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Lia Hotchkiss: I'm Lia Hotchkiss and I'm with the Agency for Healthcare Research and Quality. We are one of the 12 agencies part of the Department of Health and Human Services. The mission of our agency is to improve the quality, safety, efficiency and effectiveness of health care for all Americans. Approximately 80 percent of our budget is invested in grants and contracts that are focused on improving health care. Much of our funding is put out there for researchers and universities to conduct comparative effectiveness research, but that's just one of AHRQ's areas of focus. Our director is Dr. Carolyn Clancy and our deputy director is Kathy Kendrick. I'm located in the Center for Outcomes and Evidence.

The Effective Health Care Program is the primary program that conducts comparative effectiveness research at the Agency. It was established in 2005 as part of the Medicare Modernization Act of 2003. So, while there was an emphasis and funding for comparative effectiveness research in the new health reform law, it's actually been around for quite a while. The goal of AHRQ's comparative effectiveness research is to improve the quality, effectiveness and efficiency of health care delivered through the Medicare, Medicaid and S-chip programs. We focus on what's known now and research gaps that are critical to fill. We focus on clinical effectiveness, not on cost-effectiveness.

The definition of comparative effectiveness is something that's been discussed over the past few years. The Office of the Secretary has defined it as

the conduct and synthesis of research that compares the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor conditions in real world settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians and decision makers responding to their needs about which interventions are most effective for which patients under specific circumstances. It recognizes that not every treatment works the same in every patient and that there is this need for your personal circumstances and how you respond to treatments to be taken into consideration.

So what makes our program unique? Well, we focus on the patients and the outcomes that are of interest to the patients. We try to involve the public throughout the entire research process. A bit later in my presentation I'll talk about the different ways that we involve the public.

As I said before, we fund researchers from across the country. In the handout there is a picture of the United States with dots scattered across it. This represents the different institutions and researchers that we are partnering with to produce comparative effectiveness research.

Our research focuses on 14 priority conditions. The conditions span the entire lifecycle, ranging from pregnancy and preterm birth, cardiovascular disease, arthritis, diabetes, functional limitations and disability, to infectious diseases, etc. These priority conditions were set by the Secretary of the Department of Health and Human Services after holding multiple listening sessions and calls for nominations for priority conditions.

We've developed a framework for how we conduct comparative effectiveness research. We've identified seven steps in the process and I'm going to talk to you about four of them today. The first one is evidence synthesis. We consider systematic review to be a very important part of comparative effectiveness research. It's the synthesis of the current medical research. The idea is to provide a rigorous evaluation of what's known on the basis of existing research. So before we decide to conduct new research, we scan the environment, find out what already exists, and take a look at the evidence that's already out there for this intervention. We focus on looking at the strengths and the limits of the evidence from the studies about effectiveness and safety of the intervention. The centers that are conducting the evidence review are Evidence-based Practice Centers. We have 14 EPCs located across the country. These are the experts in conducting comparative effectiveness reviews. They also spend a lot of their time looking at the methodology for conducting systematic reviews. The EPCs adhere to rigorous methodological processes. A Methods Guide for Conducting Comparative Effective Reviews is posted on our website and the EPCs follow this.

We have many reports in progress but I want to highlight a few that might be of interest to the audience here today. One of them is Comparative Effectiveness of Post Acute Rehabilitation for Moderate to Severe Traumatic Brain Injury. We have another report on TBI and Depression that might also be of interest to you. If you want, you can go to the Effective Health Care Program website and check it out. It's in progress right now so there may still be an

opportunity to provide input on the research questions that are being asked and the outcomes we are studying. Another report is a Technical Brief on Wheeled Mobility Service Delivery or wheelchair service delivery and, again, more details about this report are on our website. The third one I want to mention is the Comparative Effectiveness of Physical Therapy for Knee Pain Secondary to Osteoarthritis. There is still an opportunity to comment on this research.

The second area of the framework I want to highlight is the set of investments we are making in evidence generation. This is the conduct of new research that compares the effectiveness of different interventions. We were able to make significant investments in new research and in new studies because of the Recovery Act. We received \$300 million to do this work. For our agency, with an annual budget of about \$350 million, when we received \$300 million for comparative effectiveness research, it was a really exciting and really busy time. We are now knee deep in the research. The awards have all been made and the researchers are really busy doing the work. We are starting to see the results of these investments and we'll see more over the next few years. We made some significant investments in developing different data networks for conducting comparative effectiveness research as well as in developing patient registries and supporting pragmatic clinical trials. These are clinical trials that don't necessarily look like the randomized control trials that we're used to. These are clinical trials that include patients who may have multiple morbidities or might not adhere to the drug regimen exactly as it was prescribed. These studies are different in that they take into account how patients function in the real world, and

the effectiveness of the drugs in the real world. The other important point to note about our new research investments is that we tried to include underrepresented patients in these trials, so those populations that you wouldn't normally see in RCTs such as the elderly, children, racial and ethnic minorities are included.

The third area I wanted to highlight is training and career development. I know we probably have some researchers in the audience. We are continuing to award grants to individuals and institutions to enhance their research and methodological capacity for conducting comparative effectiveness research. In the slides you'll see I highlighted one award that we made recently to a scientist to study the implementation of a stroke telemedicine access recovery project at the University of North Carolina. We are excited that we were able to make this investigator award in the area of telemedicine and telerehab.

The last area I want to point out is the investments we've made in translation and dissemination. The idea here is that all of that research that's synthesized and generated is translated into products or into guides and tools that can be used by different audiences including patients, clinicians and consumers. Most people likely won't read a 300 page systematic review and not everyone has the expertise to read through these scientific manuscripts. So, what we attempt to do is take the scientific information and the evidence that's coming out of the program and translate it into summary guides for different audiences. We have many summary guides available across the 14 priority condition areas. These guides can be used by and disseminated to the different audiences.

I have a slide here that highlights the systematic review and then all of the different arrows coming out from the review shows the different tools that can be derivative products from that systematic review. I mentioned the consumer guides but we also have continuing education modules, patient decision aids, faculty slide sets, interactive case studies, executive summaries, etc. so there is a vast array of products that come out of that research.

So how can you get involved in the Effective Health Care program if you're interested? Well, you can go to the Effective Health Care program website. It's listed here on the next slide, effectivehealthcare.ahrq.gov. You can go on to our website to nominate research topic. You can let us know where you'd like us to conduct comparative effectiveness research. If there is a research topics that you would be interested in, that the results could potentially benefit you, please go to the website and nominate that as research topic.

We post all of our draft key questions and draft reports up on the website for a comment period. People can go to the site, take a look at the research that we are proposing, and let us know if the outcomes we are proposing are really the outcomes that are important. The program really does take the input that's received from the public into consideration as we are developing our research.

You can also go on the website and take a look at the guides and the other tools that we have available and begin to use them or disseminate them. If you're a practicing clinician you can go on and complete continuing education modules. Also, as I previously mentioned, we have training grants available to investigators and institutions. We have conference grants available so we can

support conferences like this. I think there is a great opportunity for anyone who is interested in funding to go there and take a look at the announcements that are posted. I encourage you to go to the Effective Health Care website because that's our primary way to interface with the public and everything from the program is posted up on that website. All of the research is posted up there. It's all free. All of the guides are free to download or you can call and request hard copies of them. We also have podcasts and many other tools that are all free for anyone. So please, go on and check it out.

In closing, I want to mention the Patient Protection and Affordable Care Act or PPACA or healthcare reform. The Act established a new, independent, nonprofit institute with public and private sector funding. This institute will conduct comparative effectiveness research so this is obviously something our Agency is very interested in. Our director, Dr. Clancy, is on the board of the Patient-Center Outcomes Research Institute, as is the Director of the NIH, Dr. Collins. This new institute has been tasked with setting priorities, coordinating with the other agencies conducting comparative effectiveness research, and supporting CER. This institute will also make awards for comparative effectiveness research but it's still in the early stages. There have been a few open, public meetings, but the priorities for research have not yet been set and awards have not been made. The language does state that the findings from the comparative effectiveness findings cannot be used to deny coverage. If you're interested in learning more, I encourage you to go and take a look at the actual language. Language in the Affordable Care Act also states that

PCORI will provide funds to AHRQ to disseminate the findings and also tasked AHRQ with establishing grants to train researchers and to support methods. So, while there is some uncertainty about what PCORI will do, it is clear that AHRQ is going to do the important work of disseminating information, making training awards and supporting research in methods.

I encourage you to go to the Effective Health Care program website. There you can sign up for our email list and you can check off when you want to be notified by the program. For example, you can be notified if there is new research up for comment, if you just want to get program updates. So, please go to the website, check it out, sign up if you're interested, and if you have any follow-up questions, you can contact the program at effectivehealthcare@ahrq.hhs.gov. Our phone number is on the slides, so if you leave a message someone from the program will return your call. Thank you very much for your time and for your interest in comparative effectiveness research.