THE BROOKINGS INSTITUTION

USING COMPARATIVE EFFECTIVENESS RESEARCH TO IMPROVE THE HEALTH OF PRIORITY POPULATIONS

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PANEL 3: USING EVIDENCE TO IMPROVE CARE FOR PRIORITY POPULATIONS

Moderator:

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Closing Remarks:

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PROCEEDINGS

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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