

A National Web Conference, E-Prescribing and Medication Management: Current Realities and Future Directions
(August 27, 2009)

Ladies and gentlemen, we appreciate your patience. Now I would like to turn things over to Bob Mayes AHRQ to introduce the panel. Bob?

Welcome to the national web conference sponsored by AHRQ. This is the third and final in a three-part series in which we have been exploring electronic e-prescribing as well as electronic medication management in general. In the first couple of conference we looked at the current state of electronic medication management and focused primarily on aspects of e-prescribing implementation, both from the prescriber's point of view and the pharmacy's point of view. In today's conference we are looking at where things are headed in the future, the potential impacts of electronic prescribing and electronic medication management will have on practice in general and also to examine a couple issues and challenges we will face as we move towards a more universal adoption of this kind of technology.

We have two great speakers today, Dr. Michael Fischer is an Assistant Professor of Medicine at Harvard Medical School, as well as an Associate Physician in the division of Pharmacology Epidemiology and Pharmacoeconomics at Brigham and Women's Hospital in Boston. Dr. Fischer has done extensive research in the areas of e-prescribing and medication management looking at issues around electronic prescribing, medication adherence, reimbursement policies, as well as appropriate use of prescription drug and the complications that can ensue from drug therapy. He's going to speak on the impact that e-prescribing is having and will continue to have for patients, providers and pharmacies. He will also talk about future directions, where we are going with research on this, as well as some of the challenges that we're going to face as we move forward in this field.

He is being followed by a presentation by Dr. Grant Carrow. Dr. Carrow is Deputy Director of the Bureau of Health Care Safety and Quality in the Massachusetts Department of Public Health and he is also the Director of the Public Health Department's Drug Control Program. Dr. Carrow has done a wide array of research and is currently principle investigator on a number of grants, looking at issues around prescribing controlled substances. He will talk about where we are in that area today. That's been a big problem in terms of overall adoption of e-prescribing and as many of you probably know, the Drug Enforcement Agency (DEA) is in the process of putting together new regulations around e-prescribing and controlled substances. Dr. Carrow will talk a bit about the challenges in that particular area.

We have about 30 minutes for each of the presentations. Then we will have a question and answer period. There is a Q&A panel on your screen, I will monitor the submissions during the presentations and at the end we will direct those questions appropriately to Dr. Fischer or Dr. Carrow, or both. In the past we found that people ask similar questions. I will try to combine those that are similar for the sake of time. We will, however answer all the questions when we post the recording of the conference on the website, as pointed out, in a couple of weeks. So if we don't get to your question, we will provide an answer, or it may be combined if there are several other similar questions. With that I will turn it over to Dr. Fischer and we can begin the conference.

Thank you very much, Bob. As Bob indicated, I am going to talk about, for the third of these conferences – and perhaps appropriately as we wrap up the summer and get ready to get back to the work and academic year, I will talk about where we really stand in terms of what we know about e-prescribing, what's been demonstrated so far and what do we need to still learn and understand as we move forward with wider utilization of e-prescribing. To give an overview, the promise of e-prescribing is something that has been widely touted by clinicians, researchers, certainly in the policy arena, as anyone interested in the topic and logged onto this call knows, e-prescribing has appeal across the political spectrum, from Newt Gingrich to the president and everyone in-between, talk about the promises of e-prescribing to improve multiple areas of medication use, to make it substantially better. What I want to do is talk about that promise and review the evidence to date, both quantitatively and qualitatively. What do we actually know about where e-prescribing delivers on that promise and how far we've made it toward that promise, I will talk about things still unproven, talk about remaining barriers to really achieving the potential of e-prescribing. I will focus on the areas listed on this slide, start with drug safety, where many of the initial benefits of e-prescribing were identified. Talk about the efficiency of prescribing processes, medication processes, then talk about medication costs, and finally some of the barriers to adoption and use that remain. I will give away the ending since this is not meant to be a mystery presentation. My take on the evidence, and I will lead you through some of that work and hope you will end up agreeing with me, I do believe the proponents who say e-prescribing has the potential to improve patient safety, and increase the quality and efficiency of prescribing, however the evidence that these gains can be achieved in the out-patient setting and with our current systems is really still being developed. And at this point we haven't for the most part – and by we I mean the research community – been able to demonstrate conclusively the potential gains in the out-patient setting, and to get the full adoption of e-prescribing and full effectiveness we need to aggressively go after the barriers to best use e-prescribing, understand what are the most effective practices and what are the most effective interventions in e-prescribing.

Let's jump into the specific topics. The first area I mentioned is safety. The promise of increasing drug safety through e-prescribing has been probably the most widely touted. I think anecdotally and on a personal and emotional level it is the legibility problems that seem to have the most appeal to the public. The idea that you won't have to deal with doctor's messy handwriting, something that I think we have all probably heard anecdote about -- that's great, but only takes one so far. Most legibility problems lead to inefficiency, rather than errors, it is uncommon for pharmacists to randomly dispense drugs, instead it leads to inefficiencies in the process. On the other hand there's a strong suggestion that better information at the point of prescribing really could improve the safety of drug use. Going back several years, the Center for Information Technology and Leadership did a study where they estimated that one quarter of adverse drug events (ADE) could be avoided if that better information was provided across a number of areas, better information about patient allergies to avoid those kind of reactions, better information on drugs and drug lists, to avoid drug/drug interactions that harm patients, and generally the kind of clinical decision support to allow physicians to prescribe drugs more safely and pharmacists to dispense more safely and patients to use more safely, identifying doses to be avoided, or adjustments of drug frequency that need to be made for patients' co-morbid conditions, adjusting

the dose or type of medication used based on a patient age or other characteristics. That's really the promise that is there for e-prescribing and safety.

Well how about the proof of that. Well there is a lot very good proof that electronic prescribing in the in-patient setting, usually when implemented as a part of a computerized order entry system for in-patients can really improve patient safety, these studies have been done in a variety of settings, at Partners Health here in Boston, at Regenstrief and several other large centers where they have looked at electronic prescribing for in-patients and shown a definite reduction in drug errors in terms of drug/drug interactions, dosing errors, even the ability to guide specific and more complicated areas such as antibiotic management, prescribing dose adjustments for the elderly, some work some of us did here on use of high-risk medications biologics used for severe sepsis. This is all in closed in-patient settings.

In the out-patient setting the data so far in terms of increased safety have really been qualitative in focus groups, interviews, physicians talk about the ability to review medication history and know what patients are on when they prescribe; identifying patients on high-risk drugs, for example for an evaluation that we did recently where the nurses working in a practice, when the black box warning for Avandi Rosiglitazone came out we're able to identify all the patients in that practice on Rosiglitazone and reach out to them. The ability to avoid tampering with prescriptions again is qualitatively identified as something that may improve safety.

However, the pit fall here, the problem is that the quantitative out-patient data are limited and in fact the data there are, so far are not as encouraging as we might hope. This goes back several years. Tejal Gandhi and her colleagues did a study here in Boston looking at several ambulatory clinics that adopted e-prescribing systems and found the e-prescribing did not appear to actually reduce the drug errors in terms of what was dispensed to patients. One of the reasons for this may have to do with the systems we currently use, as you may recall in the introductory slides, I mentioned one of the issues is have we been able to demonstrate improvements with our current systems. Well in our current systems most alerts and most safety warnings are overridden by prescribers.

Saul Winegard demonstrated in a paper in the Archives of Internal Medicine back in 2003, and he was actually the senior author on a recent paper that Zack Isaac and others collaborated on showing that that continues to be the same case now, six years later. Kate Lapane and her group have done some work trying to look at why it is that the alerts in current systems don't seem to have the clinical relevance that prescribers would hope for, so that when they see them they often dismiss them.

In addition to the current alerts not necessarily being what prescribers are looking for, another pit fall is the possibility of new errors. This again is something that has not been quantified, but is a concern for patients, physicians and pharmacists, the possibility of selecting the wrong patient, or wrong drug, when many things are done on drop-down menus, the idea when those are transmitted electronically, and there are not legibility issues, it shows up, its printed, it looks official, things may be dispensed. Pediatricians in particular have struggled with problems with certain doses or formulations not necessarily being in their e-prescribing dictionaries, all of these are problems that can be addressed, but these are the barriers that systems face right now, and

these barriers seem all the more pressing when we don't have the strong quantitative proof of increased safety from the use of e-prescribing in the systems we currently have.

The challenges for increasing safety, and I think this is going to be one of the really critical areas over the next couple years, as more and more prescribers adopt e-prescribing in response to financial incentives coming from the government, to have that be sustained use and meaningful adoption it's going to be incumbent to identify what works in terms of safety and to really define true gains in safety, as opposed to efficiency gains where we might avoid a call back from the pharmacy, but we haven't actually caught any additional errors that might have gone through. We are simply moving the location of catching the error from the pharmacy to the doctor.

I will talk more about that, but it's incumbent to define true safety gains to really convince providers of the utility, and to convince patients that it's a gain for them to have electronic prescribing. A big piece of that will be improving the acceptability of the alerts and there is a lot of work going on about that now, a little has been published previously on trying to fine-tune alerts, to increase acceptance rate by clinicians, that's an area of active research right now, one that is likely to be very important in the coming couple of years.

Another important element is developing the data infrastructure to support more robust safety interventions, so strong connectivity to other systems allowing for things like medication history, which increasingly is being provided so clinicians can know what medications patients have been on in the past, might not have tolerated or other medications that might interact with what they're already on.

Linking to electronic medical records and other in-patient and out-patient systems to provide the complete clinical data and understanding how we're going to get the clinical data into the e-prescribing systems, is it by connectivity, is it going to have to be done manually, these are the infrastructure challenges we need to confront.

Beyond safety, the next topic is efficiency. Although in the safety section a moment ago it may have sounded like I was running down efficiency as a concept. We want gains in safety, not just efficiency. Just gains in efficiency is not a trivial matter. Safety is an issue that resonates more with clinicians and the public, efficiency is still a significant issue. Back in 2004 the Department of Health and Human Services had a study where they estimated that there are 1 billion call backs per year from pharmacies to providers to clarify problems with prescriptions, at every level of the system that's a tremendous impact in terms of time used that could be used in other places. I think everybody here knows time is one of our most precious resources in terms of getting anything done. Beyond the time at each level of the system, for patients, in addition to time, when call backs are needed, when their prescriptions aren't ready, there is more risk of them walking away and not adhering to prescriptions prescribed. Pharmacists find the call backs a major distraction that prevents them from doing the counseling of patients and attending to other clinical tasks they need to. For prescribers the call-backs really interrupt workflow, getting a call-back when there are several patients waiting. And even efficient processes throughout the system one of the promises of e-prescribing has been to make that all work better.

The proof is really relatively limited so far in terms of quantitative proof. It's an area where there's a great deal to gain by convincing prescribers, especially, of the benefits to them in terms of efficiency. There's a lot of qualitative data on efficiency, focus groups, surveys and other qualitative research, identifying some of the areas important to prescribers and pharmacists in terms of efficiency, the ability to avoid lost prescriptions, the reduction in call backs which we talked about on the prior slide, the ability to group prescribing tasks, for example the ability to batch requests from patients, refills, renewals, for large practices is a huge gain in efficiency that really makes a difference in their ability to manage workflow and their ability to manage patient medication lists, and these qualitative data really do have an impact in terms of helping prescribers see the benefits to them of e-prescribing.

The challenge remains that there really isn't quantitative data, so for providers the role of e-prescribing in terms of making their workflow better, making them more efficient in the office, is less clear.

One way the current political environment that people are working around this is simply paying or providing direct financial incentive. That certainly works very well, as people are aware, having a financial incentive to do so gets people adopting e-prescribing, but to be sustained use and meaningful use – and I mean that in the broad term and not in the specific meaningful use sense, which can be a loaded term – but for it to be important use by providers, they really need to see the benefits to them. And there are a lot of threats to that gain in efficiency that can undermine the adoption of e-prescribing. It doesn't take very much, it only takes a couple of bad experiences to really sour a prescriber or a practice on e-prescribing, and that is something again that we have seen in qualitative research. When there are connectivity or reliability problems, especially for smaller practices that maybe are not embedded in a large center, that can really decrease their productivity for the day if all of a sudden the system they have become dependent on isn't working, they may find themselves much less likely to rely on it in the future.

Similarly, the fact e-prescribing isn't as seamless as we would like, not all systems can transmit to all PDMs, which requires printing some prescriptions, the inability to prescribe schedule 2 meds, and I will touch on briefly, Grant will really highlight the importance of that topic, you put all this together and you may have a prescriber seeing a patient and e-transmitting some of their meds, printing some to mail, printing some for them to carry to the pharmacy because they are schedule 2, it's not the efficiency gain that prescribers are really looking for. That's a major challenge that projects like Grant's are working hard to address.

Controlling cost is an area of a lot of focus, of course seniors are where we hear the most about it, but really for all populations, drug costs are a major concern. There's been a lot of research identifying the savings that can be achieved from using less expensive, but equally effective medications. Simple generic substitutions of identical chemical agents for the brand name entity has been demonstrated in a large variety of studies to have the potential to save many millions or billions of dollars. Therapeutic substitution here refers for example the use of inexpensive generic and effective medications like Thiazides or ACE inhibitors for hyper tension in place of more effective agents. Those potential savings, it's been demonstrated that they are out there. The question for e-prescribing now is the promise of getting there, of actually controlling costs.

As a secondary downstream improvement in cost there's also research suggesting better adherence when patient start on medication with a lower co-payment, especially for drugs for conditions like high blood pressure, diabetes, high cholesterol, if you can get patients to stay on those drugs you are likely to see a real benefit in terms of downstream medical costs due to the effectiveness of these agents.

There has been quantitative proof in this areas, from our groups and others, in our study from last year we looked at the eRx Collaborative here in Massachusetts, which put formulary decision support in to an e-prescribing system, so this was a relatively simply kind of formulary decision support, simple color-coding of how drugs appear to the prescribers with preferred drugs in green fonts, non-preferred drugs in red fonts and so on. With that relatively straightforward, non-intrusive intervention, there was a shift from brand to generic prescribing. When we did our study, even accounting for changes over increases over time in use of generics, which had been happening as a lot of you know, and for difference between doctors who e-prescribe and those who don't, even after we controlled for all of those there's additional 3.3% increase in use of generics, which corresponds to a pretty significant savings per member per month for the insurers who are paying for these populations or for the individuals if the patients are paying out of pocket. That's a quantitative benefit that really can make a difference for patients and whoever is bearing the cost of the system.

There are also qualitative benefits that have been identified. The ability to discuss costs with patients at the time of prescribing, so to be able to say “this is a drug with a high copayment,” and thereby identifying potential barriers to adherence up-front, as well as the ability to identify patients on costly medications and again this is something for specific practices when a new generic agent comes out, for example, and they want to let all of their patients know you can get to a less-costly treatment, that maybe will be easier for you to afford, and perhaps adhere to month to month. It's easy to get a list of patients who might benefit from that.

There are still challenges in this area, though. The study we did was based on a lot of work by a couple of insurers and e-prescriber vendors here in Massachusetts as a part of the eRx Collaborative, to make sure the formulary data is current and accurate when decisions were being made. Even with that, we found when the doctors in our study weren't using their e-prescribing system, when they were writing non-electronic prescriptions, the increases in use of generics went away, they went back to the baseline, level they would have been at without the e-prescribing. The data needs to be there in front of the clinician at the moment of e-prescribing in order to actually have an impact.

I mentioned medication adherence in terms of cost, and this is another area where there's a potential for improvement, this has become a focus just in the past year or two as a potential area where e-prescribing can make a difference, non-adherence to medications is common and limits the effectiveness for conditions like high blood pressure, high cholesterol, and it has been recognized that as the connectivity in the system gets better e-prescribing has the potential to improve adherence and it's a place where e-prescribing could really demonstrate its value. The medication history has the opportunity to identify when patients are non-adherent, when they start on a drug and then stop filling prescriptions, and as e-prescribing systems become more

sophisticated the ability to deliver interventions by e-prescribing holds a lot of promise for addressing this issue.

There are still major barriers besides the areas where we haven't demonstrated benefit, just in terms of getting providers to e-prescribe the adoption over the past year or so has been relatively slow. It's picked up as money has gone on the table in terms of direct incentives and penalties, driving a great deal of initial adoption. However the traditional barriers to adoption have been not just cost, and we are doing a lot to address cost either by providing funds or making cost of not adopting higher, but the learning curve is another major issue. Depending on how we do with new adopters and the learning curve it will determine whether the adoption that is going on now is actually successful and sustained or is something that is partial and incomplete.

The real barriers to getting people to sustained e-prescribing are several of the other points on this slide. They need to see that the systems are useable and reliable, that they are interpretable with other systems, billing systems, other clinical systems, and that connectivity can be maintained reliably. Once practices come to depend on the systems it's very important to them they stay connected all the time. Any downtime becomes a major barrier to sustained adoption and long-term use.

There's a perception of patient resistance to electronic prescribing, that the patient expects to leave with something in their hand. And that is something that needs to be addressed over time though I think patients are becoming more comfortable, but it remains a major challenge. Although interoperability and connectivity are huge priorities to all of us doing clinical care or research, of course there are major concerns about data security as we make all of these systems try to work together better and better.

How do we overcome barriers to realizing the gains? One of the important thing is make e-prescribing positive for practices, not just giving them money up front, but providing, especially with smaller practices, support with interoperability for e-prescribing with their other systems, figuring out the areas that matter to prescribers. One of the things the research today is showing for example is that although everybody agrees drug safety is an important priority, the alerts that we have designed don't seem to address the areas that matter to prescribers. When they are presented with drug safety alerts they mostly dismiss them. So we haven't succeeded yet in finding the way to make what we are presenting matter to prescribers in a way that will improve their practice. Demonstrating patient preference could also have a large impact. Providers tend to do want to do what their patients prefer, that's an area that could make a difference. Ensuring reliability and security of systems, the power of the negative anecdote is very strong. When prescribers start adopting a system and it's buggy or goes offline, that can really impair their willingness to stick with it long-term. So the more we can ensure the reliability and security of these systems the stronger and more sustained the adoption will be.

To summarize, I think most of us would agree the potential is there for improvement in patient safety and increasing the quality, the cost effectiveness, the efficiency of prescribing, but in the out-patient setting the evidence is preliminary. We have decent evidence on reducing use of high-cost medications; we have some qualitative evidence on the efficiency of prescribing processes and in terms of drug safety our evidence is really focused in the in-patient setting. So

there's a lot of work that needs to be done to accumulate the evidence that we can really make these gains in the out-patient setting. As we are doing that we should be able to move to address aggressively barriers to full adoption, to provide the kind of reliable and interoperable systems that will get out-patient providers really using in a sustained and important way.

I am going to stop there and say thanks. There will be time for questions at the end. I will pass the baton to Grant Carrow.

Thank you, Michael. Thanks to Bob Mayes and others for inviting me to present to you and thank you all out there for participating in today's conference.

I will talk today about electronic prescribing of controlled substances which is a subset of all e-prescribing that Michael just reviewed for you, I will focus on issues unique to e-prescribing controlled substance and how our AHRQ-funded project at the Massachusetts Department of Public Health can contribute to addressing some of those issues, especially in the ambulatory care setting.

Before I get started, I want to acknowledge the assistance and participation of the other collaborators on this project, which include DrFirst, the electronic prescribing solution provider, and the principle involved from DrFirst in this project is Dr. Peter Kauffman, their Chief Medical Officer who presented previously in this series in June. In addition eRx Network is the electronic prescribing network provider covering the transmission of prescriptions in this project, Brandeis University is our academic partner conducting evaluation and survey, I will touch on that later in the talk, Berkshire Health Systems in Massachusetts is our test site. I will give more detail on that later. We are also working closely with the Drug Enforcement Administration (DEA). And as I said this is an AHRQ funded project.

So to delineate for you what I would like to cover this morning I would like to give an overview of the current status of e-prescribing of controlled substances, what will be some of the security requirements to enable e-prescribing of controlled substances, at least the principles, not the actual, since we don't know that yet.

Then I will give you a brief overview of the AHRQ-funded project here at the Department of Public Health, and conclude with some of our preliminary findings, particularly addressing barriers to adoption, and some expected project outcomes.

Some of the challenges unique to electronic prescribing of controlled substances, and Michael just reviewed in general the challenges for all e-prescribing, which also apply, we presume for controlled substances, though we don't know because it's never occurred, but focusing on e-prescribing controlled substances, one of the major issues and Michael touched on this, currently there's a lack of security standards for such e-prescribing because it depends on regulations of the DEA, as well as the various states. I will be reviewing that issue a little later, as well.

The security standards needed for electronic prescribing of controlled substances are a unique challenge because they need to be preventative of pharmaceutical or drug diversion, an issue that isn't usually prevalent for non-controlled substances.

To make sure we are all on the same page I want to define, though many of you are probably aware, drug diversion is when drugs are channeled from licit to illicit use. Some of the ways that this can be done is through theft, burglary, tampering, stealing or forging prescriptions, doctor-shopping, indiscriminate prescribing and illegal sale of pharmaceuticals and prescriptions, as well.

Some of the impact of drug diversion is depicted in this slide. I tried to narrow it down to key elements. There are certainly many issues, but controlled substances, prescriptions constitute a little under 10% of total prescriptions in the United States. The issue of using prescriptions non-medically in the United States, it's estimated there are currently about 7 million individuals who are using those substances non-medically, and that we are adding on the order of over 2 million new users every year. That is, non-medical users or abusers of prescription drugs. So it's a huge problem and continuing to get larger.

Now, the lack of approved standards for e-prescribing and controlled substance has contributed to a delay in realizing all the benefits of e-prescribing that Michael just covered. I will move forward and say in addition to those benefits, in terms of controlled substances there are additional benefits so we would expect there would be reductions in the non-medical use I just described of controlled substances. And Michael touched on this, there would be increased adoption of e-prescribing of all substances, including non-controlled medications, because of the multiple systems that are necessary with e-prescribing legend drugs and paper or fax prescriptions for many of the controls.

I would like next to delineate for you what are the types of security requirements that would be needed for controlled substances and e-prescribing, and before I get into the details, just to give a little bit of background. The charge to the DEA and to states, both of which act to control substances, is to balance the need to enable controlled substances prescribing, whether it be electronically or via paper, and at the same time prevent drug diversion.

The standards that are in the proposed rule mentioned earlier and that I will cover here are an attempt to balance those two missions. Specifically, the DEA and others have identified the security elements that would be needed to find a solution for e-prescribing of controlled substances and they are covered in the next two slides and include a means for authenticating the prescriber, that is the individual signing and sending the prescription as well as those receiving the prescription at the pharmacy; the ability to ensure those involved in transmission, signing and receiving can't deny they were involved in those activities, that's where legal issues I will get to next come in, there needs to be record integrity, which means the electronic record has to be ... we have to be ensured that it was not altered at any point in the transmission. All these elements contribute to legal sufficiency, which means that one has to be able to prove in the case of criminal prosecution beyond a reasonable doubt that the activities occurred. One wants signature verification to ensure that the person who signed the prescription meant to do that and of course we need to ensure confidentiality of the data.

Now all these elements need to be built into an electronic system, or electronic systems to ensure that they have at least the same security as wet-signed paper prescription. In addition they can offer the opportunity to increase the security compared with a paper prescription.

Now I would like to take you through a schematic of how those elements in a security system might be applied to the e-prescribing that you know today, and those who had have difficulty seeing this slide may want to go to full screen because some of the type is a little bit small.

Right now the system is that the prescriber sees the patient, writes the prescription. This is for legend drugs, non-electronic and non-controlled. The prescriber enters information in the e-prescribing system, it's transmitted through a network like eRx or SureScripts/RxHub and then transmitted to the pharmacy system and there's adjudication with the pharmacy benefits manager in terms of payment, and then transmitted to the pharmacy for dispensing by the pharmacist and back to the patient. This is a current view in terms of e-prescribing today for legend drugs.

In order to get to the point for e-prescribing of controlled substances one needs to impose those elements that I just reviewed for you and so it would look something like this schematically in the next slide. In this case the green areas indicate what other elements need to be super imposed on the schematic that I just reviewed in order to ensure security of these systems and they include credentialing and authentication of the prescriber, some sort of hard token, security token to insure that the prescription is being signed by that prescriber, there needs to be checking of the DEA database of prescribers in order to have a continuous credentialing of the prescriber because the initial authentication step denoted here occurs once, but to ensure the prescriber is still authorized by the Drug Enforcement Administration, as well as the state to prescribe controlled substances, one needs to check the database regularly.

Another element is that the e-prescribing network, as well as the pharmacy would need to digitally sign and archive that prescription, again this is to address certain elements such as ensuring there has been no change in the prescription at any point in the transmission.

The security token could be a smart card or crypto key, which is a sort of thumb drive that the prescriber would carry. These would need to be super imposed on the e-prescribing systems and that we would be testing as part of our AHRQ funded project.

As I mentioned before I will give you a little overview of the project. The aim is to encourage the expansion and adoption e-prescribing particular in regard to medication management in the ambulatory setting by testing and demonstrating the quality, security and effectiveness of e-prescribing federally controlled substances in an ambulatory setting. Some of the key elements, Berkshire Health Systems is our test site, both Berkshire health systems hospitals and prescribers and the Berkshire county pharmacies provide a laboratory for us to conduct this work. As part of this work, of course, we had to obtain a waiver from the DEA to allow e-prescribing of controlled substances, and since it's not permitted by any current regulations now, and that would be limited to our test area, we had to develop systems for the authentication process or the providers and as part of our study we have been conducting provider and pharmacy interviews and surveys and I will give you preliminary results from that in a moment.

Other elements of our protocol include having a hard token for digital signature by the providers, having the prescriptions transmitted electronically and dispensed by the pharmacy, as well as evaluating processes and outcomes. In addition we are conducting an independent security analysis to test the security of the system we put together.

In terms of the waiver from the DEA, which many of you may be interested in, it was in the form of a memorandum of agreement (MOA) between the DEA and the Massachusetts Department of Public Health, which was completed in September, 2008. The waiver is specific to the project protocol. In addition, as many of you are aware, DEA published a notice of proposed rule making in June of last year and there are some similarities and differences between our memorandum of agreement with DEA and the proposed rule. I will go through that in a moment. But before I do, I wanted to point out that the reason for the MOA, as I said there are no regulations in place now and there are no state systems or national systems in place to do all the procedures for security procedures I just mentioned. So because of the limited scope in our project, which will only involve a couple hundred providers and that there are no IT systems in place for this, particularly at the pharmacy level, there need to be some differences in how our project will rollout as compared to what might be expected when this goes national with a final rule from DEA.

The next couple of slides detail for you what some of the similarities and differences are. This is our interpretation of the proposed rule from DEA. We shared these slides with them, but they have not specifically edited them so I would go to the proposed rule itself if you have specific questions of what it's representing. As you can see, in the first item there's a difference in terms of identity-proofing and that this will be done in our case by the vendor and Berkshire Health Systems, where as in the proposed rule it's state officials or hospitals or other agencies.

In terms of prescription information and authentication protocol, those will be the same. In terms of prescriber workflows, there are requirements in the proposed rule, but not in the memorandum of agreement with the Department of Public Health (DPH). In terms of the archiving of signatures, that is somewhat similar, and in the interest of time I won't go into the details you can read them at your leisure, but in terms of checking the DEA database there's also similarity between our agreement and the proposed ruling.

In terms of archiving signatures, pharmacies in our project will have the option to wet-sign the prescriptions because they may not be set up to digitally sign prescriptions, but that would not likely be available according to the proposed rule. In terms of audits, we weren't required to audit in terms of, as would be expected under the proposed rule, although as I said we are conducting independent security analysis to cover that particular aspect.

I know that one of the interests in this series is medication adherence and issues around that. Michael covered that very well. I will say that a secondary aim of our project is to look at that issue. That's because we were looking at the interfacing between an e-prescribing system, that we're developing and the Massachusetts Prescription Monitoring Program. The Monitoring Program collects records of dispensing of prescriptions for schedule 2 controlled substances in Massachusetts for Massachusetts out-patient clinics and retail pharmacies. What we aim to do is to reconcile the prescribing records from the e-prescribing system and the dispensing record we

get from the pharmacy and our main aim was to look at issues of drug diversion activities that way, but as a secondary part of that we may also be able to get a measure of medication adherence.

I will get back to that topic in a moment, some of our preliminary findings, but before I do I would like to cover some of our preliminary findings with respect to our prescriber surveys and their perspective on expectations for electronic prescribing of controlled substances. So for that aspect the Brandeis University team surveyed 246 Berkshire Health System prescribers earlier this year and found that about 43% use e-prescribing now, and that is for non-controlled substances of course and the controlled substances prescriptions comprise about a quarter of their prescriptions.

They further found about a quarter of the respondents expect controlled substances to be initially disruptive to their practices, however, a large number expect controlled substances e-prescribing will improve quality. About half of them, interestingly, expect the hard token that will be required for the digital signature to be a large inconvenience. About a quarter of the respondents expect the advantages of e-prescribing controlled substances will not outweigh that burden of using and keeping a hard token. That's something, very important barrier that people will need to focus on and address. This is of course expectations and we will go back to survey the same individuals once we have implemented the hard token and other features and see how they feel about it after that point. I want to go back too and mention that Michael earlier addressed the issue of providing incentives and value to providers to do e-prescribing, so certainly this is another area in which that would need to be addressed.

Another area of possible barriers to e-prescribing of controlled substances involves state law. Much of the focus, to date, nationally has been on the DEA regulations and less focus on the state level. However, the state regulations are a necessary aspect of e-prescribing controlled substances. In some states, California, Massachusetts and New York are examples, there are laws now on the books to allow e-prescribing of controlled substances pending the regulations from the DEA. However, in other states, that's not the case. For example, in Florida there is a law that requires a written prescription for schedule 2 drugs. In Texas the law prohibits e-prescribing of schedule 2 prescription and requires a manual signature. Those are a couple of examples of laws that would need to be changed in order for controlled substances to be e-prescribed in those states, even with a federal regulation.

There's of course many issues with that, the time needed to change state laws, that might be significant. In addition, states are not required to enact laws to allow e-prescribing of controlled substances, one expects they will, but they are certainly not required to do that. State laws could be more restrictive than the DEA. So although the DEA will come out with requirements a state does have the option to come out with additional requirements. They can't be less restrictive, but can be more restrictive.

Other issues we have come across in the course of the study are that many states place the responsibility for security and validity of the prescriptions on the prescribers and pharmacies, those are the entities that are regulated and licensed by the state and the DEA, but the transaction system providers, that is the e-prescribing software providers, those who provide the

transmission networks and switches and the pharmacy software, they are not regulated or licensed, either federally or by the states. So question arises, how will prescribers and pharmacies be assured the systems meet the necessary security requirements since they will have at least some legal responsibility for the transaction. Remember the issue I brought up earlier about non-repudiation. There will be a party to the transaction and how will they be assured that the transaction is actually following the DEA and state rules. That's a big question. Could be a barrier to adoption if prescribers and pharmacies don't have that assurance.

Another item we came across in the course of our project was that currently third-party payers, including Medicaid, do not allow electronic prescriptions for controlled substances, as you might expect. This will be an issue that all third-party payers will have to change their reimbursement mechanisms to allow electronic prescribing of controlled substances.

In terms of medication adherence, as I mentioned that part of our project is looking at that, we will be reconciling the e-prescribing records with the dispensing records in the prescription monitoring program. One of the things we noted in the beginning of that part of the project was that, that will require a key field for linking the two databases. Now that key field doesn't exist in prescription monitoring transmissions standards right now. We have begun to work with the standard setters to ensure there's a key field that can be used in the future to do that reconciliation.

In terms of adherence prescription monitoring only covers controlled substances, and not even all of the schedules of controlled substances. So I am not suggesting this would be a total solution and certainly filling a prescription is not the same thing as taking a medication, but it may be helpful in certain cases, especially for patients who have chronic medical conditions and are using a controlled substance chronically.

I see we are near the end of time for the presentations. I will close by outlining some of the expected outcomes for our project. Again, through findings and research to facilitate and expedite adoption and diffusion of electronic prescribing, by field testing the security standards that I've outlined, prior to and during implementation of DEA's rules, and identifying unexpected barrier and outcomes prior to implementation to facilitate and avoid some of the problems as the systems come on-line.

We feel that earlier adoption and expansion, diffusion of e-prescribing of controlled substances will lead to improved medication management by ambulatory care clinicians at the point of care as Michael so well outlined; will increase access to needed pharmaceuticals, particularly by those with chronic medical conditions, we expect reduced non-medical use and abuse of controlled substances through controlling drug diversion. I want to again thank our projects team, the members are listed here. I also provided contacts should you have specific questions on the project after these presentations and the question and answer period. I want to thank you again for your participation and patience. I understand there's a question and answer period that both Michael and I will participate in so I will hand it over, back to Bob to conduct that session.

Thank you very much, Dr. Carrow.

We have a number of questions, one thing I wanted to point out again because I got a lot of questions about this is that we will make both the slides available, as well as an audio recording of this will be available, probably within the next couple weeks and you will receive an e-mail letting you know when that is available and the link to find that. Another issue brought up about the slides, whether or not the full citations will be made available. We will make sure to supply the full citation of the slides.

There were quite a variety of questions. I will start with one that was really looking at -- we talked in most of these conferences and today's conference we talked about e-prescribing and electronic medication management, really from the formal healthcare side. So from the provider and the pharmacist side. All of us are beginning to live more and more in an electronic world, fill prescriptions via the Internet, communicate through e-mail with our providers, some with our drug management companies or pharmacies. There were a number of questions around whether or not this adoption of these technologies will offer an opportunity for individuals to become more direct participants in their medication therapy. And will be able to provide information directly rather than the way we are doing it now, to infer by doing things such as med reconciliation and that sort of thing. I was wondering if either or both of you want to comment on where that might be where we are headed in the future, i.e., participation by individuals more directly based on these kinds of technologies.

Bob, it's Mike. I can provide a couple of thoughts on that. It's an excellent and important question. It seems inevitable that patients will be taking a more participatory role. One can see in the abstract the potential positives there if you have patients participating more directly, providing information, whether it's when they are requesting a refill of a prescription or when they have a question about a medication. If you have a way to tell directly, if the patient says they "don't want it because it's too expensive" or "I'm not renewing this because it gave me a headache" you're understanding more about what drives patient behavior and how to successfully treat their condition. If you have the ability, if they say "I am not taking it because I don't know why I am taking it," well now you can identify a deficit in-patient education you can address. Those are all conceptually helpful. I think the barriers will be as much as with e-prescribing systems for clinicians to design the system in a way so that it is easy for patients to input information in a way that it gets to their provider, whether they're a prescriber or a pharmacist in a useable fashion, and then that information can come back to them. The design is not such a trivial issue. I suspect they will differ quite a bit. A lot of patients do a lot of elements of healthcare online now. I don't have hard data for this, but I think that often tracks with age and socioeconomic status. For example, it may not be a great solution for our low income Medicare population who maybe don't have access to all of the online resources that some other segments of the population might have.

Great, thank you for that.

There were several questions around the issue of alert fatigue. There was interest in knowing what sorts of solutions or ideas are being tested or developed to deal with that, if there's any that show particular promise.

I don't have specific ones to hold up as examples. There are a lot of projects in process, and I think that a lot of things that are being developed are still not for circulation. I think there is a great deal of innovation going on by particular companies, either e-prescribing vendors or electronic medical record vendors trying to find ways to make this work better. I know here in our system at Partners Healthcare, which is where I practice clinically, they have been doing work trying to identify the alerts that fire often without having clinical impact and eliminate those, so addition by subtraction. So if you can get the noise out there, if you think about this as a signal to noise problem. One approach is to try to get the noise out, then see if people will start responding to the signal once there isn't so very much noise. This is an area where there's a lot of important work to be done. Unfortunately we don't have a great answer, not a best practice.

Actually, I thought of one while you were talking, we tie the alert system to a Lexus Nexus database, flash the average liability award up on the screen every time we send an alert. That might catch the attention.

Depends on the environment. People have even talked about the common sense things like you get in a lot of commercial software applications, you get an alert, misspelling, saying no, don't show again. For the most part e-prescribing systems don't have that. We need to think hard, it's not clear if we want to give the option for every warning, some probably need to be shown every time. The clinical discrimination to determine which those are is a tricky one to do.

There were a number of questions around the issue of security tokens. You mentioned a card or a thumb drive, are things like biometrics being considered by DEA? Is the securities token a hard token on the prescriber side or also on the pharmacy side, the dispensing side? Or do you have any idea about where the final rule might come down on this factor of authentication?

I am sorry, not privy to any information as to how the rule will come down on this. There was a lot of public comment on this issue. My understanding is the rule as proposed in June would require a hard token. Biometrics could be used as one way to have a pass words to activate the hard token in lieu of having the kind of pass words you are used to typing in now. As I understand it, DEA felt that was not sufficient for the security needed for an e-prescribing of controlled substances systems. The proposed rule itself, and I gave the reference in my slides, has a lots of discussion and detail on this matter. Participants can go there to get a lot of DEA's thinking on the matter.

I think there was one question, someone wanted to know if there was a timeline for the final rule, since I am on the federal side I can say unfortunately these things tend to drag on. I know DEA is working on getting a final rule out but there is no published timeline for that.

Bob, the second part of the question I didn't answer, will there be a hard token required at the pharmacy level, no, as far as I know there won't be. There would be a digital signature required, but I don't know if that's going to require a hard token, something for the specialists to answer.

Related to this, the security approaches that are being considered and were put forward in the proposed rule, how do they compare with, for instance, the approaches to security used by the

banking industry or other sectors? Is it possible, are they looking at similar solutions or are they going to have to develop new approaches for controlled substances?

This is an excellent question. As the questioner suggests, billions of dollars, if not trillions a day are transferred by banks in a secure manner. The question has arisen, why can't prescriptions be transmitted similarly. The issues surrounding prescription go far beyond simple security of the transmission, so many steps along the way in which there could be a problem, leading to drug diversion, the main charge. As I mentioned in the outset of my talk the DEA and other regulators have to balance while they enable prescribing of controlled substances.

I am not an expert on the banking industry. Probably the DEA rule addressed some of those questions. I would have to defer to the banking industry to explain how it could work for e-prescribing controlled substances, but I believe there are unique differences.

Dr. Fischer, there are, of course, we talked a lot about the prescriber, the pharmacies, the individual patients. How about the role of pharma companies, have they been involved in e-prescribing? As well as some of the larger drug database companies, how are they playing in this field?

That's a terrific question, and it's important to keep in mind my answer is from a somewhat narrow perspective as a researcher. In terms of how people are playing in that field, I am sure there are plenty of business interactions that are not part of the research studies; so I wouldn't know the first thing about them. So keep in mind that the answer is through a limited perspective. I know that there are definitely pharmaceutical companies that are interested in looking at e-prescribing interventions. Especially around drug adherence, which is a win/win for everybody, because if it's a beneficial drug there's a sense from a clinical point of view that we want our patients to be taking it for their long-term benefit. If you make the drug, of course it's good for you if people take it. So there's interest there, but I don't know I can give a general overview of a representative overview of what pharma is doing across the board. In terms of, you mentioned the database companies, that's an interesting and important point. I think that's an area where there's potential for productive innovation because there are several major database companies that provide drug dictionaries and other things that often are the clinical knowledge base behind e-prescribing innovations, understanding how to make those more narrowly targeted, to get at the problem of alert fatigue, so you could deliver safety warnings that are really what the doctor is looking for, and that they will attend to, is a major priority. One challenge is the drug interactions, for example, identified as high danger interactions differ across the commercial databases and that is a real knowledge generation challenge for the field as a whole. I don't have an insider's answer, but those are areas where productive work could be done.

Thank you.

This actually, both of you could probably answer or have an opinion on. We talked about some of the legal issues, particularly with controlled substance, but what about the liability issues? Are we or is this seen by medical insurance companies as being a new area which requires separate

liability insurance? Or could engender a different level of liability than currently just the prescribing process entails?

This is Grant. Very interesting question. I think I touched on that a little bit when I was addressing the issue of the regulation of the transmission of the prescription. The prescriber and the pharmacy end are both regulated, but what's in-between is not. You are correct. The questions are correct, there's additional risk there. There are standards being developed that presumably, both the transmission providers and the software providers will need to meet that will offer some level of assurance, and lower that risk, and therefore lower the liability, but certainly it may be a good question that insurers may be looking at that, seeing if they have to adjust their liability measures accordingly.

Yeah, I think there's certainly something people get concerned about. People raised issues about whether there's liability created with electronic systems, if you know more about what patients are taking or not. A colleague of mine who is a physician and lawyer looked at this and there's certainly no legal precedent of any enhanced responsibility being created by electronic systems. I think there's the same potential burden of, or potential liability of being responsible for things your patients may or may not be doing with the medications you prescribe, but those could arise whether you are sending them electronically, handing them over or phoning them in.

There's a question about how electronic medication management affects the organizational relationships between both prescribers and dispensers. Historically, of course, both groups have been related but separate. The prescriber, physician, nurse-practitioner, has their workflow, and processes, they create a prescription, use the patient as an intermediary who carries that over to the dispensing agent, the pharmacy that has its processes. Except for call-backs and other communications that are episodic, those organizations, unless they are part of a large integrated system, go about their business as they see fit. With the introduction of electronic prescribing systems you now have a potentially much more persistent link between these organizations, and there's a potential for what happens on one side to actually have a direct impact on workflow on the other side and vice versa. Does the introduction of this technology potentially mean we will see a different way that medication therapy is going to occur, a shifting of tasks, different from the way we currently have defined it?

That's a broad but important question. I think in its ideal form, you know we talked about e-prescribing and the promises at the very beginning of this session, ideally, you might make a shift, instead of a problem being identified after a prescription is being handed to a patient, they have carried it to the pharmacy, pharmacist does a check, they call the physician back, you are now several steps removed, if instead the problem is identified at the point of prescribing and an alternative decision can be made, what's transmitted to the pharmacist has already gone through a stage of checking, that's potentially a benefit. Is there a way to make it a two-way street so some of the clinical expertise of pharmacist can be accessed while the patient is in there with the physician; I am not sure there's an easy way to do that with current systems, but that's the kind of systematic improvement one would hope might be available. I think being able to change the communications makes a difference. Grant's project speaks to that, right now controlled substances the law requires us to hand the patient a prescription with ink signature and rely on them to carry it somewhere. There's all kinds of concerns about diversion, tampering and many

other things. Reshaping the communications has the potential to address some of those concerns but how to do it most effectively is where some of the challenges.

This is Grant, I would just add that as I mentioned prescription monitoring databases, many states use those databases to provide prescribers with information prescription histories on their patients, particularly to assist them with those patients who may be at risk or may be showing signs of using controlled substances non-medically. Certainly that pharmacy information going back to the prescriber at the points of care. Much of that is not real-time at this point, but that's certainly one of the goals. That would be one way to have feedback to the prescriber.

Okay, great. I think we are just about out of time for questions, and at the end of the conference. I did want to reiterate that for those questions that were not answered, either directly or indirectly, because I grouped some questions together, those will be looked at by the presenters and we will try to get specific answers for your specific questions that we can then post, along with the slides and the audio of the conference. You will be notified by e-mail, the address you supplied with registration. Should be in the next couple of weeks. With that, I would like to thank the panelists, Dr. Fischer, and Dr. Carrow and all the participants who joined us. AHRQ runs a series of this type of conference throughout the year. Please keep current on what we are offering next. Hopefully they are beneficial to the range of providers and other interested parties. Have a good afternoon.