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PARTICIPANTS:

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

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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)