

## TRANSCRIPT OF AUDIO FILE:

# MEDICATION MANAGEMENT USING HEALTH IT FOR THE CARE OF ELDERLY PATIENTS

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### **BEGIN TRANSCRIPT:**

Operator: Hello and welcome to the AHRQ Web cast. Today's conference is Utilizing Health IT to Improve Medication Management for the Care of Elderly Patients. It is my pleasure to introduce today's moderator, Angela Lavanderos with the Agency for Healthcare Research and Quality. Angela, the floor's all yours.

ANGELA LAVANDEROS: Thank you. I'd like to begin by introducing the three speakers that we have for you today. Our first speaker will be Dr. Jerry Gurwitz. Dr. Gurwitz holds The Doctor John Meyers Professorship in Primary Care Medicine at the University of Massachusetts Medical School where he is Chief of the Division of Geriatric Medicine.

He also serves as the Executive Director of the Meyers Primary Care Institute, a joint initiative for the Fallon Community Health Plan, Fallon Clinic and the University of Massachusetts Medical School, and it is focused on population health research and improving the health of communities.

Dr. Gurwitz has been a principal investigator of several grants from the Agency for Healthcare Research and Quality focused on improving medication and safety. Dr. Gurwitz has published numerous original articles, reviews, commentaries, and book chapters on the optimal use of drug therapy in elderly patients.

We also have Dr. Terry Field with us today. She's an epidemiologist and health services researcher who serves with the Associate Director of the Meyers Primary Care Institute, and an Associate Professor at the University of Massachusetts Medical School.

Dr. Field's research focuses on provision of care to disabled and elderly patients in the ambulatory and long-term care settings. She has also participated as principal investigator or co-investigator on a series of grants from AHRQ and the National Institute on Aging related to patient safety.

Dr. Field's work includes a number of randomized trials of health IT-based interventions to improve prescribing and monitoring of medications. Her research interests also includes provision of care to cancer patients with a special interest in survival deficits for

patients at risk of receiving less than optimal care including elderly patients and members of minority groups.

And finally we have Dr. Kate Lapane with us today. Dr. Kate Lapane is the Charles and Evelyn Thomas Professor of Epidemiology and chairs the Department of Epidemiology and Community Health at the Medical College of Virginia, Virginia Commonwealth University. Her research focuses on improving patient and pharmacy care for older adults and in particular how health information technology can improve care.

Dr. Lapane has developed and conducted large-scale intervention trials using health IT to improve the related issues, identify and marginalize populations. Most recently through her ARHQ grant, Dr. Lapane has designed and tested novel educational materials, such as tailored DVDs, to more effectively reach marginalized populations with lower literacy. The overarching theme of her applied research is to improve the health outcomes of the elderly person through the understanding of risk and benefits of medication in patients systematically excluded from clinical trials.

And before we begin today's session we are required to read the following statement for CME purposes. This educational activity has been approved by the Wisconsin Medical Society for 1.5 AMA PRA Category 1 clinics. Speakers and planners are required to make disclosure of any relevant financial relationships which may be related to the subject matter discussed. Speakers and planners for this educational activity have made proper disclosure and have no relevant financial relationships that exist now or in the past 12 months.

And with that we would like to begin our presentation with co-presenters Drs. Gurwitz and Field who will summarize their research on the incidences and causes of adverse drug events in the long-term care and ambulatory setting. They will present the results of a series of studies of health information technology-based interventions to improve medication prescribing and monitoring. So with that, I will turn over the floor to Drs. Gurwitz and Field.

DR. JERRY GURWITZ: Well, thank you very much, Angela. And Terry and I would like to, over the next 30 minutes or so, summarize some of the work we've done over the past decade or more. And I'd like to begin with a quote. This is a - something written by William Withering in the 1700s, and one of my favorite quotes. "It is much easier to write upon a disease than upon a remedy. The former is in the hands of nature and a faithful observer with an eye of tolerable judgment cannot fail to delineate a likeness. The latter will ever be subject to the whim, the inaccuracies and the blunder of mankind." And we can't help think that this last sentence characterizes the way medications are still used in older patients in 2011, hundreds of years later.

We'd like to share with you a case study and this is a case that came up in some of our earliest work that points out a number of key points. And I'll work through this case with everyone. E.G. is an 85-year old, female nursing home resident with a history of atrial fibrillation, stroke, dementia and hypertension who is receiving chronic therapy with a

blood thinner warfarin to prevent stroke. Her primary care provider has been dosing her warfarin to maintain her at an INR of 2 to 2.5, which is the target to keep her protected from experiencing a stroke.

One evening a covering physician is called with a report that the patient has developed a fever. Patient is initiated on antibiotic therapy to treat a presumed urinary tract infection. Next morning the primary care physician is called with the previous day's INR, which was low. She increases the daily warfarin dose from 4 to 5 milligrams per day. She is not notified of the antibiotic or the previous evening by the covering physician.

One week later, the INR comes back very high at 13.8. That places the patient at very high risk sustaining a serious bleed, a spontaneous bleed. Another covering physician is notified; that evening's warfarin dose is held. The primary care physician is notified and vitamin K is administered for three days with a reduction in the INR to 0.9, which is back to the normal range. The physician writes in the record that warfarin will not be reinitiated because anticoagulation has been difficult to control for unclear reasons.

This case brings up a number of points that I'll discuss but one of the things that comes to mind first is how can these healthcare providers have been so stupid? And one thing I want to say is that that's exactly the wrong way to think about this case. That these things happen all the time and similar things have happened to me in the past on multiple occasions and I think about these issues quite frequently.

So what factors placed this older patient at risk for an adverse drug event? And there are a number of possibilities. One is warfarin is a drug that requires careful dosing and monitoring. Older patients are at risk for drug-drug interactions. Older patients are at increased risk of close calls and near misses, and this was a close call; the medication ran adrift. And communication errors between healthcare providers are common in the care of older patients. And as we look at each of these possibilities, these are areas where health IT could potentially have a benefit to improved safety. And all of these things are relevant in this particular case.

As we look at the case, the covering physician was not familiar with the patient and important drug interaction was not recognized. The primary care physician was not aware that a new medication, the antibiotic, had been prescribed. The high INR, the very high INR, was due to multiple errors. And in the end, ultimately the patient was denied a very important therapy that could have been very beneficial to her and had the likelihood of preventing a stroke, which now she's at risk for.

So what I'd like to do is to transition and to share with you some results of a study we performed looking at the incidence and preventability of adverse drug events in two large, long-term care facilities. What I'd like to do is take you through this figure, and this is a conceptual framework for much of the work that we've done over the past 10 to 15 years. And this framework was developed by David Bates of Brigham and Women's Hospital.

Adverse drug events are drug related injuries and there is this huge universe out there of medication errors. And we'll just look at that again. Medication errors' universe is in yellow, and then there's also this universe of adverse drug events by drug related injuries. Now one can suffer an adverse drug event in which there is no error involved. For example, a patient can be prescribed penicillin. There's no history of an allergy. They suffer an anaphylactic reaction, a life-threatening reaction, and that is an injury. And in 2011, if they've never been exposed to the drug before we don't have any way of preventing that.

However, if there was a record that the patient had previously been allergic to penicillin, and if that information was potentially available to the prescriber, then the patient getting the prescription for penicillin is in error. And if the patient suffered an injury, we would consider that to be a preventable adverse drug event.

The intersection between the universe of medication errors and the smaller universe of adverse drug events or drug related injuries are the preventable adverse drug events and those are the things that we are most concerned with in our work. I'll describe a study conducted in these two large long-term care facilities and they have a total of over 1200 dead.

And what we did was to have trained clinical pharmacist investigators who would view the records of these residents of nursing homes over a one-year period and they have reviewed these records in one-month segments. Incidents that they identified were subsequently classified by two physician reviewers independently as to whether this was an adverse drug event, a drug related injury, its severity and its preventability.

We identified 815 drug related injuries, or adverse drug events, that's about 10 per 100 resident-months, and we identified 3338 preventable adverse drug events. And that's a rate of about 4 per 100 resident-months. So in summary, about 42 percent of all adverse drug events were deemed preventable, meaning they were found to be associated with at least one medication error.

Now some of these events were quite severe. We identified 4 fatal events, 33 life-threatening events, and 188 serious events. The interesting thing in the opportunity is that the more severe the event, the more likely it was to be deemed preventable. Of fatal, life-threatening and serious events, 61 percent were deemed preventable compared with 34 percent of the less serious events, so clearly this presents an opportunity.

Now where did the errors occur that were associated with these drug related injuries or adverse drug events? They primarily occurred at the ordering stage of therapy and the monitoring stage. And there were many dispensing errors that occurred, there were many administration errors that occurred, but those things are less likely seemingly to be associated with a drug related injury. As you can see here, most of the injuries we identified began or were associated with ordering and monitoring. And that again presents an opportunity that we'll talk about.

What types of events did we identify? The top of the list are the things like neuropsychiatric events, and those are things like over-sedation, confusion, delirium, again caused by drugs; a bleed potentially like the case study that I described earlier, or the patient was at risk for a bleed; gastrointestinal events; renal and electrolyte associated disorders, all with or without injury; cardiovascular events; EPS or extra paramital symptoms often associated with use of anti-psychotic medication; and syncope and dizziness.

If we extrapolate these results to the total U.S. nursing home population, which was 1.6 million at the time, it shrunk a bit, there are 1.9 million drug related injuries per year in a nursing home setting. And 40 percent of those may be preventable. There are 86,000 life-threatening or fatal adverse drug events and actually up to 70 percent of those may be preventable based on the findings of our research.

So there are many possible interventions that fall under the, we referenced HIT. And today we're just going to talk about Computerized Provider Order Entry, and computerized clinical decision support systems. So let me describe briefly one of our studies.

And this was a study of computerized clinical decision support in a long-term care setting. And we developed a computerized clinical decision support system that included alerts that's related to high severity drug interaction, potentially problematic laboratory test results; that provided early identification of adverse drug effects through increased monitoring that alerted the physician or the prescriber to think about those things; that made recommendations regarding geriatric-appropriate dosing and recommendations for prophylactic measures. For example in the setting of use of opiolytes (sp) to encourage the use of prophylactic measures to avoid the occurrence of constipation.

So this is a slide, it's a little hard to see, but this is a screen shot and this screen shot is very relevant to the case study we presented earlier. Here the patient is prescribed an antibiotic, Cephalexin. And an alert shows to the prescriber warning bleeding risk, the drug involved is Cephalexin, and alerting the prescriber who may or may not know the patient that the patient is on warfarin. This drug interacts with warfarin and it is encouraging the prescriber to repeat the INR in three days and also to consider preemptively reducing the warfarin dose.

So this is the type of alert that the prescribers generally want from care facilities on certain units. Now these alerts only showed on half the units. They did not show on the other half of the nursing home unit. We're rushing though this a bit. We're rushing right through to the results. And here are the results.

This slide summarizes the effect of that intervention, the effect of showing those alerts, on adverse drug event rates. The blue bar is the intervention unit of the nursing home; the red bar is the project control unit. The rate is rate per 100 resident-months. And unfortunately, you are seeing no difference between the two, no statistically significant difference between the two rates. And the rate ratio is at the bottom of the slide, 1.04, and

you can see the competence interval clearly increases 1. Now one might say, well this is all adverse drug events. Maybe there was an impact on adverse drug events that would be deemed preventable, meaning those associated with an error.

So here we performed an analysis just looking at preventable adverse drug events. These are adverse drug events associated with a medication error. And unfortunately we're seeing the same thing. No difference between the intervention unit and the control unit. Rate ratio is at the bottom of the slide, and again the competence interval is 1. Our conclusion was use of CPOE with this particular computerized clinical decision support system was not found to reduce the occurrence of adverse drug events in the long-term care setting.

And why? You know, that's the agonizing question. Why with this all this effort didn't it work? This study was performed a number of years ago, and clearly this was a first generation system. Having said that, the systems that are available in 2011 are probably not that much more sophisticated than the system we had worked to develop. This is something I think Kate is going to touch on and a very, very important issue, the lack of specificity of the alert and that could lead to alert burden and alert fatigue. And that is something that is a real struggle when we're talking about clinical decision support because after a while, prescribers just click through them.

There is a need to increase the scope of the system to address a broader range of adverse drug events. Some of us - the adverse drug events that we would have liked to have prevented were not addressed by the alerts. We need to be able to integrate more clinical information into that clinical decision support system.

And perhaps we were setting the bar too high. We were trying to shoot a home run but really we should take a step-wise approach to doing this. And maybe the first step is to try to prevent errors and then try to prevent injuries. So with that I'm going to turn the presentation over to Terry and she will continue with describing some of our work.

DR. TERRY FIELD: Well, one of the - after we considered the issues that Jerry just discussed on the last slide, we decided that there were some ways as the systems became more sophisticated to go back in and try to respond to some of those problems that we hit the first time around or what we thought were the problems. So we did a second trial, also in the long-term care setting, again of the clinical decision support system. This time around, we focused very, very specifically.

This trial looked particularly at prescribing for residents with renal insufficiency. And there were a couple of aspects of the situation that we thought lent itself more thoroughly to the use of clinical decision support. First of all there's the very complex association between levels of renal insufficiency and dosing recommendations and that could be a real challenge for prescribers. It's not that easy to maintain this amount of information as a normal clinician who doesn't just specialize in this particular area.

We already knew from previous studies that there are substantial rates of inappropriate dosing. This is certainly true of long-term care where there are a very large percent of patients who are likely at one point or another in a year, who actually have renal insufficiency. It's also been found to be true in a hospital setting where similar studies have been undertaken.

Basically to establish a correct dose for a patient in this situation, you need information on creatinine clearance, which needs a number of different pieces of information about the patient in order to do the calculations. And then you need drug-specific dose recommendations that respond to the different levels of renal impairment. So we made another stab, this time again with a randomized trial. This time we randomized 22 long-term care units to either intervention or control.

There were a series of things that could appear as alerts. One was specifically a recommendation for dosing. If a patient indeed had a level of renal impairment and it interacted with a particular drug being ordered and the order that was started up by the clinician was not corrected from the dosing, particularly if it was too high a dose, then the system provided an alert warning them of the fact that this dose was too high given the patient's current condition, presenting them with information about what the creatinine clearance was for this patient at the time, and giving them a recommendation of one of the suggested doses under these circumstances.

For some drugs it wasn't the dose that was the issue, it was the frequency with which drugs were being administered. So there were a few drugs for which instead of the dose recommendation there were frequency recommendations. Again, these only appeared if the prescriber started to order a drug for a patient with renal insufficiency and was ordering it to be delivered too often to the patient in the course of a day.

The third set of recommendations were for drugs which at particularly low levels of renal insufficiency should be avoided. And there were quite a few attempts during the course of the year that we tracked to actually try to order drugs that should have been avoided.

And finally, in order to calculate serum creatinine in the system, the underlying electronic medical record system needed a recent serum creatinine order and needed to have the weight of the patient actually in the system. And if one or the other of those were not present there was an alert to the clinician that the system could not make the calculation and that they should try to order a serum creatinine.

Once again, we're skipping very quickly through the outcome. In this situation we actually looked at the appropriateness of ordering for nursing home residents who had renal insufficiency. And this time around we saw somewhat better results. In the intervention unit the orders were correct 63 percent of the time. And in the control units they were only correct 52 percent of the time. So this time we had a rate ratio of 1.2 and this one was a statistically significant finding. It's also an apparently substantial finding in addition to just being statistically significant. So we actually did see an improvement.

So this time around, we said clinical decision support for physicians prescribing medications for nursing home residents with renal insufficiency can improve the quality of prescribing decisions. Once again we asked why. Why this one worked and the other one didn't.

Well first of all, it is pretty much universally recognized by providers caring for patients in this setting that it's difficult to determine correct prescribing for patients with renal insufficiency. Secondly, the prescribing demands a lot of detailed patient's specific information and it demands a lot of very specific dosing recommendations. Collecting that information and then doing the calculations to come up with the correct dosing is much more easily done by a computer than by a human, exactly the kind of task we all want to hand off to a computer system.

Thirdly, the alerts that were presented were highly specific and they were always relevant. They were never general "oh this patient has renal insufficiency, maybe you should think about what you're doing with the dose." These were actually situations where the dose that was being ordered was outside the range of what would be considered by the recommendations to be appropriate given the exact renal impairment level.

And then finally, we're asking ourselves this as we go ahead and do other studies in other settings, are we setting the bar at a more appropriate level? This time around we were looking at the quality of prescribing. We were looking at errors. In the first study we were looking at adverse drug events. And I think a lot of us who are looking at HIT are really wondering whether being able to define ourselves based on the extent to which we can lead to more appropriate behavior on the part of prescribers is an acceptable endpoint, rather than actually being able to track adverse drug events, which fortunately are a lot more rare than errors and are extremely time-consuming and expensive to do a really good job of tracking. So we're not sure whether the errors that we managed to reduce in this last study actually prevented adverse drug events or not. But at least we know that the quality of prescribing was improved.

Now, so many of you are more familiar with the ambulatory setting than the nursing home setting so we also wanted to present a little bit of information on adverse drug events among older adults in the ambulatory setting. In this study we tracked a little over 30,000 older Medicare enrollees who were being cared for in a large multi-specialty group practice. We followed them for one year and we used a host of different approaches for trying to identify every adverse drug event that happened to any of these individuals over the course of a year. If you're interested in doing this yourself, we have a paper about all the different methods and how well they did or didn't succeed in finding the events.

Over the course of the one year, first of all, we saw 45.1 adverse drug events per thousand person-years. So if you were working with an ambulatory care practice that had 1000 elderly patients that you were tracking for a year and you found something similar to what we saw, you'd see just over 45 adverse drug events during the year. Fortunately,

the preventable adverse drug events we saw were somewhat less; they were 13.6 per 1000 person-years.

Again, we extrapolated these to the total Medicare population who were 65 and older at that time, and we estimated there would be just under 1-1/2 million adverse drug events per year. And of those, over 400,000 of them would be preventable. We also state that we think this is an underestimate. First of all it's very difficult to track down every possible adverse drug event and we may well have missed some. And secondly the kind of multi-specialty group practice that's willing to allow you to do this much probing into every possible error that might have happened during the year is an unusual group and is probably providing even better care than the groups that would have not have allowed us to do this.

A couple of important issues. So once again, we looked at the stages in which the errors occurred. And indeed we did locate some patient errors but the majority of the events were related to either monitoring or prescribing errors. This is going to sound familiar to you. Very similar to what we found in the nursing home settings and it's similar to what some of our colleagues have found in the hospital setting. The kinds of errors that people like to focus on if they haven't tried to look at it from this perspective tend to be the really easy HIT errors and they frequently don't turn out to be the ones that tend to lead to adverse drug events.

A little bit more detail on this. We looked deeper into the kinds of errors that led to the serious preventable adverse drug events. And looking at a more specific level, once again inadequate monitoring led the pack and failure to act on monitoring, situations where there were either actual lab reports that were out of range or there were reports by the patients of symptoms that should have been acted upon and weren't. There were also a fairly substantial number that were related to excess dosing given the patient's circumstances. There were not very many of the sort of easy HIT areas like known allergies, where an easy HIT intervention could have been set up. And not very many for drug interactions, which again is fairly easy to structure into a health information technology system. So this is giving us a very strong sense of what direction we really need to go in, in order to have an impact on these serious preventable adverse drug events.

Just real quickly, we also did an analysis of the cost related to these events and in this situation we were comparing the people around the adverse drug events to a comparable in each case a matched comparable patient. And we tracked during the pre-period what the cost differences were, what they were right through the period of the adverse drug event, and then what they were during the post period. And just as a quick summary, we found that the preventable adverse drug events, which once again were the more serious ones, the average cost difference between the people who had those events and those who didn't over that immediate time period was \$1,983. So that's a potential savings that could help to offset the cost of doing a health information technology intervention.

Just real quickly the implications that we see in this study for interventions, first of all, are that adverse drug events are common and they're often preventable. Secondly, that the types of errors that we saw suggest the interventions need to focus first on prescribing and monitoring. And finally, we had an AHRQ preparation grant in which we did fault-free analyses with teams of clinicians from this setting and there were a number of issues that they particularly highlighted in the fault-frees that tended to lead to some of the problems of the prescribing and monitoring. In particular, there were a lot of problems with the information flow to primary care physicians for their patients when they were discharged from hospitals and SNFs. Frequently these patients were on new meds that should have been monitored differently and the physicians did not know quickly enough that this had happened and weren't able to respond, so the patients did wind up with adverse events.

So at this point we are in the middle of several ambulatory HIT studies. The first one is looking at ambulatory medication reconciliation following hospital discharge. And we're almost finished with the data collection on that project so by next year at this time you'll be seeing the results. And secondly, we're also studying the use of health information technology to improve transitions of some of our really complex elderly patients when they leave skilled nursing facilities and go home. And the intervention for that one is underway and we'll be tracking levels for the next year.

Each one of these studies is including automatic notification to the primary care physician that the patient has been discharged; reminders to the provider's team of support staff about scheduling a quick visit to get the patient in to be seen; a list of the new medications that the patient is on now they've been discharged; a list about interactions with other drugs that the patient's taking; recommendations about dosing issues; and recommendations about lab monitoring of the new drugs that the patient is now on. So as I say, stay tuned and in the course of the next year we'll be putting together an estimate of whether this HIT-based study is actually improving both hospital-discharged patients and SNF-discharged patients. Ann?

ANGELA LAVANDEROS: Yes, thank you, Dr. Fields. And now we are going to hear from Dr. Kate Lapane, who is going to present her research on older adults' perception of issues related to medication and e-prescribing. She will also discuss tools that leverage health IT to improve patients under pharmacy care for older adults. So Dr. Lapane, the floor is yours.

DR. KATE LAPANE: Great, thank you very much. This presentation actually dovetails nicely with Jerry and Terry's presentation. In fact, a lot of the work that I've been doing has been stimulated by their groundbreaking work documenting the extent of the problem of medication errors and adverse drug events in ambulatory settings.

First some background, and this is - some of these bullet points are directly from Jerry and Terry's words. Important - why is it important to improve medication management in ambulatory settings? We know that outpatient office visits are highly likely to result in prescribing at least one medication. And we also know from previous research that 40 to

75 percent, a very large window of estimates, most of those don't take the medication as prescribed. And as Terry and Jerry told you the incidents of adverse drug events in ambulatory settings are non-trivial and the costs are high.

It's interesting because when I looked at those - and I can remember reading the study and thinking oh my gosh, this is really shocking and what do we do about it - I couldn't help but start to think about the role of health literacy and what's the patient's role in the occurrence of medication related problems. This slide, I know it's hard to read, but the basic point is that there are a lot of Americans who have below basic health literacy. And if you look at the last line, the people who are 65 and older, it's actually a greater proportion of people who have below basic or just basic health literacy levels.

And who's at risk below health literacy? Well, it's actually anyone in the U.S. regardless of age, race, education, income or social class. But in particular we often see that they're older adults, ethnic minority groups, people with low SES, immigrants as well as folks with chronic diseases tend to have, be more likely to have low health literacy. So when I started to think about what happens on a typical primary care visit and I started paying attention to my own primary care visits - I was shocked today by this article that came out in 2009 that shows the average duration of a typical primary care visit. We're talking between 21 and even out of (unintelligible) 25 minutes.

One thing that's of particular note is that other research not shown on this slide here is one that PCP's tend to spend less time with patients of racial ethnic minority groups. And that's not the same PCP giving more time to a white person than a black person. It's probably a function of the settings that people receive care. So what happens as a result? Physicians and other healthcare providers are only human and in that short amount of time it's likely that there's limited informed decision-making. A joint decision with patients, that must be very difficult to achieve. There's a lack of confirmation of patient understanding, often. And often there's an omission of discussions about adverse medication effects and costs because there's just not enough time.

In addition to looking and thinking about that time that's spent, you have to understand with older adults that there are many more problem area (inaudible at 0:38:45) that need to be addressed within the same amount of time because of home worker conditions and complex stress regiment. So this study that came out in 2006 shows that there's definitely room for improvement with respect to communication between patients and their providers.

Physicians in 26 percent they didn't mention the name of the medicine prescribed, 13 percent didn't talk about its purpose. This study, (inaudible at 0:39:11) shows that 1/3 did not mention how long to take the medication or what dose; 65 percent didn't mention adverse side effects. So where do they get this information? Often when we go to the pharmacy you'll get the leaflet for new prescriptions, and I know you can't read this and that's the point. But it is very detailed information and 1/3 of the patients don't read the leaflets for new prescriptions. So where are people getting their information?

The concern rises because the reading level of the average American is about the eighth or ninth grade and that's being generous I believe. The reading level of instructional materials about medication management is often geared at the 9th to the 14th grade. We know that up to 56 percent of Latinos are illiterate in English and low literacy does contribute to medication non-adherence. So here's the results from the study that was conducted a few years back.

And they looked at - well when you see this label, the prescription drug warning label Do Not Chew Or Crush, Swallow Whole, what is it that people think that means? And some folks said, "oh, chew it up so it'll dissolve." Others reported "oh don't swallow it whole or you might choke." And even a further theme was medication should be taken with plenty of water. So clearly we think we're communicating something with our words but for the illiterate populations they may be interpreting that very differently. Another example, a common label For External Use Only - why isn't it coming up - medicine will make you feel dizzy, or they thought that use extreme caution in how you take it. So, clearly a mismatch. And in this last one, Take Two Tablets Twice Daily, which seems to be pretty straightforward, 71 percent of illiterate persons correctly stated what that meant, but only 35 percent could correctly show the number of pills. So there's clearly a mismatch in how we give information and how it's received that can be contributing to medicine related problems and inherent issues.

This slide was a study that I'd done with student Jessica Jolpert. We were using the NHANES data, which is a nationally representative sample, and we just said okay, if we have alcohol interacted medications, what proportion of those people were reporting that they at least had one drink per month? And you can see here at the red bar that it's non-trivial. Again, just thinking about well what does this mean? When we think we're communicating information but it's not received what do we do about that?

So one of the studies that I going to talk to you about today we used qualitative methods to investigate in a racially and ethnically diverse sample of low-income older adults. We wanted to understand more about their attitudes and behaviors regarding medication management and we used qualitative exploratory focus groups. We had 11 focus groups with 105 participants. We used maximum variation purposeful stratified samples in the Boston, Rhode Island area reaching out to senior centers, senior housing and ethnic community centers in low income areas. So we were targeting participants who were over 65 and we engaged Spanish speaking Hispanic, non-Hispanic Black, and non-Hispanic White. We did have Spanish focus groups conducted in Spanish with Roberta Goldman, who was the (inaudible at 0:42:43.) Next slide.

So some of the results. We asked them first - one of the things we were trying to understand more about, what are the perceptions of physicians' knowledge of patient medication? We wanted to know what older adults believed. What we learned is that they overwhelmingly believed that the primary care physician is automatically and fully informed about prescriptions from multiple prescribers, even if no medication review is conducted in the office.

So they just thought, and here's some reflective quotes, "when you go to another specialist, they, the PCP and the specialist, communicate because you don't go to the specialist unless your primary care doctor tells you to." So there's this automatic assumption that if there was a computer in the office, then that somehow the primary care doctor can look at everything that was going on. And that's a dangerous assumption because then why would you tell your physician about your drugs taken if you think they already have that information?

Another theme that emerged was intentional non-adherence. We learned that the patients made varying yet concerted decisions about how they took their medications, which were often very different than what the doctor prescribed. One person told us, "Yeah I take it regularly. Monday, Wednesdays and Fridays. So I figure, you know, if I skip or didn't take it anytime that would probably harm me but as long as I keep taking it regularly that way I figure it's okay." So, the physician that's providing detailed clear, what they think are clear instructions, on how to adhere to the drug regimen, but patients would then go off, older adults would go off and make their own decisions about how to do that. We have heard quite frequently that "because I'm receiving so much medicine I was just so overwhelmed and said oh I'll drop that one." So they're just randomly picking ways to reduce the burden of a complex drug regimen. And we asked them "well do you tell your physician about these modifications?" And overwhelmingly they said no because the physician wouldn't like it. And I'm sure they were right. They also didn't seem to recognize the potential dangers in doing so. We'll go onto the next slide.

We asked them about physician-patient communication about medications, and only a minority of the participants mentioned that their doctor asked them specifically if they're having any problems with new medications. But when they did, they were happy to share all the information on the side effects or if they wanted to stop the medication. They commented that the primary care physicians rarely explained much to them about medications. And they claimed to have little understanding about why they were taking each specific drug, what the benefits were and what the dangers would be of skipping them. And no participant had reported discussing with their physician which medications were most important never to skip.

Ironically, when I wrote this project up with the grant application, I was thinking that the root cause of the problem was that the leaflets that you get from the pharmacy are written at too high of a level and that's why that may be contributing to adverse drug events. But what we learned was that the participants, most of them, said that they always read the prescription package inserts and they were a little upset that they found that was the first time they heard about potential side effects after filling the prescription and paying for it. And some reported that they decided at that point not to take the medication and they were irritated that they purchased it.

So, it was interesting because they would read it and they'd get scared because they really didn't understand the benefits of the medications and how to consider risks and benefits and how to talk to their physician about what they should do. So they did report wanting

more complete information but they recognized that their physicians are really busy and probably wasn't going to be the right person to give them that information.

Oops. What I do with the light? These data are from another AHRQ study where we were asking patients and their providers about communication on medication issues. And so we had four different questions. How frequently do you discuss the importance of medications with your patients or providers, depending on who we asked. So the blue bars shows the providers' perspectives and they were saying sometimes or most all of the times that they have discussed with their patients the importance of meds or the important or potential side effects. Or if - we asked do you think your patients would tell you if they didn't intend to buy the drug? Or do you think your patients would tell you if they don't want the drug? And each piece the providers overestimated the extent to which their patients would be forthcoming with that information.

So we wanted to think about well how could we improve the flow of communication, the sharing of information? I should say that I don't personally believe that health literacy is a function of an individual, meaning it's more characteristic of a dyad, a dialogue between a patient and a provider. If we think about that as being a problem of health literacy between the two, then you can broaden it up and think about well how can we use health IT to help get some right information in the hands of clinicians so that they can ask different questions that they may not think about asking if they assume the patients really understand the instructions and are adhering to their drug regimens.

And then also we thought that we could try to use health IT to create tools to empower patients to be active participants in their medication management. So with the physicians first, I'll talk a little bit about those. We're actually in the field right now with this study. A couple of years ago we were doing a study on e-prescribing standards and we had the opportunity to go into 90 different physician practices in 6 different states and observe 6 different software packages for e-prescribing.

And we asked the physicians and staff to fill out questionnaires and this speaks to the alert fatigue that Jerry and Terry were talking about. We said, well when you see those dose charts, what proportion of time do you override them? Never, sometimes, most of the time or always? And you can see for dose checks and drug-drug interaction, these are skipped over quite frequently. And when we talked to them about that in focus groups, because we get a mixed method design, the physicians told us they believed the interaction with alerts were beneficial to patient safety, they were highly regarded for drugs prescribed by other providers, they were - so in particular if you had patients that were seeing psychiatrists and the psychiatrists was trying to prescribe, they wanted to understand all the other drugs. So they found that of value knowing what other prescribers were prescribing while they were making decisions. But they thought that the number of trivial or unnecessary alerts were just overwhelming. And they recognized that because of the unnecessary volume of the warnings, the warnings themselves would get ignored. And they said, "Geez, it's one of the things that should be fixed somehow because right now this is the boy who's crying wolf, and nobody pays attention to any warnings."

So we tried to ask them how would you, what can we do to improve? And they came out with some concrete recommendations including removing drug-drug interaction alerts for drugs that the patients were no longer taking, so short courses of antibiotics; running the drug alerts against current drug regimens instead of entire medication histories, and they thought that would reduce the volume of warnings; and making the program more sensible and allow the providers to set their own levels of severity so they can have some say in how many alerts they get, in some ways prioritizing the interaction alerts to help units, help that would be really useful to them that wouldn't be ignored.

We also asked them what do you really want to know? We said some e-prescribing software has the capability of alerting the physician that the patient has not picked up a prescription. How useful do you think this information would be to your practice? And as you can see by the darker colored bars, many of them said "wow, that would be really useful. I'd want to know." Anecdotally I can tell you when they were first testing out the e-prescribing standards in the state of Rhode Island in 2003, that was one of the basic functionalities that needed to be turned off in the first week because the volume of alerts that the physicians were getting because their patients weren't picking up their prescriptions was really high. So this is non-trivial.

So what we tried to do in the software is use electronic medication test rate to - because we thought one of the areas that could be improved was incorporating adherence alerts into e-prescribing software. And we partnered with DrFirst on this one, and later now we're working with Furner. With DrFirst, what we, actually with any software, we wanted to make sure that the information we were trying to provide to the physicians would not take more clicks because that would just be - we know from our previous works that they're not going to go to it, they don't have time to go to it. So we worked with them kind of red light, green light, yellow light buttons to say for each drug that the patient's on, you can quickly just see by looking at the screen that we have an adherence alert of the red dot, which means that they're not compliant to the treatment regimen. And the ability to drill down, so if the physician did want to know what's going on, they can look at something like this where it would have their expected fill pattern and then their actual fill pattern.

And the idea would be that how does this technology - or if the physician knows what's going on and they can ask different questions of their patients, to say, okay - because when we talked to patients we asked them would you tell your physician, they said no, their physician wouldn't like it. But yet, the physician is thinking that they have all the knowledge. So we were hoping that we could use health IT to get the right information into the hands of the provider and that would start different conversations.

We did ask them in previous work, not in the study that's in the field right now, if the e-prescribing software did alert you to when patients didn't pick up prescriptions what would you do that would have serious consequences if not taken? What would you do? And most of them would call the patient. So, clearly they would want to act on it. I actually wondered how they would do that, how they would have time to do that given

that we know this is a big issue. On the slide to the right we asked, well how concerned are you about liability if you know a patient didn't pick up a prescription? And a non-trivial note, 25 percent or more said they were very concerned about liability issues. In focus groups, we said, listen I don't want to be a mother. At what point does this end, do we have to go chasing our patients to take their meds? So that study, we're actually in the field now so, again, next year we hope to have results from what we've done to improve triggers in the field, to improve communication of what patients are doing via using electronic history. That'll be next year; we're wrapping that up now.

I think I'll switch gears now and talk a little bit about another project that we're working on where we were trying to improve the value of e-prescribing by creating tools that use that information for the patients themselves. So a specific aim was to use health IT to develop personalized materials in English and Spanish to increase knowledge, self-efficacy in behaviors related to medication use. Again, we're looking, reaching out to older adults who are low-income, who spoke Spanish or English, and who have low health literacy levels. What we learned from our formative research we learned we had to consider readability issues in English and Spanish. I'm not a Spanish speaker. I learned that there's many different Spanish dialects. And so we worked hard to make sure that we were hitting the right demographic. We used the notes in our educational materials as well as testimonials. We used actors from different cultures rather than race-specific type educational materials. We went multi-cultural. We learned from our formative research that we need to include doctors in white coats, as well as to reinforce their participation in the healthcare team. We came up with this tagline that we repeated throughout our educational materials, We Need To Know and You Need To Know. We wanted to give this message that was clear that they were an active participant in their healthcare and that they couldn't assume that information was just being shared across these computer systems. I'm actually having a difficulty with my mouse. Could someone else move to the next slide for me? Thank you.

So what resulted, we came up with these DVDs, again because we're working with older adults who were low literate and a DVD is very small. We used color-coding to try to link the video materials to print materials. Large numbers, large print, very clear. Next slide.

Kind of again, this week, we took the stream of data and this is an example of an algorithm that we wrote for diabetes segmenting. So if you have diabetes, often patients would be on a statin, ACE-inhibitor-ARB, Solfunylurea, metformin, Insulin, anti-depressants, and they have heart failure as well. And so what we tried to do is to take that stream of information and create video segments that were relevant if you're on a drug or if you weren't because we wanted patients to - so maybe they stopped taking their statin because they didn't think it was important in diabetes. We wanted to give them a different message than if they were taking their statin. So often if they were on a medication we would have information targeted towards how to stay adherent, or what side effects may occur and how to talk to your doctor or when to talk to your doctor about things that were occurring. So we actually developed an algorithm for diabetes heart failure, sleep problems, insomnia, depression, general tips and filling pillboxes to

improve adherence. And each one of them would start with the basic, the active medication list in the EMR or with their medication history if the data stream was through short script.

Next slide. This is a screen shot, a slide shot of the equipment that's used to create them. It's basically an automated system so that we would get in a stream of data, it would run a computer program on it, and then throw it in here and it would create an individualized DVD that included content specific to an older person on a medication regimen. And the only thing that we have to add in is if the patient was Spanish speaking or English speaking because often that wasn't in the record. Next slide.

We decided we were very concerned about information overload so if you're working with a low literate population we decided to not have to give them more than three DVDs which included different information but showed the color-coding that we used because with each DVD, we had corresponding print materials. We also decided not to give them all the information at once but we scattered them about 7 to 10 days apart because too much information all at once is overwhelming. And we - all along the way with every decision we made we got feedback from focus groups and from interviews with patients. Next slide.

This is just each packet would come with print materials. The print materials were at fifth or sixth grade reading levels. These were in English and Spanish depending on what the patient spoke. Next slide.

So we ran through the protocol with 166 older adults. We ran - some of the results were linked with clinical settings in a clinical encounter. Others we worked with community health settings. We were concerned that the people we trying to reach the most may not have regularly attended the physician, so we wanted to make sure that we got some information out in the field. What we found, of the 166 folks who were in our study, our feasibility and pilot study, 68 percent reported that the DVDs were very helpful and 62 percent reported that they were very relevant to their lives. Now, granted, we have people who could have had diabetes for 20 years in this study so you have to keep that in mind when we interpret these data.

We were concerned about the length of DVDs. Ninety-five percent said it was just right, even though I think heart failure was 42 minutes long and we were very concerned about the length. But the way that the menu was, just like with a movie that you would get from Netflix, they have scenes, so a person could go back and watch a particular segment over and over again. Ninety-seven percent preferred to have the DVDs given to them spaced apart. They didn't want to be overwhelmed by too much information. Eighty-eight percent said they would've watched the shows if they were on TV, which kind of surprised me because I thought the tailored part or the individualized DVD would appeal to them, but I just think they were craved for information and I thought it would be useful in a broader format. Twelve percent watched the DVD with friends and twenty-eight percent watched it with family members. Fifty-one percent watched them only once, thirty-nine, almost forty percent watched them twice, and other people watched them

more than twice. Twenty-five percent shared the DVDs with their family members and eleven percent with friends. Next slide. Thank you.

In general, we found that through follow-up questionnaires, that there were changes in a positive direction for self-management including self-efficacy in reading labels, how they stored the medications and how they get help with their medications. So at a minimum, I feel that we taught them strategies and how to deal with complex drug regimens. After reviewing of the DVDs diabetes knowledge scores changed significantly and we experienced increase of knowledge with similar effects regardless of the language spoken, and we also had changes in sleep hygiene scores as well. And those results - with stronger effects than those who spoke Spanish relative to English speakers. Next slide.

So what we found overall we believe that we can use IT in creative ways to improve medication management for older adults in ambulatory care settings there. It's not reasonable to expect that all of this can happen in a 21 minute visit and that there are strategies to get the right information about both the benefits and the risks, evidence based information, delivered in a way to reach patients with low literacy levels and that is well received by older adults. We also believe that we can improve e-prescribing software, that improvements are made. And if we can get the physicians more information in an easy way about medication taking behaviors, what are the fill patterns, are they filling the prescriptions for the drug regimens the physicians think their patients are on. And it's absolutely possible to use IT to educate older adults about the anticipated beneficial effects of medication, how to effectively communicate with their clinicians, and what their role is in their healthcare. Again, emphasizing we need to know and you need to know. Thank you.

ANGELA LAVANDEROS: Thank you, Dr. Lapane. So at this time we're going to move into a Q&A session. I just want to use this time to remind the audience that they can submit questions using the Questions tab. And I think I will begin with our first question. I'm going to Terry and Jerry, how do you decide that an adverse event was caused by an error in handling a medication rather than the deteriorating condition of a patient?

DR. JERRY GURWITZ: I think that's a good question. We reviewed adverse drug events using an approach called implicit review. We did not have explicit criteria in characterizing these events, so it required that two physicians independently assess the event and make an independent decision. Clearly these two things can't be intertwined so there had to be some level of judgment, clinical judgment, about what was going on. However, both physician reviewers in the end had to decide that an error had occurred in management and they had to characterize the error quite explicitly. So if they disagreed they needed to meet and reach consensus. So that was the process we used. It's a process that is not ideal, but it is the process that has been the gold standard in many of the studies that all of us have seen reported in the literature related to the epidemiology of adverse drug events. Terry, do have any comments about this?

DR. TERRY FIELD: No, just that as Jerry mentioned we were extremely specific. Once one of the reviewers said that there was an error that underlaid the event, they had to fill

out three pages worth of additional information about the error that they perceived. And I think at that point it really required them to think it through pretty thoroughly. After doing this for a while, we usually find that physician pairs become pretty attuned to using the tool and we find very high agreement particularly on whether something was an adverse drug event and whether it was preventable. Sometimes there are some issues about trying to detail the level of severity but the preventability and the existence of an event are very, very highly correlated across the two physicians.

ANGELA LAVANDEROS: Thank you. Next question that comes in is for Dr. Lapane. How did you distribute DVD materials 7 to 10, and I think they mean weeks apart. Did the patient have to return to the health provider's office to pick up the materials or were they mailed or some other method?

DR. KATE LAPANE: Hi that's a great question. They were 7 to 10 days apart, and we mailed them directly to their homes.

ANGELA LAVANDEROS: Thank you. Okay, back to Jerry and Terry. Have there been any negative impacts of the decision support systems that you tested?

DR. JERRY GURWITZ: We have not been directly tracking any adverse consequences of the decision support systems we've implemented. We know that this has been an important issue but we haven't proactively tracked. We have - one thing we do, though, is at the end of the study, we have asked the physicians whether they want to keep the clinical decision support going or not, and - excuse me there's a phone ringing - and almost all of them want to keep it going. But we have not tracked the unintended or adverse consequences of what we've done.

ANGELA LAVANDEROS: Terry did you want to add anything to that?

DR. JERRY GURWITZ: Terry did you have anything to add? The adverse...

DR. TERRY FIELD: No, the only thing to add, Jerry really mentioned it but it really frankly surprised us with the first computer decision support system that we described in the nursing home study that was not effective in lowering adverse drug events, we really were struck that they decided to keep it. We thought they probably were sick and tired of getting the alerts and that this was probably an alert fatigue problem. So we were really stunned when they decided, they voted almost unanimously to keep it running. It was just, it was not what we had expected.

ANGELA LAVANDEROS: Right, okay. How about, again for Terry and Jerry, what has been the reactions of the physicians in the facilities where you have tested these interventions?

DR. TERRY FIELD: Basically so far it's, we get very positive reactions. I will tell you when we did the fault-free analyses in the ambulatory setting, we hit my favorite quote, which is the one that we're really trying to take very seriously with everything else we

do. One of the physicians said to me, “don’t tell me what to do. Just help me get it done.” And as long as we focus in that direction instead of just trying to tell people what to do, and always try to find some way to ensure that they can easily act on anything that’s being suggested, and that we’ve actually made their lives a little bit easier instead of a little bit more complicated, we are hoping we will not get any extremely negative feedback from the group. So far, we have not heard any complaints. I will say in one of the nursing homes when CPOE first went in, we had one physician who held out for months before he was willing to use it. But he eventually came around and became very comfortable with it over the year that we were tracking things.

ANGELA LAVANDEROS: Great. Another question for Dr. Lapane. Were home health providers or other members of the care team included in your medication education strategy?

DR. KATE LAPANE: Well, in rolling out the study, we were working with clinics and we didn’t reach out to home healthcare providers but that’s certainly an avenue we could do in a future research. However, I did want to say that we used, with all of our educational videos, we really tried to incorporate as part of the message that you have a healthcare team and the team members include physicians, nurses, the pharmacist, dieticians. We were very inclusive. And we had different perspectives and different healthcare providers actually on these videos giving information to reinforce that notion that you interact with a healthcare team and that includes many people not just the physician. But the most important person was them. You are the captain of the healthcare team. So I do like that idea of working with home healthcare providers because I imagine that they are facing the same type of challenges where they’re trying to educate patients but have limited time to get through everything that needs to happen. So I do like that idea.

ANGELA LAVANDEROS: Okay. So it’s about 3:45 pm, Eastern Standard Time. At this point I show no other questions in the queue, so at this point I’d like to thank the presenters for their presentations today and the audience for joining us and I will turn this back over to the operator.

Operator: Thank you very much, Angela. On behalf of AHRQ, I’d like to thank all of you for joining us today. Please take a moment to fill out the survey that you should see up on your screen if you have not already done so. This helps AHRQ improve future webinars and we really appreciate that feedback. You will be receiving an e-mail with instructions for submitting your CME certificate. The instructions are also on the credit path at the top of the screen. This concludes today’s session. Thank you for joining us. If you’re listening over the phone to end this call you can simply hang up.

**END TRANSCRIPT**