THE BROOKINGS INSTITUTION

USING DATA TO SUPPORT BETTER HEALTH CARE:

ONE INFRASTRUCTURE WITH MANY USES

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PARTICIPANTS:

INTRODUCTION: A CONCEPTUAL FRAMEWORK FOR LEARNING FROM THE DELIVERY OF HEALTH CARE

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PROOF OF CONCEPT PANEL: LEARNING FROM HEALTH CARE DATABASES

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PANEL DISCUSSION: THE HHS ROLE IN CREATING A LEARNING HEALTH CARE SYSTEM

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SUMMARY AND NEXT STEPS:

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P R O C E E D I N G S

MR. McCLELLAN: Good morning, everyone. We're going to get started for our event today on Using Data to Support Better Health Care. I really want to thank all of you for getting up early and joining us today. I also want to thank all the people who are joining us online for our simultaneous webcast.

I'm Mark McClellan. I'm the director of the Engelberg Center for Health Care Reform here at the Brookings Institution. This is an important and timely topic on using data to support better health care. It may not sound like the most important topic with all the debate about public options and subsidies and deficits, but as I hope you'll see during the course of the presentations today, this topic is absolutely essential to learning how we can make our health care system work better, and so it's probably the most important piece for getting to a health care system that's more sustainable and consistently delivers better quality care.

Before I start, I'd like to recognize the generosity of the Robert Wood Johnson Foundation for supporting this event for their ongoing support of the High Value Health Care project here at the Brookings Institution, and I'd like to again thank all of you.

This is designed to be an interactive event. Following each of the panel discussions, we're going to take questions from each of you.

If you've got a question, please raise your hand and we'll get a microphone out to you. If you're viewing on the webcast, you just need to submit your question online.

And I want to remind everyone that this meeting is being recorded and is being webcast live, so everything we're doing here is on the record.

What I'd like to do to begin with is start some of the -- is provide a framework for what we're going to discuss today, and that's how we can learn from patient care data. We widely recognize that we need to be doing a better job of improving quality and lowering cost through better information available when people are making health care decisions.

The advantages of better electronic information available at the time of patient care include reduced duplication of services; avoiding those duplicates of lab tests or imaging procedures; more personalized care so if a patient shows up at a specialist or at a different emergency room from where they usually receive care, it won't be such a big loss in terms of having the relevant information on what that patient's history is and what that patient needs, and that all leads to better decision making. It can all lead to quality improvement and patient care. That's why an underpinning of every major health care reform proposal is more reliance

on a more effective electronic data system for helping to deliver patient care.

But what's important to remember is that better data for patient care also provides a stronger foundation for evidence to improve care for groups or populations of patients. This gives us an ability to understand patterns of treatments that are being received. It would give us an opportunity to learn more about outcomes, including adverse events, complications, experience with care. It gives a better opportunity to learn about the costs of different kinds of treatment options -- different approaches to delivering care. It's the foundation for better evidence on how we can actually improve patient care at the level of populations of patients. So, individual data can support individual decision making. Better use of that data in an aggregated fashion can help drive better decisions for all patients.

Now, this is not a new concept. This is something that has been recognize by many of the leaders in this room and by the Institute of Medicine and a series of reports and activities around a learning health care system, for example. They've emphasized that it is possible or should be possible to generate and apply better evidence for making health care choices by providers and patients through the kinds of process that I've been describing viewing the use of data that is developed in the

course of delivering care as a natural outgrowth of patient care that can help to promote innovation, quality, safety, and value in our health care system. And this is also something that's being done now, as you'll hear about more this morning, in the area of drug safety surveillance and the areas of measuring quality of care and reporting on it to help lead to better decisions by patients about where and how to get their care in the area of effectiveness research, in public health reporting, in many other uses. We are starting to develop better evidence from the actual delivery of patient care.

There are a number of examples of the kinds of questions that relate to these issues, like how do doctors' performances compare with others in the region? What are the best opportunities for improving care in our own institution where evidence developed from individual patients put together can help us understand how to make better decisions both as patients and as health care providers. In the area of patient safety, questions about whether particular drugs have unknown or at least not well-defined, important side effects or complications; whether the H1N1 vaccine has an acceptable safety profile in the area of effectiveness research. What about alternative approaches for therapies, like different ways of doing a colonoscopy? What about different policy approaches, so not just questions about particular medical technologies

but if we change the way that we pay, if we provide support for a medical home, does that actually lead to better outcomes and lower costs compared to alternative policies that we might implement? All of these benefit from putting together data across multiple patients to help answer questions about evidence on quality, on safety, on comparative effectiveness. And so a very important question as we're making investments in health care reforms and making investments in our health care infrastructure is how can we best use the emerging electronic information systems to support all of these different evidence uses of patient care data effectively and also securely in a way that protects patient information and confidentiality? What kind of infrastructure is needed for these sort of steps?

Well, there are -- it's important to remember as we approach all of these different kinds of evidence questions that there actually are fairly similar data needs in many respects for all of these uses.

For questions about safety, it's important to measure the treatments that are provided, the outcomes, the potential patient-level confounders that could also affect outcomes in a well-defined sample of patients, a well-defined population of patients.

For effectiveness research, it's important to get the same kinds of information on treatments and outcomes and patient factors

influencing those treatments and outcomes, as well as on alternative treatments. And in evaluating quality of care, again it's important to understand care processes, treatments, outcomes like resource uses, resource use and cost, data on patient confounders, or risk adjustment data.

For a broad population of patients it's same kinds of data in all of these cases. And much of these data can be developed from systems that are now used to provide patient care, and looking ahead as these systems get richer, the potential for pursuing these kinds of evidence questions can potentially get even better. Right now there are many types of data systems used for patient care decisions for individual decisions about particular patients -- data like information from insurance systems, claims data which have the advantage of being a fairly well-defined population, including a broad range of services from a broad range of providers, basically, everything that's covered in the health insurance plan and it's all linked together at the patient level. As health insurance becomes more sophisticated, these insurance plan systems are increasingly relying on clinically sophisticated data as well, like lab results and things like that, not just administrative claims. Also data from increasingly sophisticated health care provider information systems -- so hospital systems, outpatient systems, physician office systems, which

increasingly are being linked to other types of data to provide a better picture of care for the health care providers that are making decisions for particular patients. And of course a lot of growth in the use of electronic medical records now and projected over the next few years, which includes detailed clinical information and increasingly also integrating patient data from some of the sources that I've talked about. In fact, many providers are using registries both for research purposes and for supporting patient care; information on groups of patients, such as all the patients in a practice with diabetes that captures data explicitly from multiple sources to try to support better decision making to make sure patients aren't missing lab tests and abnormal results or undesirable clinical complications are being followed upon quickly. Lots of data being used for patient care that's increasingly sophisticated and increasingly integrated.

If you think about moving beyond the level of individual patients, though, to summarizing these data, you get to being able to answer the kinds of questions that we've been talking about this morning around issues like quality of care and safety and comparative effectiveness of treatments. This kind of information on treatments, on clinical outcomes, on resource use and cost can be put together, not at the level of the individual patient -- you know, what matters for these kinds

of evidence questions isn't so much was Mrs. Smith treated by Dr. Jones last Tuesday for her diabetes but how many patients like Mrs. Smith were treated; what were their treatments; what were their results; what were their costs -- using things like age and sex and disease co-morbidity to group patients together, provide a better understanding of how patients with different kinds of characteristics, how groups of patients with different kinds of characteristics are treated and what the consequences of those treatment decisions might be. In fact, most of the evidence needed to develop better ways of improving care involve summary data, not the individual identified patient information.

So, for answering questions like, for example, does Vioxx increase the risk of a heart attack, the primary kind of information that's needed is not information on each patient like Mrs. Smith but how many patients like her were treated with a particular drug like Vioxx or another set of treatments and what were their results -- population-level results that need not identify individual patients, and this is a common thing that goes across all of these types of evidence development areas and quality, safety, comparative effectiveness research.

Now, there is certainly individual-level data that are needed for making the right decisions for individual patients whose information is contributing to these broader population data sets and this broader ability

to try to learn about -- to get insights about quality and safety and effectiveness and other issues from the care of individual patients. For example, doctors certainly are going to want to know which of my patients needs interventions to achieve better diabetes control -- what are -- for making a decision about which treatment is best. Individual patient preferences are really important, and so I want to make this distinction between de-identified data or aggregated that is what we primarily need for evidence from identified data or individual data, which is what we need for patient care.

There is some connection between the two, for example, to confirm that a patient really does have a serious complication from, say, the use of a vaccine. It may be necessary to go back to the individual patient records, which does create the need for using identifiable information, at least in confirmation in some cases, but I want to make this distinction between data for patient care, which is behind local firewalls, which is used for operations of care and payment and improving decisions at the individual patient level from this aggregated data that can be used to make -- to reach conclusions about important policy issues related to better medical evidence. And, again, improving health care while improving patient care does not generally require sharing identifiable data. It's the difference between decisions for individual patients from the

importance of pulling together this aggregated information that can help us understand better ways to deliver care.

We're using wires, we're using within particular institutions boxes of shared data, we're using data clouds of identifiable information to help improve individual patient decisions, but for purposes of these policy questions, these better evidence questions, what really matters is having the ability to use summarized or aggregated data.

And that does mean some work. It means having common models for organizing and summarizing these data, standard terminology for getting information from individual sites and individual types of patients in a consistent way -- and you'll hear more about that from our coming speakers in just a few minutes.

This is a challenge today, even though there is, I think, a great potential to learn more, especially as we become a more electronic health care system, to learn more about questions of quality and safety and better evidence on effectiveness of treatments. It does require overcoming a number of obstacles related to coordination and consistency.

One way to do this is to try to set up a very large project that pools a lot of individual data and use that pool data as a basis for analysis, but there are some real obstacles here, such as the participating

organizations being reluctant to contribute identifiable information on their patients because of concerns about confidentiality and data security, and even if you put these data sets together from different sources, they may not be consistent, even if they're following the same standards, even if they seem on the surface to be about the same kinds of problems, like diabetes or particular treatments. They may be coded or recorded in electronic data sets in different ways. And it requires a significant central infrastructure. And if you're going to do this, it may be difficult to apply to multiple uses, like safety questions and effectiveness questions and quality-of-care questions.

On the other hand, there have been a number of efforts launched in recent years that are more based on combining the aggregated data, not individual level data on patients. That stays behind organizational firewalls, but combining the summary information which is not identifiable but that can be used to get at these important underlying policy questions. Again, it's not data on whether Mrs. Smith went to Dr. Jones; it's summary information on how many patients like Mrs. Smith did doctors and a whole set of different institutions have, and if that information can be combined -- aggregate information can be combined in a consistent way, well, then you can get the advantages of a large data set without actually having to pool identifiable and potentially sensitive

individual information. And it also keeps all of the participating institutions actively involved in trying to make sure that their data are in fact consistent.

There are a lot of examples of these activities underway now and a lot of examples to make these collaborations more powerful to the extent that they only involve one institution or one payer's data or one type of use of data. These are going to be less powerful. They won't be as powerful in detecting safety signals. They won't produce as precise quality measures. They may produce inconsistent results, because they involve different populations or differences in methods, all of which are very difficult to understand without an effort to coordinate and support these kinds of activities. So, a very important question is can these kinds of efforts to learn from our health care system by pooling together summary data more effectively? Can they be better coordinated? And how can that lead to more compelling results?

There are multiple obstacles to developing this kind of evidence quickly in our health care system even as we're becoming more electronic. Issues about access to the data, even if it's summary data that's not identifiable for patients -- what information; what uses; under what conditions; making sure that privacy and security concerns, which are very important, are addressed; providing incentives for participation in

the data summary system. It's very important, for example, to support better decisions at the individual patient level. Ideally, the way that we pay for health care and where we might pay more under health care reform for better quality care as opposed to more services would also reinforce providing data that shows that care is getting better at the individual level by showing the summary information from a broad set of patients are getting results overall, that we're reducing the rate of complications for diabetes and patients like Mrs. Smith and paying more for that kind of care and paying more for providing the kind of summary data that come out of.

We need consistent methods for reaching conclusions, and that doesn't mean just between different sites that may be contributing data on, say, questions of patient safety, but also consistent methods across studies of safety and study of quality that may involve similar patient populations and similar treatments. And, of course, since these -- as you'll hear more from Alan Garber in particular -- since these studies are often based on -- or generally going to be based on observational, nonrandomized patient populations, avoiding biases like from unmeasured confounding factors is very important as well. So, a lot of obstacles to making this kind of learning health care system work but of a lot of opportunities as well.

So, moving forward, some issues, which I hope we'll have a chance to discuss further in terms of learning from health care data at the individual level that's aggregated or combined up to the level of populations of patients is can we define the important questions and how questions may have common elements across different kinds of uses. For example, defining the kinds of treatments and outcomes that are relevant to safety questions related to drugs used in diabetes care may help us do a better job of understanding patterns of care that are relevant to quality of care and effectiveness of different types of practices for diabetes as well.

Identifying sources. There are a lot of efforts underway, as you'll hear, for using aggregated data for questions related to safety. There are efforts underway for using aggregated data related to quality. Can we put these kinds of environments together in a way that enables us to answer both types of questions more effectively? Can we develop and apply consistent and effective best-practice methods when we're summarizing data and analyzing these kinds of de-identified data. Once again, there are likely to be some common insights from questions on safety, questions on quality, questions on evaluating effectiveness, questions on evaluating public health issues.

And how can we best support these efforts? Can we align the incentives and support from improving patient care? These individual-

level decisions -- for example, the upcoming payments for providers to use health IT to support the care of their own patients -- can we align that with incentives to support efforts to improve the evidence? For example, paying for better quality care is a key issue in health care reform. Well, it may be the case that the so-called meaningful use payments for health IT could be very well aligned with payment reforms that are aimed at the consequences of meaningful use of health IT, and that's better results for a population of patients being cared for by physicians. Again, it's about putting this all together.

And, finally, I think it's important to emphasize that we view this at least as a step-by-step process. There are many uses of data now. There are many different efforts underway to try to develop better avenues and to try to improve care at the individual patient level. Can we take at least some limited steps towards pulling together common elements of these multiple uses to build up to longer-term progress.

So, those are some of the issues that we want to cover in our discussion this morning, and I'd like to move right to our first panel discussion to provide a little bit more concrete context and a little bit more meat on the bones for some of these themes, and that includes three panelists who we'll hear from right now, and that is Dr. Allen Dobson, who's joining us from North Carolina.

Sorry, Allen, I seem to have gotten my notes a little bit out of order, but if you could come on up along with the other two panelists, as well as Dr. Richard Platt from Harvard Medical School and Harvard Pilgrim Health Care. Dr. Dodson is going to talk -- and Dr. Alan Garber from the Department of Veterans Affairs and the Center for Health Policy at Stanford University. Dr. Dodson is going to talk about some applications in North Carolina related to improving quality of care; Dr. Platt is going to talk about the infrastructure needs for medical product safety surveillance, some of safety issues that I alluded to earlier, and Dr. Garber is going to talk about data and infrastructure needs for comparative effectiveness research. After they give a brief overview, we're going to turn to a panel discussion and hope to hear a bit about some of the common themes that are emerging from all of these areas -- along the lines that I was discussing in my opening remarks.

So, Alan, if I could turn this over to you. Thank you.

DR. GARBER: Thanks, Mark. It's a pleasure to be here.

Talk a little bit about application of data from a practical standpoint as far as moving the quality a forward, and I'd summarize in just -- it's a simple thing. It requires a uniform effort on behalf of the delivery system, the providers, and some use of some standardized data whether it's aggregated or individualized patient data.

And just -- we're talking about data, but, you know, I want to put in there that it really requires some uniform effort. It requires provider engagement, a commitment to do what's necessary at the local level and at the physician-patient level to really improve our delivery system.

Also we need to recognize that local health care delivery systems are very, very different across this country, and so we need to focus on what we can do at the local level and improve the coordination.

Also recognize that to really move quality forward, even with data it's going to require additional resources or at least reallocation of resources. If health system levels are, in the case of primary care, which I think it's going to be crucially important in dealing with chronic disease intervention that additional resources are going to be necessary to get the job done. And focusing changes broadly, if we can get an engaged workforce around responding to data and applied broadly across this country really can produce significant results for us over the next few years.

The key part is standardized data so that you can compare apples to apples, and that should be multi-payer. You know, it should be quality data that's all patients, and we can start with claims data, which is the most readily available, as we build infrastructure for a robust data system. But beyond that, it needs to be more -- it needs to be timely and

actionable. In other words, we need to look at data but also be able to provide infrastructure to feed it back to the providers so that it can be actionable. It doesn't do any good to say that we only get it right 70 percent of the time if you can't tell which patient's needed additional care that didn't get it.

In North Carolina we use computing in practice-level reporting rather than individual physician-level reporting, and that's mainly because it's -- you know, the delivery system is really a team sport. And we talk a lot about that. It's also a limitation of the data we have, because we started in Medicaid doing this. The other part is transparency, which produces accountability. It produces a new level of competition not related to price or consumer choice but data around providers seeing who can be the best and move the ball forward.

Community care is the platform we've used in North Carolina to get collaboration among providers and use our data, and it's a statewide program. We started with Medicaid, but it focuses on quality, utilization, and cost-effectiveness. We have 14 networks. About 80 percent of all the primary care physicians, all the hospital health systems, and public providers managing a million Medicaid recipients, but we're now moving into -- because it is really is a delivery system model not a payer model, and we're moving to other populations.

We started with the major diseases that we saw in Medicaid -- asthma, diabetes, congestive heart failure. But one of the things I wanted to point out is that taking the Medicaid database, you can produce aggregate data, and we created a data center and we feed information back to each of our networks and then to each of our practices based on their real data. This actually shows average hemoglobin A1C values, because the providers wanted more specifics than basically a process measure -- did you do it or did you not do it. They wanted to know what the values were. But if you'll look across our networks, we have some networks who are doing very, very well in a Medicaid population, which is hard to manage, probably comparable to a lot of commercial populations in the country. So, we are actually seeing some improvements from that standpoint.

We've lowered asthma admission rates simply by using that data and feeding it back, so aggregating data, doing reports, and then feeding actionable items back to the networks and the providers in a way that they can act on it. We've lowered hospital admission rates, ED rates for asthma, and prove compliance for medications, and we're slowly moving diabetes cure forward.

The big thing is our providers want not only the aggregate data in the report cards, but they want actionable data fed back to the

networks practice levels. We're using that by, you know, giving them pharmacy claims, but the networks -- you know, a lot of them have taken it upon themselves to make an agreement with their local hospitals to have real live feeds on emergency room admissions and hospitalizations so that they can actually move the quality (inaudible) forward.

Some of our larger health systems invested in the technology exchange inside the firewall where they can actually -- and this is an example of my institution, where we have 45,000 diabetics -- that's a lot of diabetics in the Charlotte region -- and measuring each of our networks and every quarter with not only actionable data but aggregate data to move the ball forward.

Likewise, looking at those who are falling out of care and have not been -- we're seeing a steady improvement in that information. This collaboration in North Carolina around providers and hospitals led the Hospital Association -- every hospital to go to create a center for hospital quality and patient safety where even the smallest hospital -- rural hospital in our big academic centers are measuring core indicators around diseases and making it transparent.

And this is a all-or-nothing score system. You get all the care right and all the indicators that they've agreed upon for heart failure or you get a zero. If you miss one, you get a zero. So, this is really

providing the best care all the time, and you see, just by this public reporting and then creating actionable data at the hospital level, we're moving the quality bar forward.

So I think to summarize, the data elements we really need to get quality improvement is patient-level data; helping identify the gaps in care that need to be addressed; opportunities to look at transitions and avoid readmissions and duplication, as Mark said, but also putting out in front, you know, provider performance summaries. And this is not a report card about who's best. This is trying to raise all votes and provide a complete, standardized, objective datasets. The thing that needs to be pointed out I think will -- our next speakers will speak to that -- is once we show that one community is doing better, the question is what are they doing? You know, what is the best practice, and what are the elements that go into making that practical and duplicatable across the country?

I look at it this way. You have claims. You have data from claims and clinical data. They're either or process or clinical measures. The best we've got is aggregating those into quality reports and hopefully spitting out something that's actionable on the back end.

The end result is something in the business world you call a lag indicator -- is that if we do what's right, the lag indicators -- we're going to get better outcomes at a better price.

So, a final comment is that we need to use data to really get some systemization around our health care system, recognizing that health care systems are local. And it will require local physicians and health care providers and their communities to address it.

HIT alone cannot fix the quality problem. We do have to build our primary care system out, and additional resources will be needed, but a uniform effort around quality and some real standardization of data so we can compare apples and apples and actually do the research necessary to define best practice is necessary. But in addition to aggregate data, we need actionable data fed back to the local level to really define those gaps in care. And I would tell you that transparency in this framework will foster a whole new level of competition around quality versus just cost and volume.

Anyway, thanks a lot for the opportunity to be here.

MR. McCLELLAN: Thanks very much, Alan.

DR. PLATT: Although my assigned topic was to talk about medical product safety evaluation, I see this topic as part of the larger field of public health uses of electronic health data, and so while the worked example often is drug safety, I think it's important to think about the other ways we should data that arise from the delivery of health care.

The handouts have some bonus slides that I'd encourage you to take a look at afterwards that provide some extra detail about the ways to use these.

The opportunity has already really I think been laid out for us that data that arise from the routine delivery of health care can be useful in a variety of ways that serve a public health purpose that includes identification of adverse events of drugs and vaccines, cases of notifiable diseases that are of interest to local health departments. Syndromic surveillance, for instance, being able to monitor the occurrence and propagation of influenza or other conditions, and also other conditions that are of public health interest -- for instance, understanding where diabetes is most prevalent in communities so that interventions can be targeted that way.

Now, I'll show you very quickly some examples of post-marketing safety for drugs and vaccines that are being conducted now, so this is not a speculative venture. The FDA sometimes uses a list of designated medical events that are conditions of most interest to identify among marketed drugs. Shown on the left are examples that I know from my own experience have been addressed using routinely collected health data. The ones on the right I don't know -- haven't been -- and I think many of them are tractable using electronic health data combined with a

very limited amount of review of original medical records. We'll come back to the importance of medical records availability as a key component of the medical safety evaluation situation.

These are other kinds of outcomes for which there has been success in using electronic health data. The ones on the left are a potpourri from the published literature. The ones on the right are ones that the Observational Medical Outcomes program is evaluating using electronic health data.

Even as we speak, there are active programs doing real time surveillance for adverse outcomes of the H1N1 vaccine. One large program is being conducted under the auspices of the vaccine safety data link. The other is called Prism -- uses data from four large national health plans. These are the outcomes that are being evaluated. All of the heavy lifting is being done by use of electronic data systems from health plans and from large payers. The vaccine safety data link also has active surveillance programs using near real time data for these additional outcomes. So, the sense I'm trying to give you is that there is fairly robust evidence that it's possible to use these data for other kinds of conditions under a center of excellence grant from the CDC.

My colleagues and I have developed a real time system for detecting and reporting the conditions on the left here, and those are

individually reported conditions, and aggregate conditions like those on the right.

So, if you step back and ask what do you need to make these things possible, I'd say that for doing medical product safety assessment, you almost always need to be able to identify the defined population that Mark talked about. That means typically there needs to be something like a health plan substrate so that you understand enrollment demographics, have access to claims in inpatient and outpatient settings, pharmacy dispensing data, and access to full text medical records.

Why is that important? It's important in order to be able to confirm the accuracy of relatively unusual outcomes that are not coded with perfect fidelity or to collect additional information that is rarely available in electronic forms -- data about a patient's history for instance or information about other kinds of risk factors that may not be coded.

The need here is typically to be able to access a few hundred records out of millions that contribute to the underlying evaluation, so I'll show you an example in a moment of a study we've done where we started with the electronic medical -- with electronic health data from about 50 million people. We ended up reviewing about 500 records, but they were critical to being able to understand the outcome.

Now, it's also often helpful to have access to electronic medical records, and it's increasingly worthwhile to be able to link to external registries, such as birth and death certificates or to immunization registries.

Now, for the public health reporting kinds of activities, it's -- there are many useful things that be done without all that data. What's often most important here is demographic information and electronic medical records that provide information that's of interest to health departments even if it's not coming from a defined population. It's sometimes, however, necessary to have information that is often not in the electronic medical record of a single practice, such as care delivered outside the practice, treatments dispensed as opposed to treatments prescribed, and the same kind of external linkage.

I'd like to show you quickly a couple of examples of work that my colleagues and I are doing. Much of our thinking has arisen from work by the HMO Research Network of which my department and health plan are a member, and over the years it's become apparent to us that there was real value in our developing a set of standards that allow each of the participating organizations to develop an identically formatted set of its own data. It's a virtual data warehouse, meaning there's no pool data set but in each of our organizations the data are arrayed sort of like a

Toys R Us. You can always go to aisle 3 and the fourth shelf and be pretty sure that what you'll find there is the same in each of the health plans. The data come from enrollment claims, pharmacy, electronic medical records, and external registries, but they're arrayed in a series of very simple tables that are linked by a common identifier. And the -- this has been an evolving process with addition of new variables as time goes by. Various of us take responsibility for different kinds of tables. I lead an HRQ center for education and research in therapeutics (inaudible), so we've taken the lead in developing the pharmacy tables. The Cancer Research Network -- it's funded by the NIH's National Cancer Institute and it takes responsibility for the tumor piece of this. And so it's a shared activity from which all can benefit.

We use these data for a variety of different things. That's what gives me optimism that the subject of this conversation today is achievable. For FDA we do post-marketing surveillance as part of the mini-sentinel program and we have contracts with the Center for Drugs and the Center for Biologics. For ARC we lead a CERT in one of the DECIDE programs that is focused on effectiveness. We lead a multicenter diabetes research consortium, the Cancer Research Network that I mentioned, and the Cardiovascular Network. It's one data system that underlies this. So, each time we tackle something new, we usually

have to augment the VDW, but the core proves to be extremely useful to us.

Here's the kinds of things that have made a difference in our work in medical product safety. This is work (inaudible) the vaccine safety data link, which involves eight health plans that are part of the HMO Research Network. About a year ago, there was a presentation to the Advisory Committee on Immunization Practice about a new identification of febrile seizures associated with MMR vaccine and tetravalent vaccine. That came from a finding that from active surveillance -- I don't have a pointer -- oh, here we go -- monitoring overtime on a weekly basis, there was a signal of an excess number of observed events of seizure following immunization compared to the expected, and you can see here that that was occurring with a relative risk of just about a two-fold excess risk of seizure. The -- finding the signal wasn't itself sufficient to make a presentation to the Advisory Committee or for the Advisory Committee to change its recommended use of the vaccine, which is what happened from it. There was a substantial amount of follow-up evaluation that went through that, but it was -- it's really the first example of active surveillance leading to a change in practice.

It's harder to do this work with drugs than vaccines. We've done a proof of principle looking at the Vioxx and myocardial infarction

showing that if the data as they accrued in our system was capable of showing us a signal relatively soon after the drug was dispensed, and it's possible to apply these techniques in large national systems that cover a substantial part of the U.S. population. This is a study that we're just completing of pneumococcal vaccine and Guillain-Barré syndrome. It involves the five health plans on the left. They have an aggregate population of 50 million. We're targeting the -- it's a vaccine that's used in adolescence and it's covered about a quarter of the U.S. population of adolescents. We used distributed methods having -- each of the participating plans use -- develop in effect a temporary virtual data warehouse for just the data involving these individuals and were able to come to a successful conclusion of that work.

I'd like to take just a second to say that in our public health infomatics work, we've developed an operational system for doing notifiable disease surveillance detection and reporting to the health department. I'll let you read more about that in the notes. But it does better than manual reporting.

In conclusion, I'd say that we're convinced that there are a substantial number of safety effectiveness and quality questions that could be answered by using electronic health data. One of the things that has really become very clear to us is you only need a very small fraction of the

kinds of information that are in either clinical or administrative data systems, and so it's not necessary to inhale everything that's in these electronic data systems, which is what has made our work possible. We believe that because you don't have to deal with everything in those systems, it's much more tractable to develop distributed networks and that avoids many problems having to do with both confidential and proprietary data.

The way the distributed networks can work is by adopting a common data model, and our experience with these models is that they have to evolve over time, that no matter how carefully we think about it now we'll think differently about it in six months.

So, I think that a way to proceed would be to think about developing a core common data model where we would standardize the definition and format of elements that are useful to at least two of the disciplines that we're talking about with each discipline taking responsibility for the things that are unique to its own work and contributing that to the larger set and that -- I want to emphasize the fact that this is a simpler task than dealing with all of the HIT, and so in the spirit of making progress quickly, we should -- we should make sure to look for the light touch rather than having to do the heavy lift.

Thanks.

DR. DOBSON: So, I don't know about the rest of you, but my handout was missing. Pairs of slides. Every other pair of slides. It might be a nice exercise in whether we really needed all of these slides for those (inaudible), but I'll always be happy to make my full set available to everyone, and I'm sure the Brookings people can help out with that.

I just wanted to make a few brief comments today about how health care data bases can contribute to the comparative effectiveness research effort. And when we're talking about these databases, we're generally talking about observational analyses, which is really what Rich and Alan have talked about and Mark as well. And observational studies I just want to review very briefly. I'm sure this is familiar to all of you.

There are several compelling advantages, the most obvious of which is cost. Once you have an electronic database set up and a way to query it, the cost of doing a study is much, much lower than for an alternative that is custom designed -- usually a study like a randomized trial. All right, you can have access to an enormous number of observations I think was particularly clear with the database that Rich was talking but also Alan. And that means you can answer questions that simply aren't possible in other settings.

Speed. We talk in medicine about the prospective study. The prospective randomized trial. In fact, we often do what's sometimes

called historical prospective studies, which have the statistical characteristics of studies that you start out today and follow people for a long time, a true prospective study. And you can query a database by setting up this study properly and instantly have five or ten years to follow up because you're basically going backwards in time. Simply not possible with the genuinely prospective study.

Real world. In the world I live in of medical care, we actually have patients who don't take their medicines when they're supposed to. And most of my patients would be ineligible. I practice in a VA hospital, but it's true of many other practice settings. Most of my patients would be excluded immediately if they were screened for a randomized trial. They'd have to agree to show up for a lot of visits at a scheduled time, get a lot of tests, and so on and so forth. Your typical randomized trial patient is simply very, very different from your typical patient period. In fact, a common number that you will hear is that roughly 5 percent of the people screened for randomized trials are actually enrolled. So, this is really about capturing the other 95 percent.

The other thing which I'll mention briefly later is in the real world the interventions that patients receive are not necessarily the same as in the trial. It's one thing if you're talking about a drug trial where you have a pill with uniform characteristics from person to person, but what if

it's an operation? What if in particular it's a very complex operation and you have surgeons with varying experiences, some of whom do an operation five times a year and some who do it 200 times a year? You get very different results. And who enrolls in the trials? Who participates in the trials? You're typically going to see the surgeons who are doing 200 operations a year.

One of the great advances -- and Mark has talked in some detail about this -- is the databases assembled from electronic health records. They're different from what we've worked with before, because they have extraordinarily rich detail about the patient's characteristics, the doctors, the facilities the patients were treated were treated in, and that really extends the horizon tremendously for appropriate use of observational studies.

Now, this last bullet point I have in some circumstances -- statistical methods can adjust for bias -- I don't want to get in the weeds here about methods, but methods are crucial. ARC, in fact, has been a major supporter of efforts to improve methods. Other federal agencies have as well. FDA has actually worked on this also as has VA and NIH. But -- and Mark would not talk about this too much today, but he used to be a very promising young academic, and his dissertation actually used a novel method, novel at least in the health world, called Instrumental

Variables, to find out what the effect was of having access to open heart surgery and hospital facilities that could actually provide cardiac catheterizations for patients having heart attacks. And he was able to analyze what the effects were of having -- being more likely to get treated with one of these procedures because you had your heart attack somewhere near a major facility that offered these kinds of resources.

That study really -- it's hard to imagine how this could have been done in a randomized trial framework, and it was very convincing about effectiveness. So, that's the kind of thing you can do.

So, these are used more broadly as compliments to form a randomized trial. There are many, many questions that can be addressed that can't really be addressed by randomized trials.

Alan has talked about quality improvement and how these kinds of data can be used. I won't talk more about that. Rapid implementation. And if we develop the infrastructure -- and this is part of what the National Health care IT Initiative is all about -- if we develop the infrastructure, the cost of accessing these kinds of data rapidly and in large scale, this will go down dramatically. And this is already being --

(Interruption)

DR. GARBER: Okay, got it. So, you need to extend my time by 30 seconds. Thank you.

And there are some times, actually, when you can't really do the study at all without observational data. So, I just mentioned Mark's study, which I don't think you could do very well with randomized trial. Sometimes you can't randomize patients. There are all kinds of reasons for why that might be true. Accrual, by the way, is a huge issue for randomized trials. With observational studies, you look at what people actually got, but sometimes it's unethical, because you actually think denying a particular treatment that you want to study would not be ethical. In the real world people don't get that treatment for all kinds of reasons, so you might be able to learn something.

I alluded to treatment adherence. I am told that for, say, HIV drugs, once you get below 70 percent compliance with the treatment regimen it basically is completely ineffective. You look at the people in trials and they have near a hundred percent compliance. You get a very different picture of how the intervention works.

I already mentioned surgery, and think about analyzing the effectiveness of diagnostic tests. It's pretty easy to figure out if a diagnostic test is accurate. A new diagnostic test is more accurate if you have the right circumstances. But those circumstances often apply. For example, you have a way to confirm the diagnosis.

But what if you want to know if a newer diagnostic test actually improves health outcomes, lowers mortality, reduces hospitalization and so on and so forth? There are very few trials of that kind, because embedded in that trial has to be an assessment of the treatments that you administer based on the diagnostic test and that you may get a very small number of people with the disease in question where you expect treatment to make a difference, and the number of people needed and the length of follow-up needed can make a child prohibitive. This is something that you can do much better with observational studies.

So, I just wanted to point out some data. In the world of randomized trials, they are considered gold standard in terms of evaluating whether an intervention works. And I do believe that myself. But you have to ask how do they compare where we have data from both. And let me just show you. This is from a study published in 2000 in *The New England Journal of Medicine*. It looks at five different questions, if you want to call it that, that have been addressed by both randomized trials and observational studies, and this may be too small in your handouts to see, but the light dots give the results of observational studies and the dark splotches are the results of randomized trials. So, these are for, as I mentioned, five different situations -- a vaccine to prevent TB -- and what you see is when you have the benefit, if you want to call it that,

of multiple randomized trials, the results vary quite a bit. And then you look at the range of results of the observational studies. In this case, they are sort of on top of each other. Mammography and mortality from breast cancer. The observational studies show a slightly greater benefit than you saw in the randomized trials. The cholesterol levels in death due to trauma -- this has been a highly contentious issue, and you can see why when you look at how widely spread those splotches are. Treatment of hypertension and stroke, an outlier study. There was randomized trial. But otherwise, the observational studies give you similar answers. And same thing with treatment of hypertension and coronary heart disease.

The bottom line is observational studies vary. Randomized trials vary in terms of their results. But the ranges typically overlap. Here's another study by a different group that looks specifically at cardiology -- at cardiac treatments. And I'm not going to go through these in detail, and all you really need to see is that these bars are right on top of each other. The dots are the central estimates of the treatment effect and the ranges are given by those bars with the little things at the end. And what you see is that the observational studies, with the exception of this study of cabbage -- the fourth one down. There's just overlap. It's not really that close. But you also see that the randomized trials had a wide range of results, and there's little confidence in the results.

So, particularly when you look at cardiac treatments, the observational studies have tracked very well with randomized trials.

Now, this doesn't mean that all observational studies are good, and there's an art to it, and you happen to have here people like Allen Dobson and Rich Platt who are doing path-breaking work. You can get very reliable results, but you can also get lousy results. So, one of the things that helps a lot in being able to do a good study is if you have a lot of clinical detail. So, I've just listed here some of the things that you would typically need to have a good study in that respect.

Now, I'm going to just mention two examples very briefly. A successful use of observational databases, both from electronic health records that have this kind of detail. This is from a Kaiser study. So, Kaiser Permanente has long had electronic health records, and they've had the ability to query them in order to do studies, and this study, if you'll just look at the left column of results, the angiography necessary. What they have looked at is people who met these guideline-based criteria for having -- it being appropriate to receive angiography, people who had heart disease or suspected they have heart disease. So, what they showed is that in hospitals that had a high rate of performing angiography, the mortality rate from heart disease was two-thirds as great as in

hospitals that didn't. And if you look at any heart disease event, it was 70 percent as great.

Now, the footnote -- I'm not -- there's a lot of nuances to this. Part of the purpose of the study was to look at which were the good hospitals and which were the hospitals that needed improvement, and the Kaiser system -- but if you look at the bottom and it says what was in the model, this gives you an idea of what kinds of data you need to have a successful study of this kind. These are basically demographics, a bunch of diagnostic information and some measures of the severity of the illness, as well as characteristics of the hospital. The VA also has electronic health records. They have for several years. And, incidentally, the VA now has the ability, relatively recently, to be able to pool electronic health record data nationally. And so I think in the coming years we're going to see an explosion in the studies coming from the VA, because you can tap into the entire patient population pretty much and get clinically detailed data.

This is a study -- a little bit complicated but you probably all heard about Plavix, this drug that is given to patients who've had stents and some people who've had heart attacks or angina, and there was an observation that wasn't very well supported at the time they initiated the study, that it seemed that people who were stopped -- who stopped taking

their Plavix, maybe under the doctor's instructions, would experience a high rate of heart attacks after it was stopped. And this is something you didn't really see in randomized trials particularly. So, they actually took data based on the electronic health records at the VA, but they were supplemented by additional data and looked at the rates at which these events, like heart attacks, occurred in different time intervals after stopping the drug. And what it showed was, if you take a look at this left column, for example, the incidence rate in the first 90 days was about twice as great as in days 91 to 180 and the rate declined after that, suggesting that we need to be particularly careful about guarding against heart attacks immediately after stopping Plavix. This is, again, the kind of result you couldn't easily get from a randomized trial.

So, to close, just basically I hope I've made the case that these are important compliments to randomized trials. I'm not saying randomized trials are unnecessary by any means. I could also give you some examples where observational studies have been extremely misleading. But they really open up the range of questions that you can answer with good data, as Allen has gone into in detail. You can very easily tie the results of this kind of research into quality improvement efforts. You can implement these findings very rapidly. And as I

mentioned, the investment in database infrastructure means the cost of doing these studies will likely fall dramatically in the coming years.

Thank you.

MR. McCLELLAN: Alan, thank you very much.

To open up the discussion, I'll just pick up on one point that Alan just made, improved electronic data.

Yeah, everyone's mikes are right on the side of their chairs here, and you're going to need that for the audience to hear you.

And, Rich, if you don't mind, I'll ask you a question while you're putting the microphone on. Alan was saying about how the capacity to do these kinds of studies really does seem to be increasing rapidly. You've been on the leading edge of a lot of those activities. You mentioned at the end of your talk that a good place to go next might be to define a set of common data elements or models that could be used more productively across many different kinds of applications -- not just quality, not just safety, not just effectiveness but potentially in a broader range of areas. I wonder if you could say a little bit more about that. What might be involved there, just to get concrete, and if this really is becoming a routine part of the use of health care data, is it really research? Is this something that's more part of our routine delivery and improvement of care?

DR. PLATT: Let me start with the second part of that. I think in some ways we are doing a disservice by using the word "research." We ought to call it "evaluation," because the superstructure we have built to supervise research doesn't serve us well, and it communicates, I think, the wrong message to the whole society. I think we need to change the normative expectations to say all of us should insist that our data that is part of these systems be used for thoughtful inquiry and evaluation and improvement, and we shouldn't call that research. It needs oversight, but I think it doesn't need the kind of oversight that accompanies sort of truly novel therapies that have not been tested.

In terms of what we can -- so, some of that is a matter of degree. I say, for example, this Prism study that I mentioned, the H1N1 vaccine study that's going on now, is the very first study that I've been involved in that's been defined as public health practice rather than research, and it's made a huge difference in our ability to bring health plans on board and to link the health plan data to state immunization registry data. Very important. If we did it as a research study, we'd be able to tell you next year what the safety profile of the vaccine is, but that doesn't help very much this year.

In terms of what we might do as next steps, I think the notion of developing reusable data systems is a very powerful one. It's been the case for the last umpty-ump years that every time we start to do an observational study, we go and build a data set from scratch, and it takes a long time and it's expensive to do, and part of the notion of the virtual data warehouse is to say at least some of this should be reusable. And, to be very honest, we started by saying what's commonly available and familiar to most organizations? That's claimed -- it's the kind of data that CMS insists that every organization provide. So, if you look at the actual data structures of our virtual data warehouse, big sections of it look like claims data submissions that organizations make to CMS. We would still live with that notion of saying start with the things that almost everybody has or is familiar with, and then build the additional ones as needed, and it is really startling how much you can do with how little in terms of the kinds of data elements and what you need to know in them.

In a health care delivery system, a functioning delivery system, it's important to really understand and be able to distinguish between probably 90 different venues for delivery of care. In our work, it's unusual that we need to know more than ambulatory emergency room in-patient, and so not having to keep all 90 of those in mind, it's a big help and makes the overall job a relatively simple one, and it makes me think

that it's worth starting now with the notion that it's a semi-disposable system that we're building, because you should be able to tear it down and build it up as needs change and as data capabilities improve.

DR. DOBSON: Well, Allen Dobson picking up on this point that Rich made and Alan Garber made about how if we do this carefully we can get a lot of mileage for a limited amount of resources. One of the things you emphasized was that it's still difficult; it still has some -- there are costs associated with providing this kind of infrastructure, financial costs, and also costs in terms of just broad participation from providers. I wonder if you might say a little bit more about some promising models for how these kinds of costs for shared data uses for multiple purposes could be overcome both in terms of bearing the financial costs and in terms of bringing the providers along. You emphasized, in particular, the importance of feedback that actually improves patient care, and I -- you know, to pick up on Rich's point, not something that gets published in a journal next year but something that can affect patients right now. Are those the ways to go to make this more sustainable?

DR. GARBER: I think there's two points that -- one that Rich made and I think Allen as well is that we have to be more standardized in defining what the data elements need to look like so that they can be used, you know, in getting standardization. The other part of the question

is do you build a centralized database or do you -- you know, I like the notion of, you know, having a virtual if you can go get the data when you need it rather than redoing it.

I think there is, you know, an issue related to getting actionable data which is protected. So, the closer you can get that to an operating unit that can actually do something but yet feeding aggregate data up for research makes a lot of sense. And I think that it's extremely important that I think the federal government can take some leadership in defining these elements but also, you know, putting multi-payer. I mean, it really needs to be about all the patients we care for in a community in a practice level. That starts to make it more economic when you start talking about doing actionable item -- you know, actionable steps and creating a delivery system, because the real cost is really changing the delivery system. And that ought to be -- if we do it, if we build it right and thoughtfully, it ought to be very cost effective when we start putting more and more people into it.

MR. McCLELLAN: Thanks, Alan. And Alan Garber just picking up on these last points. You know, we've got a, as you know, an ongoing health care reform debate here in Washington. I was reminded of the -- in the debate -- in the discussion this morning of a political cartoon recently where somebody's watching their television and announces that

"And the Senate is about to begin the debate on health care reform."

"Begin"?

I think we're getting pretty far along in this debate. As we get into what may be the final stages, what's most important for this legislation to include in order to support the kinds of goals that Rich and Alan have talked about in order to further -- and Allen -- you have talked about -- in order to further the development of this multiple-purpose infrastructure?

DR. DOBSON: Well, Mark, am I allowed to ask about things that I know aren't in the legislation?

MR. McCLELLAN: Absolutely. This is a good time --

DR. DOBSON: -- as a researcher to pick up on Rich as an evaluator, there are many things that could be done to facilitate the research, and David Blumenthal is here now and we could start with something that I know he's trying to do, which is make sure that there are common reporting formats for these data elements. So, I would like to see the comparative effectiveness research effort include some real investment in both methods or pooling data and statistical methods as well. Now, methods for pooling data will include things like common data reporting format, which I see as crucial. I don't -- for quality purposes and for payment on the basis of quality, I can envision a world where we have

an agreement about which data elements are needed. I don't think that will be the case for research and (inaudible), because when we're looking at a very diverse range of questions, we're going to need different data elements. So, instead I think the model is a platform that we can build upon. So, I don't see the federal government specifying what data elements are needed for research in any form. But I can see the federal government saying you need to use the standard reporting format to facilitate this. So, this isn't exactly what your question was about, but one of the things that comes to mind, hearing both Alan and Rich, is that I gave two examples of closed health systems. Virtually everybody in Kaiser Permanente gets all their care within the system, so everything pretty much is captured in their electronic health record system.

It's somewhat less true at the VA, but it's still largely true of the VA, that you get almost complete data capture. When you talk about integrating data across multiple providers who are in different networks or aren't in networks at all, you run into problems, like will the Eclipses electronic health record be able to format data the same way that the Epic system will? And can you even get the vendors to agree to a common reporting format? And what about those practices that don't have electronic health records at all? So, that's what the health care IT money

in the stimulus is supposed to alleviate, and it would be nice to think we'll get to a hundred percent, but I suspect that won't really be the case.

So, I'd like to see the legislation encourage that. But on my wish list also that's not in the legislation is some clarification of HIPAA standards to ease the use of individually identifiable data, because, as Mark well knows, and I think everybody would agree, we can do at least as good, maybe a better job, protecting patient privacy while also easing availability of data for research purposes, and I think that has been a major impediment. I know that's not a big part of the health care reform debate. But if we're going to make maximal use of this kind of information, it will be important to address that.

Thanks.

MR. McCLELLAN: Thanks, Alan.

I'd like to open up this discussion to some of you who are here, maybe some of you who are watching online. Any questions in the audience?

Back here, and when you get the microphone -- please wait for a microphone. When you get the microphone, if you could tell us very briefly who you are. Nice to see you here.

MS. PEROT: Good morning. My name is Ruth Perot. I'm the Executive Director and CEO of Summit Health Institute for Research

and Education. Abundant research points to the importance of the collection of race, ethnic and primary language data if we're going to address health disparities and also improve health care quality for those vulnerable populations. The most recent report came out in August issued by the Institute of Medicine and made that connection. Can you tell me or tell us what use and applications you've been making of race, ethnic and language data in your work? You've all talked about demographics, but this is an extremely important component of the demographics and we'd like to know a little bit more about how you're using it and the importance and value of that data.

MR. MCCLELLAN: Any comments, Allen?

MR. DOBSON: I'll just mention briefly there is a huge amount of research being done with this. You're raising a very important question of what are the causes of the disparities and how can they be addressed, so I'll give you just one example of a study we did using Medicare claims data. Again we don't have great clinical detail, but we were interested in why nonwhites had higher rates of sudden cardiac death than whites in the Medicare population where everybody of course has insurance, it turns out one of the things we found is that there was a much lower rate of invasive procedures that are used to prevent sudden cardiac death. For example, for people who have survived an episode,

yes, you can survive sudden cardiac death, by the way, but for people who have survived an episode, if you get an implantable defibrillator you will live much longer and there was a lower rate of those kinds of procedures being put in place. I think most of us in the research community take it as a given that you absolutely have to have that kind of data, but we also see a clear path for using the data to better answer these policy questions in essence.

MR. MCCLELLAN: Rich?

MR. PLATT: It's terribly important, but these data are usually missing in electronic health data.

MR. MCCLELLAN: Usually what's missing is the details on race and ethnicity.

MR. PLATT: The individual's race and ethnicity classification is usually missing and that hasn't been an oversight. By and large the practices and especially the large health plans whose data are so important have been reluctant to ask for that information or to capture it. That's starting to change, but for the time being what we have had to do is to link addresses to census information and use census data as a proxy for race. So in the scheme of things, we need to have a change in expectations about the kind of data that are made available for use, goes

along with saying it's important to improve care to have that information be part of the medical record.

MR. MCCLELLAN: Bring the public along with this. Are there other questions?

MR. SINGERMAN: Richard Singerman. I think you said a very important point about there is on be-all, end-all data model to keep flexibility in a registry. I'm wondering what kind of suggestions do you have for creating a meaningful-use criterion for organizationally creating this minimum set of registries that have some sort of standard but also build in the notion that every year from how there's going to be a new technology that's going to make it easier and more effective? How do you strike that balance?

SPEAKER: I think that being prepared for new kinds of data is in a way the simplest piece of the work because if you imagine a structure of a series of linked tables that have a common identifier, when it comes time to add genomic data to the virtual data warehouse, we can build that table so that that part is pretty straightforward. The part that gives us pause is when it becomes apparent that we want to make an improvement that breaks the model, that is, if it becomes necessary to change the format of an existing table in the virtual data warehouse, suddenly the thousand programs that have been written already to expect

the data to be in a certain format don't work and so you make those changes only grudgingly. It's not the end of the world to do that. The vaccine safety data link developed its model in the mid 1990s, and when the same organizations built this virtual data warehouse that I showed you, it's somewhat different. Suddenly, for this H1N1 vaccine work that we're doing, we've want to do exactly the same analyses and there are two slightly different data formats and we'd like not to have to write the programs twice. So what we're trying to do is very quickly write a translator from one to another. Eventually there will be enough layers of translation that will say it's not worth it, we'd better start over, but for the time being while we're finding our way along we can use those kinds of ways to adapt to new decisions to old data formats.

MR. MCCLELLAN: Investments in translators. I have a question from one of our online participants. Andrew Croshaw asks roughly nine states have through legislative authority begin developing all payer claims databases for where the claims data in the state are aggregated together and can be analyzed at the state level. If these databases continue to appear throughout the country, how are they going to relate to the other types of databases that we've talked about, either virtual or centralized? I think this is part of this general question that we've been pursuing about how do you standardize these different data sources

enough especially in the short term so that they're comparable enough to do real analysis? All-payer databases -- seem like a valuable source of information.

SPEAKER: Absolutely. The question is who sets those standards. I think that's a role for governmental leadership to set the standards so that we don't have to rebuild these databases.

MR. MCCLELLAN: And just to be clear, what we're talking about in terms of standards here is not what some people who have been in the IT field think of as data element standards, we're really think about data use standards that for all these multiple uses the data sets are similar enough that they are comparable.

SPEAKER: So that you can get an apples-to-apples comparison to be able to do it. I think it's already been stated that you start somewhere and you build onto it, so I think it's really important that we do in these multipayer data sets start aggregating that so we can compare one state to another. An inherent problem in the Medicaid program in the country is you see one state, you will see one state and it's impossible to compare from one to the other because we haven't got a standard format and I think this is the opportunity to do that and build on it over the next few years.

MR. MCCLELLAN: I'd like to thank our panel. I know there are some questions and we're trying to get to those in the next session too. I'd like to thank our panel for getting this discussion started in a very excellent way. Thank you all very much.

Without any delay we'd like to move to our second panel of speakers, and I'll introduce them as they make their way up to the table here and ask all of you to get that microphone on your lapel or collar. Most of you know the people who are here. Sitting at my right is Dr. Carolyn Clancy, the Director of the Agency for Healthcare Research and Quality. Next to her is Dr. Janet Woodcock, the Director of the Center for Drug Evaluation Research at the FDA. Then at her right is Dr. David Blumenthal, the National Coordinator for Health Information Technology at HHS. What we've asked these three federal leaders to do is to give a few minutes of opening remarks from their standpoint about what they are involved with in terms of implementing some of the steps to learn from our health care system to develop better evidence on top of patient care delivery, and they've each got a tremendous amount of activity going on. Then we're going to have some discussion following those initial presentations. As one might expect, with everything going on these days, they all have a very right schedule. I know, David, you need to leave a few minutes early, so we're going to take that into account as well.

Janet, let me start with you. Can you take just a few minutes to talk about FDA's Sentinel Initiative, where it is in its implementation and how it's contributing to this kind of data infrastructure for drug safety but that it might also fit into some of these broader issues?

DR. WOODCOCK: I wanted to do this in slides because it's not just Sentinel. Let me say that FDA and of course many agencies have been doing this for years, but as Rich Platt said, it's always one off. We study together, we find a health care system, we set up a pharmacoEPI study or what have you and then we do the work and several years alter we have the answer, and that's not good enough in today's world. As everyone has said, there are new opportunities that are existing because of the electronic health data. There are multiple examples now of trying to do more real-world, real-time analysis across multiple health care systems including the vaccine safety data link that's already been mentioned by Rich Platt, Prism which is looking at H1N1 vaccine OMOP which I'm going to talk about, and Sentinel. So a variety of these systems are being set up that are trying to use data, real-time existing health care data, in various ways and I'm going to talk a little bit if that's okay about how these are structured. I'll go really fast.

Prism you already heard from Rich Platt. They're comparing selected events during the postimmunization window to historical and

personal controls. You can easily find the data on who's been vaccinated and then you can set up different events that you're looking for in the postvaccination period and compare those to what's going on historically. That can very rapidly yield information of extreme interest as to whether there's an unusual reaction to a vaccine. OMOP is the Observational Medical Outcomes Pilot that's going through the foundation for NIH. That's a fairly complex and ambitious enterprise both assembling commercial data into a central database where then we can do a lot of methods development and methods analysis as well as extended partners where the data is run behind their firewalls. The focus here is on the data model. You've heard about the data model from Rich Platt and from others. The focus is can we build a data model that across all these disparate data sources so that we understand what each data element means in each of these systems or databases and then methods to query this data once it's put into the data model. OMOP is about drug safety outcomes primarily and so we've defined known drug and health outcome of interest pairs such as fluoroquinolones tendon rupture. We're going to look in all of these databases both the distributed and the centralized with different methods and see how well we can find things that we already know about.

It looks like this. We have a centralized research lab where you put the commercial data, we have some research core partners that are health care systems and then we have extended partners who are going to do it behind their different firewalls in a separate type of manner. The common data model I think is important for the discussion we've been having. It's a single data scheme that you can apply to disparate data types. This system, and this is what the last panel was talking about, collects the data this way, another system collects the data this way. But with a common data model, you can match those elements up. You do that once and then you know how they relate to one another.

We also are working in OMOP on standardized terminologies so that we have a consistent data transformation when we move the data into the common data model. This allows you then to do repeated analysis against all these distributed data sets because you're using a common data model so that you don't have to transform the data over and over again in a one-off basis for each new analysis that you're going to do at least in theory. What OMOP is going to do is test all these theories. We're also developing query tools. In fact, there is an OMOP Cup that's a competition for the best methods against the standardized dataset that is being made available. We're looking for various analysis methods.

The common data model is not combining datasets into one big dataset. The common data is a way of using distributed data in a way that you have more reliability. It is not trying to force claims data into an EHR database. It could use either. We're trying to also develop a graphical user interface so that we could create those structured queries against the common data that's in the methods part of this. I'm sorry if you can't see this very well, but you can listen to what I'm saying.

The schema though is that we have these data elements that we're talking about and OMOP is for drug safety observations. There we're looking at the period the patient was observed under the drug, the condition, the observation that was done, any procedures, visits, and then this outcome of interest, this health outcome which might be say a tendon rupture or a whole list of other outcomes that are known to be associated a given drug. Rich already presented these, but these are different drug outcome pairs that we're looking at.

To standardize all this and the terminologies, for example, for drugs we have some standard drug terminologies, RxNorm, that's already accepted and that's what we're using, so that part of the data model is you'd have a standardized name for the drug so that no matter what people called it, you would be able to transform it into a common name.

What happens is you have all kinds of ways of capturing the data at the top, you work with people at their sites to transform and you pay them because somebody has to pay for this. You pay them and you transform the data into a common structure and then you can run multiple analyses against that structure. We hope as everybody has been saying to have systematic learning, in this case about drug safety activities, from setting up this sort of laboratory. OMOP is not intended to find new knowledge about new drug event pairs, it's really to find the best methods and the best data model that could then be applied by others.

The Sentinel which Mark asked me to talk about is we're trying to develop an active electronic safety monitoring system for medical products at FDA. We have a prototype that Rich Platt already alluded to, a coordinating center with distributed data sources, and they'll also be developing a data model and then be testing methods. Because that's under an FDA contract, that will be a real-time example where we can actually run new signals against that system and see what we find. Then we have a partnership internally with the federal government with CMS, VA and DOD, to identify the same things, medical product adverse event pairs and see how we can do data mining within each of those systems and see what we come up with.

I wanted to have one final point here in my final minute. One of the issues that's only been alluded to but I think is one of the most important issues that we're going to have to face is we can make the data model, but how do we know that reliable information was captured from the get-go? In other words, if the raw data isn't any good, transforming it isn't going to make it any better. Pharmacoepidemiology is a health outcome. In classical epidemiology you do a case definition and then you have all of these elements. But if the doctors or the health care workers out there haven't recorded the information in a way that would meet the case definition, you're not going to find it. Pharmacovigilance we call an adverse event in the emerging science of genomics. You can easily write down the genotype information in the medical record, but what about the phenotype? If the phenotype or what is actually going on with the patient isn't captured correctly then you're not going to make that genotype/phenotype linkage that you're looking for. In meta analyses now there's much more interest even looking at cumulative clinical trials and there if the data are not collected in a standard way, it's very difficult, and we know, we do this all the time at the FDA, to put the data together into an organized format and perform that larger analysis which can be extremely informative. The challenges are very similar as everybody has

been saying for effectiveness outcomes, for quality of care, whatever you're looking for.

The common themes I think with this new infrastructure that's going to be built for all of this is perform analyses at the site of the data owner. Do not create a centralized dataset, and I think that's been said enough already probably. Build analytic capacity and data standardization at the sites. This means giving people money so they can develop data infrastructure at their site and as this cumulative improvement say in data structure and data elements occurs, they're able to implement it at their site so that it's not something that's imposed externally. How do we integrate this standardized data capture with the medical workflow? I know CMS did a small experiment in this that I heard from Peter Bach about. It's more difficult than you think. If you want more detailed phenotypic information about your patient, you're going to have to do with at the site with the doctors, with the health care workers, to help them in their workflow to capture that information in a rational manner. In sum, capacity building at the sites will be needed if we want to get this to a higher level, although I agree with Richard Platt and others that there's a tremendous opportunity that's emerging right now. We'll be able to learn a tremendous amount without capturing additional data and just from the data that we have right now.

MR. MCCLELLAN: Janet, thank you very much. Now I'd like to turn to Carolyn at ARQ. Carolyn obviously wears multiple of these secondary use hats already in quality improvement and comparative effectiveness research and so on. So I'm looking forward to hearing your perspective on these data and infrastructure needs and also if you could comment a little bit about where things are headed in the federal government with ARQ's role and the Federal Coordinating Council for Comparative Effectiveness Research.

DR. CLANCY: That's a lot to do in 2 minutes. Mark, I want to thank you and your colleagues for doing this because I think this is incredible important. It reminds me of the time I told the former editor of "Health Affairs" that data aggregation was the central issue. Then I had to rouse him from the coma that he went into immediately. I couldn't quite make it concrete enough.

Mark I think many of you know has been a brilliant researcher in a prior life before he came to government, but I think the quality about him that's most impressive is he's fearless. And the description you heard today about how you can keep personally identifiable data behind a very restrictive firewall but still learn about other applications whether that's quality improvement, quality assessment, comparative effectiveness research and so forth, is the result of his being

completely unafraid to take this on, roll up his sleeves and launch some pilot projects. So I just wanted to salute that work.

ARQ has actually been in this business for 20 years this month and the general theme behind the creation of ARQ in late 1989 was that, after all, Medicare has all that data lying in a warehouse, can't you guys spin these tapes and understand how to find that cost without benefit that is so apparent from practice variations that we see everywhere. So in addition to supporting brilliant research done by Mark, by David Blumenthal, members of the last panel, we've also been in the data business for a while so I think together with the researchers whose work we've supported we're probably the world's leading experts in the limitations of milling data to make inferences about clinical care. We also work with states to make their hospital discharge abstracts available and to use those same databases as platforms for quality and patient safety indicators. But of course the big news for us, and I also want to say my only visual and no slide, this is the "Annals of Internal Medicine" September 1 of this year which has two articles on two different prototypes that we've funded starting in 2007 for distributed data networks. I'm not going to replicate what people said before. Let me just say that as part of our investment, ARQ will continue investments in this area, continue investments in registries, and some of you may have been aware that the

spin plan for the Office of the Secretary's $400 million was recently released to the Congress, and some of the projects that you will be hearing more about include clinically enhanced state data for analysis and tracking of comparative and effectiveness impact, distributed data networks, improving and building new registries and a registry of registries which I think could be a very important tool for research.

Let me turn now to some opportunities and challenges. One huge opportunity is that both the House and the Senate bills direct the secretary to -- actually, the secretary has got more instructions than you could possibly believe. The secretary shall dot, dot, dot, but one of those dot, dot, dots is to create a national strategy for quality. So for those of you who are familiar with the current quality enterprise and are sometimes reminded of 6-years-olds playing soccer, rest assured that we will have a national strategy. But coming up with a new movie is really, really easy within a new set of priorities and it's a lot of fun. The real challenge is creating an operational transition from where we are today because the bills also direct CMS to keep doing what they've been doing but faster and more of it and getting to rewarding quality and not just volume and creating a transition path from that state to a better state that completely aligns with meaningful use of health IT is a huge, huge opportunity. It's going to totally change developing quality measures from an enterprise

that's opportunistic, what data do I have, to one that is strategic. We've got lots of data. Data are no longer scarce. What are the most important aspects of care for all of us to learn about and improve? Ruth Perot, I know you're back there, I would include disparities very much as part of that and I'm really thrilled by the work that's going on in Massachusetts.

Essentially at 50,000 feet what this all means is that the delivery system becomes a platform both for discovery, what works and what doesn't for which patients, can we anticipate new harms and so forth, and for rapid translation into practice. In addition to that, I think it will help us detect very important signals that today are lost. When a patient who ought to on paper meet all the criteria for a new breakthrough treatment fails, we don't capture that very easily. It's an active altruism for the people providing care to get that signal back to the biomedical enterprise and we can do much, much better than that.

But at the same time, that suggests that there's many more participants in the research enterprise. We have to do much better than what I heard a former colleague at NIH say that doctors are just going to have to get used to collecting a lot of data that doesn't have anything to do with patient care. I don't think so. In fact, I very recent example I heard about was that some measure developers have submitted some measures for endorsement to the National Quality Forum and they have e-

specifications for building them into electronic health records, but when tested in another system they didn't work. Part of the reason they don't work is that the docs don't use all the functionality of electronic health records so that that gives Dr. Blumenthal a big challenge. Does he tell docs to get with the program or does he encourage vendors to make it easier to get the information from using what some people sometimes refer to as epic lite? I want to reinforce everything in terms of specific challenges but also opportunities that Alan Garber had to say about common data formats and about methods.

The real question facing us in the 21st century for research is with more better data, does that change the threshold for when we have to have a clinical trial and when actually learning is a byproduct of providing care is actually as good and a whole lot faster? That I think is going to be a really, really important question. So in addition to the data we've got to be making investments in continued methods. I would include not just for researchers but also the peer review function because it's been my observation that a lot of journals don't appear to have a robust cast of reviewers, and it doesn't matter whether it's a journal or something else that's certifying the quality of the work, you need people who know how to ask the tough questions about the work that was done and why did you do the analysis this way or operationalized the variables

that way. A huge, huge challenge, but one that I think is very exciting is one that Mark highlighted early on and that's incentives for participation, or as I would say much more concretely, what's in it for me? Why should I be part of this? Researchers have long looked at Kaiser and places like that, Harvard Pilgrim, look at all that data. I could do such great things with that. It's a very different kind of enterprise that is not quite so colonial but much more participatory, and by participatory I mean health care leaders, I mean the clinicians, I mean the patients, I mean people in the community. It gives new meaning to the definition of team sport. Ultimately those collaborations have got to include health IT vendors and, frankly, IRBs and others. I was thrilled to hear about the public health practice operationalization, but I think we've got to scale that up in a really big way if we're going to get to the kind of rapid learning envisioned by many people here today by Lynn Etheridge and others.

Mark, you spoke to alignment of incentives and I'm all for that. That's always a great thing to say. I will say though I think we may learn a whole lot about the psychology of transparency which I think most people would define as something that's really good for other people. To give you a concrete example, we funded a project a few years ago in the wake of concerns about Vioxx and this was inspired by the idea that probably many docs in small practices didn't often report to Medwatch.

I'm sorry, Janet, but I know that you're aware of that. What we did was to create a web-based tool for reporting on both adverse drug events and medical errors. The first thing we learned was that docs wanted regular feedback. Not a surprise. I want to get something back or other people seeing this too. I think that has got to the model for the future. The docs had very, very different feelings about sharing information on adverse drug events than on medical errors, and I'll just leave it at that.

One huge challenge it seems to me is something that the Brits often refer to as information governance. We are moving from a world where data are scarce and it's very common to hear researchers say my database, and believe me, they mean my database, to one where we've got multiple uses coming from the same set of data. So in addition to common formats we're going to need some common operating rules. This is not a policy world that anyone had anticipated.

Finally, let me say data will not solve all of our problems, and I would highlight two issues. One is the need to think about the systems improvement that go along with wiring the health care system so as not to diminish the work that Dr. Blumenthal and his colleagues have to do, but to say that adding onto that is going to be very important if we're really going to get some of the waste and improvement capability that we have. The other is evidence doesn't answer all questions, and I will simply refer

you to the recent debate and discussion we're having about what age you should get screened for breast canter, and I'll leave it at that. Thank you for having me here.

MR. MCCLELLAN: Thank you very much Carolyn. David, let me turn to you. You and your office have been very clear in both the goal of supporting health IT availability to improve patient care but also being cognizant of all of these secondary uses or benefits of aggregated data, and it was interesting that Carolyn was making that central issue in health care reform so I think there's something to be said for that. You also have a lot of opportunities for support and incentives coming up with the upcoming regulations on meaningful use and with the other activities in the Office of the National Coordinator. I would very much like to hear from you about how this all fits together with your priorities.

DR. BLUMENTHAL: Thank you, Mark. It was great to hear the other panelists, and I'm sorry I couldn't hear the beginning of the morning conversation.

Let me take off by saying that the Office of the National Coordinator in implementing our high-tech provisions has a number of tasks and a number of priorities and we are very cognizant of the fact that to be successful in achieving the improved health care goals, improved efficiency goals and improved population health goals that we are all

committed to, we really have to lay the groundwork for that now somewhat clichéd term, a learning health care system. It is possible to imagine many variations of learning and many sites of learning and one of the tasks that we collectively, those of us sitting on this panel in the federal government along with our many private-sector partners are going to have to think through and which we haven't I think begun to think through in any systematic way, is what we mean by that and how it can be implemented. The vision is there. The path to implementation is just beginning I think to be conceived. Learning can take place at the level of individual clinicians and also at the level of individual patients and consumers and we haven't I don't think talked a lot about the uses of data by consumers for managing their own health and learning about their own health, but that's a very powerful use of health care information.

It can take place at the level of the practice or an organization, at the level of a community, at the level of the state or at the level of the nation. The questions that each of those entities might as are going to be different and their needs are different. The types of learning that go on in a health care system are different. We've heard a number of them mentioned here today. Individual clinician level there is the need to understand and learn about existing health care information, what are the current guidelines? How do I do the routine things that I'm supposed to do

but may not remember that I'm supposed to do? How do I improve my practice day to day, moment to moment? How do I improve my decision making? How do I use the existing data in a better way to make higher-quality decisions? We talk about quality a great deal in national discussions. Mostly we're talking now we're talking about quality is measured by the adherence to established processes, scientifically proven processes, rather than improving the quality of decision making which is a much more complicated factor. How do we learn to decrease variation at the individual practice level, at the organization level, at the level of the polity? Then of course the uses that we've been talking about, comparative effectiveness research, enhancements of safety through postmarking surveillance of medications, clinical research, bio surveillance, epidemiology. Multiple actors, multiple uses, is there a common pathway to creating and making possible all these uses? By the way, we've been trying to move beyond the term secondary use because it implies that there is a primary use that's more important, so we've been experimenting with the term enhanced use of data. That might be better than aggregate use or aggregate data. Enhanced data may be better than aggregate data.

The first thing to note very clearly is that this has never been done. People point to other health systems around the world that have

much more robust electronic health systems than we do, but none of them do this. None of them are models for what we are talking about at this discussion. We're pretty confident, we could be wrong, that it starts with creating a robust electronic infrastructure. You can't collect the data unless it is collectable and it's too difficult and costly to collect it in paper work. The wider this electronic infrastructure is and the more fluid the information is within that infrastructure the further we will be toward these multiple learning purposes that we all support.

It would be nice as we built that infrastructure if we had some sense of what the priorities were for learning. I think there are some implicit in the high-tech law but they're not called out explicitly for emphasis. It does matter what you want to do when you build an infrastructure. It matters at a fine-grain level, not just at a conceptual level. But it's also clear that in addition to having that infrastructure, we need standard definitions of information and data and that is clearly one of the responsibilities that we have at the Office of the National Coordinator. We have to as a matter of fact by the end of this calendar year produce a regulation with standards and certification criteria for electronic health records, and one of the clear requirements for that is that we define the data elements that have to be recorded in an electronic health record and we are hard on that as we speak. We got a lot of advice on that from a

FACA committee, a federal advisory committee, called the Health Information Technology Standards Committee which has publicly been available. You would be amazed by the way at how much controversy there is over how to define data elements. As someone who did not come out of this field but was a researcher, this was one of the things that I found absolutely stunning about my new responsibilities is the level of intensity that people feel about how to define data elements.

But I think that's possible at a certain level. We won't necessarily be able to define all the elements that should be in the data collection. What you need is very much dependent on what you want to do with it and what the problem is that you want to solve. I agree totally with Allen that it would not be a good idea for the federal government to define anything about research needs unless perhaps it is about how you identify patients who might be useful in a recruitment effort for clinical research. I think the other thing we can do is create a framework for interoperability so that information can flow within the system. The third thing that we can do is create a framework for privacy that supports trust in the learning health care enterprise and that can't be overemphasized.

We have a series of tools to do those things. We have this meaningful use program set of incentives that will give physicians and hospitals and other health care providers enhanced Medicare and

Medicaid payment if they become meaningful users. To be meaningful users they electronic health records have to be certified against criteria that are based on standards so that there is some leverage there, but it's voluntary. You don't have to be a meaningful user, and I could imagine lots of people deciding that it isn't worth the effort. If you just don't see yourself as having a financial incentive to become a meaningful user, I could imagine that there will be people who will make the decision not to do that.

We also have invested in and are investing in social structures to enhance information exchange. That is a very important part of this activity and I think information exchange is going to take diverse paths and diverse methods. We have worked for a number of years on something called the Nationwide Health Information Network. That is one model of exchange, but I think that there will be other models. We want very much to continue to make that available as an option for exchanging information and for aggregating these enhanced uses of data, but we expect others to evolve.

This discussion about what you can do with data that's widely available and at less cost is a discussion that much has to proceed and I hope will get more concrete over time and also will rise up the level of government priorities to the point where it can provide direction to our

office about decisions that will affect what data might be available in the future at what points in time. Thank you for your attention.

MR. MCCLELLAN: Thank you very much, David. I'd like to start the discussion down in the technical details a little bit, because it has been such a recurrent theme all of you as mentioned it as well this notion of standard definitions of data being essential for supporting aggregation as well as for supporting patient care. David, maybe I could start with you. I know you have to go shortly. You are clearly thinking very carefully about promoting interoperability at the level of individual patient data, lab tests and discharge information and so forth from different sources that directly relates to an individual patient's care, but as we've heard about today, there is also this issue of interoperability of aggregated data for what you called enhanced uses. Those seem like somewhat different problems. Are they or are the same kinds of technical solutions with one are going to help with the other and they should be approached in a unified way?

DR. BLUMENTHAL: They're overlapping problems. They're not identical but they're closely related. Diagrams overlap considerably. So you need standards for defining blood pressure and sediment of urinalysis so that when you are looking at a medication's effect on blood pressure over time you comparing blood pressure measured the same

way and it has to be entered in an electronic format in a comparable way so you do have comparable data. Interoperability does not if you're comparing incomparable information, that is, if interoperability is more than just dumping data stores in different places. So to make that data computable in one place and another place that you need the same data, it has to be defined the same way. The content standards are critical, the vocabularies that are used to define information are critical, and it's critical that one be able to interpret, use the same language. It doesn't mean that an organization has to define things always internally the same way as another organization. You could allow an organization to have somewhat different standards for internal use than for external use. The critical thing is that when you get out talking to one another that you're all using the same language, and one has to be speaking English in that interoperable parlance even if you're speaking Japanese inside the kitchen. That's what we're aiming for.

MR. MCCLELLAN: Carolyn or Janet, from the applications that you focus on it seems like a big task. Do you see a step-by-step process to get there?

DR. CLANCY: Yes, and I'll give you an example. My observation right now is that the folks who worry and care and get up every day passionate about assessing and improving quality of care and

the people who feel the same way about health IT that there's no enough people who are bilingual to state it very, very succinctly. I know there was before the Recovery Act and before David's joining HHS as the National Coordinator we were trying to think through how could you begin to figure out how to bring this together for the purposes of public reporting. The National Quality Forum convened two health IT expert panels. I think they found the three or four people who are bilingual. Essentially they said of all the measures weren't using now, which are most important and what are the common measures where we need good standards and what would the path be so that we're thinking about a supply chain if you will of health IT standards that are necessary? That's kind of an early fast step. Allen, in a research that sounds to me a lot like what we could be doing for some types of clinical research. I would think of comparative effectiveness, but there could be others as well.

But trying to organize both communities and figuring out what's the legitimacy or what's the group that can do that kind of convening I think was probably easier for quality than it might be for research where there are multiple kinds of organizations. I think David's point about different languages, I like that metaphor at a lot, is also relevant to the application of the type of analysis you're doing. For internal quality improvement you don't need to be all that rigid and it doesn't matter

if Kaiser and Harvard Pilgrim or anybody else are defining it differently. For public reporting you definitely are going to want to be very consistent if we want to assure all Americans that wherever they land in this country they get high-quality, affordable care. It gets very complicated because as the adoption curve gets very steep for health IT and electronic health records and so forth, we're likely to be seeing people reporting in at least three different media. One is billing claims with some sorts of clinical data elements or enriched claims data. Another is good old paper. That's pretty much what we're doing for hospitals today. A third will be I think the Holy Grail which is being able to hit F7 in an electronic health record and up go the quality measures. What that means is that a focus on data quality and some operating rules for what you do when you get different results. They asked people in a number of systems this question, there are apparently different results, I've only found one so far who could answer it with a straight rule which is we give the benefit of the doubt to the doctor. I don't know if that's the right answer, but it is an answer. Most others have trouble actually understanding the question, so there are interesting challenges.

DR. WOODCOCK: I think FDA on this side, the very granular side, we have been working on standardized terminologies for years particularly for adverse event reporting. For pharmaceuticals and

others we've internationally harmonized them. We have drug standard terminologies that we have developed that are used by pharmacy systems in hospitals and so forth. So we have some of the foundational elements.

I think this, Mark, as being iterative. Hopefully we'll get the records going and get more quality assessment going. A lot is going to depend on, I agree with David, adding value at the level of the practitioner, of patients feeling that this is something that's good them. I think Carolyn said this too. Another thing I think that has to be considered which is the other end which is the new science that's coming along. I know nobody wants to talk about this because the current barriers to getting everything electronic and measuring quality is so high, but the real question is can we do better? There are two real questions. I think question number one is can we apply the current knowledge in a uniformed and beneficial manner to health care which we aren't doing very well? But then the second one is can we rapidly start applying new information and can we use health care as a feedback system so we can get to a higher level? That's where for example we're going to need more granular phenotypic information on the patients. It's one thing to measure the laboratory data and get that standardized in things that have been around for 50 years, urinalysis or whatever, it's another thing to figure out how do we define what's wrong with someone in a way that can differentiate fairly subtle differences and

not just look at the population base but look at individuals. We're working on some of that because we are very interested in the genetic basis of adverse drug events because not everybody gets harm from a drug, only a small group do, and some of that is genetically based. But to figure that out not only up to the genotype we have to be able to identify those adverse events at a pretty specific level and because they're so rare we're going to have to do it in the electronic health world, we can't do studies because you can't find the people. I think it's all going to be moving parts for a long time and we have to push onward and be patient and keep plugging on each one of these elements, but we can't forget the new science because that will bring NIH into this and that's very important.

MR. MCCLELLAN: It is a circular issue. In order to have that information on phenotypes you need richer information at the clinical level, but conversely, in order for doctors and patients to make better decisions with all of this genotypic information, they need to have that information at the clinical level. So hopefully that we can make that into a virtuous cycle.

I'd like to open up to questions and in particular I would like to ask if anyone has any questions for David Blumenthal who has to leave momentarily, so I would like to start there.

MR. SMITH: Bruce Smith, Brookings retired. My question I think may be a little bit more to Dr. Clancy, but perhaps others can join in too. You were talking about linking the different languages, the IT with clinical practice. I have a suggestion. Get the patient in there. If I look at the world divided up into diseases, diabetes and cystic fibrosis come to mind as rather effective arenas where you've got associations that work to get more basic research, get more clinical research, get more advocacy, get more patients engaged. Cystic fibrosis is quite different from diabetes, but they have a great patient team connected to the clinical team and they've doubled life expectancy. I'm interested in AFIBs as Mark knows. I don't think we have an AFIB society or council out there, but if this is a team game where the patients can see something in it and not just the scholars who are grinding out the data and you can mobilize your team which has congressmen and patient advocates and researchers and clinical researchers, basic researchers and people who are doing comparative effectiveness, maybe that's the way to get some oomph behind some of these things that we're all interested in.

MR. MCCLELLAN: David, if you wouldn't mind commenting on that. I think this also relates back to your mention of the need for social structures to help educate the public and to help support the notion of information exchange. We had some comments online as well. One

participant said there's a strange mistrust here. I'm not sure how strange it is, but there are some real questions in the public about whether these kinds of enhanced data uses are really going to be beneficial for them. Is there a way to connect better with those kinds of concerns and to build up this kind of patient support if that after all is the goal?

DR. BLUMENTHAL: We have to make a better case for benefit and sometimes making a case for benefit means identifying particular groups who can answer the Carolyn Clancy question, what's in it for me, in a very clear and concrete way, and I think disease-specific groups are an excellent potential place to work in mobilizing social support. They have I think a more personal understanding of the value of connectivity. They live with the need for better information on a day-to-day basis. And their particular perspective on the tradeoff between privacy and security on the one hand and the availability of data on the other has to be factored into the discussion in a very important way. So I think they are a great place to start. They are represented in the discussion about electronic health records, but I'm sure they could be more represented and better represented.

The need for a governance structure is something that I've been thinking about more in recent days because there are tough decisions to make about what data to standardize and what to require

clinicians to collect. When we talk about phenotypic data we're talking about collecting information that is much more difficult to standardize and much more burdensome to enter into an electronic health record. If we make that a priority we will almost certainly have to reduce the priority we associate with something else. So having some kind of way to make those decisions in a planned manner to build them into subsequent iterations of meaningful use as we go forward is I think a discussion that needs to be entertained not just in government but broadly through open and inclusive and transparent processes.

DR. CLANCY: The only point I would add very briefly is there is already a registry called Patients Like Me where patients are out there collecting their own data and sharing it and so forth. That's going to get back to a data quality issue, but I think as we begin to take advantage, we researchers and so forth take advantage of the power of electronic information, the capacity to know over time how treatments would be just utterly fantastic so we're going to have to wrestle with some issues about is data coming in from personal health records over my home computer the same quality as or good enough for this work?

MR. MCCLELLAN: David, I know you have to go. You've mentioned a number of regulations that have to be out by the end of the year, so please get to it. Thank you very much.

We do have a few minutes for a few more questions. Are there others?

MR. ALTMAN: I'm Fred Altman and I think Allen Dobson mentioned that with the additional data you're going to get quality competition which is going to motivate people maybe not to be totally honest as you're building your systems. Is any attention being paid to that?

DR. CLANCY: I'll say, I mentioned it very briefly, that I think the psychological aspects or unintended consequences of transparency and assessing quality and so forth need continued attention. What doctors often say is I'd submit the right stuff, but I don't know about him. I'm not sure all my colleagues will be quite as truthful. But we may also need some checks on that validity of that data. For people working with registries this is already a common kind of concern to worry about and there are a number of strategies to deal with that.

MR. NOVIK: My name is Dmitry Novik. I am speaking not as a professional but as a patient. The basic problem as I can say is quality and the effectiveness of health care, and from this point of view I have two questions. Number one, why analysis of medical data is restricted to only the United States? Medicine is an international business. No one says that achievement in health care outside the United

States is negligible, so that's the number one question. And the number two question is the basic problem of increasing the quality of health care is of course the qualification of health care providers. From this point of view, we need to change certification of health care providers. Each 5 years health care providers must be recertified because progress in the science of medicine, in clinical experience, must be certified that people are health care providers know this and probably the only way to do this is with recertification.

DR. CLANCY: Very quickly, they're both important points. Thanks for the questions. The first is that we do some work with other countries in terms of looking at quality of care. There are a lot of issues that relate to the context and how the systems function differently, but at the end of the day, how you get to improving care looks awfully similar even in developing countries as it does here and how do we all row together. So I would agree with you that there's a whole lot to learn there and we don't plan to be stopping that anytime soon.

Interestingly, the point about specialty certification, virtually all boards now only certify physicians on a time-limited basis. They're using the phrase maintenance of certification instead of recertification, but by 2010 just days away, 87 percent of physicians in this country in order to maintain their certification will have to participate in this process and there

is a lot of effort to link that with literally the care that they provide, shifting from the model that if you know a whole lot, you will therefore provide high-quality care to literally aligning some part of that maintenance of certification with the care that you are providing. I think it's a very, very exciting direction.

MR. MCCLELLAN: We've gotten a number of questions in from our webcast participants and some of them relate to this topic of governance or coordination of activities that David and others of you have mentioned. Maybe just to pick one out that focuses on these topics, assume we've got a health system in a local area that's a perfect world of clinical data, operational data, financial data with virtual sharing across all the partners, the payers, physicians, providers and so forth. Who owns the system dashboard for managing all of this information? How does that relate to these enhanced uses, these multiple uses? And doesn't this get back to both the issues of common data element standards and the issue of incentives? How should we be envisioning this working even in an ideal world a few years from now?

DR. CLANCY: I think that's why I see this as a challenge. First of all, I think if we find a community like that we should check our pulses to see if we're still actually alive. But there are going to be a whole array of questions that come up like this in terms of who controls the data.

Most people I think in the IT world are much more comfortable talking about access and use rather than ownership of data, but the legal world has very specific definitions of ownership and in some fashion we're going to need to reconcile those.

Just to make this incredibly concrete, one of the issues that they have struggled with in Britain is can patients change their records if they think an error has been made? They get to see the record. The short answer is no. They can add a note almost like a virtual pasted Post-It note if you think about it, but they can't literally change the content. But it's that kind of detail which means that this collaborative team is going to have to be pretty big.

DR. WOODCOCK: I agree with what Carolyn said. I think that to keep everyone comfortable we're all settling on a model where the data really "belongs" to those who use it for whatever they're calling it, it's primary or it's health care use, patient use is better term probably, and the extent to which it belongs to the patient versus the practitioner I agree has to be sorted out by the legal system. But I think as far as governance goes, we're going to have formal agreements on the access to those data by others who wish to do either public health practice or research or whatever you want to call it. That's how we're looking at it at least, that transparent agreements that acknowledge the primacy of the health care

as well as the patient's ownership of their own data or whatever you want to call it.

MR. MCCLELLAN: You've all emphasized this happening from an incremental standpoint, identifying some of these particular enhanced uses for safety or for quality or for effectiveness where there's a clear benefit and where these issues can be worked out and then building from there.

DR. WOODCOCK: Yes. I think that if we just say the government's going to be able to look at everything all the time that you have, that's going to make people extremely uneasy, so that this is very concrete that we're trying to improve the quality of our health care, we're trying to keep people safe and determine if a medical product has a safety issue or something as quickly as possible; we're doing public health surveillance of outbreaks. There are still folks who don't agree with that of course so there's a range like anything else of societal opinion, but most people feel that there is definitely an easily identifiable greater good there.

MR. MCCLELLAN: I think we have time for one more.

MS. JOHNSON: Nancy Johnson, Baker -- it is too bad that the American people couldn't share this and just to understand the depth and breadth of the challenges that we face and the intelligence and dedication and integrity of the people who are working on this. I thank

you, Mark, for your leadership and all of you for your good work on these challenges.

Sitting here listening and being very interested in the subject but far from the expert, one of the things that's begun to worry me is how do you keep contact with the entrepreneurial community? We have a young entrepreneur, this is not a client, this is just one of the people you run across and you keep in contact with who has developed a technology he is now selling to hospitals that can discover the various earliest signs of never events. You need to know he's there and he needs to know what you're thinking about in standardized data. It's like those websites where people are just going ahead and sharing their data with people who have similar diseases. We need to reinvent. I know we have these advisory panels, but they tend to be the big guys of the world, the GEs and the Cerners, and that's not actually where interoperability is being invented. I just put that out there. I've spoken to a number of venture capital organizations so there are people who really keep contact with all these people and it would be interesting to every few months try to invite them here to hear what you're talking about and get their input because they're just doing it. When these guys sit down and show me what they're doing with never events and they can put this in place in 2 months and it's very cheap, they're managing data that we're interested in and we want to

make sure that in the course of events that Washington doesn't structure these data issues in such a way that they can't contribute. So I just throw that out there because what's happening in the entrepreneurial community is so dynamic. The one problem with the health care bill in my estimation is that it doesn't really recognize the pace of entrepreneurial activity that is already driving the cost and knowledge base, but I think all the things have said have been very useful to me and I thank you.

MR. MCCLELLAN: What is the role of the entrepreneurial community in supporting these kinds of goals?

DR. WOODCOCK: The tools and methods obviously are going to come -- we wouldn't have had this discussion 10 years ago because the IT wasn't at probably a level of maturity that you could do it. That's why we're running the OMOP competition which is a public competition with a prize to see who can get the best methods because we think it's going to come out of the bright young people who are going to figure out the best analysis methods, and we've put up a public database that they can do the analysis against. So from my point of view, we have to have a system that can keep incorporating innovation and continuously improve, you're right, not just set something in stone.

DR. CLANCY: Nancy, thank you for your comments. I've always a pleasure to see you. I would only disagree that you are not

terribly expert in this area. You're probably the most expert member of Congress I've ever had the privilege of interacting with on these issues.

I would agree with what Janet said. I think in many ways this is a huge communications challenge and it can't just happen in Washington, but it's got to happen regionally and locally as well. The feds have a very important role in defining the innovation corridor, if you will, and that is very much needed by entrepreneurs. We have huge opportunities to learn from them. I will tell you in comparative effectiveness that part of ARQ's investment with the Recovery Act resources is going to be to try to build a methodology of horizon scanning. What's on the horizon and what are the kinds of questions that we will anticipate that will be need to be asked? It's very early days, but no developed country has figured out how to do this surprisingly enough. What I usually say to the secretary these are the kinds of questions you'll be asked about in a hearing in 3 to 5 years. It's not academic navel gazing, this is very real, but it's been a struggle to figure out how to do that well. So keep reminding us.

MR. MCCLELLAN: I know there are some more questions out there. What I'd like to emphasize to you is that viewed this event as a start or a piece of an ongoing process. You've heard from all of our speakers about a couple of important points. One is that these issues of

data aggregation, of thinking about our health care system as being both about supporting individual patient care that is as high quality as possible and as low cost as possible is critical, but there are a number of enhanced uses that if we use our opportunities now around health reform, around building up these electronic systems, we can help make that patient care much, much better for all types of patients, all of our diverse racial and ethnic groups. This is going to be an ongoing process. You should look for a white paper coming from our group at Brookings based on this discussion today that will review some of the major themes that we've heard about such as the importance of these enhanced uses as a key element, a fundamental element of health reform. This is really important to getting to a health care system that actually performs better, that delivers better care at a lower costs and knows what it's doing, that describes some of the activities going on, you've heard about many today, to move from these very disparate uses of data often in small settings and in ways that are not very well coordinated to these broader public-private efforts to identify key opportunities, some short-term uses of enhanced data that can have clear benefits for patients and can put us on a track toward a much more effective health care system.

So you will be hearing more from us about all of these issues and I think as somebody suggested, some follow-up events as well. But

we've gotten a lot of this accomplished today and I'd like to particularly thank all of our distinguished speakers for making themselves available. These are people who are extremely busy and have many other things to do. In some cases they flew all the way in here just to be part of this event and hopefully help us on an ongoing basis. I also want to thank the Robert Wood Johnson Foundation and the Brookings team who made this event possible, Josh Pfeifer, Megan Carey, Marisa Morrison, Sally Cluchey, Beth Rafferty, Brynn Barnett, Joachim Roski, Erin Weireter and Joshua Benner. It takes a village. And especially all of you for participating in this effort and making it such a great dialogue. Thanks again for coming and have a wonderful holiday.

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