

Effective Health Care Program

Listening Session

Transcript

The U.S. Department of Health and Human Services hosted a listening session on
Wednesday, January 11, 2006,
to solicit input on research priorities for the Effective Health Care Program.

Introduction

Dr. Straube

If I could ask people to take their seats, please, we'll try to go ahead and get started. Good morning. I want to welcome everybody here in the room, and the folks on the telephone line, and thank you for participating in this listening session this morning regarding next steps in effective health care research and evidence development at the Department of Health and Human Services. These activities are very important to every health agency in HHS and to the entire American health care system.

My name is Dr. Barry Straube. I am the Acting Chief Medical Officer and the Acting Director of the Office of Clinical Standards and Quality of the Centers for Medicare and Medicaid Services. And I would like to welcome you this morning, and I'm very pleased to have been asked to moderate the session this morning. I'm joined here this morning by Dr. John Agwunobi, who is HHS's new Assistant Secretary for Health, and Dr. Carolyn Clancy, who is the Director of the Agency for Health Care Research and Quality, also within HHS where the new Effective Health Care Program is currently housed. I wanted to add that the secretary of HHS, Mike Leavitt, and my boss Mark McClellan are extremely interested in the proceedings here this morning, but they were unable to be here. I particularly send Mark McClellan's regrets. I was in touch with him around midnight last night and he was still concerned that he really wanted to be here but wasn't able to do so. So I send his greetings to all of you for sure. In addition to those of us here in the room-we have at least 50 people I would say here in the room. We're joined by over 250 people on the telephone lines who will be participating with the session this morning from around the country.

This is the second listening session that we've had, to obtain input on priority areas for the effective health care activities that were authorized under section 1013 of the Medicare Modernization Act that came out at the end of 2003. The purpose of this meeting is to provide an open door forum, if you will, for public input in order to help the Department of Health and Human Services as we review the priority conditions that should be included in our next round of effective health care research and synthesis. The first listening session took place in May of 2004. And it was part of the open process that resulted in the Secretary's selection of ten priority conditions for the first phase of the comparative effectiveness review process. The first ten conditions were focused on the Medicare program in particular, and that first list of conditions was published publicly in November of 2004.

The Effective Health Care Program was then established at AHRQ and the reviews have subsequently been launched. For those of you who are following things closely, the first Comparative Effectiveness Review under this program was issued last month and is published on the AHRQ Web site. Nine more reviews are currently being developed. And a new set of topics for the next set of reviews is currently being proposed on the Web site which is <http://www.effectivehealthcare.ahrq.gov>. That next set of reviews will also be based on the initial list of ten priority conditions.

Our purpose here this morning is to look beyond these initial reviews and to consider what addition or other changes may be needed in the list of priority conditions for future years. In particular, we want to review whether there are conditions of special importance, not only to the Medicare program, which we focused on in the first ten conditions, but the Medicaid and the State Children's Health Insurance Programs which are also covered under this program. This is the beginning of a process of reviewing the priority conditions. We don't have any preconceived ideas about what should be and should not be identified as priorities, and how many should be included. But we welcome the ideas of everybody in the room here and on the telephone in guiding us in picking additional priorities. We also welcome your comments on the program as it's developed so far and any other ideas you may have on the future of the program. Let me remind everyone that with this program you can participate very actively by going to the Web site that I mentioned previously, signing up at the Web site. You can get regular communications from the program on what's happening. In addition, you also have the opportunity on the Web site to make comments and give suggestions at whatever time point you want. It doesn't have to be restricted to open door sessions such as the one today. The Department of Health and Human Services wants this to be a very transparent and open process, and I think the Web site and these open sessions are a part of that. And the Web site, again, is <http://www.effectivehealthcare.ahrq.gov>. Now before we begin our public comments this morning, I'd like to invite my colleagues at the table here to say a few introductory words, and I'll be making some also from Dr. McClellan. And I'll begin with Dr. Agwunobi on my left here. As the new assistant secretary of health for the Department, Dr. Agwunobi assists Dr. Leavitt in managing the agencies of the U.S. public health service as well as formulating and carrying out public health policy. So I'd like you to welcome and introduce Dr. Agwunobi.

Dr. Agwunobi

My name is John Agwunobi. And as my colleague just indicated, I serve as the Assistant Secretary for Health in the Department. I recognize that there's work to be done today, and that this is truly a work session. To some degree, I'm but the garnish, and so I'm going to keep my comments nice and short so we can move on to the real purpose for which you're here. It's pretty clear, and Carolyn and I have had these conversations over the years, that as our Secretary has built transforming health care into his 500 day plan, his 5,000 day plan, as he has clearly stated across the agency that he wants to leave the department when he's done having impacted the health care of our nation in a positive way. That it's incumbent upon all of us who work within the department and all of you, the community, the larger community, its incumbent that we holler the word quality wherever we can and whenever we can. It's important that those plans to transform our health care system, our health system in the larger sense, always have the goal of improving quality. I'm very grateful to be here, although I must admit I'm not an expert in the field. I am a practicing, or have been in the past, a practicing pediatrician. I have been on that front line. And I recognize and understand that sometimes in the fog of the clinical war, it's easy for us to reach out to tradition and to common practice and to the quickest source of information that we can find.

The truth of the matter is we are a health system that has—suffers from both too much and too little information. Too much in that there is so much research, there's so much progress. We live in an era where there is so much going on in both research and clinical medicine. So little

because it's hard to access. Sometimes it's hard to find the answers to critical questions. There are gaps in research. It's hard to tell where they are. And this process of trying to find a way to compare therapies, compare interventions, rank opportunities, offers us an ability to better organize all of that information, an opportunity to make for a much better quality of health care delivery. Steven Wolfe wrote an article-he's with the Virginia Commonwealth University-in the *Washington Post* Outlook section, that hallowed journal of science, last Sunday. And in it I think he stressed the point that we definitely as a larger community need to push for greater efforts to help our health care system deliver the best quality care to America's patients.

As we watch the sunrise on this dawning of genomics and the pushing into new frontiers for clinical science, it becomes even more important that we understand how these new opportunities rank relative to each other. Now that I think about it, many of the old tried, true, and tested therapies and interventions have never really been compared in a real scientific way against each other in different settings for different individuals and for different populations. And that's the challenge that we face. Mark McClellan often says that high quality of care is absolutely essential to any strong plan to transform the health care system. But he also goes on to say as he is known that we can't afford to do it any other way. It really is about money as well. That it's not just about clinical outcomes, but a truly transformed health care system holds quality first, but it's efficient. It's productive. We have to work together. And I recognize that we haven't always made these kinds of comparisons, these kinds of decisions out in the open. I blame Carolyn for the culture of transparency, the culture of openness that she's pushing, in trying to do this task. She wants your opinion. She recognizes that there may not be consensus as we begin the discussion on a particular subject. But she wants that lack of consensus to be apparent. I urge you not to just listen. I think we're the ones that are supposed to be listening in this particular forum. Participate. Don't throw anything at us, however. The right place to start, you know, we have to find a way to figure out where do you begin? It's a long journey. The vast number of opportunities in terms of comparing therapies, in terms of the ability to look at the difference and the relative value of interventions. There are so many opportunities today, and as science progresses, there will be so many tomorrow. So we have to figure out a way, a strategy, to be able to select where we're going to begin. What are the priorities? Now once again, I've sat next to Carolyn, Dr. Clancy, on many different panels and settings, and I've always felt a little inadequate beside her because of her intense intelligence, and her understanding of research and the broader issues that are involved in nurturing a research community. I'm told, however, that she's not the smartest in her team. That there are many just like her on her team. And it's true that we could turn this task over to them and they'd come up with a solid product, a strategy, a plan, and they'd be done in maybe all of three days. But it wouldn't include you, and it wouldn't include your perspectives, and it wouldn't include your points of view. So I applaud this method of getting it done.

This open approach to trying to develop a strategy. The work is already underway, and you've already participated. I would urge you to stay the course, stick with us, and see it through to the end. And if there are others on the outside that you think need to be a part of this, invite them to these forums. Invite them into the debates. It is a listening session. So I would urge you to also listen to what others are saying. You can learn as much as we can from listening to a colleague from across the room. I think as we look at this program we're seeing an important part of the future of health care. This concept of not just knowing what's a quality drug, what's a quality

intervention, what's a quality piece of equipment I guess would also be included, but also comparing one quality product, one quality drug, one quality therapy to another to try to figure out which works best in a given setting, which works best on a given population for a given disease or intervention need. That's the way of the future. I think the other piece in that test is getting to those answers by including everyone. It's also relatively new. Over the past two decades we've learned about the wide variation in medical practice, and we've learned that there all too often is very little rationale for the things that we do, or at least for the variation in the ways that we apply those interventions. I was reading an article recently that talked about the fact that we all too often over-research long after we've proven a point, long after it's well established that an intervention is effective, or not. We keep flogging that horse to see if it will move any faster. I'm hoping that this process and others will be a way for us to rationalize and to, not reign in, but at least put a semblance of structure on that process. And you can only get there by involving everyone. There's no way you could do this in some regulatory office in the back room of a large stone mausoleum-type building on Independence. You really have to come out and have a discussion. I'm happy to see a systematic movement towards effective health care taking root in our public health service agencies for which I have now been given the unique honor of being a part of. I've actually only been on the job for a few days. I congratulate AHRQ, and I congratulate Carolyn, for their work and for their accomplishments in this young new program. I look forward to the comments that we'll hear today. I'll be leaving a little early, but we'll leave someone behind so they can brief me later on what exactly was said. But focus on AHRQ, and on CMS, and on your colleagues. I think the reverberations of the conversations, they may not be loud noises that you hear, but I think the waves will travel far. I do know, and I'll end on this, that the Secretary himself plans on using the priority lists. For example, he asks every once in a while what are the five most important diseases afflicting our community today? And every once in a while he updates that. His 500 day plan contemplates those kinds of discussions. And I'm hoping that we talk not only about what are the priority conditions, how should we select interventions to be measured and ranked against each other, to be compared in a relative way against each other. I know for a fact that our secretary is going to be looking to AHRQ for input as he tries to formulate his strategies and his priorities for the future. And that you will influence him in these conversations, so let it out as I know you have. Thank you very much.

Dr. Straube

Thanks very much, Dr. Agwunobi. I'd like to put into context what CMS is doing and how the Effective Health Care Program fits in with what we're doing and try to put this in a national context too to show how important we believe this program is. I'm going to talk through-I have some slides here for people in the room on Power Point, and I'll try to talk through these for folks on the phone lines. First of all, again, Mark McClellan sends his regrets. He really did want to be here this morning, but much of what I will be saying here comes from the leadership of Mark and the direction that he's put CMS in. I think first and foremost, Mark has expanded the image, and the perception, and the vision of what CMS is meant to do above and beyond our just serving as a payer organization, as a beneficiary rights protector, and as a quality improvement type organization. And what I'm referring to specifically is the concept of CMS as a public health agency. And this I don't mean going out and doing flu clinics and providing preventive care services, which are all important activities.

This is a much broader grander view. It's using the agency's influence and the fact that we spend \$600 billion a year on health care services to our beneficiaries in our various programs to leverage and transform the entire health care system. So we're going to be focused on working with other folks to not affect just the Medicare and Medicaid programs, but the entire U.S. health care system. The focus in this vision is not just for high quality, although I've listed that here as the first priority. I think we also focused on value, on efficiency, on cost effectiveness. And as Dr. Agwunobi mentioned to you, these are all issues that Mark has been very passionate about and has instilled in the rest of us in the agency. And tied in with this is the need, in order to achieve those goals, to assist patients and providers in receiving evidence-based technologically advanced care while reducing avoidable complications and unnecessary costs. I think that phrase really captures all of the points that Mark has stressed to us inside CMS, and that directly relate back to the Effective Health Care Program we're here to talk about this morning.

Just to put in international context, this is just showing the growing number of Medicare beneficiaries over the years. And you can see projected to year 2030. There is somewhat of an asymptotic rise here in the number of beneficiaries. The other points I'm about to make are especially relevant to us in our Medicare population, but it's also relevant to the Medicaid, SCHIP, and the commercial health care sector, as well as the uninsured in this country. This shows-the slide that I'm projecting right now shows what we spend in the United States as a percentage of gross domestic product compared to other industrialized nations in the world. And as we all know, I think, in this room and on the phone, the United States spends more as a percentage of GDP than other industrialized nations. This is juxtaposed to the fact that-I'm now projecting a slide which shows the results of a seminal study that Beth McGlynn and folks at the Rand Corporation did, published in the New England Journal about two and one-half years ago now where they judged patients coming in to a doctor's office, whether they received the type of care the national consensus guidelines would suggest they should receive. And Dr. McGlynn's study showed that about just barely over half of patients coming to a doctor's office on average received recommended care. The slide also projects here variation with respect to individual disease states. The best that was listed in the study was cancer care where 76 percent of women received recommended care. But I would flip that and say 24 percent, even in the best condition, did not receive the type of care that they would be expected to receive under guidelines. And when you go to some other disease states such as hip replacements, pneumonia care, et cetera, as you can see on this slide, the care received was clearly way out of conformance with recommended guidelines.

This slide shows-what I'm projecting now for the folks on the line is again, Jack Linberg's, one of his typical geographic variations across the United States. This projects differences of the amount of money spent for hospital care for Medicare beneficiaries across the country. Now for those folks in the room, the dark red colors reflect high levels of spending, on average about \$3,500 per beneficiary per year. The whiter colors reflect lower spending, an average about \$1,500 per beneficiary per year. And for the folks on the phone, there's great variation. There are concentrations of very high spending, not surprisingly in some urban areas like Los Angeles, New York, Chicago, the Bay Area in California, et cetera. But surprisingly there are many rural areas where the expenditures for hospital care are very high also. But the main message from this slide is that there is gross variation in the dollars being spent for health care across the United States. Now if you keep in mind this slide for those of you in the room, and for those folks on the

phone, I'm now showing a slide which reflects the quality of care based on CMS hospital quality metrics received across the United States. And on this slide it's in black and white. The dark areas are in fact the lowest quartile of performers, that is, the worst amount of care. The white areas are the highest quartiles. And if you remember back to the prior slide and for the folks on the phone, there seems to be some relationship between high expenditures and poor care outcomes conversely to the areas that are the lowest spenders that have the highest quality of care outcomes. So again, gross variation in expenditures across the country, gross variation in quality outcomes, and perhaps some inverse relationship between the amount of money spent and the quality of care that we receive in the end.

CMS developed-this past summer we published a CMS quality road map. And our vision is to have the right care for every person every time. We have six aims which align with the Institute of Medicine's six aims of safety, effectiveness, efficient care, patient-centered care, timely care, and equitable care. And we have five strategies that we intend to roll out, our quality agenda in 2006 and beyond. I've listed them here on the slide. The first, which is germane to this session, is to work through partnerships to achieve specific quality goals. And again, we have to have broad open consensus efforts with multiple stakeholders at the table in order to achieve our quality goals across the United States. And this forum is an example of that. We also believe very strongly in publishing quality measures and information as a basis for supporting more effective quality improvement efforts. Again, germane to this session because of the effective health care studies that Carolyn and her team are developing, and the need to publish those, and get them out to providers and beneficiaries. The third strategy is the need for us to reform our payment system. Again, we're not going to be talking about that today. But clearly the evidence that comes out of these reviews can be used in a variety of ways in so called pay-for-performance initiatives and can be tied in in other ways to the reforms that we're going to be making and that Congress will make in our payment system in which we pay health care providers. The fourth strategy is we need to assist practitioners in making care more effective and less costly, particularly through the development of health information technology. And I think that health information technology is going to be very, very important to disseminate the results of the effectiveness reviews that are being done by AHRQ. As an example, the Web site already is a very effective tool in trying to include many, many folks and assist practitioners in providing better care. And then last but not least, we're focused on a fifth strategy which is trying to bring effective new treatments, but also effective assessments of those treatments to patients and providers in a more rapid manner, to develop better evidence so that doctors and patients can work together to use medical technologies in treatments in a more effective manner, and to improve the quality of the care while avoiding unnecessary costs and complications, as I mentioned earlier.

Again, I'm going to let Carolyn in her remarks talk more about MMA section 1013 so I'll skip over that. But, we did in conjunction with AHRQ and some other stakeholders select ten conditions that affect Medicare beneficiaries in particular, and people will be commenting about those and others this morning. I've listed them here: ischemic heart disease, cancer, chronic obstructive pulmonary disease, stroke, arthritis and non-traumatic joint disorders, diabetes mellitus, dementia, pneumonia, peptic ulcer disease, and depression and other mood disorders. Clearly conditions that affect the Medicare population.

Our partnership with AHRQ, we have been represented on the review committee that has looked at proposals for the DEcIDE research centers that I suspect Carolyn will talk about and people will comment on today. We've also been supporting the registry project which is addressing topics of registry creation, registry operations, and the evaluation of the design and operations of registries. And as I said, Carolyn will likely review other aspects of the Effective Health Care Program.

Why do we need-why do we at CMS believe we need comparative effectiveness reviews? Well, several points to be made. First, they provide a sound foundation of evidence about which treatments work best. And we believe that this is essential to help doctors and patients achieve the best quality health care. We need to have such information available in useful and understandable formats. And I think again, the first report that's been put out and the presentation on the Web site, et cetera, is evidence of where we need to be heading. We think that AHRQ's issuance of the first review and subsequent reviews are simply a milestone in achieving our goals at CMS, but likewise everybody in the health care system achieving their goals. And we feel that because of these reviews, that Medicare beneficiaries and their doctors and other clinicians clearly have better information now about costs and benefits of treatment for now one condition, but soon to be many, many other conditions in which multiple treatment options are available. We think that better evidence is a centerpiece of the prescription drug program which we've just launched, and other reforms which are being implemented by CMS right now to try to bring the Medicare program up to date. So this Effective Health Care Program is essential to help us achieve that. We need to do more to learn about and measure the effectiveness of alternative treatments for common health problems. And this is the first step in that regard. We also need to do more to help patients and doctors get unbiased practical useful information on benefits, risks, and costs.

I've listed on this slide, and for the people on the line I don't want to go into great detail, but we have a number of other initiatives at CMS dealing with evidence collection, evidence development, and evidence implementation. And they include the use in our national coverage decision process including our most recent coverage under evidence development process which we have just implemented over the past year. We clearly are using evidence development to help us in developing quality measures and benchmarks both for quality improvement efforts as well as pay-for-performance programs which are becoming more and more known to the American public. We clearly use evidence in selection of new medical technologies and innovations within the Medicare and Medicaid programs. We've been listing medical evidence information for our beneficiary and provider use and consumer use on our Web sites, the Medicare Compare ones in particular. We use them in medical guidelines, clinical guidelines, dissemination is a key part of our quality improvement programs. We use them in the prescription drug program we just launched. We use them in the Medicare Advantage Program. We use them in our health information technology strategies and e-prescribing that are currently being provided. And the list goes on and on and on. So in summary I think again that the use of better evidence in clinical care and health policy decision making will improve the quality of care, will improve health outcomes, and well-being of patients. It will achieve better value for health care dollars spent, and it will promote better health care partnerships between patients, and doctors, nurses, and other clinicians. And we at CMS certainly look forward to today's sessions with the identification of new topics for effectiveness reviews. That's the CMS perspective.

And I now take great pleasure in introducing Dr. Carolyn Clancy who is the Director of the Agency for Health Care Research and Quality. Carolyn is a leader in health care in the United States. She's certainly a colleague that I respect and look to for counsel many times, and certainly helps us at CMS in innumerable ways in improving our quality agenda. Dr. Clancy.

Dr. Clancy

Thank you, Barry, and good morning. I think you can see how much we enjoy collaborating with CMS on a regular basis, and why I was so excited. One of my best Christmas gifts was learning that Dr. Agwunobi had been confirmed about a week before the holidays. So I want to welcome all of you here in the room and on the phone to the second listening session for the effective health care program. I'm really pleased at the turnout. This is not a great weather day, but including everyone here, I've been looking forward to this, to a way to continue our work as the Secretary identifies the next round of priorities. What's new about this new authority in the Medicare Modernization Act are a couple of things. It's all about informed choices. Today Americans have many, many situations where there are two or more options for them to choose from. And the information that is going to be produced from this program is actually going to help them make better choices about what's right for them as individuals. This program does not make recommendations or prescriptions. It's not about guidelines. It's about presenting people with the facts in a way that they can understand. It's also very much about ongoing engagement with all of you. So I think John Agwunobi emphasized that very, very clearly. So again, it's part of the reason I'm thrilled that you're here today. So let me wish all of you a happy new year and tell you that the timing for today's session couldn't be better.

It's a new year, and it's just a few weeks after the release of our first comparative effectiveness review on GERD, or gastroesophageal reflux disease, for those of you who occasionally leave the world of acronyms. I want to say-express my thanks and gratitude for all the work our stakeholders have done both in preparing this report and helping us to spread the word about the findings which shows that certain drugs can be as effective as surgery in the treatment of GERD which affects more than 10 million Americans. And I'm really very, very pleased by the response from CMS to this report as well as from a broad array of stakeholders across the health care industry. By comparing treatment alternatives for GERD, examining their effectiveness, and reporting the findings in a way that is immediately useful to patients, providers, and payers, we believe that the program has already begun to demonstrate its value right out of the gate and there's a whole lot more to come.

In the coming months we're going to be releasing a series of reports of comparative effectiveness reviews on high priority topics that include breast cancer diagnostics, heart disease, stroke, and depression. So let me tell you right now a few areas that we would love to hear from you. Before I do that, I'm going to just walk you through one of the three components of the program. The priority setting is a very, very clear part of it, and as Dr. Agwunobi mentioned, there was a very nice article also from that journal, the *Washington Post*, recently making the case that we would be much better off as a country if all of our investments in very large trials and very large clinical studies were preceded by systematic reviews. And that's exactly how this program is set up. We start with systematic reviews, establish priorities, start with systematic reviews. Those reviews

will identify what we know, and will also identify very important research gaps at which point we will then be turning in two directions.

One is to a new research network called DEcIDE that Barry mentioned very briefly which takes advantage of the fact that many health care organizations have already begun making big investments in electronic health care data at the patient level. So we're going to take advantage of that. Sometimes that network will help us fill gaps, other times we're going to have to turn to partners in the public and private sectors to address the research gaps that are most important to address. But any time we do establish those partnerships to launch very significant studies, we'll do it with the confidence that we know that we've already done the systematic review to know that we're not flogging a dead horse as Dr. Agwunobi said a few minutes ago. The third part is the English to English translation part. No researcher on the planet thinks that they're not putting things incredibly clearly. And they are. Often for the researchers it is very, very difficult to communicate scientific information in a way that everyone can understand and use and understand what it means for them. To that end in recognizing how challenging it is we've established a new center out at the University of Oregon which will help us get better and smarter at this. In your book you'll see the summary of the first review as well as the patient page. That's only the beginning. We're also going to be looking for partnerships to be able to get this information into personal health records, into a variety of venues so people can use it when they need the information. This center was named in honor of our prior director, Dr. John Eisenberg. So we're hoping that we get better over time in terms of making this information actionable and understandable to a broad array of audiences. Now for systematic reviews, choosing the topic area is very, very important, again why I'm glad that you're all here today.

Secondly, though, is actually getting the questions right. Right now on our Web site there are some key questions that we're putting out for public comment. And some specific areas I just wanted to mention to you. One is the comparative benefits and harms of drugs for Alzheimer's disease. Another is the comparative long term benefits and harms of ACE inhibitors versus angiotensin receptor blockers, or ARBs, for treating hypertension. Another is comparative effectiveness of review of coronary artery stents versus bypass surgery. And the list will go on and grow over time. So please know that in addition to giving us feedback about priorities, in addition to the opportunity to weigh in on the draft reports, we also want your input so that we make sure we get the questions as correct as possible.

My expectations today are great for several reasons. One, all of you are here and on the phone. Secondly, after the first session I think all of us left terribly energized. This program will be successful to the extent that we can continue to engage all of you throughout the process. And so far, I think we're doing very, very well. We very much appreciate your commitment and combined wisdom, and your collaboration is going to help us ensure the long term success of this program. And we think we're off to a good start. The second reason I'm confident about the success of this program is the equality of the process we're using. Dr. Agwunobi emphasized the notion of transparency, and every step of this process will be transparent, from establishing priorities to the opportunity to comment on questions, to the opportunity to comment on draft reviews. I should note that we actually solicit reviews as well. But any citizen can actually go to our Web site. For those of you in the room, that page is in your book, effectivehealthcare.ahrq.gov. For those of you on the phone, I think you just heard us say it

again, and we'll remind you before the session is over. So as we gear up for the next set of priorities, we're very much looking to all of you to give us the best kind of input possible. Finding ways to deliver effective health care to all Americans is a task that's worthy of all of our efforts and enthusiasm. And I don't think I need to tell all of you that it's a big job. As George Carlin, the humorist, is fond of saying, some people think of the glass as half full, and some people think of it as half empty, and some people see the glass as just plain too big. The glass, if you will, the health care system in front of us is pretty big. But there is no doubt that our commitment to turning evidence into action is much greater. With each topic that we select, with each Comparative Effectiveness Review that we release, with each informed choice made by patients, providers, and payers we serve we're making a difference. Thank you again for joining us today. And now we get to listen. Thanks.

Comments

Dr. Straube

We're ready to start the formal part of the listening session. And the format for this, again we have a large number of people here in the room present, but we also have a very large number of people on the telephone lines. So we're going to alternate. We'll begin here in the room in D.C., but we'll periodically go to the telephone lines and ask people there. I'd like to ask folks to first of all try to keep your comments to three minutes or less. I know that's hard sometimes, but we want to try to get as many comments as we can. And for those people in the room here, we do need you to use the handheld microphones. This is being recorded this morning, so that other people in the room can hear you and people on the telephone line can hear you. If you would all identify yourself by name and the organization you're with, that would be very helpful also. So I think we'll start here in the room. Who would like to make a comment or statement?

Mr. Burkholder

My name is Randy Burkholder. I'm with the Pharmaceutical Research and Manufacturers of America and the policy department there. I first want to just thank all of the speakers who have already made comments, Dr. Straube, and Dr. Clancy, and Dr. Agwunobi, for the high quality of your thoughtful comments. And I wanted to just start by underscoring the fundamental importance of the shared commitment to the goal that Dr. Agwunobi articulated when he opened, which is the shared commitment to improving quality in health care and to transforming health care by starting with improved quality as the basis for getting better value and as the basis for reducing the cost of disease. I also want to make a point that I think we still see something of a persistent disconnect between that goal and the research agenda that has been undertaken thus far under section 1013. In regards to Dr. Wolf's piece in the Post on Sunday and as well as the work of John Weinberg, I think they both make the fundamental point about the importance of health system's challenges and addressing basic health system challenges if we truly are going to transform quality in this country. And the fundamental point we would make is to orient section 1013 towards engaging in those health system level issues to truly make a difference in improving quality.

I'll try to hit on just a few other points. We certainly appreciate the opportunity to provide comments. And we do believe well-designed health outcomes research from the public and private sectors such as that described in section 1013 can help us make the fundamental quality improvements we need, can empower physician and patient decisionmaking. We recognize and appreciate the important progress that HHS has made in implementing this section of MMA over the past couple of years, most recently and notably through the rollout of the Effective Health Care Program a few months ago.

At the same time, as I indicated, we do remain concerned that key elements of this provision have not been implemented, and we believe some further steps could be taken to improve the transparency and openness of the process. I would also point out in regards to the orientation of the program that Congress, in passing its funding bill this year, affirmed both the direction AHRQ has taken in beginning with the disease-based approach to research under section 1013. It also underscored the importance of conducting research in additional areas such as the organization, delivery, and management of health care items and services, research which directly addresses points made by those such as Steven Wolf, but research that we feel has not yet been addressed by AHRQ, yet is mandated in the statute. So we believe that is an important area to consider going forward under the program.

Finally, two other quick points. One, just since enactment of MMA there has been a considerable additional research that's affirmed the importance of this broader quality-centered research agenda mandated by Congress. Just two quick examples, an August 2005 study in the *Annals of Internal Medicine* found a strong link between improved quality of care and better survival among vulnerable older patients. Quality indicators in this study looked across the continuum of care, at processes of care, patient follow up, prevention, diagnosis, and treatment. Another recent study published in *Medical Care* found that increased compliance to prescription drug regimens improves clinical outcomes and can reduce medical costs. Finally, a lecture that I know Dr. Clancy you're familiar with, Don Berwick's John Eisenberg lecture in April 2005, called on health services researchers to adopt broader health systems approaches to research in order to address the fundamental health system challenges we face. We do appreciate AHRQ's support for research that looks at this broader scope of inquiry. For example, the special emphasis notices recently published by the agency looks like it's an example of that. We appreciate that perspective. We think it's important to build that perspective into implementation of section 1013 as well as directed by Congress and stated in the statute.

Regarding process-and if I'm running over my time, just cut me off please. But we appreciate the steps AHRQ has taken as well to establish broad and ongoing process of consultation such as through these meetings, other steps as well, such as the implementation of an electronic docket for review of input you've received also has been valuable. We recommend a couple of additional steps to improve the openness and transparency of the program. First, AHRQ should, through an open public process, develop clear objective criteria for selecting research priority topics, and when it proposes research topics can then provide the rationale based on those criteria. Finally, we would recommend a consistent approach to soliciting comment on draft reports when they are released. We trust that will be the approach going forward, but note that in release of the first couple of reports, one has been released as final and one has been released as draft for public comment. We would hope that going forward all of those would be released as

draft with opportunity for public comment. So we appreciate the opportunity to provide and thank you. We appreciate the opportunity to provide input today and we look forward to continuing working with you to support a well designed research agenda under section 1013. Thank you.

Dr. Straube

Thanks very much for your comments. I want to commend for commenters going forward, the specific suggestions are very, very helpful. So I thank you for your specific comments on how we might improve things. Another question here in the room or on the phone?

Operator

Yes, we do have a question from Tricia Leddy. Please state your organization.

Ms. Leddy

The Rhode Island Medicaid Program.

Dr. Straube

Tricia, go ahead. You're on the line.

Ms. Leddy

Hi. I just wanted to comment on, from the perspective of Medicaid and running a Medicaid and SCHIP program for families. I looked at the ten priority conditions that were set, I guess it was last year. And most of those conditions focus on conditions prevalent in older people. What we struggle with in running Medicaid and SCHIP programs particularly for families are conditions that aren't necessarily listed on that list. And I wanted to suggest that maybe some of the conditions in the future be focused on some of the areas where States struggle to know whether to cover a treatment or not. And specifically, I would suggest that for children and for adults, that behavioral health for people who are on our program, not just because they have a behavioral health condition, but that behavioral health is a very big issue. We have to decide all the time about what type of treatment is best. And because in some areas such as in Rhode Island there's a shortage of psychiatrists and particularly child psychiatrists. Primary care physicians really struggle with these kinds of issues.

The specific conditions I would say get the most questions are depression, which I noted is on your list already, but also other mental health conditions such as bipolar disorder and schizophrenia in adults. Those three conditions result in a lot of hospitalizations. They're the number one cause of hospitalization as a group for our disabled adult population is mental health conditions in Medicaid. And for children, conditions such as conduct disorder, and ADHD, and ADD, where there is a lot of treatment, drug treatment. There are often not available enough child psychiatrists to be able to on an ongoing basis monitor that treatment. And primary care physicians are put in the role of having to make decisions about what's the appropriate treatment

for mental health conditions in children. And those are just a couple. Another related thing that we really do struggle with as far as treatment is concerned, and this is not necessarily drug treatment but other kinds of treatment, is autism. Autism spectrum disorders are a big issue in Medicaid and SCHIP, and there are treatments that we are covering and asked to cover such as very intensive home based therapy. They're expensive treatments. We want to make sure we're covering the most effective treatments, and yet there is not a lot of research out there about the effectiveness of the treatments. There are a few different kinds. They have different names. There's little research with few subjects about these treatments, and we want to make sure that those treatments that we are funding are effective for the children that have autism. So it would be great to have guidance on that. Another thing that is more and more prevalent in our society is obesity. And thus Medicaid and SCHIP often gets questions and requests to cover procedures such as surgical procedures or drugs to treat obesity. Guidance on that such as when to cover a treatment for-a surgical treatment for obesity would be useful to us. I would say another issue that results in enrollment and cost for both Medicaid and SCHIP is infertility treatment. There are 12 states including Rhode Island that have a mandate in our state health insurance laws to cover infertility treatment. Now infertility treatment is not covered on Medicaid and SCHIP. But what we're finding from the very useful data that CDC puts out in their PRAMS data set that infertility treatment is associated with a higher rate of babies born with special health care needs resulting in neonatal intensive care admissions and other ongoing health problems. We find that a lot of these infants do end up, even if the mothers were not on Medicaid or SCHIP during pregnancy, that because of their special health care needs or because of the working or employment condition of the family changes, that these babies do end up on Medicaid and SCHIP. And some of the age ranges of the women who are having babies conceiving using infertility drugs and other treatment are from young to old, and from 20 into 40. And I wonder if there are some kind of guidelines that could be developed for when is it appropriate to use infertility drugs given that-is it only after a year, such as our state law in Rhode Island says, of not being able to conceive, or given that there would be-at least in Rhode Island-a twice as likelihood of having a baby go to the NICU after infertility treatment.

Dr. Straube

Tricia, again, I think you made some very helpful suggestions there. We're going to have to move on to the next question asker. Thank you for your comments. We appreciate them very much. We'll go here in the room and we have a question up front.

Mr. Milzman

Good morning. My name is Dave Milzman and I'm a practicing emergency physician here in the District for almost 20 years. I'm representing today the American College of Emergency Physicians. Myself and almost 30,000 other physicians certainly appreciate this opportunity to address you. As you know, we are on the front line 24-7, providing not only care for all urgencies and emergencies, but as our self-dubbed health care safety net. We feel that we are a very active participant in all of the diseases under 1013 that you have elucidated. We see all forms of those diseases from acute exacerbations of COPD, asthma. We see the failures of arthritis treatments. We see acute problems with ischemic disease, as well as a high rate of recidivism with many of these diseases when both pharmacologic and surgical treatments fail.

Based on this, we would like to let you all know that the American College of Emergency Physicians very much shares your research agenda. And based on that, that we want to let you all know that we feel that there's a serious need for the acute care perspective that we offer more than anyone in terms of significant numbers in the assessment of any device, drug, or other technology. That based on rates of repeat visitors, for instance, depression, we see a lot of those patients on a recurring basis that might not be picked up if you're basing it just on office care numbers. And in addition to the national ambulatory care registries, still these are retrospective, but any prospective evaluation we feel should involve our perspective. And I'll easily stay my three minutes.

Based on the Institute of Medicine report, there continues to be a need to support the foundation for emergency medicine research at AHRQ. And we also strongly urge AHRQ and HHS to give a significant consideration of your priority conditions in their acute care phase in the emergency department when assessing what drugs are actually available to the general public. There are many drugs that just aren't available within the emergency department setting or the ambulatory setting that many Americans either cannot afford or cannot get access to based on their payer plans. And in the end while we fully support the guidelines for your patient registries which we do appreciate, we know better than anyone that these registries, without including more of the acute care perspective in them, would be mistaken. And lastly, we just ask that you give priority to the continued support of emergency medicine in this and in all future evaluations, and that the American public is very well aware of our availability on the 24-7 basis. And we do appreciate the continued support. Thank you.

Dr. Straube

Dr. Milzman, thank you for your comments. Operator, before we take the next questioner on the line and then we'll come back here, have we made it clear to everyone on the telephone line how they get into the question queue?

Operator

That is correct. If you'd like to ask a question press *1 at this time and please limit your remarks to a maximum of three minutes.

Dr. Straube

Okay. And do we have someone on the line then?

Operator

Yes, our next question comes from Doris Lotz. Please state your organization.

Dr. Lotz

My name is Dr. Doris Lotz. I am the Medicaid Medical Director for the State of New Hampshire. And what I would like to say is that there is so much opportunity in Medicaid and so few internal

resources that we rely very much on Federal agencies like yourselves to do this kind of research and to make it publicly available so that we can build policy off of it. That being said, there's no specific topic that I would like to draw your attention to. What I'd rather do is talk about specific contents for each topic that you may take on in your research agenda. Specifically, in reinforcing some statements that were made earlier, we need cost effectiveness information. It's very helpful certainly to talk about what exists out there with respect to comparing clinical treatment one to another. But without the cost effectiveness information, it's incomplete. In addition, I'd like to ask that part of your research agenda be to look at more head to head comparisons for which those little industry interests or research funds to do. We need the kind of information that takes new drugs, new technologies, new pieces of equipment, and compares that to what is currently out there that is certainly less exciting but perhaps more cost conscious. And that research is not being sponsored by anyone else. So I find often times that the best treatment is a value judgment and we need information on cost effectiveness and information on how emerging technologies, emerging new medical interventions compare to existing ones to really set an appropriate policy agenda, especially for public payers like Medicaid.

Dr. Clancy

Thank you very much. I can tell that enthusiasm is really starting to pick up here in the room, and I'm sensing on the phone as well. Since we will be here until 11:30, if you don't get a chance to put your two cents or two hundred dollars, however you want to think about it, to state your comments today, we very, very much welcome comments which you can submit through the Web site. And you can submit them any time. For those folks who have spoken up quite passionately and articulately about Medicaid and SCHIP, I just wanted to clarify one point. You're quite right that the first round of priorities was focused on the Medicare population. This was the decision of then-Secretary of Health and Human Services Tommy Thompson. We are quite explicitly looking to broaden that mandate for here. So your comments will be heard. I can assure you of that.

Dr. Straube

Thank you. Next question is here in the room.

Ms. Montalvo

Good morning. This is Isis Montalvo from the American Nurses Association. Thank you for the opportunity to comment on the Effective Health Care Program at AHRQ's listening session. The American Nurses Association considers the registered nurse component a critical component in any health care program. As you proceed in establishing priorities and reviewing your Effective Health Care Program, we ask that you consider including language that evaluates the entire health care process. The nurse is in a pivotal role in assessing, planning, implementing, and evaluating interventions. For example, teaching weight management and intake and output measurements for the congestive heart failure patients. Teaching patients and families to change injection sites when administering insulin. Evaluating a patient's response to therapy and how compliant the patient is in following their treatment. As you proceed in selecting a new condition or selecting a comparative review from existing conditions, the Effective Health Care Program

would benefit from inclusion of all related nursing interventions and identification and evaluation of those nursing outcomes. Thank you.

Dr. Straube

Thank you very much. We're going to the phone line now. Next question.

Operator

We have a question from Sue Tolleson-Rinehart. Please state your organization.

Ms. Rinehart

Good morning. I'm calling from the UNC CERTs at the University of North Carolina at Chapel Hill. The UNC CERTs is the nation's only center for education and research on therapeutics devoted to pediatric therapeutics use. We have a global concern. Children are not small adults, as we all know, and the history of concern for the protection of children as human subjects, combined with an absence of obvious economic incentive has in the past significantly reduced the number of drugs actually labeled for pediatric indications. If you put these two things together you see an urgent need for more and more pediatric therapeutics effectiveness research of all kinds for all conditions affecting children. Recent legislation has improved this situation somewhat. But even now by the FDA's count, 50 to 75 percent of drugs used to treat the pediatric population are not labeled for pediatric use. We need more comparative effectiveness research and pediatric therapeutic use across the board.

Now to three more specific questions related to SCHIP. North Carolina like many other states, created a separate SCHIP program. Now, like other states again, it is moving at least some of its SCHIP age groups into Medicaid in an effort to reduce costs and increase enrollment. This change and general questions of delivery of high quality care to SCHIP-eligible children suggests several areas of research, not restricted to diseases or conditions, but for questions of therapeutic use generally. North Carolina is presently experimenting with a voluntary academic detailing program to reduce Medicaid drug costs with the ultimate goal of moving toward an effective formulary. We urge more systematic research on the comparative effectiveness and cost effectiveness of drugs both common and more exotic used to treat children and the effectiveness of the use of formularies to improve quality and efficiency, and perhaps to standardize pediatric treatment. Our State's Medicaid primary care managed care structure which is now beginning to include SCHIP-eligible children under the age of six is experimenting with the use of standing orders for prescriptions to transfer prescriptions to appropriate in-network medications so long as there's no clinical reason not to do so to reduce cost and improve effectiveness. We urge more research on strategies such as the use of standing orders to evaluate comparative effectiveness and to improve quality and efficiency. And finally, in North Carolina, specialists, pediatricians, and others, will be reimbursed 30 percent less in the Medicaid fee schedule than under the SCHIP schedule as it had been constituted. As SCHIP-eligible children under the age of six are moved into an expanded Medicaid program, will this change reduce the incentive for specialists to see children in these public programs? The literature does suggest that such reductions in incentives can reduce access to care. So we urge more research on such questions of access to

pediatric specialty care for children relying on public programs as a part of the larger consideration of effective care. And the UNC CERTs thanks HHS and AHRQ for this opportunity to participate this morning in the discussion on ways to make care of our nation's children more effective. Thank you.

Dr. Straube

Sue, thank you very much. Great comments. We now have a question here in the room.

Ms. Lee

Good morning. My name is Teresa Lee, and I'm here on behalf of AdvaMed, the Advanced Medical Technology Association. AdvaMed is a trade association that represents the medical device industry, and our members include more than 1,300 medical technology manufacturers of all sizes. We appreciate that HHS has held this forum today. We at AdvaMed have been closely following AHRQ's efforts to implement section 1013 of the MMA. And we've seen a good deal of activity on this Effective Health Care Program from priority setting, to comparative effectiveness reviews, to evidence generation, to communications of research findings, all in a remarkably short time frame. We've noted the sheer volume of activity that has taken place in a remarkably short period of time. Overall we support comparative effectiveness research when it is done appropriately because it can provide valuable information for patients and physicians.

However, we believe that comparative effectiveness research is not generally appropriate for the use in the context it covers decisionmaking because the treatment that is more effective on average may not necessarily be best for a particular patient. We believe that it is critical to protect the physician's ability to make independent medical judgments for individual patients. For medical devices in particular, comparative effectiveness research poses distinct challenges. For example, medical device technologies pose a difficult moving target for technology assessors due to the iterative and continuous nature of device innovation. Medical devices have quite short life cycles compared to drugs, and their effectiveness is dependent on user training and physician experience. In studying medical devices, assessment findings can quickly become dated as the technology matures and physicians gain user experience and training. Consequently, a snapshot of comparative effectiveness of a particular device at a specific point in time may potentially understate the effectiveness of an innovation.

Today I have some very brief comments concerning the work that is currently underway. First, the priorities you've established through listening sessions and public comments are ambitious. We tend to think that if they are to be expanded, you might also address areas where there is underuse of proven interventions that would improve the effectiveness and efficiency of the Medicare and Medicaid programs which is the statutory mandate, statutory goals section 1013. We note that evidence-based practice requires practitioners to not only avoid the overuse of ineffective care, but also the underuse of effective care. In addition, we note that section 1013 requires research on improving the efficiency and effectiveness of Medicare and Medicaid through the examination of ways items and services are organized, managed, and delivered under these programs. And to date, AHRQ has not yet addressed these priorities.

In addition, we've noted that AHRQ has undertaken a number of specific research endeavors and we commend the extensive outreach efforts via the Effective Health Care Program Web site. However, in comparative effectiveness reviews and with respect to evidence generation, we note that the initial set of specific research topics were not vetted publicly. And while we believe this was due to AHRQ's desire to move quickly to implement section 1013, we think that the law's requirement for broad and ongoing consultation with stakeholders is equally important. Our concern is that these specific initiatives need to be discussed as fully as the broad research priority. For the research efforts already underway, where those topics were not openly vetted, we believe those efforts should be made to extend-efforts should be made to extend the comment period on studies as they are prepared. We also think that the times allotted for public comment on draft studies seem to be a little bit short, and that this may potentially impact the quality of the public comment.

We also want to commend AHRQ for its efforts for communicating clearly and fairly the findings of its comparative effectiveness reviews to date. We understand the importance that the agency is placing on this matter, and the results to date are commendable. We have some concern, however, with how the evidence generation efforts AHRQ is undertaking as part of the Effective Health Care Program will be handled. Our concerns do not relate to the research on the methods that are underway, but rather to the collection of observational data on particular interventions. The rationale for selecting and prioritizing the current efforts is unclear, and we think that this should be made available to stakeholders. We also think that this data, due to its observational nature, needs to be weighed carefully and should not simply be posted. We at AdvaMed appreciate this opportunity to comment on this important program. Thank you.

Dr. Straube

Teresa, thank you very much. Some very good comments. I'll take the opportunity to put a plug in again for effectivehealthcare.ahrq.gov, the Web site, because I do think again some of what you mentioned can be partially dealt with if people in between times go to that Web site and make comments on any topic. But I think your comments are well taken. We're going to go here in the room.

Ms. Shearer

Thank you. My name is Gail Shearer, and I'm from Consumer's Union. I'm the director of health policy analysis at Consumer's Union, and the director of our effort to translate evidence based medicine on behalf of consumers which is called Consumer Reports Best Buy Drugs. I'd like to start by commending you on your strong start in implementing section 1013 of the MMA. As you know, the initial funding was a small down payment in light of the scope of the task ahead, and we commend you for making the most of this early funding.

I'll briefly address some findings from work that we have done that demonstrate why the work that you are doing is so important for both the health and the pocketbook of the nation's consumers and taxpayers. Our project at Best Buy Drugs launched in December of 2004. We launched with three categories. We're now up to ten categories where we look at the comparative effectiveness and the comparative cost effectiveness of drugs in ten very common categories:

high cholesterol, high blood pressure, arthritis pain, acid reflux disease, depression, menopause, allergies for example. Our task is to translate complex systematic reviews of the clinical evidence of effectiveness for consumers and their doctors so that they can put the findings to work for them in the selection of drugs. We've also translated our short reports into Spanish. We've prepared print materials, two-page and twelve-page booklets, in our effort to get the word out to consumers. During the month of December, we had about 150,000 visits to our site, and about 65,000 downloads from our sites, and about 65,000 downloads of our reports. So as you can see, we're getting some traction, but we're still at the beginning. And we realize that we need to focus on the challenge, as you will when your reports are completed, as how to get this important money saving and health improving information into the hands of consumers. And we look forward to working with you on that challenge.

I wanted to talk a little bit about two lessons, two key things that we've learned. First is that we can have a major health impact. This kind of information can have a major health impact. Just looking at one of the categories which turns out is the category that is most often downloaded. It's the most interest of consumers, and that is cholesterol reducing drugs or statins. In our analysis, we found that if a person needs a modest reduction in their cholesterol, they had a variety of drug choices that were equally effective in meeting their cholesterol-reducing goal. One of them, generic Lovastatin, was available at a cost of about \$1 a day. Many people who need modest reduction in their cholesterol are actually spending about \$5 a day. Well, in this nation we have tens of millions of people who cannot afford their statins, and if we can get this word out about equal effectiveness of drugs and help people have access to drugs at an affordable amount of money, I think that we can have a dramatic effect on health care in this country.

A second major lesson and it has to do with the potential to save taxpayers and consumers billions of dollars. Today we are releasing an update of our statin report. We've updated the clinical effectiveness information and the drugs that are available, and the price information for the cholesterol-reducing category. But we're also releasing an analysis of developments in the market place, the sales of various statins and the price over time. But what we've done today is we've done an estimate of what's at stake as we turn to a new Medicare benefit. What's at stake for taxpayers and consumers when the generic of Zocor, simvastatin becomes available in June of 2006? Our findings were very dramatic. A lot of money is at stake. We estimate that if people switch from the high priced brand drugs to generic Zocor, simvastatin when it is available, that nationwide in the year 2007 the potential savings are on the order of \$8 billion a year. Now as we all know, not everybody is going to switch for one reason or another, but it's important to understand the scope of money that is at stake. And this is just for one widely used drug category. Access to information that educates the public that the lower cost drug is as effective as the higher cost drug is essential to achieving these savings.

Turning to some comments on your research priorities. In May of 2004, your first listening session, we urged you to select as priorities therapeutic categories that have a broad impact on consumers, in particular categories that include expensive drugs that are used by a large number of people. We commend your initial selection of priority areas including arthritis, cancer, diabetes, asthma, and peptic ulcer disease. We note that we have selected many of these categories as well, and the key factors in our choice of categories was both the high incidence of

these diseases and the existence of drug effectiveness review projects, systematic review of the clinical evidence. And of course, our main source of information, clinical effectiveness, is the OHSU-based drug effectiveness review project. We believe that your first report provides valuable information to patients with GERD. One key task, of course, is to ensure that this valuable information gets put to use by practitioners and gets into the hands of patients. And we plan to incorporate your findings in our next update of drugs in this category. As you shape your priorities for the next year to expand to conditions of Medicaid and SCHIP, we urge you to once again focus on conditions that affect a lot of people and where there are real differences in treatment options. Some of the studies already underway will be valuable for these populations, but we also would suggest that you consider studies in the area of ADHD, asthma, obesity, and AIDS. We think they could be very valuable for these populations. Again, one of the considerations for you should be whether there is a credible database of information about treatment alternatives such as DERP or the UK-based National Institute of Clinical Health and Effectiveness, or the Cochran Collaboration. We appreciate the opportunity to provide comments, and we look forward to advancing our shared goal of providing the public with credible information about the comparative effectiveness of alternative medical treatment. Evidence based consumer friendly information is needed in the marketplace to help consumers and taxpayers get better value for their health care dollar. Thank you.

Dr. Straube

Gail, thanks very much. We have another question here in the room.

Mr. Shaw

Good morning. I'm John Shaw, and I'm a health systems engineer, and I'm with Next Wave in Albany, New York. And I wanted to suggest two priorities, one a methodology priority and the second a topic priority. And it's related to several of the other comments.

The first thing is the Institute of Medicine wrote an order in one of their recent reports. The order is for partnering with health systems engineers. And health systems engineers are focused on addressing the issues in that 45 percent that we're not doing yet. And the clinical area that I wanted to focus on is also a problem and issue in the Medicaid population and that's pediatric asthma. I'm also a parent of asthmatic children. I spent six years on the board of directors of the American Lung Association in New York, and I'm currently the board president for the Healthy Schools Network where asthma is one of the major health issues for children in schools.

And let me try to tie those two together and see how it might help. Dr. Clancy mentioned that getting the question right is a big part of the process. That's what the system engineers are taught to do. So we're going to collect everything like you say and see what's out there currently, but then we go a little step further. We're sometimes accused of over specifying what it is we're looking at. So we take the traditional description that we get from the literature, and then we try to get inside it. And getting inside it, we go talk to the patient, we talk to and perhaps follow around the sharp end care givers. Those that are actually providing care to the people who are receiving the care. And that gives us a better perspective on issues that may be missed otherwise. And if we're talking about getting care to the consumers, that's a big part of it. We're also taught

to look beyond the normal definition of the problem, to look at the environmental construct, to look at things that may have a big impact on the problem that are beyond the direct definition of the solution. And lastly, we're taught to look at materiality, to constantly throughout the process make sure we're focused on important parts.

So let me apply that to pediatric asthma. If we look at Eddy, Eddy is a first grader who depends on Medicaid or SCHIP for controlling his asthma. The traditional view of asthma is the chronic disease that requires close monitoring to keep it under control. Eddy can't do it himself. He requires caregivers to do it, which is typically his parents. So we're focused on making sure they know how to do it. But Eddy, right now as we speak, is in the school yard, in the school, looking at his friends kicking up the dust, looking at the school buses idling over here, looking at the construction over there, and environmental factors are a big part of triggering or exacerbating asthma. If we look at the medical solutions, including an AHRQ report released just a few months ago, looking at suggestions for improvement, from my perspective I looked at it. There was no recognition of school environment or caregivers. Applying materiality to that, here are half of the caregivers that are monitoring my child's condition and the environment where they are spending a third of their time is missing. So that's part of what incorporating systems engineering can do. If anyone is interested in going into that further, a mile down E Street, the Healthy Schools Network is meeting with its national coalition members, talking about how to integrate health care, education, and the environment and looking at the total picture from the perspective of my child. Thank you.

Dr. Straube

Thank you. Interesting perspective. I think we're going to go to the phone lines for one or more questions.

Operator

Okay. Our next question comes from Kathleen Weaver. Please state your organization.

Dr. Weaver

This is Dr. Kathleen Weaver from Oregon Health Policy and Research. I'm the director for the health resource commission there, has been working with Oregon Health Sciences University Evidence Based Practice Center for the past four years. And we've done 16 comparative drug studies and have 6 new ones that are underway. We've had a tremendous experience in working with this drug evaluation review project, or DERP as it was mentioned by Gail Shearer from Consumer Union. And they're now working with the DERP. The DERP is a combination of 15 different Medicaid States and COTA, which is the Center for Evaluation of Technology from Canada, which allows different Medicaid States to pool their resources to buy these particular reports. We found that having the ability to be in on developing the key questions is so important because if you don't ask the right questions, you don't get the right answers. And also, the ability to comment on draft reports. What I think you're going to find is, from AHRQ's standpoint is, that when your reports when finalized are going to be utilized a lot more because people have access to be participating early on.

The health resource commission is now expanding and going on to look at things outside of drug comparison things. And one of the ones that was mentioned already we applied if you would go in this direction is the treatment of obesity, the surgical versus non-surgical treatment. In that case, it leased a preliminary check of the type of systematic reviews. There's almost an excessive amount of literature so we'll help to sort through this. One of the other areas we're looking at is in the area of chemical dependency. And I would hope that perhaps maybe this could be added to the list of things that you look at. Specifically, methamphetamine use which is on the West Coast a huge problem. In this case, preliminary look shows that there's not-there's minimal literature or systematic reviews. So perhaps doing this one would then point towards gaps in the research where things need to be done. Also, I would like to commend the new areas that are key questions that were just recently posted. We particularly are excited about the comparison with ACE versus ARBs because although we compare drugs within a class, we've not compared different classes. So this would be helpful for us. Also, we've not taken on combination drugs such as the lipid-lowering, where you're going to look at a combination of drugs. And we welcome your looking at stents versus CABG and the effectiveness of Alzheimer's drugs. People probably know in Britain these are usually not considered effective at this point. So anyway, we think it's a great process, and we look forward to working with you. Thank you.

Dr. Straube

Thanks very much for your comments. We'll go back to the room here.

Ms. Weber

Good morning. My name is Jennifer Weber, and I'm the Manager of National Nutrition Policy for the American Dietetic Association. I'm also a registered dietician and a public health specialist. The American Dietetic Association represents 65,000 food and nutrition professionals and is guided by philosophy based on sound science and evidence based practice. We've already cited the Washington Post as a scientific resource today so I'm going to point you all to the New York Times. For those of you who read the *New York Times* on Monday, you saw a compelling story about the impact of diabetes on individuals and communities. It's a crime. Little did I know that today's *New York Times* would be an exclamation point on my comments.

Diabetes is a disease where food and activity habits can be both preventive and treatment. For those with diabetes, research documents the value of nutrition services and the management of the disease. Persons who receive medical nutrition therapy, or MNT, services are likely to require fewer hospitalizations and medications, and have reduced incidence of complications. Not only is the person's quality of life enhanced, but additional costs from complications are cost to taxpayers. Diabetes is a research priority for the effective health care program, but AHRQ has yet to identify the priority and evaluate the behavioral aspects of diabetes prevention and treatment under section 1013. Furthermore, it has not been looked at the role of nutrition and activity lifestyle modification when drugs are taken. Without including these lifestyle modifications, the comparative effectiveness of different medical interventions cannot be fully assessed. We know that diet and activity are safe, work, and cost effective, but most people don't know how to implement, or do not have the resources needed to help implement lifestyle changes. And apparently, according to today's *New York Times*, no financial incentive. Look at

the photos and read the *New York Times* articles. It is evident that drug intervention alone is doomed to fail. It is access to preventive care and disease management that matters.

We believe that MNT, a proven cost effective intervention for diabetes, is an underutilized service which may significantly improve the prevention and treatment of diabetes. The underutilization of MNT can be attributed in part to the fact that the service is not well known or understood, and that it's not universally covered outside the Medicare program. AHRQ can help consumers, health care providers, and others make informed choices among treatment options, including MNT, by including lifestyle modification in the Effective Health Care Program. Making lifestyle modification in diabetes a research priority under section 1013 would go a long way towards shaping policy that supports a healthier nation.

Dr. Straube

Thank you for those comments. Appreciate that. We'll take another question here in the room.

Dr. Anderson

Good morning and thank you for taking my comments. My name is Dr. Carol Anderson and I'm a legislative fellow with the American Dental Education Association. We're pleased to offer comments on your priorities for research under the AHRQ Effective Health Care Program. As you know, dental services are a small part of the Federal Medicaid and SCHIP budget, but these services are a continual target for cuts. Cuts that have an immediate and devastating effect on our most vulnerable citizens, and have long lasting consequences. The challenge to provide dental services to the underserved will only be exacerbated as the health care programs face further budgetary restrictions.

Recognizing the challenges faced by dental professionals in providing care to Medicaid and SCHIP beneficiaries, ADEA strongly encourages AHRQ to consider the following dental health services research areas as priorities and strongly urges you to incorporate dental considerations into current and planned projects.

Number one, an evaluation and comparison of state based dental Medicaid innovations that have sought to increase dentist participation and increase utilization of services by mirroring such programs within the commercial dental benefit sector. Two states have reformed their Medicaid program by contracting with a single vendor to administer the dental program the same way they administer the private insurance program. At least four other states have established unique programs to address barriers that dentists and communities have identified within the program, namely inadequate reimbursement, administrative complexities, high appointment failure rates, and lack of oral health literacy in the patient population. Many other states have attempted program reform with little to no success. And this is believed to be a result of focusing a limited programmatic reform as opposed to a comprehensive reform approach.

Number two, studies on the effect of incentives such as state tax credit, loan repayment, and scholarships increasing dentist participation in Medicaid and SCHIP. Several Federal and State programs have used the strategy to improve the distribution of dentists within states and

communities, and increase services. Such an evaluation would assist in determining whether these incentives are cost effective and do improve recruitment and retention of dental providers within public programs. Number three, an examination of whether a correlation exists between graduation indebtedness of dentists and their participation in Medicaid and SCHIP. Dentists are small business owners and practices differ from medical practices with much higher overhead costs. Past reports by Health and Human Services' Office of the Inspector General and the U.S. General Accounting Office have indicated that there are limitations-that one limitation to dentist participation in public programs is inadequate reimbursement. And we need further research to determine how to develop a balance between the two. ADEA appreciates AHRQ's consideration of our comments. Thank you very much.

Dr. Straube

Thank you for those comments. I think we'll go to the phone line for the next question, please.

Operator

Our next question comes from Lawrence Brown. Please state your organization.

Dr. Brown

Hi. This is Dr. Lawrence Brown. I'm an assistant professor at the University of Tennessee Health Science Center in Memphis. And one of the things that I'd like to put forward as a focus area and it's been alluded to a couple of times and that is the fact that medication alone, although it's very beneficial, it's the appropriate use of medications that really needs to be primary focus. And within the final role of CMS's final role, they mentioned that they felt that MTM programs, the medication therapy management programs, would become a real cornerstone of the Medicare program because again, getting seniors medications without making sure they have programs that get them to use them appropriately, especially those with multiple chronic conditions and multiple medications, a lot of seniors are having tough times managing their medications.

And now that they have access to them, I really think the medication therapy management programs will be very important. Having said that, in terms of specific areas of research, it will be really important to know which models of medication therapy management programs really have the best quality and best outcomes. For instance, many of the PDPs, and MAPDs have in-house medication therapy management programs where they may have pharmacists in-house to provide the services through a call center based, or maybe nurses providing the services through a call center based program. You also have pharmacists and other qualified health professionals who are providing medication therapy management in the community setting, or I guess in a face to face visit. So there should be some comparison between those two models to see which one actually provides the best quality care, the best benefit to the patient, and fits in well within the health care system. Or, if there's even a modified version of the combination of the two where you have the call center taking care of minor issues with referral to pharmacists or other health care providers in the community setting for more intensive or advanced care. So again, I would just hope that you would look to trying to answer that question as to which model is most important because it seems like it is a program that will be slow to take off because of people's

lack of understanding, but will become an integral part of the health care system. And it would be good to get some early answers to the questions about which model is most effective both from a cost standpoint and outcome standpoint. Thank you very much for taking my comment.

Dr. Straube

Dr. Brown, thank you. Very good comments. We're going to next back to the room here in DC.

Mr. Sperling

Thank you. I'm Andrew Sperling representing the National Alliance on Mental Illness. NAMI is the largest national organization representing people with severe mental illness and their families. NAMI shares the goals of section 1013 and AHRQ in improving quality and getting better value for America's health care dollar. We commend AHRQ for undertaking both reviews on depression, particularly the one on off-level use of atypical anti-psychotic medications as commonly done as many use as mood stabilizers in the treatment of bipolar disorder. And it's very important this review be undertaken, and we commend you for that. In the field of psychiatric medicine and severe mental illness we are making progress on clinical research, on treatment in real world settings. This is critically important.

NIMH has three major studies, some of which have been released in their first stages, some of which are moving forward. There's the CATIE study on schizophrenia. The Star*D study on treatment resistant depression. It was just released last week, the first stage last week, and the Step-BD study on treatment of bipolar disorder. What's important about those is it's no longer-it's not just comparative advocacy, it's also treatment in real world settings, and it undertakes the really complex nature of these disorders. And we encourage AHRQ and CMS to recognize the complexity of the treatment of illnesses such as schizophrenia and bipolar disorder and major depression. They're episodic illnesses. They don't follow a pre-determined course. They often are accompanied by many, many co-morbidities including substance abuse, diabetes, other types of complicated co-morbidities. And there's an enormous challenge of ongoing treatment adherence. When the very symptoms of an illness like schizophrenia is the better someone gets, the more under control their symptoms get, the less likely they are to adhere over time. And it's an enormous challenge. And we need more research on that.

And finally, most importantly, the treatment needs to be individualized. This is something we believe you need to recognize. And along those lines, Dr. Clancy noted earlier that this undertaking is not about implementation of uniform treatment guidelines for any particular disorder, and we commend AHRQ for that. We think that's the route you want to go. But unfortunately, we're increasingly seeing comparative effectiveness research being labeled as "evidence based practice," and then being used as pay arch (phonetic) because we state Medicaid programs as a justification for a restrictive policy such as prior authorization, step therapy, and in many cases outright removal of therapeutic options from preferred drug lists. We believe that this is not what comparative effectiveness studies need to be used for. We're already seeing this in association with the first stage of the CATIE trial where you have some of the newer atypical anti-psychotic medication compared against only one of the older agents. And we see payers already using just the first stage of this, we believe, in an inappropriate way to restrict access to

the newer more effective medication to treat schizophrenia. So we strongly support what AHRQ is doing, and we support section 1013, but we just want to make sure the comparative effectiveness trials are not essentially unjustifiable used as the basis for restrictive policies both in Medicare and SCHIP and Medicaid. Thank you.

Dr. Straube

Thank you very much. We're going to go in the room again for the next question.

Dr. Wright

Donna Henry Wright. I'm president of Wright Associates Health Care Public Affairs, but I speak today as a liver transplant recipient. There is now currently available an FDA approved test called the amino assay for immune system function that is not in widespread use. However, this test has the ability to give physicians making clinical decisions on prescribing and withdrawal of treatment in organ transplantation, in cancer, in AIDS, and other immunomediated diseases. And I would encourage CMS and other Federal agencies to find mechanisms so that this test can be put into widespread use as it has implications to affect not only the quality of treatment, but also the cost and effectiveness of treatment by reducing patient risk for, in the short term, for rejection of organs, as well as in the long term cardiovascular incidence and stage renal disease incidence and cancer. So I would just encourage more exploration in this area and dissemination so it can be used more widely.

Dr. Straube

Thank you very much. We're going to go to the next question on the phone line.

Operator

Our next question comes from Judy Kramer. Please state your organization.

Dr. Kramer

I'm Dr. Judith Kramer. I'm the principal investigator for the Duke Center for Education and Research on Therapeutics. The CERT centers are an AHRQ-funded program whose goal is to conduct research and provide education that advances the optimal use of drugs, medical devices, and biologic products. So by nature, my comments are going to be focused on therapeutics. I'm speaking not just for myself, but for the seven national CERTs principal investigators who have gotten together and synthesized their ideas into the topics I'm going to list for you today.

I'm listing general topics for study rather than specific diseases or conditions. The first involves the safety and efficacy of off-label use of drugs and devices. And Sue Tolleson-Rinehart from the University of North Carolina CERT has already mentioned the tremendous need in this regard for study of off-label use in children where many of the things we use are off-label. But there are many other areas and examples where this is important. And we would recommend, for instance, the convening of an expert meeting in major therapeutic areas to identify the highest

impact off-label use areas for study, and continued study of patterns abuse of off label use through large data sets.

The second area is one that AHRQ, as Carolyn Clancy has mentioned, very involved in already, and that is the area of comparative effectiveness. We applaud AHRQ's efforts to commission evidence reports as the starting place here and to use DEcIDE network to convene meetings and conduct research in this area. One concern that all of the CERTs PIs have are methodological issues in this regard when conducting comparative effectiveness studies with observational data sets, and even direct randomized trials when you're dealing with non-inferiority hypotheses. Fortunately, ARHQ has already commissioned some supplemental funding for the CERTs to explore some of these methodological issues and is already working on this. But it's a big area to focus on. In addition on comparative effectiveness, we think it's important to prioritize head-to-head comparisons that really are needed, things that actually need to be sorted out through direct randomized clinical trials. For instance, pulling together expert meetings by medical condition or patient population to focus upon, to identify these lists. In addition, we believe that it would be wise to explore the use of group randomized trials, kind of practical clinical trials, where you have commonly-used products that could be studied in this type of setting where you randomized practices to alternative choices within health plans.

The third area that we would recommend focus on is that of drug-drug interactions. There's been an estimate that the average Medicare patient takes 17 different drugs per year. You can imagine with this that there are significant problems with adverse reactions. There is definitely the need for more pharmacologic and pharmacoepidemiologic studies on this area of drug interactions. It's particularly a problem with many of the older drugs that are used and are generic now because there frequently is less information available in the pharmacokinetics of some of these older agents. And there's added complexity when you consider the combination of alternative medications in combination with prescription drugs.

The fourth area we'd like to focus on and it is covered with some of the other topic areas, but I'd like to focus on, is that of medical devices. Because of the different regulatory requirements for devices, often there is less known about the benefits, risks, and clinical outcomes, especially long term clinical outcomes with medical devices. And we think that this is an area where we do need more complete knowledge on comparative effectiveness and off-label use as well as benefits and risks of many of these devices.

The fifth area is one that is noted in the Medicare Modernization Act and that is computerized provider order entry. The MMA mandates that specifications for CPOE be issued by 2008 and full implementation within a year after that. However, there's really been little research to date on creating standards for CPOE, and there are early reports indicating entirely new types of errors from CPOE from coding malfunctions to provider entry errors. Now we're not saying that this is not an appropriate concept. We are very supportive of the added safeties that can be provided by CPOE, but we need more generalizable knowledge about CPOE because we feel that it is lagging behind the implementation of systems. So we think this is a very important area for continued research and exploration.

The sixth area that we'd like to highlight is that of the need to look at factors that influence prescribing. That gets into areas of both under prescribing of effective therapies that some other people have mentioned as well as overuse. And we think that there should be research into testing novel methods to improve appropriate prescribing of therapeutic agents. And then the last area, but not least, and silent area frequently not mentioned, and that is laboratory monitoring of drug therapy. There's significant variability in the frequency of laboratory monitoring, both drug concentrations and renal and hepatic function affects of therapeutics. And yet the effects on clinical outcomes of these variable intensity monitoring schemes are really unknown. And this is an important area to explore because we may be spending a lot of money on things that aren't particularly effective in terms of outcomes, or we may be missing monitoring things that could really improve patient safety and outcomes. But we really don't have a lot of data on this at this point. So I went fast through this so I could cover all of the items in three minutes, and we'll be submitting written comments as well. I appreciate the opportunity to speak.

Dr. Straube

Thanks very much for your comments. Appreciate that. We're now going to switch back here to the room for the next comment.

Ms. Galbreath

Yes. My name is Laura Galbreath with the National Mental Health Association. On behalf of the association, I want to thank the agency for this opportunity to offer testimony on effective health care programs. This new initiative has potential to have a significant impact on Medicare, Medicaid, and other health care programs. Further, AHRQ faces significant challenges in organizing and communicating the vast amounts of research that exists on the different medical conditions. We have several comments and questions that we'd like to present on public comment, methodology, and structure of the key questions.

Regarding public comment process, we are pleased that AHRQ is holding public comment periods for both the development of the key questions and of the draft reviews. We strongly recommend extending the comment period for the draft reviews to 30 to 45 days to allow for adequate time for constructive comments from the public. We'd also like to request more information on how the public comments will be used, and incorporated into the final reviews. We're still a little unclear about the public comments and whether they'll be put into the public record, and how AHRQ will respond to some of the questions that are raised through the public comment process. And then we also further recommend that AHRQ explicitly requests public comments on some of the missing studies, the alternative methodological approaches and revisions to the text of the reviews. Regarding methodology, as AHRQ considers how to evaluate the effectiveness of different medical treatments, we strongly recommend that the agency consider a broader approach in selecting different studies for inclusion in the systematic reviews as others have said. NMHA recognizes that randomized controlled studies are generally considered the gold standard for these reviews. However, we're concerned that such a strong emphasis on them may be misplaced for systematic reviews that will be used for public policy. While efficacy studies are important, the effectiveness health care program should also look at ways that measure the effectiveness of treatments, studies in not just symptom reduction, but also

changes in functioning such as reduction in emergency room visits, psychosocial changes, reduction in homelessness, returning to work, and the ability to communicate. To capture these effective measures, the AHRQ may need to change its criteria for inclusion when identifying studies for systematic reviews. For example, AHRQ should plan to increase the use of observational studies to better capture the effectiveness information. Regarding the key questions, as AHRQ looks for better strategies to measure the safety and effectiveness of different medication treatments, we first and foremost recommend a revision of the key questions asked at the outset of the reviews. NMHA has three core recommendations. We recommend that AHRQ include at least one question to ask about the changes in outcomes for people receiving different treatments. The search strings should include such measures as increases and decreases in hospital visits, emergency room visits, ability to return to work, school, daily activities. We also recommend that AHRQ include at least one question to focus specifically on adverse events, including consumer reports of side effects, physician reports of side effects, in addition to specific adverse events such as emergency room visits or encounters with the criminal justice system. Last regarding key questions, we also recommend that AHRQ include at least one question that focuses specifically on reviewing racial, ethnic, and gender differences in responding to medication treatments.

We were very concerned that the draft review of off-label use of atypical anti-psychotics did not include any questions to look at this key measure. And given studies that have shown differences in the metabolism rates of different medications, we think it is critically important to include this question. So, again, we thank you for this opportunity to provide comment, and look for future opportunities to partnership.

Dr. Straube

Thanks very much. Very good comments again. We're going to the phone lines for the next question, please.

Operator

And our next question comes from Kathleen Lohr. Your line is open.

Ms. Lohr

Thank you. I am from RTI International and the Evidence Based Practice Center that we share with the University of North Carolina. And my one question really and suggestion for topic is to understand the extent to which AHRQ, in either the EPC work or DEcIDE Work, or CERTs work will be examining issues relating to genetics and genomics to try to understand what do we know now about those fields and their applications in clinical practice, what sorts of tests are available for what kinds of purposes, and what applications may be available for individualized or personal prescribing. Thank you very much.

Dr. Straube

We'll go here in the room for the next question, please.

Mr. Wojcik

Hi, Steve Wojcik, National Business Group on Health representing about 250 of America's largest employers. I'm going to be very brief because we're going to submit our written comments electronically. And most of the recommendations for future priorities for comparative effectiveness research that we have, have already been mentioned by a number of groups. We're pleased to see that the list of future priorities that Dr. Clancy mentioned includes the comparative effectiveness of stents versus surgery. Related to that, we also recommend and other people have mentioned the comparative effectiveness of statins for lowering cholesterol. That's also very important. Alternative hypertension medications for lowering and managing blood pressure. And then the other area of research that we would recommend and other groups have mentioned is obesity, which as we all know affects all three of the programs as well as the private sector in America as a whole, increasingly the world as well. The effectiveness of various bariatric surgeries including gastric bypass, banding, biliopancreatic diversion, I hope I got that right, I'm not a clinician. And then also the relative effectiveness of various weight loss medications, and then the effectiveness of medically supervised weight loss. Those would be our recommendations in the area of obesity. Thank you very much.

Dr. Straube

Thanks, Steve, for your comments. We're going to go here in the room for your next-I keep saying question. Your comments, so I apologize for saying questions repeatedly.

Ms. Bough

Thank you, my name is Marcie Bough. I'm with the American Pharmacists Association, and we're just pleased to be able to comment on research issues with Medicare drug benefit and medication therapy management services that are more addressed within the DEcIDE program, but I just want to make you aware that MTM is a major priority of the association right now in looking at the appropriate use of the medications with the Medicare population and in just patients in general, whether they're Medicare or not, is very important. And it will be a good focus as MTM becomes more robust as we move along through the implementation of the benefit. But we'd also like to point out that with looking at the Medicare claims database information, there will be a lot of information coming in through the Part D claims data, but it's also important to loop that in with the entire health care cost through Part A and Part B to look at the overall health cost for the benefit, but then the implications it has for the other parts. So wanting to just make you aware of that. Another point would be to look at the Medicaid population which is kind of a unique set of individuals coming into this claims database now. Coming from a state perspective in what's going to happen with the information from the states as they move into the Medicare database, and how are any issues with moving them into this new drug benefit going to have implications on their safety of medication use, compliance, issues with this transition to Medicare and how that might affect the outcome of the medication, and the appropriate use of the medication along with access. Thank you again, and we look forward to working with you in the future.

Dr. Straube

Thanks for your comments. And we will now go to the phone line for the next comment.

Operator

Joanne Lynn, your line is open. Please state your organization.

Ms. Lynn

I'm with RAND, and I represent only the interest of living long enough to be very sick and be a burden on everybody. I notice in the list of things that are already committed to in this set of projects, a real growth of some relatively small but exciting possibilities of working on continuity and methods rather than just on particular diseases, diagnoses, the typical way we split things up. And I just wanted to give voice to really encouraging us to take on seriously the problems of cross site continuity, continuity throughout serious illness, the degree to which we can free ourselves of diagnosis and setting limitations, especially in those last few years of life when most people have multiple illnesses. A parallel issue is that I think we really need to expand our scope to tackling the problems of caregivers and how to make sense of their important role in the care system. We face an enormous crisis in numbers of unpaid family care givers going down at just a time we're going to need a substantial increase. And we have almost no data on that. So effective health care is going to turn very heavily upon the unpaid services of women who regularly impoverish themselves and ruin their own retirement by dint of their work. We've done very little to ease that work or even to catalog it. So I would encourage that.

In methods issues, I think we need to develop the methods to tackle the very intriguing small area variations work that doesn't lend itself very well to randomized control trials. Sometimes the RCTs are, while conceivable, are just too expensive to ever get to. And it seems that we really need to figure out how we can learn from system reform in regions from demonstration, to quality improvement in ways that are good enough to go forward rather than tying our hands and saying we just can't learn about this because we can't run the proper study. So we really need to see some methods work and one methods issue that is especially close to my heart is figuring out how to account for the variation in longevity as you get into the last few years into life you can make almost any measure look better if people die more quickly, with the exception, of course, of living longer. But we have very little way of understanding that interplay and we're going to need it as more and more of the health care gets allocated to the piece of time we're spending living with serious illness. So that's something I would encourage you to keep nurturing despite the fact that at the present time they are only a small part of the portfolio.

Dr. Straube

Joanne, thanks very much for those comments. We're going to go for the next comment in the room.

Ms. Friedman

Good morning. I'm Susan Friedman with the American Osteopathic Association, and I've already heard this morning three times obesity referenced as a topic for Medicaid and SCHIP. And I

would like to echo that and say that our council on scientific affairs has looked at the material and they strongly recommend adding obesity as primary and secondary disorder. Thank you.

Dr. Straube

Thank you. Back to the phone again.

Operator

We have a question from Gerald Boyd. Please state your organization.

Mr. Boyd

I'm medical director of Employers Coalition in Rockford, Illinois. My concern is I listen to all of this. You're getting plenty of suggestions of what should be studied from a variety of sources, and all of those are very good. My concern as a practicing physician as well as the director of employers' coalition is the point at which these guidelines become deliverable, specifically at the point of the interface of the patient and the physician. As we go along developing these, we need some kind of rapid delivery to that point. Ideally this would be an automatic import to a Web-based system, perhaps eventually in a docket system that is being developed. But until that time, we need to get this information once it's pulled together from all these sources and get it in the hands of the physician because it may take years to really get these guidelines to an effective application. One way may be to have some kind of alert, some kind of delivery system announcing to physicians that this is available. Many things that happened in the past have floundered in the mass sea of information, and it isn't easily available to the physician. Currently we do have a lot of sources for evidence based medicine, but we must go to various sources, Web sites, programs, et cetera to get those. I'm trying to go to bring to focus on a rapid transit from the evaluation to the point of delivery of the guidelines.

Dr. Straube

Thank you. Some very good points. We appreciate those comments. We'll now continue on the phone with the next comment.

Operator

Lisa Simpson, your line is open. Please state your organization.

Ms. Simpson

Good morning. This is Lisa Simpson from the National Initiative for Children's Health Care Quality. I'm sorry I can't be there in person. I'm going to focus my remarks on priority setting for children in the Effective Health Care Program who are insured under Medicaid and SCHIP, and make four points.

One that when you engage in priority setting obviously criteria that are developed should take into account at least two things for children. First is the unique characteristics of children's health and their health care which has been described as the four D's: the differential epidemiology of children, their dependency on adults for their care and others, their rapid developmental change, and the differential systems that they are served by, which is obvious in their reliance on Medicaid and SCHIP. And I know full well that our colleagues at AHRQ are very familiar with these criteria.

The second point I want to make is that the priority setting should really take into account the needs of multiple stakeholders and today's process is part of that, and including families, providers, purchasers, and clearly State organizations. The second point is that the research program should include studies of the effectiveness of both discrete clinical intervention and organizational and system intervention, particularly since we have chosen a health care system with 50 states and 35 different SCHIP programs. So the positive side of that is we have lots of opportunity to learn from this experience if we choose to do so.

The third point is given the significant variability and quality of care and outcomes for children, we've got to invest in research to understand which strategies are effective in improving care. And these studies should include broad and diverse populations and settings. It should focus on spread and sustainability going beyond single site studies to demonstrate improvement, to sustaining change in a positive direction. And also, they should include a cost effective component. States are very interested in understanding how to spend their money efficiently to improve care.

And given these comments, I would just mention three areas which have, I'm sure been mentioned already, will likely warrant attention regardless of whichever priority setting process is adapted, and those are obesity, behavioral health for children, and the care of injured children. We must not forget that children, while luckily they do not die very often, after they survive their first year of life, they do die from injury and trauma. And there's much that we can learn about how to improve the effectiveness and quality of care for injured children in this country. Thank you for the time.

Dr. Straube

Thank you for your comments. Next comment will be here in the room.

Ms. Matthew

Good morning. My name is Sarah Matthew, and I want to thank you for the opportunity to present comments from the American Association of Colleges of Pharmacy. U.S. colleges and schools of pharmacy are actively engaged in a broad array of Department of Health and Human Services-supported research and programs. Section 1013 of the MMA seems to speak directly to the role that colleges and schools of pharmacy can and do play in improving health outcomes and determining the appropriateness of pharmaceutical services.

AHRQ has made very positive steps in both CERT and DEcIDE program to strengthen linkages with U.S. colleges and schools of pharmacy inside and outside of academic health centers to fulfill the missions and goals of these important programs. Regarding the list of priority conditions, AACP would bring to your attention that all ten of the conditions recommended for consideration by the Secretary depend on drug therapies for patient management. This requires a greater attention to the best use of these medications so Federal programs are operated to achieve the Institute of Medicine's aim for health care delivery.

AACP does not recommend any particular prioritization of the list of priority conditions. What we would recommend is that HHS, across the totality of its programs, look for opportunities to bring academic pharmacy closer to the side of the practicing physician in an effort to improve medication use. Especially in the ambulatory and physician practice settings, these opportunities should be considered in the context of the Medicare prescription drug benefits, Medicare pay for performance demonstrations, telemedicine projects, or support to state Medicaid programs for the development of academic detailing programs. Regarding the methods to answer questions of safety and effectiveness as quickly and efficiently as possible, colleges and schools of pharmacy are actively engaged in the synthesis and generation of knowledge regarding medication use that is being readily translated to state Medicaid programs, Medicare quality improvement organizations, and private sector health plans. It might prove useful to inventory the research in program relationships currently ongoing at our nations' colleges and schools of pharmacy. This would provide HHS with a quick response as to whether some of the questions you have, have already been answered by the academic community. To move our health care delivery toward a more patient-centered process, HHS should require research questions to be addressed through interprofessional teams. This approach, supported by both the Institute of Medicine and the National Institutes of Health, would readily take advantage of the special knowledge-based extant in specific health professions. Toward this end HHS should strengthen support for interprofessional health education programs. Health profession students, through their experience on residency training, could readily be catalysts for translating research finding in practice on a real time basis. The AACP appreciates this chance to comment on the important work of HHS to improve the effectiveness of health intervention. We look forward to continuing to work with AHRQ and other agencies to more closely link academic pharmacy with Federal programs for the benefit of the public's health.

Dr. Straube

Thank you very much for those comments. We'll take the next comment from the room here. I'm not seeing any hands. Do we have anybody on the phone lines?

Operator

I'm showing no comments at this time.

Dr. Straube

Okay. One last chance here in the room. It's been a long morning. I'm impressed. First of all, I want to thank everyone for one, attending and coming, and participating in this session.

Personally my reaction is when I come to meetings like this I learn something at every session. And I've learned some things, Carolyn, that won't apply just to the Effective Health Care Program but will apply to some of the work we're doing at CMS. So I want to thank people for some great ideas and insights into a lot of areas that we don't think about every day. I was jotting down, I thought it might be helpful, some general areas here that at least I heard. I know Carolyn and her staff are going to be going through all the comments and analyzing the other ones that they get on the Web site. But what I heard today were a number of themes or topics.

One had to do with the area of transparency. People were talking about how valuable the public comment aspect was, such as it is, but we're looking for even more ability to improve and increase the public comment period, the amount of public comment being made, public participation more in the issue and question formulation, certainly more participation in the draft review process, not only by increasing the time frame but allowing more input there. So I think that's one general topic that is going to certainly be heard.

I've also heard something that we've started to talk about internally at CMS certainly, but very loud and clear that people were interested in cost effectiveness information. That was repeatedly mentioned by a good number of the commenters.

I think the third area people were- there's a whole area of issues in health systems reform and how health systems and health organizations affect the actual effectiveness of these various modalities that AHRQ is focused on. And it's perhaps a variable that we don't think about regardless of how individual services or devices or whatnot are effective depending on what system they are in, or depending on whether we can tweak the systems and make them more effective.

There was a whole series of special needs areas, if you will, or special factors. I appreciated the nurses, the dieticians, medical nutrition therapy, health systems engineers, the dental aspects here, medication treatment management, medication therapy management, the comments made about the last years of life, and people with chronic illness in that time frame. And there were several others. I probably missed some, but I think there were some very, very good suggestions and awareness brought to us about these special areas.

A fifth area, clearly a number of commenters were talking about access to care. And that being- I guess it gets back to Carolyn's comment about asking the right questions. If you can't get care, if you can't get access to care, the questions don't even matter. So clearly access to care.

And I think as a corollary to that- that has been a topic very near and dear to my heart that we need to address more. Continuity of care was mentioned also across different sectors and across different settings of care and how we coordinate that. You can have the best performing medication, but if you don't educate the patient and then assure they're receiving that across care settings, it's not going to work. Clearly there were a whole bunch of specific areas, disease specific mostly, ADHD, behavioral health issues. Very important, I think, on behavioral health, the emphasis we heard today- asthma. Certainly obesity was another one that was very highly commented on. AIDS, diabetes, and many, many other conditions including the dental health that I mentioned earlier.

And then last, but not least, in a not all-inclusive summary here, I think that there were one or two comments made. Something probably we have-we didn't comment as much about today, and that has to do with communicating the results of this whole process. How do we make it known to providers, to patients, and to all people who need to get the information that comes out of these reviews. So that's my quick and dirty summary. I'm going to, in addition to thanking you all again for all the good comments, turn it over to Carolyn for some last words.

Dr. Clancy

Well, my first word would be wow. This is officially the end of the beginning. The comment period on priorities extends until March 15th. So for those of you who didn't have an opportunity to speak your piece today, or had additional thoughts triggered by the discussion today, or know of others who would like to contribute, you can do that through the Web site and we'd be delighted to hear from you. I think Mark Twain once commented on, if you were going to speak for a short period of time that takes a whole lot more work than for speaking for a long period of time. I know that the brief brilliant contributions we heard today reflect an enormous amount of work. So I want to thank all of the people who spoke both here in the room and on the phone for the amount of work they put into their presentations before coming. You can listen to this session for the next two weeks by dialing this number, 866-386-1299. After that, there will be a written transcript and all entries in the spirit of transparency will be posted on the Web. Again, this period is going to extend until March 15th. As with the last time we did this, I'm leaving feeling very energized and my head is spinning with all kinds of ideas. So let me just echo Barry's thanks and wish you all safe travels wherever you're going. And we very much hope to keep hearing from you. Thanks again.