

**MCH Research Network:  
PECARN, PROS and CARN**

September 15, 2004

ANN DRUM: Welcome to the most recent research round stable. This is Ann Drum, the director of the research training and education at the Maternal and Child Health. I would like to welcome all of you to this roundtable where we're going to have an opportunity to hear about MCHB's investments in research network. And on behalf of the division, we would like to thank you. We're going to go through the three networks toss, CARN, PROS, PECARN. I would like to give thanks for helping to arrange this wonderful technology. Without further adieu, I would like to introduce Stella Yu, Sc.D., M.P.H; she will go over background information.

STELLA YU: Yes, hi. This Stella Yu. I would like to take a couple minutes to give you an update about the research program. In addition to the networks that we're going to be talking about today, we also fund an extramural program known as the R40 program. That program is intended for primarily funding applied MCH research. We have two application cycles a year, with due dates of March 1 and August 15. We encourage applications that focus on our four current strategic issues, in particular. They are Public Health Service systems infrastructures, health disparities, qualities, care and studies that promote the healthy development of MCH population. We at the branch look forward to assist you with any questions that you may have. And we are Stella Yu, and others. Our phone number is 301-443-2207. I'd like to move on to today's program. We're fortunate

to have Dr. Chris DeGraw as our moderator. Doctor DeGraw has had extension sieve experience in pediatric research.

CHRIS DEGRAW: Thanks, Stella. We have an interesting program for you today. But before I introduce today's speakers, I'd like to review technical information about the webcast. Slides will appear in the central window and should advance automatically. The slide changes are synchronized with the speaker's presentations. You do not need to do anything to advance the slides. You may need to adjust the timing of the slide changes to match the audio by using the slide delay control at the top of the messaging window. We encourage you to ask the speakers questions at any time during the presentation. Simply type your question in the white message window on the right of the interface, select Question for speaker from the dropdown menu, and hit send. Please include your state or organization and your message so that we know where you are participating from. The questions will be relayed onto the speakers after the third presentation. If we don't have the opportunity to respond to your question during the webcast, we will email you afterwards. Again, we encourage you to submit questions at any time during the webcast. At the end of the webcast, the interface will close automatically and you will have the opportunity to fill out an online evaluation. Please take a couple of minutes to do so. Your responses will help us plan future webcasts and improve our technical support.

This research round stable today will highlight three funded research nets. The Pediatric Emergency Department North East Team, known as the CARN, is a national network whose goal is to direct multi institutional research into the prevention and management of

acute illnesses and injuries in children and youth of all ages. The second network, the PROS network is a national practice-based research network where primary care practitioners partner with researchers to develop and conduct research studies aimed at improving the health of children. Finally, the ambulatory research network is a network of practicing obstetricians, gynecologists which conduct research used in the development of standards and guidelines for perinatal health care. Now I would like to introduce our first speaker, Nathan Kuppermann, M.D., M.P.H., he will be speaking about the PECARN. He is an associate professor of emergency medicine in pediatrics and he practices at U.C. Davis school of medicine. Nathan Kuppermann.

NATHAN KUPPERMANN: Thank you very much. Good morning to everybody from California, where's it is the morning still here. I'm happy to be able to participate in this webcast and share with you some information about our relatively new research network called PECARN, the Pediatric Emergency Care Applied Research Network. You say what is PECARN. PECARN is the First Federally funded national pediatric funded research network. It was started in the year 2002 after proposals were invited for nodes to participate in a research network in pediatric emergency medicine. I will be discussing the concept of nodes with you shortly. That RFK came out in 2001 and the network started in 2002. PECARN is funded through HRSA with the purpose of developing an infrastructure that is capable of overcoming barriers for research. I'll be using the term emergency medical services for children and pediatric emergency medicine interchangeably. PECARN provides the leadership and infrastructure to conduct collaborative research studies and to encourage informational exchange between the researchers and the EMSC

practitioners communities. And our ultimate goal as Doctor DeGraw said is to conduct high priority, multi instance institutional research into both the prevention and management of acute illnesses and injuries in children and youth. Important to note that the funding provided by MCH supports the infrastructure for PECARN, then we go out and seek research grant funding to conduct actual research projects in the network. What are some of the barriers to research in pediatric emergency medicine, and these are the barriers at which PECARN is aimed to overcome.

Well the first is that there are low instant rates of pediatric emergency medicines adverse events. To study these, we need to pool many sites. EMSC research is conducted at care centers, almost 90% of pediatric emergency visits occur outside of the academic Children's Hospital setting. We wanted to create a network which includes a variety of types of hospitals. There is complexity of obtaining informed consent in the setting and difficulty in tracking patients from out of hospital settings to a hospital setting. Another barrier is that it's difficult to maintain data quality and integrity in the ED setting. There historically have been few severity outcome in adjustment measures and finally there has been a lack of funding for EMSC research. These I would consider the top seven barriers at which PECARN is aimed to overcome. I'd like to briefly review with you the structure of PECARN. PECARN consists of four regional node centers. They're abbreviated as RNC's, and they're located at diverse sites across the country. Each RNC hosts a regional network of hospital emergency department affiliates, for a total of participating HEDA's across the United States. If you look at the structure in the slide, you will note that the regional node center and each of the HEDA, there is a lot of bi-directional

exchange of information idea, research concepts, but the regional node center provides the leadership of each node and four nodes constitute a full network.

Now, I won't go into the details of each center in each node, but I want to just give you an idea of the representation of hospitals across the network. The first node is the Academic Centers Research Node, that's the node of which I'm the PI. This does represent six academic centers across the country. U.C. Davis, Wisconsin, Philadelphia, Salt Lake City, and Saint Lou. The second node called the Chesapeake applied research network, or CARN, that is a network that is based in the Washington, D.C. area. That node consists of both academic, general, children's and non-Children's Hospitals. The third node is the Great Lakes regional node. By the way, I just want to mention the Chesapeake area network node is the -- the P.I. is Jim Chamberlain. The third node, the Great Lakes node, the P.I. is Ron Maile. The pediatric emergency department northeast team, or PEDNET, the New York node chaired by Steve Miller at Columbia is a node of eight hospitals. Again encompassing children's, non-children's, academic and non-academic hospitals. So if you were to look at this network across on a map across the country, you will see that it's spread out pretty well from west to east. In addition to the four nodes of PECARN, we have a data management center, called the PECARN central data management and coordination center, or the CDMCC.

As you will note we have many acronyms in PECARN. It's the only way we can keep ourselves from becoming too hoarse. The data management center is based at the University of Utah. They manage all data under a separate cooperative agreement with

the MCHB. I want to review with you some of the strengths that PECARN has in conducting multi-institutional research in our field. First of all, as I mentioned, there are 25 hospital emergency department affiliates scattered across the country. We serve approximately 800,000 acutely ill and injured children around the country. Therefore, we are powered to do big and important studies on even diseases that are infrequent, but have important implications for health in children. Besides the wide geographic and hospital representation, we have very senior level expertise in epidemiology, statistics, health services research, both amongst our PI's and with our consultants. We have very senior level researchers and clinicians in PECARN. If you were to go around the nodes of PECARN, some of, if not most of the senior researchers in PEDS emergency medicine are included in the network.

The next slide goes over the administrative structure of PECARN. A little bit of a complicated slide, but I'll walk you through it. At the center you see the PECARN Steering Committee. The Steering Committee is made up of 21 members, five each from each of the nodes. And one representative from the data center in Utah. We work in close conjunction with the data center, the CDMCC as well as our partners at HERSA and the Steering Committees oversees the four separate nodes and the PECARN subcommittees which I will describe to you shortly. The PECARN Steering Committee really acts as the primary governing body of PECARN. As I mentioned, there's equal membership from each node and the data center in the Steering Committee. You'll note that we have been very adamant about the democracy of PECARN and there is equal representation in every committee, be it Steering Committee or subcommittee amongst the four nodes of

PECARN. The Steering Committee is responsible for reviewing and approving a specific PECARN research proposals and formulating and monitoring policies which guide PECARN research activities, not only has the Steering Committee established bylaws, policies and procedures, but these are updated and adjusted as needed as the network matures and grows.

Finally, the Steering Committee has established important subcommittees to carry out specific tasks. Of note, the Steering Committee meets about three to four times yearly, in fact we're meeting in Chicago next week. In addition we communicate on a very regular basis in three other media. One is we have a virtual interface called E-room, in which we post documents and communicate freely. We email each other, I would say, on a multiple times daily basis and frequently we hold conference calls, particularly amongst working groups that are working on specific research projects in PECARN.

The next slide shows you the different PECARN sub committees. We have five of them. Again, I won't go over the details. They're somewhat self-explanatory. But the first one, the concept protocol review subcommittee is the committee that takes the initial research pre-proposals submitted to PECARN and critically reviews and scores them, provides feedback to the Steering Committee for votes of approval or not for those particular proposals to move forward. To date, I would estimate that approximately 30% of proposals put forward to PECARN are actually endorsed for conduct in PECARN. We have a fairly rigorous process, because again our goal is to conduct not only important research, but very high quality research. Safety and regulatory affairs subcommittee and

quality assurance subcommittee, somewhat self-explanatory. Again, each of these subcommittees, by the way, are made up of eight individuals, two from each nodes.

The budget and feasibility subcommittee is an important subcommittee that reviews grants proposals that go out from PECARN. As I mentioned, when we conduct a specific research project, we submit extramural grant. Now, fortunately, the amount of money that we request per grant is much less than if we did not have this network infrastructure in place. But be that as it may, the budget and feasibility subcommittee, they are charged with reviewing the budgets to making sure that the budgets are adequate to cover what we need to do and that the project is, in fact, feasible within PECARN. Then finally, we have the grant writing and publication subcommittee, whose job is to really establish authorizeship guidelines and review not only grant proposals, but manuscripts and abstracts before they go out to the public.

The next slide is just an idea of how the proposal intake procedure and work flow moves forward in PECARN. I want to mention, by the way right here is as good a spot as any, that research ideas for PECARN can come from within the PECARN network or they can come from people that are outside of the PECARN network. For those of you who are interested, there is a manuscript we published in June of 2003, simultaneously in two magazines which describe the process by which people from outside of PECARN can have their research studied in PECARN. The process goes is that there is a proposal, a five-page preproposal sub submitted to the concept protocol review subcommittee. They make the recommendations. And if the Steering Committee endorses the preproposal,

the investigator and their colleagues move forward to submit their proposal. Prior to that being submitted, it goes back to the Steering Committee for final review and approval. During that time, that is during the grant preparation time, the investigator is interacting with the different subcommittees to make sure that the key components of the grant are being met. Once the Steering Committee approves the final proposal, it's then submitted to a funding agency for consideration. With that as a background, I just want to give you all in the last five minutes some idea of some of the research that's ongoing and completed in PECARN. PECARN just started in 2002. So we're very young in our lives, but we feel that we've gotten a lot done in the past two years.

The first project, the PECARN data project is a study that we did with core funding provided to us for infrastructure. The objective of that study was to describe the PECARN patient population to determine the availability and completeness and agreement of data that is abstracted from charts with data that is abstracted from electronic data sources. It tests our ability to collect and transfer and manage data from all sites to establish some benchmarking among sites and built into this core data project, we actually did do a couple of studies in which we looked at pain care and asthma care. There were six abstracts that were presented at the pediatric academic society's meeting based on this study. The second study I want to talk about is the Dexamethasone study. This, too, has been conducted with just infrastructure money, without going out for extramural grant funding, because once our network was established, we wanted to get going on research immediately. So this is a study we did with -- acute moderate, severe, outpatient patient bronchiolitis and it was a study that we felt was very important in response to a study that

was published in 2002 showing that oral Dexamethasone substantially reduced hospitalization amongst children with bronchiolitis seen as an outpatient. However it was a study of only 70 patients. And at one center and before this gets adopted nationwide or worldwide, we thought it would be important to study in a very robust manner in a multi-center setting.

We have enrolled 200 patients to date, and we are resuming this winter. Our sample size estimate will be 800 patients. We hope to complete this in 2005. The third study I wanted to mention is the hypothermia for pediatric cardiac arrest planning grant. This is a study that was funded by the NIH. The goal of the study is to describe a cohort of [PO-ED/] trick patients after cardiac arrest from either the outpatient or inpatient setting to describe them with regard to patient characteristics, time intervals, et cetera. It is a planning grant for which to submit an RO1 on therapeutic hypothermia for pediatric pulmonary arrest.

The next study, 4, on the next slide is called child head trauma. This study is a very large study, funded by HERSA-MCHB to develop a decision rule for neural imaging for those at a high risk or zero risk of brain injury. The goal is to decrease the amount of CT's that we are using in evaluation of children with mild to moderate head trauma. Our sample size is actually 25,000 patients. We started in June and in the first three months we've enrolled 5,000 patients to date. The fifth study, again I'm going to abbreviate now just for sake of time, the fifth study is the study pertaining to mental health issues in the pediatric emergency department. It's a pilot study that we're conducting with internal funding just to ascertain the resource utilization of pediatric patients with psychiatric complaints in

pediatric emergency departments. And possible variation in PECARN sites of these problems. The sixth study is a study regarding diagnostic grouping system for childhood emergency department visits. This is funded by an EMSC targeted issues grant. The goal of this study was to develop a parsimonious grouping system using ICD9 visits for childhood visits. The ICD9 system is cumbersome and the goal here is to collapse these down into 25 to 30 diagnostic groups using an expert consensus process for use in future EMSC research. The last study I wanted to mention is about terrorism surveillance objective, bioterrorism surveillance project. The objective of this study is to develop and evaluate an information structure for PECARN that creates an automated data stream for real time information from the emergency departments of PECARN to a data analysis center which is located' Children's Hospital-Boston. This being an example of a non-PECARN investigator doing a PECARN study. This is real time data stream of information to Boston which will be used for bioterrorism surveillance and clinical research.

There are many other PECARN projects under development and revision. One on cervical spine immobilization after trauma. A study looking at short-term emergency department followup mechanisms after acute illness. Other studies in racial disparities and a study that will hopefully be funded by the NIH regarding the management of epilepsy. To summarize our goals, our goals are to finalize and implement a formal research agenda to guide development in PECARN, to design and implement a plan to study and encourage the transfer of our research findings from the practice community. And to work closely with more personnel to provide information, opportunities, and bi--

directional exchange between the research and practitioner communities. Thank you very much. Moderator:

CHRIS DEGRAW: Thank you, Doctor Nathan Kuppermann. I would like to remind you that you can submit questions for any of our speakers at any time by typing your question in the messaging center on the lower right of your screen. We'll save the questions till after the third presentation and present them to the speakers at that time. Our next speaker is Richard C. Wasserman. Doctor Richard C. Wasserman is a professor of pediatrics at the University of Vermont college of medicine and is director of the pediatric research and office settings, PROS, the practice-based research network of the American Academy of Pediatrics. Doctor Richard C. Wasserman will speak with us about PROS today.

RICHARD C. WASSERMAN: Thanks very much. It's really a pleasure to have the opportunity to speak to members of the MCHB community, the Maternal and Child Health community. The bureau has been a cofunder of PROS since its earliest days and have the pleasure to report that we've gotten a new cooperative agreement with the bureau for another five years of work. So we're really excited to move forward. The first slide there just has the PROS logo and a website there. We also get some core funding from the American Academy of Pediatrics. We are a program of the American Academy of Pediatrics. And we've had smaller amounts of core funding from the agency for health care research and quality in recent years under their practice-based research network grant program.

Next slide. My objective for this talk really is to briefly describe pediatric research in office settings, or PROS, which is the national practice based network of the American Academy of Pediatrics. The PROS mission is on the next slide. And we have a mission statement which we've revised over our 17 or 18 years of existence. And it's currently to improve the health of children and enhance primary care practice by conducting national collaborative practice-based research.

Next slide shows the rationale behind the PROS mission. What we're trying to do is generate new knowledge about primary care practice. Influence policies about how practice should be conducted, in other words, influence guidelines and practice parameters. See those changes in policy result in changes in actual practitioner behavior, changes in the way pediatric practitioners care for children. And this hopefully leads to improved health outcomes for children. So that's how we in PROS are hoping to improve health outcomes for children. It's a pretty ambitious mission, but we think we're on the way towards getting there.

Next slide shows the map with current PROS practices. Currently we have 695 practices, and they're listed in this map. They're displayed, rather, by AAP chapter. So we actually have a practice, at least one practice in every state in the country. We have a smattering of practices in Canada, we have five practices in Puerto Rico. You can see the participation by practitioners is a bit sparse in areas of the country that are also somewhat less populated with pediatricians. So we are not evenly distributed throughout the

country. Our participating practices tend to be in places where there are lots of pediatricians. We have certain areas where we probably are over represented, which tend to be rural areas. And we have some areas where we're under represented, as well. And I'll get into that.

The next slide tells us a little bit about PROS practitioners. Currently, there are 1,941 PROS practitioners, or at least there were that many when I made up this slide last week. And it really does change from day-to-day. Of those practitioners, 1,765, or a little over 90% are pediatricians. And they comprise about 5% of all the AAP general primary care pediatricians in the membership. The rest of the practitioners, by the way, are nurse practitioners and physician assistants. When you compare our pediatricians to random samples of AAP general pediatricians, we have some differences. We're slightly more male than the AAP membership as a whole. We're slightly older than the AAP membership as a whole, which is an area of concern for us. And geographically, we tend to be more rural, equally urban, and less suburban than the AAP general practitioner membership. How do we get PROS practitioners? Where do PROS practitioners come from? Well, participation is completely voluntary. So this is not a random sample of pediatricians. And we recruit pediatricians into PROS through several means. The original means was word of mouth. We identified interested people through the American Academy of Pediatrics leadership, people who were interested in research and who were in practice, and then asked them to recruit people.

By the mid '90s, we found that we needed to have a more large scale recruitment, and we start today recruit through publications of the academy of pediatrics, mainly through articles about new studies in the AAP News, a monthly publication put out by the American Academy of Pediatrics. In one year, '94 to '95, we doubled the number of practices in PROS through this means. And as of this year, now, all new American Academy of Pediatrics members receive PROS recruitment materials after they joined the Academy. And somewhere over 1,500 member join each year, so we now have a system for approaching young members to join the network. This is one way we hope to make our membership more female and younger. Because those are the characteristics of new pediatricians. As I said before, practitioners need not be pediatricians. But at least one member of each practice must be an American Academy of Pediatrics member. We don't find this is a barrier to membership. In fact, we have family physicians in the network.

Next slide is a figure displaying the age distribution of PROS patients. We estimate, based on a PROS study of the early '90s, in which we learned that the average PROS practitioner cared for a little over 1,500 patients. We estimate that in the network, the 1,941 practitioners care for about 3 million children. And you can see from the slide that at least when these data were collected, and this is probably still true, the great majority of the pediatricians practice population is younger children. And as the age of the children goes there across the absolute numbers of children in the practice of that age of youth or adolescence gets small. We know this to be a fact that when we do studies involving youth, it takes longer for us to recruit our patient samples.

The next slide we describe just a little bit of a PROS patient race and ethnicity. We have no really accurate way to measure this, other than from particular studies. Because we have no database of all the patients in the network. Those would be very hard data to come by. But we can look at some recent studies. And you can see that in the studies we have about 70 to 80% white patients, African-American patients in the 9% to 12% range and Hispanic Latino patients in the 11% to 13% range. Now, even these numbers actually under represent the population of minorities in this country, and so that's a problem for us. They were achieved actually through over-sampling. So we know that the actual 3 million patients that are covered in PROS practices do under represent the racial and ethnic minorities in this country. And this is a challenge for us. I'll talk about how we address that challenge a little later. So we can get the minority numbers in particular studies up by doing focused recruitments, but in fact we are under representing those highly vulnerable populations, a problem for us.

Next slide shows a bit about the PROS organizational structure. The basic unit of membership actually is the practice. Each practice in PROS, each of the nearly 700 practices, has a practitioner within the practice designated as a conduct practitioner. And that's the individual that we communicate with when we want to know what's happening in a practice, want to recruit a new practice into a study. Next level up. The practice is in each American Academy of Pediatrics chapter are represented by chapter coordinator and if possible a co-coordinator. So these folks are, for the most part, real, live practitioners. They tend to be more zealous about doing more research and practice than most PROS members and they are willing to come together twice a year to discuss new

research and to advise study teams on research. This kind of infrastructure is what the Maternal and Child Health Bureau grant covers is maintaining the network and allowing it to meet on a regular basis so that we can develop new studies and keep our work going. Over the Chapter Coordinators, a Steering Committee determines policy.

The Steering Committee is comprised of six voting members, three of whom are chapter coordinators, so three of the voting members are actual practicing pediatricians. And the other three represent various academy of pediatrics research committees and constituencies. We've learned it's important to let the practitioners drive the network and that's why they have three votes on the committee with the chair who is also a practitioner who can dominate the voting if there is a tie. The PROS research staff is in Elk Grove Village at the academy of pediatrics, and that varies in number depending on how many studies we're doing. Currently, there are 11 staff there at the academy, and I work as a director of PROS from Vermont, which is obviously not in Elk Grove Village. But that relationship seems to work just fine. Now, very importantly is we have collaborating, investigative teams from literally across the United States so that the research activities are combined between the PROS research staff and the investigative teams from across the country.

How does a research idea become a PROS study? Well anybody, and literally anybody, can suggest an idea to the PROS leadership. We have on our web page a little place where anyone can suggest an idea. About a third of the ideas actually come from practitioners, but the majority of ideas are coming from investigators who know or aware

that we are a research laboratory for work in primary care pediatric research. And so anybody suggesting an idea is asked to write it up into a short proposal. The kind of thing one might submit as a summary to an institutional review board, maybe five pages, some references. And that proposal comes to myself or our Steering Committee chair or to doctor Eric Sora, who is the head of primary care at the academy and then it is presenting to our Steering Committee. So our Steering Committee reviews the proposal and we actually have the people who presented it come to a Steering Committee meeting. That process takes about an hour. About a third of the proposals get rejected right there, at the Steering Committee. About another third get accepted for the next step. And a third are asked to be revised and resubmitted to the Steering Committee. If the Steering Committee approves the proposal, then it goes to the Chapter Coordinators.

So there are about 40 of these folks, practicing pediatricians, and they, not the Steering Committee, but they have the final say on whether the network goes forward with the study. So we let the final review be done by vote by practicing pediatricians. We have evolved to this point because we've learned that if we don't do it this way, we choose poorly in picking studies to do, and the studies actually are not conducted well. If the Chapter Coordinators approve a study, then we go out and get funding. As Nathan Kuppermann mentioned with PECARN, we are seeking extramural funding. We're not doing studies from our core resources. So we go out and submit grants to various funding agencies, federal agencies, as well as foundations. And once we get the funding, then the study is conducted. What characteristics apply to a study that's appropriate for PROS? Well, a study appropriate for PROS is one that requires a geographically disperse sample

of patients and-or of practitioners. And requires a very large sample size or a very large population base, because we are studying an uncommon condition or an infrequent outcome.

So basically our studies tend to be large studies, with thousands of subjects from around the country. What are the characteristics of a study that's not appropriate for PROS? Inappropriate? Because we get lots of suggestions now. Well, one is a simple practitioner survey. If one simple wants to ask practitioners what they are doing in their offices, not to study their patients, but really just to ask the practitioners to report what they do, we're not the right place to come. There are better ways to do that. For one thing, we are volunteers and you really want a random samples and you can get random samples to do such surveys. A second inappropriate study for PROS is one where the data is proprietary. We've had pharmaceutical companies come to us and with ideas which would have been of great interest to our practitioners. New pharmaceuticals that our practitioners would have been glad to help evaluate, however, every pharmaceutical company that's approached us has felt that they wanted to own the data completely. They would not share the data. And that circumstance is not consistent with our desire to interpret and public the results as we see fit. So we've never done a pharmaceutical study. It could happen, but it hasn't happened yet.

And finally, in general, studies that require invasive procedures are inappropriate for PROS. We've never required study participants, practitioners, to actually do invasive procedures. When I say invasive, I mean simply drawing blood. Now that's likely going to

change. We have some important studies coming our way in which blood drawing is going to be required. And we've discovered that there is a subset of PROS practitioners who will actually do these kinds of study, but in the past we have shied away from studies that have required invasive procedures. I have a couple of slides here that list PROS studies. I'm not going to go through them all. But you can see that there's a real diversity of topics. In the early days, our studies were largely descriptive studies, in which we looked at certain aspects of health care delivered to children, whether it involved screening or immunizations or acute illness, like gastroenteritis or asthma. Or chronic problems like psychosocial problems. We would look at practitioner behavior. And then we would look at the differences between the way practitioners manage patients, differences in management, and associations with short-term outcomes. And that was the typical PROS study for the first 10 years or so. And some of these studies have had a lot of impact.

The second bullet in the first column, two young girls has been a very widely spread and somewhat controversial study in which we were able to demonstrate that the norms for the development of puberty in young girls that were in textbooks were not consistent with what practitioners were seeing in their offices, that girls were maturing a lot earlier than they had before. So in the next slide, you'll see more studies. These studies, by the way, have been funded by national institute of mental health, the MCHB under its research program, and agency for health care research and quality, as well as various foundations and private sources. You can see that where the asterisks are denotes interventions trials. You can see that PROS is moving, as we are maturing, from descriptive studies to

intervention studies. And if our mission is to improve the health of children, certainly we need to be able to be testing interventions in order to do that. Just looking back, the previous slide, please. The PROS study number one 1 slide, if you could go back. The last one on the right. Helping improve pediatric practice outcomes is a study of quality improvement in pediatric practice. I mention that because I think that's a direction we are continuing to go in and will go in the future. And although we still have a fair amount of descriptive work in our portfolio and some of it is very important work, the child abuse recognition experience study just wrapping up now. It's a good example of important descriptive work which looks at how pediatricians decide that an injury seen in a child is worth reporting to children's protective services. You can see the general trend is towards intervention studies.

We have particular study looking at immunization disparities, which is ongoing right now. We, in our immunization work, had noted that there was a disparity between African-Americans and other ethnic and racial groups in immunizations, even after controlling for social economic status and even after controlling for the race and ethnicity of the provider. And so we're kind of drilling down on immunizations and trying to learn more about that. The translating immunization research into study is an ongoing distance learning, quality improvement study, trying to help practices improve their immunization rates. You can see the final three asterisks there; two of them have to do with tobacco. The first having to do with adolescent tobacco cessation. The second just recently funded will look at pediatricians and pediatric practices trying to help Parents quit smoking. And the last one, healthy lifestyles refer to a study that will be looking at a prevention strategy in the office

for preventing obesity. So we're really moving more into lifestyle changes here in our more recent studies.

Next slide just shows an example of one of our recent publications. This one comes from our study on the management of very young febrile infants. This was a recent publication in JAMA. It's exciting that there is a pediatric emergency room network, because most of the research on the care and management of very young febrile infants came from pediatric emergency rooms. This study on febrile infants was probably the most popular study that PROS ever has or will do. It had 500 practitioners collecting data. And it was on how practitioners in office settings, rather than in emergency room settings, managed very young febrile infants. We learned that they do not follow the guidelines that exist, and in fact that there's an error on that slide because they don't follow not only the guidelines with urine testing, but they don't follow the guidelines with blood testing or cerebral spinal testing or using antibiotic. In this study, we found no evidence of adverse short-term outcomes in association with failure to follow guidelines. And this conclusion wasn't surprising to us, because the population of febrile infants seen in PROS is probably different than the population seen in inner city emergency rooms. And the management strategies available to practicing pediatricians in the community, namely close followup, is different than the management strategies available to emergency room physicians. But it's a good example of how different settings and a research organization like PROS of practicing pediatricians in community, can come up with different answers than previous research.

Next slide. Why do pediatricians participate in PROS? Well, it's a good question, because as with other clinicians, these are very busy people for whom research is not their top priority. But in general, there's a curiosity about practice and pediatricians and practitioners are curious about their own practices. We try to give them specific feedback after each PROS study on how their practice compared with the network as a whole. The second reason for participation is, I believe, altruism. We hear this; there is a real desire to contribute to child research that goes beyond contributing to the care of individual children. Finally, there is a desire for affiliation with others, pediatric practice can be very isolating, I think. Participation in a group like PROS allows pediatricians who are out in the trenches to feel close to others. I think this accounts for our disproportionately high representation from rural communities. It's interesting for me to reflect here that Doctor Robert Hagerty, his original idea in starting PROS was that it would be a good thing for pediatricians, not only a good thing for generating new knowledge in child health, but would be a good activity for pediatricians themselves.

The next two slides just have quotes about what PROS practitioners say about what they do. And I'll let you read them. You can add the second one. So I'd like to wrap up just a little bit by talking about the future of PROS, what lies in the future for us. Well, certainly more intervention studies, since our mission is to improve health for children, we need to learn how to take better care of children and the best design of studies to do that is in fact the randomized controlled trials. So a large proportion of the studies that are just starting up in PROS or under development are in fact randomized clinical trials. Secondly, we are working hard to get more minority and disadvantaged subjects into PROS practices and

into PROS studies. We do this in several ways, but the one I've noted here is continued collaboration with networks serving these groups. So actually all of our immunization studies since 1996 have been done in collaboration with the national medical associations pediatric research network.

The African-American physicians in this country, and back in the mid to late '90s, we realized that our group and the NMA pediatric section shared an interest in the new polio recommendations. We teamed together to do a study and out of that study came the national medical association PEDNET. We continue to collaborate with them and feel that in helping them to grow, we serving ourselves as well by getting more minority children into our studies. A second network that serves the minority and disadvantaged populations disproportionately has just recently been founded. It's called the Continuity Research Network and it is a program of the ambulatory pediatric association. The general pediatricians and general pediatric academic association. And we have been helping them to get started and are about to collaborate with them on studies. So those two networks, which disproportionately serve minority populations, really compliment PROS. And in our recent cooperative agreement with the Bureau we asked for funding, small amounts of funding to allow us to continue to assist those networks. And so we will be doing so.

Finally, we will have more studies oriented towards practice systems and quality improvement. We had one on asthma management in the late '90s. We're doing a second one now on improving immunization rates in practice. Randomized control trials

often give us information about what the best way to care for children is, but we know in fact from many, many studies, including our own studies, that pediatricians and pediatric practitioners often don't follow evidence-based guidelines. And in part, that's because their practice settings, clinics, are not set up well to deliver evidence-based care. And so we wanted the studies to actually demonstrate or to learn what the best ways are to help pediatric practices improve their systems and deliver higher quality care. And that is certainly one of our objectives for the future. So that's really all I have to say. Once again, I'm really delighted to have the opportunity to present this to this group. And when Doctor Jay Schulkin is done, I'll be happy to answer any questions. Thank you.

CHRIS DEGRAW: Thank you very much, doctor Richard C. Wasserman. A reminder that you can submit questions for our speakers and we'll field those questions at the end of the webcast. The final speaker, Doctor Jay Schulkin is the Director of Research at the American college of obstetricians and gynecologists. He's currently a research professor in the department of physiology and biophysics at Georgetown university school of medicine. Doctor Jay Schulkin will talk to us about the collaborative ambulatory network.

JAY SCHULKIN: Good afternoon. It's interesting to hear my colleagues talk about their network. Mort and I collaborated a long time ago. Our network is exclusively devoted to serving the gynecologists in the college. It's a way, as it was originally envisioned to find out who they are, what do they know, how do they self-report how they practice, do we could get them to be better at what they do, as their own fields changed. That was part of the original conception of it. And it's called CARN, The Collaborative Ambulatory

Research Network. I arrived 10 years ago to run this. And that's figure 1. Figure 2, just a little introduction. It's the college. It was founded in 1951. Originally housed in Chicago, now in Washington, D.C. It represents about 47,000 members. And that varies, but not by much. And it's devoted primarily towards health care for women. And the ACOG mission statement is strong advocate for health care for women, trying to maintain high standards of clinical practice and linking the practice to education for its members. That's an important part of my theme here is the link between who they are, what they know and what they need to know in an expanding field, where knowledge is exponential and the demands on the physician has grown quite a lot. Another part of this is promoting patient education in the same context as we're trying to get the physicians educated, as well, in expanding fields. And increasing awareness in general about the importance of women's health care.

Next slide, please. 97% of obstetricians and gynecologists are members of colleges. There are several categories that are listed here. All have to be board certified. Fellows have to be board certified. Next slide. This is divided up into districts, of which there are 10. This gives you an idea of roughly where the 10 districts are located. As Mort alerted, this represents our CARN distribution. Females have grown, women have grown in the field of obstetrician and gynecology. When I took this job 10 years ago, it was 70% male, 30% female. In 10 years, it will be just the opposite. That's a figure to show you the trend for some of this. The number of ethnics, minorities has grown, but at a much slower pace. Next slide, please. The network here is of Fellows, obviously. And there are roughly about 750. And that varies a lot. We work hard to keep our membership up. There are

750 CARN members in practices, often there are four or five or six other people, so that adds to the number here quite a lot. We've worked hard, best we can, to have it distributed across the districts and be representative. It's not a perfect representative sample. Like Doctor Richard C. Wasserman, it tends to be older males, still, and we've worked hard to have women be as representative in the Collaborative Ambulatory Research Network as they are in the college in again. That gives you an idea where it is now. 60% male and 40% female. It's not significantly different from the college in general. Age, males are older. Females are younger. And so on. It began in terms of membership by just writing people for different states targeting different states. Now we have a letter that goes out where we just go after different states to try to get it be as representative as we can. In any study that we do, we run the CARN group, which is a highly-motivated group. And so we always worry about, you know, whether the data is going to be meaningful. So we run a random control. -- in most of our settings, but not all of them. The difference between the two groups are not significantly different. When they are different, we check into it and look into it further. I would say most of the time, 90% of the time, we don't see differences between them. But we keep looking to see where that might come up.

The next slide. CARN study objectives, focus on ambulatory care issues. That's our bread and butter here. We link clinical practices, but link them to guidelines. Most colleges emphasize the guidelines. That has changed somewhat the way things are done at the college. We are trying very hard to promote to not only read them, but change the behaviors as a function of it. Our results are used to form educational strategies. I want

to come back to that. One of the things that we do, where there is a knowledge deficit, where they are over prescribing antibiotics, or worried about CF, that we develop a course or some educational method that helps their sense of not knowing about an issue. It's important to them. We work on that hard. We do so by getting together with different people, by having conference calls, by introducing groups at our annual clinical meeting. I would say at least three times a year we're trying to do something towards that end. It reaches a climax when we have the continued medical education commission. And I think that several people from the agency have attended that to see how what we find in terms of where they're poor in something and how we could implement something to at least address it is couched. That's an important part of the continuing medical education part of this.

The next slide basically gives you a rough idea of the study logistics. This is not a perfect way we do. We look for ideas from most of our Fellows. One of the reasons for this also is to get our Fellows involved in research questions as part of their idea of a network here. They're out there, they're practicing, they're overwhelmed. Their knowledge basis expanding. You know, what are the questions they have about issues that they're confronted with? And are they practicing like other folks are reporting practicing? So we work hard to solicit responses, not only from the CARN members, but from anybody in the college. We have a website and we have different ways of doing that. But it comes to the research department and there are several of us in the department, all P.H.Ds in the department with backgrounds in doing research. And looking at the surveys. I would say in a year probably 100 different fellows, not necessarily CARN Fellows will have access to

us. Will have access to generate questions, to engage issues, to find ways to do a study if we can. As a review process that we go through and we pilot test it and I present it to different groups here. But in particular, the continuing medical education group and we get feedback from internal sources and external sources. And then when we're ready to go after we pilot test it and change the questions around, we're ready to sample stuff.

The next figure is some of the papers we've been at over the last five years, basically.

This is a rich field. For one like me, there is always something to think about here. From the point of view of being a clinician, there is so much for them to know in a world what they're mostly concerned about is getting sued. That's not a trivial thing. The two prominent things that are burning out obstetricians and gynecologists are lawsuits and hours. Now it's clearly liability over and over again. That impacts practice. Risk of errors. List willing to do something other than what's absolutely safe and secure. And unhappy a lot. And unhappy physicians probably are not good for maternal-fetal health. That's something that we've been looking at in general. So that's some of the stuff we do. I put down a couple of examples. Cystic fibrosis was an easy one. One of our interests is prenatal screening, CF, cystic fibrosis is one that has some common currency. We wanted to get a feel for what the fellows know. That's surprising they don't know a whole lot unless they're specialists and have a kind of orientation, you know, genetic specialists or some other kind of specialists. We wanted to get a sample of what they know about a topic and cystic fibrosis was a good model for thinking about disorders.

The next slide, please. Some of the results from our study on CF. Physicians were likely to inquire about CF. The college would like them, because they're treating women in a primary care context, and that's a role that the obstetrician gynecologist wants to play and a non-pregnant patient should be screened. We wanted to begin to tap into that and see where they are on that. But over and over again, here is an example here. It comes up a lot. Liability comes up. In this case from not offering screening. That's a big concern. All right. Physicians were clearly deficient, it's not surprising, this is genetics, if they were taught, they would know it.

The next slide, please. Since the college and us in particular have something to do with the development of these evidence-based guidelines, if they really read this one that just came out on cystic fibrosis and are familiar with it, it tends to do better and that's both in the CARN group and the non-CARN. This is something we want to do more. Next slide, please. It's a summary of what I just said. And I think preconception screening, the second line, for CF which affords patients the widest range of options to reduce the option of having a child with this disease. Neonatal encephalopathy. This is an issue that you can find after all these years, it's not understood in any great detail. There is more known now. It came up to a liability issue. Are they responsible? And what do they need to know and how much do they know? And how much is known out there? And we did a study in 2001 where we looked at it.

Next slide, please. Of the questions that we asked, which were some basic questions, they didn't get a whole lot right. Of course, this worried my colleagues, worry about

lawsuits for not getting it right. We need to know what they know and don't know. The nice thing so far, they tend to be fairly honest here, because it's blind. We know who the CARN people are. So they're willing to say they don't know something a lot. To our amazement they report that a lot. This was clearly one where that was an issue. They often report that their training and residency was inadequate, particularly for something like this. If I could have the next slide, please. Again, the more familiar they are with reading an evidence-based pamphlet on neonatal encephalopathy and cerebral palsy, and again if they're reading this stuff and we want to begin to look at who reads it more than others and even how to make it more friendly to them, again so that their practice is better. Obviously their patients are better. So this is our way, I guess, of thinking how are we intervening. We're intervening with education material and the interaction of development of education material and the expansion of knowledge. Knowledge that's evaluated in an evidence-based context.

If I could have the next slide, please? Just a summary of this. In this context, one of the discouraging things, however, has the document been read? Not surprising. Like was said, they are overwhelmed. They only read what they need to. They don't like to be told what to do. We're working towards the end of reading the information. An issue which ties a lot of our interest together is obesity. Not a trivial problem in America, not a trivial problem as it relates to race and ethnic issues. The study of obesity brings a lot of our other issues together such as hypertension, diabetes, and met to -- metabolic disorders that we've inquired into. Next slide, please. We found that, maybe not surprisingly, they're interested in this issue, they're interested in their patients, they're interested in

figuring out what they can do about it. We want to begin to probe this a lot more. If I could have the next slide, please. We're in the process of developing a follow upstudy on obesity to begin to look at exactly what they're telling their patients, and how it relates to the offspring, the health of the child. The next figure, please. Is some of our ongoing or future studies. A big study for us is going to be preterm delivery low birth weight babies. I've had an interest in this since I came down here from Penn. It brings a lot of stuff that we've been investigating in the last 10 years and this will give us an opportunity to link the different studies together and some of the other things that we have ongoing or are about to do.

Next slide, please. Again, I come back to what I emphasized at the very onset which is the CMA connection. What we've done now is we summarize in our first group, 1995 to 2000, our studies, which then in a peer-reviewed journal, which all of our stuff goes to, was accepted and served as a CME. So that's another way we get out just the actual description of the CARN material. And we have another CARN, which summarizes basically 2000-2004, a similar CME. That's another way in which we can sort of impact and get folks thinking about diverse issues. And the final figure gives you an idea of what we've been up to this year and part of last year, I guess. And it's a tremendously Rich Field. I went from being a very specialized scientist into when I turn around there is something worth thinking about and worth doing. This is the range of stuff. And I thank you for your time.

CHRIS DEGRAW: Thank you, Doctor Schulkin. I'd like to thank all three of our speakers for their presentation today. If you have a question for any of them or general comments, please submit them now. Again, questions for Doctor Nathan Kuppermann about the Pediatric Emergency Care Applied Research Network, Doctor Richard C. Wasserman or Doctor Jay Schulkin about the The Collaborative Ambulatory Research Network. We have a couple of questions. Our first question comes from New York state and is directed to Doctor Richard C. Wasserman. What has been the cost range for the PROS studies? How long do the studies usually run?

RICHARD WASSERMAN: Okay. Well, a total cost for PROS studies vary. But the most elaborate of these studies are at or even slightly exceed half a million dollars per year. And typically, PROS studies from the onset until the data analysis included would take four or even five years.

CHRIS DEGRAW: Okay. Thank you. The second question, is it possible, I believe this is directed at Doctor Nathan Kuppermann. Is it possible that guidelines take too long to review during emergency cases? Is there a shortcut to review guidelines that may make them more useful and useful by practitioners?

NATHAN KUPPERMANN: A very important question. One of the really stumbling blocks to not only conducting research in the emergency setting, but also caring for patients in the emergency setting is how to follow guidelines when you have an acutely ill child that you have to make pretty quick decisions. Our goal, I'll give you the example for the head

injury decision rule that we're developing with this study of 25,000 infants. I mean not infants, 25,000 children. In any sort of decision role, the goal is, A, it has to be accurate, but it has to be parsimonious, that is simple. Because first of all, if it's not accurate, than it's not good. If it's not simple to implement, then no one will use it. One of our goals in the research that we conduct is to make things simple. The bronchiolitis study we're studying, we're doing, is a randomized trial of whether you should administer oral Dexamethasone to children with acute moderate bronchiolitis. Yes-no. Simple. The decision rule for head injury will be collapsed into a very simple decision rule. So, yes, the answer is if you have a convoluted guideline, it's a hard thing to read when you have a patient right in front of you that needs emergent decision-making, but our goal is to generate decision rules and research findings that are simple and easy to implement.

CHRIS DEGRAW: Thank you. Our next question is for the CARN network presentation. How have the outcomes of the CME programs been measured?

JAY SCHULKIN: You mean in terms of what?

CHRIS DEGRAW: Okay. I'll have to ask the submitter of the question to elaborate.

JAY SCHULKIN: Guess probably what he or she means is one of the ways we've measured it is by at the ACM, we'll have individuals look at some of the material who had looked at the material earlier and see whether or not they respond differently to some

issues, like an issue about antibiotics or an issue about CF, if that's what they have in mind.

CHRIS DEGRAW: The questioner was particularly interested in how you measure changes in behavior that occur based on the programs?

JAY SCHULKIN: The main way we do it, the ideal way is to get into the electronic records and see what they're doing. So it's self-report. You know the limits of self-report. But just looking at self-report over time, in a situation where they can be honest. It's done in different ways, either at the annual clinic meeting where we relook at individuals who have participated or relook at them after they've been exposed to an evidence-based guideline. And then we look at what they report.

CHRIS DEGRAW: Thank you. That's all the questions that we've had submitted so far. At this point, I'd like to thank again all three of our speakers today, and I'd like to thank all of you in the audience in participating for this MCH roundtable webcast. We would like to thank our contractor for making all this technology work. Today's webcast will be archived and available within a few days on the website, [WWW.MCHCOM.com](http://WWW.MCHCOM.com). We encourage you to let your colleagues know about the website and hope they have the information be useful. On behalf of our Maternal and Child Health Bureau program, we want to encourage your participation in future webcasts.

>> Thank you.