interfere with care delivery, but actually enhances it. So it's in sync and integrated, not in parallel so that you move from a separate research track which I think is our traditional way of thinking of medical research so that it's embedded in care delivery and part of the system itself.

Two problems that I'd like to consider some solutions for is one, how do you capture that data? How do you make sure that, for instance, the issues that Lisa was bringing up in terms of functional status or presence of disability, how do you embed that in the process of care in real time, embedding patient demographics, patient questionnaires, what medical interventions are done? What are the outcomes you're seeking? The other issue that I think is really important that we address is the collaboration of clinicians. And

in order to be able to capture that data you need shared and common care processes that are agreed upon and owned by the clinicians who are practicing that medicine. Standardized documentations and tools are really essential, and that requires networks and collaborative organizations. At Kaiser Permanente we're fortunate to have those built into our system, but I think there are lots of opportunities otherwise.

I want to give a brief example of how we've -- one example of how we've built this into our processes. We have a total joint registration, for instance, that was created in 2001. We have 350 orthopedists. We do 17,000 joint replacements a year. They wanted to have the opportunity to do post-marketing research on the different implants, being be to compare them, look oat safety, cost, OR time, revision rates, outcomes. They developed within our electronic medical record consistent pre-op, inter-op, post-op data capture systems standardization that allows them to capture the data they want, feed it back to the clinicians in real time. The clinicians are the ones who own that data capture and the results and outcomes so that they are much more likely to modify their practices as they see the results.

We have over 100,000 implants, joints -- individual joint procedures in our database right now and it really has made significant changes to how they deliver orthopedic care. I think there is an infinite number of unanswered clinical questions that could be addressed in similar ways. In my specialty of women's health, pregnancy, pregnant women, reproductive-age women are often not included in randomized clinical trials. There need to be ways that we can look at outcomes and understand different types of care in ways other than randomized clinical trials. The data elements need to be captured proactively and prospectively. As was brought up in the last panel, we don't always know what elements are going to be relevant, so if you have a broad pallet then as things turn up you can go back and search and look for what is relevant to the outcomes you're seeing.

I think clinicians are ready to own this sort of work. That we need to be instructive and embed the research methodology in the clinical practices. We can't expect them to just hit the ground running, but there are great opportunities to do that and I think they're ready.

So that's all.

MR. McCLELLAN: Thanks very much, Ruth. Phil.

MR. WANG: Thanks, and good morning. It's a pleasure to present to you what are largely personal observations collected during my time as a researcher. They don't necessarily represent the

positions of the institute.

I think panel one clearly established both the need for and I think the benefits of conducting CER in priority populations. But as you're hearing from panel two, that's going to take developing some new capabilities. And I can be brief here because I think my colleagues have already covered some of the major ones. I'm just going to try to add a few things to what they've said.

The first are some unique patient samples and data sources that are going to be needed to study priority populations. The real world practice-based networks from which patients are drawn and recruited to conduct CER trials often don't contain sufficient numbers I think as you've heard of people from priority populations. And so the fix here is going to, you know, require essentially existing practice-based networks or any new ones to explicitly go out and recruit practices that have sufficient numbers of patients from priority populations.

Likewise, with prospective data collections, cohorts, some of the registries that you've been hearing about, they have to develop explicitly oversampling schemes that actually draw in sufficient numbers of patients from priority populations so that you can create, you know, essentially conduct studies that give you some kind of reliable or stable estimate about how something is effective or not or safe or not within these subgroups.

And then we've been hearing about the observational studies that are going to, you know, need to take place because trials aren't often possible and that are going to rely on administrative datasets. And you're hearing about some of the weaknesses within these datasets. A fundamental issue is that often these datasets come from health plans. And as a requirement to be in a health plan you have to be employed. But we know people from priority populations are often not in these datasets because of the poverty and disability that come along with being in those populations.

So in this regard it's critical to both develop and exploit administrative datasets from public pairs -- Medicaid, Medicare -- because, again, these are the data sources that often are enriched with priority populations, again, because of the accompanying poverty and disability.

The second large area that my colleagues have been pointing out to are there's unique methodological challenges to conducting CER studies in priority populations. And some of these challenges are going to have to be overcome. One is to run a trial you have to have sufficient recruitment. And it's hard

enough to conduct clinical trials, you know, the general population. It's especially hard for historical reasons often and current, frank mistrust, in priority populations. So, you know, there are methods that, you know, of community engagement, CBPR, that have got to be developed and employed here in order to get sufficient numbers of patients actually in CER trials.

Even with that, you know, there are limits to the time and also the resources that can be invested in actually conducting trials. So some of these observational studies that people have been talking about hare going to be critical, especially for studying how effective interventions are in priority populations. So for that reason these general efforts to increase the validity of clinical epidemiology and quasi-experimental studies and simulation studies. All of these methodologies are going to be particularly critical, I think, for shedding light on the effectiveness of interventions in priority populations. And so they have to be enhanced.

I think the -- just two more things. This issue of how to deal with extensive co-morbidity. Co-morbidity is, you know, these conditions don't come in ones. They come in multiples. And it's not just chronic conditions. There are lots of disadvantages that come along with, you know, having, you know, chronic conditions. And priority populations tend to have a lot of this. A lot of burdens. And our abilities in, you know, particularly observational studies has been alluded to to deal with this heavy morbidity and burdens is not good. We don't know how to assess them accurately. We don't know how to control for them well in studies.

So some concrete suggestions as a former researcher would be -- one is developing more accurate measures that can capture this co-morbidity, these burdens that disadvantage priority populations. The second is for those who are developing interventions to test, developing ones that can handle not just single conditions, again, because that's not what the norm is I think for many priority populations, but interventions that can handle multiple conditions and disadvantages.

The final in this regard is broader outcome measures. We've heard a little bit about how, you know, they're -- certainly just measuring symptoms isn't going to be good enough. You have to, you know, have outcome measures that capture functioning. And ideally they'll be rigorous and allow for comparison or cross groups. And so that's another, I think, specific need here.

The last is, in terms of methodological challenges, panel one I think proposed a very useful

suggestion to use value of information calculations to help set priorities in this area. And that's going to be critical because, you know, resources are constrained. And so tough decisions are going to have to be made. And ideally decisions would be made, you know, rigorously and they'd be also made on the basis of, you know, where are you going to get the most value and impact, you know, for your research. But there's a whole other field that's going to need, you know, enhanced methodology because as you are hearing, I think your comments this morning, what exactly are the inputs that go into this calculation? Is it just prevalence of it? Is it the severity of the disability? Is it the scientific opportunity? How much good could you do with additional resources?

That's even just to, you know, pick the highest value research projects across populations and across conditions. Within conditions and within populations there's a whole bunch of decisions that have to be made, too. Do you go after new intervention targets? Do you develop and test interventions for them? Do you disseminate effective ones? You know, there's a lot of decision-making that's going to have to happen. And the value of information methodology is going to have to be improved to the point where it can actually support some of this decision-making.

MR. McCLELLAN: Phil, thanks very much. And I'd like to thank all the panel for covering a very broad topic in a very substantive way that adds up to what Joel said at the beginning really amounts to a pretty fundamental change in thinking about how to do research in order to have an impact that's relevant and timely on individual care decisions, particularly individuals from these very diverse priority population groups. I think one of the things that I found notable about the work of this part of the effort was its attention to both laying out a big picture vision for where we needed to go in terms of better data at the individual level, including interactions among conditions, better data to support individuals from the community level since those are -- those neighborhood environmental factors are so important, as well as better measures, including a big emphasis on outcomes that are more reflective of quality of life and function and key issues like that that historically haven't been collected all that well in these diverse populations -- so data and measures -- but also some steps on methods or a new vision of methods to get to individualized, accurate, relevant estimates for particular subgroups of patients, subgroups of individuals, subgroups in the population, and people to do this, this path towards pipeline programs and the like. And there's a mixture here of both the broad vision for where we want to get to, but a recognition that that's a big change.

These are a lot of steps. They're not going to be easy to take and may even be hard to do anything like all of them at the same time. And that's why I like this emphasis on some practical, specific steps to help get there.

So this is a comment. I'm not going to ask a question. I do want to open this up to all of you though. But particularly within this broad framework, emphasizing how we can get from here to there in practical steps using the unique opportunities we have right now has been a big focus of this whole panel and one that we hope to build on.

So with that, since there is a lot of material to talk about here, I'd like to just open it up to all of you. So hands up for questions. I have one up here and then over there as well.

MR. GRISS: Bob Griss with the Institute of Social Medicine and Community Health.

I'm impressed with the way CER can be done within systems, whether it's the VA system or the Kaiser Permanente system in seeing what works. But I'm not hearing any attention to the translation mechanisms for systems at the community level. I don't hear much talk about community health planning. I don't see a role for state departments of health in holding communities accountable for equal standards of care. We're talking about protected groups, and we are not using terms like discrimination. And yet there are ways of measuring equal access to quality care that are not being addressed so far in the panel and reports. And I'm wondering if there is any attention to how to create an infrastructure that really ensures that everyone has equal access to quality care. I don't think this is going to happen through the competitive marketplace. That's what 200 years of experience has taught us, but I'm not hearing what infrastructure we're trying to create to counter or mediate these market forces.

MR. McCLELLAN: Well, let me take it back to the research questions. We did have some discussion, as you pointed out, of networks of care like Kaiser, like the VA, and how this kind of systematic approach to focusing on special populations and relevant outcomes can happen there. But as you heard, I mean, that's not most of the country today. So maybe a few extensions of how we can get that same systematic focus.

Newell, you talked a little bit about this and I know the rest of you have some views on this, too.

MR. McELWEE: So this is a really great point. And the IOM roundtable -- it's called the IOM

roundtable on health disparities and inequities, and it's the inequity portion part of that that you were talking about that's really sort of an ethical, social justice issue that needs to be higher priority. So I completely agree with you on that front.

There are efforts in health care reform to start paying for performance. And I think to the extent that we can try to build these sorts of incentives in, not just for quality, but for focus on health disparities and inequities. I think that would be good. But I agree with you. I have not seen that be part of the debate so far.

MR. McCLELLAN: So maybe for further comments on how we can build in some measures that could tie to those kinds of financial incentives to help get there. Ruth? Others?

MS. SHABER: Well, I can -- I'd be curious to know your thoughts on the subject, too. I can tell you from some limited work that at Kaiser Permanente we have a very robust community benefit program because of our nonprofit status. And we have partnerships with what we call our safety net providers in the community that are very robust relationships where we share our learnings. We have some pilot programs that have actually gone beyond pilot programs in cardiovascular disease prevention, for instance, where we have very fluid interaction with our continuing medical education, sharing tools, sharing our thought leaders who come out to the community clinics to help with implementation.

And actually, in one program in particular, we call it our aspirin, lisinopril, and lovastatin project, which is for prevention of cardiovascular disease in patients with diabetes or CAD risk factors. They've done a much better job. Our safety net providers have done a much better job of implementation, having had better medication adherence than our own members.

So I can't say that we do it all the time. We have piloted, and I think that there are many more opportunities to do it and would love to hear your thoughts on it, too.

MR. McCLELLAN: Phil (inaudible).

MR. WANG: Yeah. I think our NIH director, Francis Collins, recently convened a health economics meeting -- summit, if you will -- including many thought leaders. Mark, you were there as well. And I think to kind of try to sum it up, one of the major priorities they focused on for the NIH to kind of -- is to develop I think what you're talking about. It's, you know, health care reform is going to provide this large natural experiment where there's going to be expansion of access. There's going to be attempts to improve

quality. There's going to be demonstration projects. And it's going to be implemented over time. It's not going to happen all at once. And it's going to happen in different areas. And so it provides a kind of natural experiment that could be studied and used to not only do quality assurance and, you know, change what isn't working and hopefully, you know, promote what is, you know, useful and working.

But it's going to take, again, some research infrastructure in order to do so. And it's some of the same research infrastructure I think we're talking about to study priority populations. It has to be capable of getting at subgroups, getting at regions, getting collected over time so you can see how things change after, you know, again this big change that's going to be coming. So same infrastructure; probably the same data needs.

MR. McCLELLAN: Ruth and then Joel.

MS. BRANNON: Yeah. I don't know a lot of the details, but one thing I draw your attention to is the Office on Disability, NHHS just awarded a $6 million contract to basically look at research on disability services, care coordination, and integration, which is in support of Olmstead philosophies, and in specifically looking at the concept of systems of care for individuals with disabilities. And I think that ties in with one of the priorities for CER, which is not just to do research on treatments, but to look a health services delivery, which there hasn't been a huge amount of funding for for quite a long time. So we're picking up where we left off a decade ago to a certain extent.

MR. McCLELLAN: I like that phrase "urban space practice" or "urban place system." It's a good thing to be able to measure and evaluate.

Joel?

MR. KUPERSMITH: Well, first of all, translating research in the VA is no less complicated than it is outside the VA. For many things, regional differences within the VA are the same or similar to regional differences outside the VA. When we take on a topic though we can change things through performance measures, through a variety ways. I think through systems -- very fundamental systems changes. It's not just the physician-patient or the provider-patient interaction, but it's everybody. If you want to increase immunizations, everybody the patient meets as he walks into any kind of health facility has to be part of it. Saying we did research on and then instituted a method of collaborative care for depression. Everybody has to be involved in that. It's not just the people who are doing the collaborative care, but

everybody. Ward clerks. Everybody has to think about this and how to get patients organized.

There is a whole field now of implementation science. There are journals of implementation science. I think you're going to see a lot more research in it. I think the VA actually has a fair amount to offer outside systems or non-systems as to how to translate these things. And I don't think you need a system to translate it. In fact, much of it really is just focusing at the local level and integrating and organizing what people are doing.

MR. McCLELLAN: And we are going to come back to the issue of using evidence in the next panel as well.

A question over here and then I know there's one up here.

MR. FRIZIKER: Hi. My name is Rueben Friziker . I'm a psychiatrist and a clinical researcher at Johnson and Johnson. And my question is about the opportunities, the feasibility, and the politics on the culture of public-private partnership. Many of the topics of this panel actually involve or suggest opportunities for improved public-private partnership.

I'll give a brief example. I lead a large clinical study that is focused on vulnerable populations and functional outcomes. I will also give an advertisement. I'm looking for investigators. I'm looking for site investigators. I'm looking for sites. There's every reason why we would be happy actually to involve sites that have disparate populations, investigators who represent diversity. We'd also be quite interested in having a discussion around, you know, developing measures or utilizing measures that actually would be meaningful to CER evaluation after the study is completed.

So, again, what are your thoughts about opportunities for public-private partnership and barriers to public-private partnership?

SPEAKER: Well, we do a lot of that actually. We have a lot of cooperative studies with industry, for example. Herpes zoster vaccine was with Merck. Many, many studies with -- our cooperative studies program collaborates with both NIH and industry. And many of our medical centers, individual investigators, are parts of industry studies. So this is not an issue for us. We certainly do it.

SPEAKER: For doing it more generally, building it into the coming infrastructure for comparative effectiveness research or lessons for --

SPEAKER: Yes. Well, the Patient-Centered Outcomes Research Institute is essentially a

public-private partnership. And I think it will -- let me just say that a paper we wrote several years ago outlined this pretty much the way it happened. The thought was you get everybody in the room -- industry, government, patient advocacy groups -- and they together will synthesize what can be done and what will be done. So I think that is the beginning of -- now, hopefully, that will turn into studies that are collaborative efforts by all these entities. But I think to begin with that is, I think, a very important step in synthesizing what different groups want to do as far as this area of research because there are big differences.

We had some meetings at the IOM several years ago about this and I can tell you in the room there were big differences. But we can synthesize out of that a way to approach the future, and it has to be in a partnership.

MR. McCLELLAN: So two other questions here that we're going to try to fit in. One back there, one up here.

MR. COVER: Sure. Thanks. This is a question left over from the previous panel, and it's Matt Cover with CNSNews.com.

A question about CER generally. During the health care debate there was a concern among the public that CER would lead to or could be used to ration health care. And then, in fact, Don Berwick, who has been nominated to run CMS, when asked said that the question really isn't any more whether or not we ration care, but whether we ration it, and his words were, "with our eyes open."

And I wanted to know, Mark, in your opinion as a former head of that agency and the panel generally, if you agreed with that, whether or not that (inaudible).

MR. McCLELLAN: Well, again, I get to be the moderator here today, but just -- (Laughter) -- since this question -- this is an important question. And one thing I want to emphasize from this meeting is that by focusing on the kinds of issues we're bringing up today on comparative effectiveness research, I mean, the whole intent is to help some very diverse populations get getter treatments and avoid unnecessary costs. It's something that we are clearly not doing a very good job of in our health care system. So I wouldn't view that as being about rationing; I would be viewing that as about improving care as well as avoiding unnecessary costs and improving value as well.

I don't know if the rest of the panel has any views on that, but I don't see how you achieve that goal without really taking on exactly the kinds of issues we're trying to deal with here today.

MS. BRANNON: The comment I'll make is I'm a modernist, not a post-modernist and I believe in progress. And I think what this is about is adding knowledge where we don't have sufficient knowledge to make decisions. And what we have to guard against is having that become ideology and that is what the debate is really about. You know, randomized controlled trials are an ideology because they're not the only way to find evidence. We just need to be aware, but that doesn't mean you don't continue to seek better information on which to make decisions, which is the heart and soul of what CER is.

MR. KUPERSMITH: A couple of other comments.

MR. McCLELLAN: Go ahead.

MR. KUPERSMITH: I first want to say that the opinions I'm about to express are not my own or anybody else's. (Laughter)

I think I agree very much with what Mark said. I mean, we have to get information on effectiveness and that will include differences in resources required. And I think that we do -- we need to see what's good. You can look at -- we've done a lot of studies in the VA that have been very prominent in both the public eye and always published by the New England Journal and so forth. And you can look at how they have been carried out and really estimate what their value might be.

I mean, for example, one study on doing invasive cardiology procedures along with vascular surgery. I'm a cardiologist. That was very common. That requires -- if you don't do -- what we found is it doesn't do any good. Now, if you follow that you will save money, but you will also save risk and kinds of other things to the patient from doing this. You will save delays in surgery. So I think that we have to start with effectiveness and then after that we see how resource allocation might be altered.

MR. McCLELLAN: Newell?

MR. McELWEE: So the R-word is kind of an incendiary word I think in this country, but if you just sort of forget about the word for a second and think about what we're really trying to do here. The premise is that if we have better information we'll have better decisions. And there's a lot of things that we do in this country for which we have absolutely no evidence or very poor evidence. So when you think about it from that perspective, I think it really makes a lot of sense that we would go down this path.

MR. McCLELLAN: And one more comment from Joel.

MR. KUPERSMITH: What this is is about informed decisions. And I think we have to

remember that the patient and the physician and everybody else who is involved, caregivers, are part of that informed decision. So we have information. We provide information for informed decisions and then that's how this is carried out.

MR. McCLELLAN: And I have another question right here that we're going to try and squeeze in.

BYRON: Good morning. My name is Byron. I'm with the National Medical Association and I'm curious about the bullet here about methods for interdisciplinary collaboration and the conduct of CER. I've been singing this song for a while now about the echo chamber that we have created in health care where we have these health care meetings and it's all health care people. And it seems to me that CER is going to require that we put in a room the systems engineers and the mathematicians and the IT people and the grocers and the school systems. And everybody all the way from up where the river starts all the way into the mouth of the river into the sea. And perhaps we should have a more robust discussion about that. When are we going to have these meetings where we have these discussions between all these disciplines, not just interdisciplinary in terms of get the clinical guy and get the public health guy, but interdisciplinary in terms of getting all these multiple disciplines that will get us to a place where we have not only systems for making these decisions, but meaningful data that will inform these systems.

MR. McCLELLAN: So just a couple of framing things on that. We talked a little bit earlier about priority setting process that would include meaningful input across a diverse range of participants. Another way to look at this more from the perspective of this panel is how do you actually design and implement an infrastructure and the studies themselves to carry out that kind of broad based perspective. And any comments on any of this from you all?

SPEAKER: Well, we do this. First of all, the answer is yes, I agree very much. I think we all do, I'm sure.

And we do this now. We are more and more getting into areas that are going to require social science, economics, and maybe you could say less medical. For example, access. We have issues related to access to care in rural areas that we are studying. That requires a number of disciplines that you mentioned. So we have to do this. We have to get people in the room. We have to think of our research career development awards and our early pipeline issues as developing all these kinds of people to speak

together. I think the CTSAs have begun a lot of this, by the way, as well.

SPEAKER: Just to say, I enthusiastically support your point and maybe Mark you're going to convene a panel on the subject next month. (Laughter) We'll all be back to talk about it. But obviously work needs to be done.

MR. McCLELLAN: Well, certainly it's going to be a part of the follow-up and it fits with the recommendations from this panel and from the overall meeting, so more coming on that, Byron. Thanks for the question.

Ruth, go ahead.

MS. BRANNON: The one thing I was going to add is, you know, in the world of disability the concept of consumer involvement is deeply rooted. And in our agency we have had many years of involving consumer and requiring consumer involvement as research ideas were developed and as research was then interpreted and applied. And it works and yet it's imperfect because it's costly and time-consuming. And what I notice is it's difficult to sustain. So I think sustainability is an important issue when you start to talk about bringing all these groups together so it's not a one-time event.

The other issue and I meant to say it before is the issue of accessible health IT is a critical issue and one that has been looked at in healthy people 20/20. And there was not a lot of consensus about the whole concept of making it accessible, particularly to people with disabilities because of the cost issue. People were really concerned that it would be a mandate. That it would be very costly and yet you can't do this research and you can't move this agenda forward without having accessible IT. So that's another recommendation.

MR. McCLELLAN: I think this discussion could go on for a while. There are some great comments and points. I would like to thank this panel for taking on a broad and complex topic and turning it into some next steps on a path forward and thank all of you for your questions as well. Thank you. (Applause)

THE BROOKINGS INSTITUTION

USING COMPARATIVE EFFECTIVENESS RESEARCH
TO IMPROVE THE HEALTH OF PRIORITY POPULATIONS

Washington, D.C.
Thursday, June 3, 2010

PANEL 3: USING EVIDENCE TO IMPROVE CARE FOR PRIORITY POPULATIONS

Moderator:

MARK MCCLELLAN
Director, Engelberg Center for Health Care Reform

PARTICIPANTS (CONT'D):

Panelists:

MICHAEL CROPP
President and Chief Executive Officer
Independent Health

JEAN D. MOODY-WILLIAMS
Group Director, Quality Improvement Group
Centers for Medicare & Medicaid Services

MARGARET K. O'BRYON
President and Chief Executive Officer
Consumer Health Foundation

GARY PUCKREIN
President and Chief Executive Officer
National Minority Quality Forum

ELENA RIOS
President and Chief Executive Officer
National Hispanic Medical Association

Closing Remarks:

MARK B. MCCLELLAN
Director, Engelberg Center for Health Care Reform

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P R O C E E D I N G S

MR. McCLELLAN: And with that I'd like and transition to our third and final panel, which is addressing the topic of Using Evidence to Improve Care for Priority Populations.

This panel is going to be presented by Gretchen Wartman, who's graciously agreed to stand in for the chair of the panel, Dr. Gary Puckrein. Getchen is the vice president for Policy and Programs, and Gary Puckrein is the president and CEO of the National Minority Quality Forum, so we're very happy to have Gretchen here.

And Gretchen is going to be accompanied on the panel by Michael Cropp, who's the president and CEO of Independent Health, who brings a health plan perspective to efforts that have actually been underway to implement some of the ideas we've been discussing today; also Jean Moody-Williams, the group director for the Centers for Medicare & Medicaid Quality Improvement Group, who has long been involved in quality improvement efforts for Medicaid beneficiaries and other vulnerable high-priority populations; Margaret O'Bryon, the president and CEO of the Consumer Health Foundation; and my old friend, Elena Rios, who's the president and CEO of the National Hispanic Medical Association.

I'm very pleased to have you all here, and, Gretchen, I'm going to turn to you for introducing this panel and to thank you again for doing this on short notice.

MS. WARTMAN: Thank you. I think you just introduced the panel for me, however, so I appreciate that, and I appreciate the fact that we have the smallest number of recommendations. We have only two, but that means that the devil is indeed in the details when it comes to communicating the outcome of comparative effectiveness research in a useful manner.

We have two broad recommendations. The first recommendation, 3A, is to develop and evaluate strategies for disseminating CER evidence to the public. As an initial step, the discussion draft suggests that efforts be made to clearly articulate the objectives and potential benefits of CER as a means of encouraging participation and research as well as increasing receptivity to information regarding evidence-based care. The discussion draft suggests that these efforts could use social networks of trusted messengers and community-based health educators.

Implementation of recommendation 3A also includes employing linguistically and culturally competent communication strategies -- a lot of words there -- to disseminate the findings from specific CER

studies in a variety of formats such as, for example, those appropriate for individuals with visual and hearing impairments. The companion recommendation, 3B, is to simply do the same thing for health care providers to develop and evaluate the strategies for communicating CER findings to the provider population. The discussion of 3B advisors that findings from specific CER studies should clearly explain both the population level and clinical subgroup level effects of the interventions under study. Dissemination channels could include but not be limited to medical education programs and professional society meetings; clinical decision support modules within electric medical record systems; and quality improvement organizations interested in translating evidence into best practices.

Finally, the discussion draft suggests that the effectiveness of all communication strategies associated with both recommendations should be evaluated using comparative effectiveness research methods.

My comments from the perspective of the National Minority Quality Forum are really -- there are three, and they are interrelated. First of all, the National Minority Quality Forum recommends that all communications regarding comparative effectiveness research in general should be governed by principles of transparency and full disclosure, such as those recently articulated by President Obama through the Office of Management and Budget.

We believe it is essential, secondly, that communications to the general public to patients and to health care providers should describe both the benefits and the limitations of comparative effectiveness research.

And, finally, these principles of transparency and full disclosure must carry through to communications regarding the findings of specific CER studies. The Forum believes that it is essential that all CER reports, executive summaries, fact sheets, or other communications clearly define the populations for whom the findings have relevance and validity and those populations for whom they do not.

Patients, physicians, and the general public must be able to clearly identify the treatments and devices for which evidence exists regarding both clinical and cost effectiveness. As discussed by the preceding panels and as is well documented in the peer review literature, there are significant gaps and evidence resulting from incomplete data collection, as well as the decades-long, possibly centuries-long, failure to constructively include in clinical trials and research certain racial and ethnic populations, older

adults, and individuals with multiple chronic conditions. It is, in our view, no longer justifiable to use the lack of evidence or data as a rationale for extrapolating the findings to populations that were not included in research cohorts.

Thank you.

MR. McCLELLAN: Thank you very much, Gretchen, and also for being concise in the presentation, too, and go down the panels again for comments on the recommendations, on their views as well.

Mike, start with you?

MR. CROPP: Sure. Thanks, Mark.

Just a bit of context. I'm with a not-for-profit health plan in Buffalo, and we have three distinct types of challenged populations that we serve. We have about 57,000 seniors, about 15,000 of whom either are burdened with multiple chronic conditions or are poor and have low-income subsidy that they access the plan through. We have a Seneca Nation of Indian population that we serve that's nearby, and then we have about 36,000 folks that are in our state-supported programs largely in the inner cities of Buffalo and Niagara Falls.

So, our approach -- we're not a research organization. We haven't used the discipline that we need to going forward, but we're just sort of a just-do-it type of organization, and we have worked extensively in trying to disseminate the findings that come out of the comparative effectiveness research into the population by using the trusted channels that exist in the communities that we serve, and it's been largely of two approaches.

One, with the seniors, we've had great success in adopting a model that came out of Stanford in living healthy with chronic disease. And in this model we pair up professionals with seniors who have the chronic disease, who are out in the community teaching their folks how to make the adaptations they need in their life and how to be living in practice that is consistent with the recommendations that come out of the literature. And that program has been extremely successful with about a 4-to-1 return on investment for it. So successful, in fact, that the New York State Health Department has asked us to take this program beyond independent health members out to the entire community, and we're in the process of doing that dissemination right now.

The other programs have been more neighborhood specific or community specific. We have a program called Good for the Neighborhood where, again, we engage block club leaders as peer leaders to take the information, again coupled with professionals, to the community on regularly scheduled programmatic elements. This has been about a four-year program, and the degree of engagement in these neighborhoods has been absolutely incredible. We don't have the same kind of ROI on this, but the local ownership in the sense of commitment that we've seen in these neighborhoods in getting folks more aware of and engaged in the right kind of behaviors has been dramatic for us.

We also have what has been to referred to earlier as the Community Out Reach Workers Program going across our population that we know that there hasn't been a return on investment when we calculate for the short term, but that's just from a purely economic perspective. From a quality perspective we have seen dramatic improvements in practices consistent with the evidence in terms of both screening for diseases and in managing chronic disease. So, the numbers are quite dramatic there.

And then the last area that we're actually pretty excited about is in the development of a tool that we've taken out to a specific aspect of our community that is really focusing on enhancing health literacy through a local center that started as a soup kitchen and has grown into much more of a community center now with a health literacy center within it. It's a tool that we call Mortar. And it is a tool that enables the trusted individual who works in the center to be able to interact with the individuals to develop, in essence, a personal health record, but a personal health record that contains more than just the traditional diagnoses, prescriptions, and the other things that we include in the health record. It also has some of the factors that we like to collect relative to what we've talked about as the social determinants of health. And it's been a great tool that's been working in this center -- we're taking it to some of the centers now -- as a way to really bridge the gap, help people put their other factors into context, and bridge the transitions into the health system to be able to address some of the health problems that they need in the context of the other issues that they're dealing with in their life.

So, those are some of the things that we've been doing. What we see as a need coming out of the discussion earlier today and with this panel is the need for a little more discipline, the need for some resources that organizations like ours can turn to, to determine which of these interventions that we've been working on are really the most effective and what tweaks can we make to them as we go forward to get more

mileage out of these investments to reach a broader segment of our community.

MR. McCLELLAN: Thank you, Mike.

Jean, lots of experience with trying to use evidence-improved care in Medicare and elsewhere.

MS. MOODY-WILLIAMS: Yes. Thanks, Mark. Thanks for inviting me. And I think all the federal disclaimers have been said already, so I'll just say ditto.

I think it goes without explanation that CMS is extremely interested in the topic of -- particularly as we look at priority populations and as you've already defined that being the economically disadvantaged, racial and ethnic minorities, children, women, older adults, individuals with disability and multiple chronic conditions. A large number of the individuals on that list are covered through programs administered by CMS, including, of course, Medicare, the Child Health Insurance Program, and Medicaid.

So, CMS strives to not just be a payer in these instances but also to be a champion, a change agent for innovation and for improvement. As you mentioned, I've been involved with quality for a while at CMS as a director for Medicaid and SCHIP quality, but now I'm also the director for the Quality Improvement Group for Medicare, so I have an interest from birth throughout the entire stages of life. And I think that there's real promise in what we can learn by the tools that are available to us. And I think in quality over the course of the many years we've come to some agreement that we want to give the right care at the right time, the right place, but we still have questions about what is right -- you know, what is right. And so I think that CER is one tool that can point us in the right direction. As the previous panel said, it provides information that we can use among the other tools that are available to us.

At CMS, Dr. Straub, our medical director, likes to point out we have many tools; we work with contemporary quality improvement, public recording, incentive payments, conditions of coverage, participation, and survey and certification. All of those tools can be informed by what we learn through CER.

But for purposes of this discussion related to dissemination and throughout my -- I enjoyed the comments about working with the staff on this particular paper. I can attest to that. But one of the things that I continually stress, probably to the point of being a little bit annoying, was that dissemination is not the end point and that while we need to disseminate, we must after dissemination continue to implement, to monitor, to look at the effectiveness of these strategies that we are putting out. I think as Gretchen has

mentioned, you know, is it the right thing? Is it working the way we thought it would work? What are those metrics that we are using to evaluate the effectiveness of the interventions that may come from the research? What are those desirable outcomes? If they are desirable, we continue them; if they're not, how do we go about discontinuing them?

It's been pointed out several times that CER is not just about the effectiveness of the drugs, of the devices, but also about behavior change and delivery system strategies, and I think that's where this panel can really be important as we look at behavioral changes and strategies. It's here that I think that we look -- as we look at what's happening locally how do we disseminate information and how do we get it out so that it's most effective that I think an importance can be made? You know, how do we activate that behavior that we would like to see?

The fact that we still have to have a panel to talk about how you disseminate information to -- you know, providers who give care to priority populations after all these many years I think is very telling, and so we need to get on to the answers about how we do this. And I think we are fortunate in that we have many avenues available to us to help in this dissemination. CMS itself works with a number of contractors and partners whose sole purpose is to help at the local level, kinds of boots on the ground, translating evidence into practice, fine, working with hospitals, physicians, other providers, and our beneficiary.

I had mentioned I have oversight of quality improvement organizations, the end-stage renal disease networks, and Medicaid. I work with external quality review organizations. All of these entities have as their core value and core competencies the ability to work at the local level to get information out to monitor its effectiveness through evidence-based metrics, which is very important.

These entities might also be helpful in monitoring some of the unintended consequences that I think have been alluded to throughout the course of this conference of things that people are concerned might happen, and so we have mechanisms and infrastructure to monitor for many of those things.

We have to look at reaching out, and it's already been mentioned, to providers through incorporation of decision support tools to get this information out, electronic health records. One example is a project that we're currently supporting. While it's not based on CER, I think it's very replicable. It's our Every Diabetic Counts project, and the champion of that is here, Terrence King, and it reaches out to priority populations and the providers to help to ensure that both are improving implementations of evidence-based

practices. We started it about 18 months ago at the sub-national level. It's now at the national level.

We have seven states in targeted communities. We're working in over 900 zip codes with thousands of beneficiaries from priority populations, and we're working to help improve diabetes control, and we're working with the QIOs, other federal agencies, state agencies. We're disseminating information and getting this out to improve care. So, how -- and we think we've been successful, and how did we get there? So, this is why I believe it works, although I don't have any comparative effectiveness research to tell me that this approach is definitely better than four other approaches that I could take, and I think that we need to look at that, and that's one of the things we need to get to -- to have that research to say -- to point our interventions and our efforts more targetedly.

But I think it's effective because it's the science, the policy, the people, and the passion. There's evidence. We're trying to disseminate it. We have the infrastructure to disseminate it. There's consensus, fairly good consensus, around the fact that diabetes control is important. There are actionable interventions that can be taken.

And the policy piece, CMS has institutionalized this project through contracts, through -- you know, we have benefits that are coordinated. We work with our other federal policies that have -- partners that have policies. We've engaged the people that we are trying to collaborate with. This is both the beneficiary and the providers.

And the passion, you know, people care about this topic. They understand it. They see the impact in their communities. They look around. They see themselves, their uncles, their aunts, others. They're impacted by it and they want to work, and so we've been able to engage and we talk about recruitment and retention in this area.

So, I think those are some of the things we have to look at as we look at disseminating CER. So, I think the bottom line is that the right care, the right place, the right time. We need to know what is right for all populations. We need to disseminate to all and be inclusive, being inclusive of priority populations.

We need to have actionable interventions that come out of CER that people care about: technical assistance, as Michael just mentioned, there's a need for the resources, to have technical assistance, to navigate the complexities, and I believe we have an infrastructure for that we could explore; measurable outcomes and monitoring; aligning payment incentives and policy to support effective practice;

and using technology effectively. And I think all of that requires consultation from everybody in this room, outside this room, the communities that we're working with, and, most importantly, the people that we're trying to impact.

MR. McCLELLAN: Jean, thank you very much.

Margaret?

MS. O'BRYON: Good morning or almost good afternoon. It's great to be here. I rarely present to this kind of audience, and so that if we can expand the scope of who we talk to -- "we" meaning foundations and people working right on the ground -- I'm really thankful for that context.

I run a local foundation. We are small. We are not the California Endowment, but we march to the beat of the California Endowment. We work on the ground with nonprofits, serving communities of color, low-income marginalized people, racially and ethnically diverse. That's our lens. We just changed our mission to look much more critically at health inequities in addition to, like what Bob said, equitable access to care. So, that's where I'm coming from. I'm a city planner by training, not a great researcher, but I admire what you guys do. So, it's like yes, yes, yes, yes, yes, you know? And here I am, the second to the last person on the last panel, but have a couple things to say.

First of all, there is stunning evidence in the public health community and elsewhere about the effects of health inequities, the social determinants help on health outcomes. End of discussion. Poverty, disinvestment, structural racism, all these issues that affect people's health. And 80 percent of your health is determined by that and the other 20 by really important equality and equitable access to care. So, I -- and there are funders all over the country who get this, you know? So, I would say to Mark and others, involve the private funding community in this. I don't know exactly how, but I know that we have the on-the-ground information, and I would say that the funding community, in looking at this, has adopted a strategy around place. The California Endowment has a $1 billion program looking at 14 places saying that if you look at place, geography, it is an organizing principle for looking at both the health care piece and the health inequity piece. So, I would say that interdisciplinary -- I love it. Off the charts. And bring the grocer to the table and bring the minister to the table and bring the social science researcher.

And, I mean, a lot of this is being done not so formally in communities, and I want to say that, which brings me to CBPR, community-based participatory research. Excellent work going on in

Montgomery County, Maryland. The guys running it, Steve Galen, is in the back there. He runs a primary care coalition. Couple of thoughts there. One is piggyback on what people are already doing. Go to Georgetown University. Go to the local universities and ask what are you doing in this area and how can we piggyback on that?

Also I think it's an opportunity to drill really deep in some of these intractable questions. One question that I would put out there, and I'm going to read it because I worked on this: What are the strategies for meeting and overcoming the challenges of consumer empowerment and engagement in the decision-making process, given the multiple and complex social and economic forces at play? Because you want people engaged. Engagement is huge in this population. It's a huge challenge.

So, what methods of dissemination? I don't have a lot new here, only to say that I do think CER does need to look at the effectiveness of these strategies: multiple decision aid tools; low literacy; low innumeracy; multilingual; culturally informed, ranging from printed pieces to the web; personal health records. We actually are doing a project around that, which has engaged lots of front-line workers. So, you know, we could be part of the -- sort of the, I don't know, the test base for that and we would love to do that.

Trusted messengers, A number 1. Trusted messengers. These communities have been -- I can't tell you -- taken advantage of, sapped of knowledge, you know? And so -- but there are people -- we've done research around their front-line workers. That's where people go. After their family and friends, they go to the Korean Service Center -- whose running the Korean Service Center. They go to the church. They go to school secretary, get the -- you know, places that are formal and informal messengers. Really important.

Community health workers were mentioned. In this town, the local community college, which is brand new, is doing a credentialing course for community health workers so that we can really elevate that profession, so I don't know if that's being done around the country, but this needs to be kind of integrated into that.

Bob -- I know Bob -- but the notion of equitable access to care gets us back to primary care medical homes, which there's a lot of work being done around here, and that's a great -- that's the place to disseminate this information, because they're going outside the community through social workers, through community health workers.

And then the fourth is certainly community-based participatory research.

And let's see, he hasn't -- I don't have "end" up yet. He has this card that says that.

The incentives that will encourage application of evidence -- and I read this social worker's response to CER. I went online, you know, social work community. I couldn't agree more with this, which is payment support for enabling services. If you're in this population and you want to seek care and you don't have anybody to take care of your child, you do not have a car, et cetera, et cetera, and foundations probably could help with that if we sort of got together in a real strategy.

Connection to social networks. You know, you have an issue with hypertension, obesity. You need to walk. Well, walking clubs really actually work, but how do you get connected to that and how are there enabling services that enable you to do that.

And third, I think the faith-based community has a really strong role in this in communities, certain communities in particular, and when -- I mean, we worked on this with HIBA. What aids -- when there is a message from the pulpit, your pulpit, about this kind of work and what it means for you and what it means for your community, an endorsement there, that is huge.

So, I'm going to stop there. "End." I did it. I'm going to stop there and, again, thank you so much for inviting me.

MR. McCLELLAN: Well, thank you, and thanks for your very outstanding timing there, too, Margaret. Thank you.

MS. O'BRYON: You're welcome.

MR. McCLELLAN: I'd like to turn to Elena. And Elena, you've got a lot of experience with doctors, other health care providers, and that's obviously a key part of this whole effort to use evidence effectively.

MS. RIOS: Yeah, Mark, thank for inviting me. I'm from the National Hispanic Medical Association. We actually have two different organizations. I'm going to talk a little about both, but just to orient you to our mission -- is to improve the health of Hispanics and other underserved. It's really about the populations we come from and the neighborhoods. And I couldn't agree with you more about the planning needed for our communities, and I actually have a master's in health and health planning before President Reagan abolished them all, and I went to medical school. But at any rate, I think what's important to know about the focus here on dissemination of CER is why we need to target racial/ethnic populations and

physicians; what is needed to increase patient-centered knowledge; and how to disseminate the CER findings to physicians who care for the racial ethnic populations and suggestions to consider to facilitate this specific dissemination. I was asked to focus on the physicians.

The first major point really is that by the year 2042 -- and it was said earlier today -- the United States population is going to be over 51 percent minorities. The IOM report on equal treatment, you know, proved -- demonstrated the evidence that even with health access minority populations do not have the equal care. And the literature demonstrates that Hispanic and black physicians and dentists tend to provide care for the uninsured, Medicaid, poor populations, and especially ethnic minority populations. Yet only 5 percent of the total populations of both Hispanic and black are physicians -- of the total population of physicians are Hispanic or black. So, we really need to target, in a critical way, the minority physicians who are in our society now, but more importantly we need to develop the pipeline.

And the NMA partner organization here -- and, you know, we've talked about this forever -- since the 1970s the pipeline in our communities has stayed flat-lined. So, we recognize the very critical importance of having role models and champions among those few Hispanic, African-American, Native-American, Asian physicians in our communities. But we also recognize the importance of the cultural competence trainings to all physicians and health providers about our populations.

A second point is that the comparative effectiveness research, according to the health care reform law, is going to have a priority for new patient-centered research in this institute that will address gaps in evidence for clinical outcomes, practice variation, and health disparities in terms of not only health care delivery but in terms of treatment and patient preferences. So, it's not just the delivery that we need to change and the cultural competence training, for example, to increase dissemination but how to get to our populations.

There's a real need for increased awareness and acceptance of the results of CER and the incorporation of this paradigm shift that's about to happen with health care reform to prevention and to life style changes and to the behavior changes in our communities. And I think that in order to increase the quality of health care delivery -- and we're all looking for integrative care and health care to minority populations here -- we have to change the behaviors of the population. And we also have to change the behaviors of the providers to make better informed decisions so that both communities can come -- the

provider community and the patient community, the consumer community -- can come together with an understanding of why there will be certain types of care that will be seen as the best to go for, because it's going to give us quality care.

And I don't want to talk about rationing, but I know that that's going to be part of the discussion. But it's up to us to be able to discuss the importance to the quality of our life styles that our communities have not had. The focus, therefore, needs to be on cultural competence training, on language services so that there can be better communication with our subpopulations. And looking at the subgroups in our communities, the Asian, the African-American, the Native-American, the Hispanic were not at all homogenous. The regional places in our country -- the U.S.-Mexico border, the undocumented -- I mean, for the Hispanic population there's very distinct subpopulations.

And then there's health literacy and the importance of focusing all of this on the movement on the increase the efforts for primary care physicians especially to be the focus of new research.

So, how to disseminate to minority providers. I think one aspect -- and I'm going to just give our example of our organization -- all of the minority medical associations have been building their own networks, because there are so few physicians. Our networks include Hispanic physicians, but we also have -- and there's over 45,000 Hispanic doctors in this country. We have yet to reach all of them, but that's the goal. And the other goal is to -- we are an umbrella group now of all the Hispanic medical societies in the country that are statewide in about 14 different states. We also have Hispanic medical students and residents, and that's critical to understand that there is a pipeline from medical school to residency to practice where our minority physicians tend to be isolated and need the networks.

So, our result -- the result of our organization has to been to build a sustainable communication network and to change behavior in the Hispanic population. I think this is -- part of this dissemination strategy has to be to figure out how to build these networks through social networking, through internet, et cetera, and include key physicians, again the champions in building the role models within the new institute whether it's the Board of Governors, the executive staff, peer reviewers, et cetera.

And then just one last comment I think on the -- health care reform itself has a national workforce strategy and commission. So, for physicians to be looked at in health care reform, there will be state-level workforce development. There will be regional programs, including the primary care extension

programs, and the networks that need to be linked into all of this -- not only are the medical practices at the ground level in our clinics, et cetera, health systems like Kaiser and others, and the safety net hospitals, the safety net clinics, but the medical societies and the medical schools and residency programs, because the new knowledge is going to have to be developed within the training context for the next generation.

And the Office of Minority Health -- and Jamila was here earlier -- is going to have, because of this health care reform, Offices of Minority Health in every agency, and the workforce targeted to minority populations and minority providers could be done in a m ore collaborative way with workforce training focused across the agencies -- CDC, CMS, HRSA, you know, SAMHSA, the Indian Health Service, ARC, FDA -- working through this new OMH structure and really focusing on building the sustainable dissemination through minority medical associations.

Thank you.

MR. McCLELLAN: Great. Elena, thank you very much.

So, we've heard from the report and from your comments collectively a lot of good ideas and promising steps on how to have a bigger impact of effective -- comparative effectiveness research, and a lot of that focused on trust -- trusted messengers, including faith-based, other community groups, health care providers who are trusted. But I wonder if you could -- if you all could -- if I could push you a little bit more on further steps to build trust.

Margaret mentioned community-based participatory research as a way of maybe giving people more of a stake in adding to the relevance of the research studies that are conducted. Gretchen emphasized accurate communication about what the research does and doesn't show that's relevant to particular individuals. Are there other things that can be done in this process to build up that trust? Are there other steps through insurance programs or other initiatives, other things that we haven't gotten on the table yet? Because that does seem like a key issue for impact here.

And I'd say, too, that -- and we didn't really talk about it much in the comments, but several of the commenters mentioned -- I think there's going to be a unanimous view that comparativeness effective research includes research on effective strategies for getting the evidence into use and actually having a positive impact on health. But we'd really like to focus on this trust issue a little bit more. Any comments?

MS. WARTMAN: I can respond from our perspective, and I would like to first say that I was

under instructions from Josh to be detailed yet brief, and so I'd like points please for my presentation.

But I'm going to beg your indulgence for a moment now and say that the National Minority Quality Forum has had I would say a contentious relationship with the notion of comparative effective research for the past few years. It is an idea that is theoretically sound, but we have concerns about how it will be used in practice. During the Senate Help Committee hearings, one of the legislators -- one of the senators continually referenced CER as news you can use, this is news you can use. And the question I have to ask is: Is it news that should be used? Do we have the data and the evidence and the knowledge to apply comparative effectiveness research to what is essentially going to be the majority of the American population in the not too distant future? And I submit that no, we do not.

So, the challenge that we have to build trust, I believe, is to make sure that these populations that are being defined as priority populations -- and we can have a conversation about that term further -- are truly being given priority in the allocation of resources. And in the research that's being conducted for comparativeness effectiveness that we are not continuing to be somehow marginalized or treated as a set-aside in the way grants are awarded or funds are allocated.

There was a question asked during the previous panel about rationing care, and I'm going to address it. The concern I had with the response from the panel was that I heard defensiveness, and I think we need to be prepared to respond to questions about whether CER could be used to ration care in other than a defensive manner. The issue I'll put on the table is not whether the intent is to ration care. I prefer to believe it's not. But the fact of the matter is that human behavior does not necessarily comport with ideals in the real world, and there is a history that everyone brings to this conversation that causes that question to be asked and to be a legitimate question. So, we need to include in any recommendations monitoring, reporting, and a course correction if necessary, to ensure that populations are not being harmed by the provision of care that has been informed by or driven by the outcomes of comparative effectiveness research.

So, that being said, if those issues are addressed, then, yes, at least through the lens of the National Minority Quality Forum, some trust could be built, but you can't build trust if it is inappropriate for trust to exist.

MR. McCLELLAN: Those (inaudible) steps really go to building trust, that's right.

Others? Mike?

MR. CROPP: Sure. I'd like to just talk about trust more on the micro level than the macro level, because I think that trust is an important principle in terms of how we have tried to operate our programs. And I think that talking a little bit more about the Mortar program is a good example of that, because many of the folks who come into this facility live in -- Buffalo is the third poorest large city in the country, and this is the poorest of the poor neighborhoods, and they have big issues that they're dealing with every day -- shelter, safety, water, you know, those kinds of things. And the tool is really designed to help build the relationship and the trust between the folks who work in the Center and the individuals to understand what are the basic elements that they're having to fight off on a day-to-day basis to build context for their health issues. And so it really enables that kind of dialogue and that trust building on an individual level to build that relationship. And while health care isn't provided at this facility, the folks who work at this facility, in gathering that information, can get the basics of not just the life issues but the health issues and then be a bridge into the health care community where these folks have largely been disenfranchised from that community. And we're seeing that these folks are now able to access health care with a greater degree of trust and confidence and come in with some data up front. And we look forward to -- this is kind of a vehicle of not just building the trust, but being a basic data collection tool that we can then build upon to help determine which of these interventions are a little bit more effective.

There's a twist on trust, too, that I just learned about yesterday when I was talking with the individual who headed up the Living with Chronic Disease Program, asking him how it's going as we transition it from our ownership at Independent Health into the community. And he said he's a little bit concerned, because as it's transitioned into the community, it's now being run by a different organization and they haven't put the same kind of energy into determining who the peer instructors would be. And so for us, it was a matter of really doing our homework to identify those peer instructors that they had, some of those basic qualities that could connect to people that could build trust and passion. And in transitioning the faculty, we're beginning to see a little bit less engagement, because that up-front investment in determining those qualities hasn't been as robust as we'd like to see it carried forward. So, the passion side I think is one of those softer issues that's going to be hard to address and research, but it's going to be very important.

MS. MARTINEZ DE CASTRO: With us there, yeah, that's right.

Yes?

MS. MOODY-WILLIAMS: Yeah, I think, to just to kind of echo some things I've already said, but to also emphasize honesty and transparency, to really listen to concerns and not dismiss them and to look at CER really as one of many factors when making decisions. Also I think that sustainability, as I think Michael was getting to, when you go into communities, you know, programs come and go and things come and go. You know, how are you going to sustain your presence there or if your presence isn't going to be sustained there, you know, what have you set up so that efforts could continue on so that the population that you're working with don't just see oh, there's another trend or thing that's come through?

And then, again, I can't emphasize ongoing monitoring evaluation with evidence-based metrics in a formal way to know the impact of whatever it is that your doing has on the communities and involving the community in establishing those metrics.

MS. O'BRYON: Really quickly, two things. One is I think we need to engage young people early on in these conversations, because their elders often look to them for information, and if you're going to build this bank of trust, these could be the potential leaders. So, that's one.

The other thing is -- and I guess Elena knows a lot more than I -- is that in the workforce piece is to train up people that are of the community and from the community, and I've noticed in the clinics in which we funded some of the interesting dynamics that go on when a person is of the community as opposed to not being of the community.

So, those are my two.

MS. RIOS: I would just add how important the media is to our communities, and it's not just Internet. You know, our -- my parents' generation still watches TV and radio and newspapers, and I do think the importance of the community-level media in letting people know what has been happening and what are some of the positive spins on the research results and how important it is to realize that, this is part of the next wave of life. You know what I mean? It's just part of -- it has to be part of the community's lifestyle.

MR. McCLELLAN: Health care and health.

We have time for some questions from the audience.

Diana?

DR. ZUCKERMAN: Thank you. This has been so interesting, and there's just one issue that --

MR. McCLELLAN: I know you, but everybody else --

DR. ZUCKERMAN: I'm Dr. Diana Zuckerman. I'm president of the National Research Center for Women and Families.

The comment I want to make that I think hasn't been addressed quite enough and it's really raised some concerns in my mind is that as we look at comparative effectiveness research, postmark it -- which is what we're talking about and which I fully support -- if drugs, for example, have not been adequately tested on diverse populations before they're sold. And so we don't have a good measure of dosage levels that are appropriate for elderly people who may metabolize certain drugs differently or some racial and ethnic minorities that because of genetic variations, called polymorphisms, may also metabolize certain drugs differently, we may end up finding that certain drugs are not effective or not so safe for certain groups. But it's not because they couldn't be; it's because the dosage levels or the way they're used were tested on and established for mostly white populations. And looking at FDA's own data and our Center's analysis of it -- for example, in clinical trials that FDA uses for the basis of approval decisions it's something like 1 percent of the population of those samples are Hispanic and 1 percent are Asian and possibly up to 8 percent African American. And if you have a sample size of a couple of a hundred people, that's obviously not enough people to give you the information you need.

So, just to say that if we can start the comparative effectiveness earlier while we're developing dosage levels and making more judgments about safety and effectiveness earlier, we can do a better job of doing comparative effective research later, too.

MR. McCLELLAN: Yeah, that's a good point. I mean, our strategy here has focused more on the post-market side, and the like, but -- and really try to change those numbers and the change the evidence, because dosage can matter, but pre-market's important, too.

Gretchen, I know your organization's worked some on these kinds of issues. I don't if any of you have any further comments on Diana's points.

MS. WARTMAN: Well, I have a concern -- I have lots of concerns that -- first of all, I agree with everything that's been said. Every population has genetic polymorphisms that affect the way they metabolize drugs, so I think it's important that we use all knowledge to determine how we design a health care research delivery and financing system going forward that is representative of and responsive to the

American public, not just subsets of the population. To choose significant a degree, the whole concept of disparities is based upon norms that have been defined for a diminishing percentage of the population, and we have to begin to incorporate into our knowledge and our research. I believe the notion that multiple norms can coexist in the same space, because that is the America going forward.

So, I would challenge the researchers and the policymakers and those on the Hill to find a way to incentivize that new health care research delivery and financing paradigm that does respond to the American public that is not simply trying to bring the past forward into the future.

MR. McCLELLAN: Other comments? Anyone here?

MR. HALL: I'm Bob Hall with the American Academy of Pediatrics and sort of piggybacking on some of that. There's a reason we had to pass the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. Those actually incentivize drug manufacturers to do studies in kids. And so as a population that actually experiences disparities more than any other slice of the population, I'm wondering what the panel thinks about how those pieces of legislation fit with comparative effectiveness research.

And then additionally -- because kids are a priority population we're very lucky that they were included that way, but then additionally what the likelihood is to look not only at specific clinical interventions, but also models of care coordination, sort of a larger aperture of what really happens in terms of kids with special health care needs or others that may not have as many opportunities to look at, you know, those specific clinical interventions, but then additionally really need, you know, different medical home models or different models of care.

MR. McCLELLAN: On the last point I think there's a lot of support, and you've heard it on the earlier panels, too, for evaluating systems of care and, you know, evidence-based not just care -- not just treatments, but practices and systems, and I think the recommendations are very consistent with that.

In terms of supporting research, you know, obviously patent extensions are one way to provide incentives. The focus here has been more on direct funding for comparative effectiveness research. But as Diana pointed out as well, these things ought to be interacting as part of a comprehensive strategy.

Any of you all have any comments or views on that? Mike.

MR. CROPP: Yeah, I would be very excited to see more research that's directed at shorting

that 17-year timeframe from, you know, when it's proven to be effective to into common use. And I think that many organizations are working at this on their own without the kind of discipline that an infrastructure could support to accelerate the national movement to shorten that time frame. So, I think it's a great comment.

MR. McCLELLAN: Yeah, and clearly that infrastructure isn't going to work unless it's got this big community-level, practical emphasis that this whole panel has been focusing on. Yeah.

Question over here, and up here if we have -- you've already had one, but --

MS. LEATH: Good afternoon. I'm Brenda Leath, and I'm a senior study director at WESTAT and president emeritus of the National Consortium for African-American Children. Special thanks to all of you on the panel for sharing your perspectives this afternoon.

I guess what I want to reiterate is the importance of the trust issue and the whole notion of stakeholder engagement. It's one thing to develop products that come out of the CER research and to package them and then test the messages versus having the involvement of stakeholders at the very beginning. I think that will go a long way in terms of how one accepts the information, whether or not there is confidence that we should adopt the information, or of the strategy and then hearing how our input is addressed from the research community. All of that I think plays a very important role and factor in whether or not there's confidence in whatever information they're trying to disseminate. Thank you.

MR. McCLELLAN: I saw some head-nodding. Any comments?

MS. RIOS: Yeah. I couldn't agree more, and I do think the concept of stakeholder engagement includes the team approach and the interdisciplinary approach to I think the future research teams need to be more than just the physician and patient or looking at decisions between physician and patient. I think it does need to include how to address the community changes that also need to be part of this research.

MR. McCLELLAN: And also have more of an impact as you were emphasizing.

MS. WARTMAN: Just one quick comment, I think. During the first panel there was a question about using -- building public/private partnerships to address these issues, and we do believe firmly that we cannot resolve this issue without the constructive engagement of the private research sector. And so I would encourage us also to find ways to incentivize the private sector and the public sector to increase inclusiveness in both pre-market and post-market research. We can't simply focus on post-market actions.

MR. McCLELLAN: We've about one minute left, so time for one quick final question. Bob, you want to --

MR. GRISS: Bob Griss with the Institute of Social Medicine and Community Health.

I can't help but think of the way we desegregated hospitals in this country in 1965 when Medicare said they had to do it. That got their attention. In your words, that incentivized them to overcome 200 years of discrimination. I haven't heard mechanisms for public accountability that were not entirely voluntaristic in this discussion of CER. And I think we need to be thinking of communities as organisms for mobilizing and look for mechanisms that these tools that we've been talking about -- all the good concepts -- community engagement, the CER methodologies -- there are institutions that are not being talked about. We used to have health systems agencies in this country that were funded by the federal government to do this kind of community health planning so that these decisions wouldn't just happen because private providers had an incentive to do it. I think that needs to be reflected in the reports.

MR. McCLELLAN: Emphasis on really pushing the community approach forward. Any quick comments on this?

MS. O'BRYON: The health care reform positive step here is to have community transformation grants, and it's the next generation of the REACH concept from CDC, public/private partnerships, but also engaging not just the academic, but the public health department and the safety net.

The other concept I think that's positive and is more in terms of health planning is the workforce strategy for not only the supply of the workforce, but the geographic placements and the interdisciplinary workforce where we're going to break down the barriers, I hope. So, primary care is going to be oral health care, mental health care, physical care, nursing care, you know, working together. So, those are positive steps.

MR. McCLELLAN: Now, I'm going to ask you to hold your applause and things for this panel just for a second while I make a few final comments.

First of all is thanks to everyone who's been involved in this effort. That includes this panel here, who I think has done a terrific job on some very challenging issues that really get at the heart of what it's going to take for comparative effectiveness research to have a positive impact on these priority populations. I think you all did a wonderful job of that.

I want to thank the rest of our panelists for all of their efforts to help us get here. And, again, our co-sponsors for this event, the Office of Minority Health, Veterans Health Administration, NIMH, the National Institute for Disability for Rehabilitation Research, the National Minority Quality Forum, and the American Academy of Pediatrics coming together to make this background paper possible and facilitate this discussion was incredibly helpful and hopefully something that we'll be able to build on. You should expect us to follow up on the discussion and all of your comments, which were tremendously valuable, too.

We are going to reconvene these groups, and I'm going to take that comment earlier -- what was it, sausage making at its best -- maybe that should be our new little slogan here at the Engelberg Center for Health Care Reform. But we are going to have more of that process to get to a revised version of this paper and to stay involved with these issues. As you all made clear, this is one of the most important and most challenging sets of issues related to health care reform really having an impact on improving health. So, I tremendously respect all of your efforts and participation in helping us do it, and look for more from us.

And, finally, just some very special thanks. Carolyn Clancy, who helped us with conceiving and framing these ideas; Michael Marge, consultant to this project from the start, who's been terrific at every step of the way; and our staff, the whole research team at the Engelberg Center: Larry Cococh; Shawn McBride; Michelle Rue; Elizabeth Rafferty; Bren Barnett; Erin Wyratter; and Josh Pfeffer. And a special thanks to Colawn Taylor Clark, Idol Inese, and Josh Brenner for the tremendous amount of work, including very late -- I should say very early this morning, on getting things together.

Thank you all for making this possible, and we're looking forward to next steps.

Thank you. (Applause)

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