National Action Plan for Adverse Drug Event Prevention Webinar Transcript

February 25, 2015

Laurie: The Quality Insights Quality Innovation Network team welcomes you to today's webinar - National Action Plan For Adverse Drug Event Prevention. My name is Laurie Fink and I am the communications specialist for the improving care coordination and quality initiative. Before we get things started I'd like to take a moment to review a few housekeeping items. First, all participants line has been muted and will remain in a listen only mode during the presentation. There will be a question answer session following the presentation.

So if you have any questions that come to mind during the session, please feel free to type them in the chat window which can be found on the right hand of your screen and we will address it during the Q&A session. We would prefer that you use the chat feature rather than the Q&A feature as this will allow us to more accurately track your questions. Please note that this webinar is being recorded and the recording along with the copy of the presentation slides will be posted on the Quality Insights website within the next week. You should have already received a copy of the slide deck via e-mail this morning. If for some reason you did not, the presentation slides like I just mentioned will be posted on the Quality Insights website along with the webinar recording at **www.qualityinsights-qin.org.** Both resources can be found under the events tab as an archived event.

Today's presenter is Quality Insight Adverse Drug Event Network task lead Nicole Skyer-Brandwene. Nicole is a pharmacist with a background in long term care and ambulatory care. Nicole has been leading mediation safety projects for the past 6 years and is here today to talk about adverse drug event prevention. So, without further ado, I will hand things over to Nicole.

Nicole: Thank you Laurie for that great introduction. I am very excited because I understand there are quite a few people on the line with us today. I have a little bit of a cold so hopefully that won't interfere with the presentation too much. I just wanted to give a quick review of who we are for those that may not be familiar with Quality Insights, you may be familiar with the QIO, our quality improvement organization program that has operated in individual states for almost 30 years and we are healthcare consultants that do quality improvement work in areas of healthcare in our states for example working on reducing hospital readmissions and reducing infections in the hospital setting or the nursing home setting. The structure of the program has recently changed and we are now part of a quality improvement network which is a 5 state region where we can now not only work within just the state of New Jersey but as the Quality Insights Quality Innovation Network we can work across the 5 states that have partnered together. And those states are New Jersey, Pennsylvania, Delaware, West Virginia and Louisiana.

So before we get into the content of the presentation we have a polling question, our first of a

few. We would like to get a sense of who is on the call today, so please enter your response in the polling box on the right of your screen and please make sure to click the submit button on the bottom of the polling box on the right. Just review what the question says for those that may not be in front of a computer we would like to know who is with us today so we are asking "I am a pharmacist, pharmacy technician, nurse or nurse practitioner, physician, physicians assistant, administrator or other".

So we will just give a little bit of time for people to get an opportunity to respond and then we will post the results and see who we have on call with us today.

Laurie: Nicole, I will just read the results to you. Looks like we have 15% pharmacists, 1% pharmacy technician, 44% are attendees or nurses or nurse practitioners, 2% are physician, we have no physicians assistants, we have 7 administrators and 11 that selected other.

Nicole: Okay, so the majority of the people on the call today are nurses. So I am very excited about that because those are the people that are on the front lines of health care along with the rest of us the pharmacist and physicians and I am excited that we have a couple of pharmacy technicians on because the role of pharmacy technicians is expanding so much and pharmacy technicians are getting involved in care transitions and care coordination and medicine reconciliation.

So I guess at this point we can now move on to the actual content of the presentation and we are here today to talk a little bit about the National Action Plan for Adverse Drug Event Prevention. This is a report that was released by the Department of Health and Human Services last August. It was developed by a federal interagency work group to address issues of preventable harm related to high risk medication. On the bottom of the slide you can see a weblink that will take you directly to the full report, it is free to download and view. We're also going to try to put in the chat box the link as well. One of my colleagues is helping us put something in the chat so hopefully you should see a link in the chat box as well.

Okay, so what is an adverse drug event or an ADE? One definition that is commonly used in a healthcare setting is an injury resulting from medical intervention related to a drug. This definition originally comes from the Landmark Institute of Medicines report "To err is human - Building A Safer Health System" from back in 2000. How common are ADEs? Well we have highlighted here and you are probably familiar with these statistics, you have probably seen them before from some Landmark government reports and studies, ADEs can occur in any health setting and one study shows that ADEs were the cause of one third of all hospital related adverse events. Another showed that they caused an estimated one million emergency department visits and 125,000 hospital admissions each year. The likelihood increases during transitions of care. In one study two thirds of complications within 3 weeks of a hospital discharge were related to adverse drug event. And this is a scene that you will see repeated throughout the course of this discussion where transitions of care and events that occur or breakdowns during coordination or the long term care setting are often an area where events

can occur. But the good news is it is also an area where we are working with the communities in our states to put in intervention so that we can have an impact and improve.

So what drugs cause ADEs? Well there was a Landmark study a few years back by Dr Dan Budnitz and he did an analysis of emergency department visits for outpatient adverse drug events. And this study really highlighted the role that a few select high risk drug categories play in the majority of serious outpatient events that lead to health care utilization. His study anticoagulants, insulins and opioid analgesics were most commonly associated with events and there were a couple things that were also high on the list that were not addressed in the action plan and those are antibiotics drugs.

So who is most vulnerable to events? Well additional research as well as follow up analysis by Dr. Budnitz shows that the elderly are particularly vulnerable and you can see on the slide ADEs often contribute to complicating an inpatient hospital stay, ADEs in older adults are two to three times more likely to have an ADE requiring healthcare utilization such as physician office visit or an ED visit and they are 7 times more likely to have an ADE requiring hospital admission, so that's pretty significant. So why do the action plan choose to focus on the three drug classes that we mentioned? Well it is found that anticoagulants, diabetes agents and opioids caused ADEs that (a) account for the greatest number of measurable harms, ADEs associated with these drugs can be effectively measured and they are considered to be largely preventable. So the action plan currently does not address illicit or recreational use of drugs, drug withdrawal or use of drugs for intentional self harm. It is focusing on that medically used definition that we talked about in the beginning of the presentation but they may expand their focus into these areas in future report. Just keep that in mind.

So one of the things that the action plan does is it identifies 3 areas of focus – surveillance, prevention and incentives and oversight. So let's just take a look at ADE surveillance for a second. You know the action plan identifies existing programs that support ADE prevention but acknowledges that no current program is comprehensive enough in its current form and therefore more work must be done to improve how we can prevent ADEs and how we can monitor for them. So the action plan also distinguishes between active surveillance and passive surveillance. Active surveillance is proactively collecting information on the health condition it is usually limited to a specific setting such as the hospital, and don't worry there won't be a test on what all these abbreviations on the slide mean later but if you could just look at the active box on the left for a second you see on the bottom bullet the NEISS CADES data set, well that is a data set of information that is extracted from electronic health records. It's a small sample size but that is actually the data set that the Dan Budnitz study we mentioned used for his research. And then in passive surveillance most of us are probably familiar with what used to be referred to as the FDA Medwatch system and it is now called FDA FARES, Federal Adverse Event Reporting System and that's a voluntary reporting system and that was really set up to have pharmaceutical companies and healthcare professionals have a mechanism for reporting severe and rare adverse drug events associated with prescription medication after they come on to the market. But they would be a post marketing methodology of surveillance so it's a little bit different than the kind of ADE screening and surveillance that the action plan is talking about.

So what does the action plan say about prevention? Well it identifies different factors that can lead to adverse drug events, approximate factors which are usually more patient and provider driven, things like poly pharmacy or inappropriate monitoring and then latent factors which are more systemic organizational things that may be a little bit more difficult to recognize or change such as limited time for patient counseling or look alike packaging of medications, maybe a little bit more difficult to change readily. One of the things that action plan stresses is the value of performing root cause analysis to investigate factors that contribute to ADEs and that is actually where Quality Insights comes in because that's one of the things that we do. For example in the communities that we work with on care transition and reducing hospital readmissions, we have root cause analysis tools that hospitals can use where they can identify the causes of re-admission. And we've actually recently modified those tools to include medications specific elements to address issues related to the high risk medications and those tools are actually available on our website. So hopefully we are getting those links up in the chat but if not then we can certainly send those along to you after the webinar is over.

Ok let's just talk a moment about incentives and oversights. There are many existing quality measures from various organizations that can have an impact on ADEs, but most all address ADEs directly or they may encompass other things besides just drug related events such as sentinel events or xx serious medical errors that hospitals report. ADEs are included as one type but other events are included in sentinel events as well. Long term care regulations touch on drug safety issues by looking for unnecessary drugs and drug interaction and things like that but they encompass more than just screening for specific ADEs. And then you know there are other programs that address medication safety in different areas.

And how it's time for our second polling question, so now that we have talked a little bit about ADEs, I would like to get a sense of what is happening in the field there. So again please click on your response on the right and make sure to hit the submit button on the bottom and the question is "My practice setting routinely monitors adverse drug event rates for one or more of the three high risk categories, yes or no". And again we will give you a little bit of time, if we have the functionality to post the results we will, if not then Laurie will just read them off as she did so well the first time.

Laurie: Okay, looks like we had 67 people respond yes to that question and 25 answered no.

Nicole: Okay thank you Laurie. I am excited that the majority have answered yes and I would encourage those who have answered yes to participate in the discussion that we will be having very shortly once my formal part of this presentation is over and let us know what you are doing and how you're doing it because it is not easy to track data and to gather that sort of data. So those who answered no we would love to hear feedback as to you know why, is it due to lack of resources or that sort of thing or other barriers and we would love to hear more about that as well to see if there is any way we can help that. I see the results have been posted that's wonderful so hopefully everybody that's on the computer can now see the polling results themselves as well.

Okay so not long after the action plan was actually released there was an in person one day conference held in Washington DC where many leaders in the field of drug safety participated and spoke and shared best practices. Parts of that were broadcast live on the day of the event but fortunately the full slide decks from that conference is now available for free online through the **healthcare.gov** website. And you can see the weblink on the bottom of the slide right in front of you and we are going to also try and get it up in the chat if we can because sometimes you can't click directly from a slide deck but you will be able to click it from the chat if you wanted to take a look at it. So let's talk a little bit about what came out of that conference and we are going to look at anticoagulants first.

Nicole: So we will go through the highlights of the discussion on the 3 drug classes looking at anticoagulants first. So the speakers highlighted some recommendations for supporting anticoagulants safety in the 4 areas that you see listed above on the slide. So better surveillance to understand the scope of the impact of the problem is one of the things that was discussed using evidence based prevention tools. They recommended supporting development and uptake of optimal anticoagulation management strategies and here is that seen again especially during care transition and in long term care. We will talk in a moment about what we mean by optimizing anticoagulation management, incentivizing optimal anticoagulation management and there is some technologies out there that are used more than others you know as a point of care INR testing, home INR testing and these things are actually covered by Medicare but there are some barriers to that coverage that have hindered in the past to wide spread uptake of that use. And also the new oral anticoagulants, much more research is needed to guide the real world management of those drugs, again we are going to talk about those in a moment.

The overarching message of that conference was that to take a similar approach to anticoagulants to what we have done with antibiotics. We are very comfortable and familiar with antibiotic stewardship programs now and they recommended taking that model and applying it to anticoagulants to have anticoagulant stewardship, that health system should be anticoagulant centers of excellence. And they recommended provider education and using wherever possible guidelines, tools and protocols to guide the safe use of anticoagulants in general. And again this is an example of where Quality Insights comes in because Quality Insights for example we provide a lot of tools and resources and one of the things that we have developed is an oral anticoagulant medication guide which is detailed guide it includes Warfarin and the new oral anticoagulants and its kinds, dosing, dose adjustment, bridging in the periprocedural period things like that. It also has tools in there that can be adapted to health care setting to communicate information about a present anticoagulation amongst, help the healthcare provider on the team and I am not posting a link to that because it is not yet available. There was a fourth new oral anticoagulants that was just recently FDA approved in the United States and I am in the process of adding that to the toolkit. So as soon as that is available we will send that out to make that available through the usual channels so be on the lookout for that. And you know they recommend as we said evidence based anticoagulant models such as anticoagulation clinics, and patient self-testing.

Incorporating anticoagulation management into chronic disease education programs. Chronic disease education programs do their general program that anyone with a chronic disease can participate in and then there are diabetes specific for diabetes, diabetes self-management education program that are just for people that are diabetic or pre diabetic and this is a great area where people that have these conditions can get support. It is emotional support and moral support but it is also education about how to manage their condition and participating in programs like that can educate people so that they will adhere better it their medication and possibly prevent unwanted events from medications. Again the Quality Insights Network is working throughout our 5 state region, we are setting up these diabetic and chronic disease programs, we are trained to lead those program, we are also training others to be leaders of those programs as well. So if that is an area that anyone on the line is interested in getting involved in please reach out during the discussion or after the call. Again the common theme repeated about better long term care or home care coordination of care across settings and again we have all these technologies but we can make it better, improving our electronic health system so that we can get real time data, link laboratory data and pharmacy data so that the health care providers and pharmacies can work as a team.

All right now let us just talk a moment about new non-Warfarin oral anticoagulant. Maybe some people that are on the call are old enough to remember a commercial from I don't even know when, it was for rotisserie chicken oven or something like that, it was one of those things you brought in the mail and the commercial was “you set it and you forget it”. Well unfortunately the NOACs are not set it and forget it drugs. They have potential great benefits, they in some cases may actually be more effective than Warfarin in doing their job in the right person but they also may in certain cases have a greater risk of bleeding attached to them and there is one recent study that’s on the slide which points to that and patients that are on the new oral anticoagulants may not get INR monitoring. But there are still a lot of monitoring and lot of management that needs to go along with that that's no different than traditional Warfarin. Most of these drugs are renally excreted, so they need to be dosed appropriately based on renal function, they still need to be managed appropriately around if the person is having surgical procedure, adherence is a huge issue with them because of the short half life.

There are some drug interactions with the new oral anticoagulants, not as much as Warfarin but still some that maybe significant and need to be managed. So the messaging from the experts at the conference was that patients can benefit from anticoagulation management services just as people on Warfarin can and again using tools and guidelines for drug selection and dosing etc, and all the things that I mentioned. And then they also talked about some developing areas of research such as the potential for laboratory assays to monitor those drugs in the future the same way that we do with Warfarin now and developing protocols for management of bleeding events and reversal of the drugs affect if and well when reversal agents become available and then research into identifying potential pharmacogenomic issues with those drugs.

Okay so moving on to diabetes now, again just quickly going over those 4 areas, 4 domains that were discussed, the overarching message was hypoglycemia, hypoglycemic events are the

biggest problem when it comes to adverse drug events related to diabetes drugs. Improving surveillance for hypoglycemia is key, understanding risk factors for those events, and again using evidence based educational tools to prevent hypoglycemia, collaboration amongst health care professionals and again they recommended drive those diabetes self-management programs that can help empower people and get them educated so that they can better manage themselves before happen unwanted events. And you know glycosylated hemoglobin goals for older adults can be more conservative, not to over aggressively lower the HbA1c because that often when glycemia can come into play. And again I think we do this better with diabetes then we are at with Warfarin so far, we are more comfortable with using point of care technology and patient driven technology in the monitoring of diabetes but are we using that optimally, does that information on blood glucose that the person is monitoring linked to the pharmacy and linked to the doctor, can the two talk to each other, those sorts of things.

And again there's other recommendation out there about cautioning against lowering the haemoglobin A1c too low in older people with diabetes. If you are thinking about what kinds of interventions I can put in place to minimize hypoglycemia or minimize events associated with diabetes drugs, the literature shows us that there are 3 top predictors of hypoglycemia and those nutritional interruption, prior hypoglycemic events or inappropriate prescribing. And some of the recommendations on how to combat that are moving away from sliding scale insulin and using basal bolus insulin protocols instead, implementing nurse driven protocols for hypoglycemia management should it arise and of course coordinating meal time blood glucose testing, insulin administration and the administration of the actual meal. Now I am sure most of you can see how those 3 recommendations would probably be more easily implemented in an inpatient setting and manage in an inpatient setting but what happens in the outpatient setting, what happens in the long term care setting or assisted living, what happens in the community? Really it may be a little more difficult in those settings. So thinking about how you can carry over those in-patient interventions that we are already so familiar with, how we can move those over more into the community or the patient centered setting is you know one of the challenges that we see and that Quality Insights is working on with our communities that we are working with.

Okay and moving on to the final topic of opioids, you know the recognized at good outcome measures related to opioid ADEs are lacking. We have the prescription drug monitoring program which were regionally developed to help prevent drug diversion or drug overuse. One of the things they don't do is track drug use across settings and again it is more heed into diversion as opposed to error prevention or adverse drug event prevention. They recommend some models some of the existing programs that are out there that have worked and the Department of Defense and Veterans Administration has the opioid prescription protocol and guidelines that they use in their settings and patient education tools, how can some of those types of tools be adapted to other settings and the SAMHSA, which is the mental health organization, they have a very good opioid overdose prevention toolkit which addresses patient education, it addresses emergency responders and how they can help manage and there is a lot of good information in there as well.

Using prospective and retrospective drug utilization reviews of pharmacy claims, sharing data amongst pharmacies and again maximizing how health information technology works to make all these sharing and make this information accessible and make it happen. You know as we know opioid prescribing has sky rocketed in recent years and opioid overdose deaths has similarly increased. According to one study, the IMS health study, hydrocodone with acetaminophen is the number one prescribed generic drug in the US. According to an ABC news report from 2011 the US represents only 4.6% of the world population but consumes 80% of the world's opioids and 99% of the world's hydrocodone. Now assuming that these statistics are correct and you know I haven't independently verify that but I do trust the news, despite what's been going on lately you know these numbers are really staggering. So some of the recommendations in the action plan and again the action plan wasn't developed at least as of yet to address drug diversion and illicit drug use but I think a lot of the best practices and a lot of the interventions that can be used for opioid safety to prevent side effects and adverse events associated with them can also help with abuse and diversion as well such as you know some of the things listed or you know use surveillance to identify patients that are at risk for ADEs. Look at patterns of use that suggest overutilization, performing a behavioral health assessment prior to prescribing, developing metrics to identify high risk patients and prescribers, optimizing clinical decision support to guide the dosage of these drugs, improving the availability of safe opioid prescribing practices and patient education tools and you know again always promoting the patient centred team based coordinated approach to care.

So now we have our third and final polling question and again please answer on the right and do not forget to hit the submit button. "My practice setting as a protocol or best practice in place to prevent or manage adverse drug events for one or more of the 3 high risk categories, yes or no". I will give everybody a little bit of time to respond. And hopefully we will be able to display the results. I hope everybody has been enjoying the presentation so far and very shortly we are going to start to have a discussion. And I see that it is, I can't really read the percentages it is little hard for me to see it looks like it says about 60+% of people have answered yes that the practice setting is monitoring or has some best practices in place and about a third of people have answered no. So again very shortly we will be very excited to hear from some of you and share what you are doing or what you would like to do, about what you might need to make that happen.

Okay so moving on to the next slide, you know the real reason that we held this webinar and that we called everyone here today is not so I could read you my cliff notes from a report that you could very easily go on the website yourself and read it. It was really to create a call to action you know Quality Insights we are already working which communities throughout our 5 state region on improving care coordination, reducing readmissions and other areas of health care as I had mentioned and we are in the process of expanding our assistance, building new communities working with new communities and really the focus of our work is we would like to see that care coordination activities include efforts to reduce ADEs associated with these high risk drugs. You have to monitor rates of what is going on in your care setting or community to know it is really happening. We encourage communities to implement interventions to prevent ADEs and some examples of some of the things that you can do and some of the things

that we would like to work that we are already working with some of you on and we would like to work with more of you on is improving patient education, improving and increasing screening of patients for adverse drug events.

I just want to pause for a second what do I mean by improve increased screening patients for adverse drag events? Well last week last Thursday an organization called TMIT their website is safetyleaders.org and they actually have their own webinar on the national action plan and they went into much more detail than I have gone into today in to Warfarin and anticoagulation safety and it was actually the first in the series of 3 webinars. So I suspect in the upcoming ones they will be addressing diabetes drugs and opioids as well but one of the things that was raised in that discussion was how do you know if a person on Warfarin has not gotten their INR when they were supposed to, has not had that blood test when they were supposed to. So those are the people that are falling through the cracks and those are the people that would be at risk for having an adverse drug event if they are not caught. So if you have some kind of screening then those are the kinds of people that you can capture and those are the kinds of events that you can tap into and prevent things from going wrong. So that's one example of what screening can mean.

Collect and track data to monitor ADE rates over time. One of the things that Quality Insights is doing is you know we are in the process of developing very simple basic tools that communities and health systems can use to track what is going on with these certain drugs over time. And you know a lot of larger health systems may have clinical intervention software built into their EHRs where they can document. But it is important not only to document but then pull out the data and then take a look at trends to see what is going on. Another important aspect is involving pharmacy and pharmacists in the process of medication safety especially as part of the care coordination process. And just an example of one of the many good things that's happening in New Jersey is a lot of care coordination or care transitions efforts are starting to include pharmacists. A lot of hospitals are hiring care transition pharmacists so they are pulling from their existing staff to do some care transition activities and some examples of some of the things that those pharmacists do is not only doing medication reconciliation before the person leaves the hospital and making sure that the person has all the medications that they need before they go home from the hospital but also following up once they are back out in the community and sometimes it is telephonic by phone and doing a home medication reconciliation over the phone.

But other times in one group that we are working with the pharmacist is actually making 2 home visits after the person goes home from the hospital doing a medication reconciliation in that setting looking for side effects, looking for adverse drug events, making sure that other things that the person needs such as oxygen and things like that are in place in the home to prevent them from having adverse drug events and also prevent them from being readmitted for something that could have been avoided. And you know what we are starting to do and we would like to do is we want to develop multi-disciplinary groups that are working together to promote best practices and interventions across care settings because we have many different groups and many different organizations in New Jersey. We have got nurses on the line, we

have got physicians on the line, we have got pharmacists on the line, we have got administrators and everybody is doing a lot of really great things in their own setting. But wouldn't it be great if we were also talking to each other and sharing with one another the tools and the best practices and the things that have worked so that we can spread the impact even more.

So I think with that I am going to end the formal portion of the presentation. I keep talking about how we are working across our states as part of a network, so I would like to take a moment to introduce my counterparts in the Quality Insights region and all these individuals are on the line today. So if anybody is calling from Delaware let's say and has specific questions for Sally Jennings who would be the ADE contact in Delaware by all means don't hesitate to ask a state specific question and get to know who your state person is. And just because I want to be complete I want to go through the list of all my talented colleagues. Louisiana we have Chris Gatlin, New Jersey is myself, in Pennsylvania we have Christine Bernes and then in West Virginia we have Jill Aliff. So at this time we are going to start to take some questions that are coming in through the chat and we do prefer if you put the questions in the chat not in the Q&A, we may try to open the phone lines a little bit later on but since it is not an operator assisted call it will be difficult if we open 300 phone lines at one time. So we are going to address questions through the chat first and then time permitting we will try to open the lines later on.

But while you are thinking about what questions you may have you will see posted on the slide information about some upcoming events that we have scheduled. We have a series of seminars scheduled on Alzheimer's disease and related dementias which is something that was put together by our West Virginia staff and is being made available throughout our whole region. I strongly urge you to participate in that as well and we are planning upcoming events maybe webinar, maybe another format of event related to the other drug classes we mentioned such as anticoagulant and insulin safety. We don't have firm dates for those things yet but check your e-mail, check your newsletters from us or check out the events page on our website and stay up-to-date with when those things are happening as well. Ok so I will be happy to take questions now, Laurie would you like to take a look at some of the questions that have been coming in?

Laurie: Sure we did have one come in, it says “I am very interested in learning more about the diabetes related programs in Louisiana, I checked out the site that was provided in the chat link but did not find any resources for Louisiana, is there a different link for me to search”?

Nicole: Yes there is. I don't know exactly on our website where information would be, I know on the events page of the Quality Insights the website that is showing on the questions slide right now if you go to that website and you click on it and you click on events our calendar will come up and on that calendar all the scheduled events by state. So you will see diabetes class New Jersey, diabetes class West Virginia, diabetes class Louisiana, so if there are things currently scheduled in Louisiana they should be showing on there. If not we can certainly get back to you with that information and Chris Gatlin who is our ADE point of contact also happens to be

working with the diabetes project as well, so you can hopefully in the chat see her contact information and it was also on the slide deck.

Laurie: Ok the next question asks “Is there a state or national repository for reporting ADEs?”

Nicole: That's a very good question and the answer is to my knowledge there is not. There are a variety of different mechanisms by which ADEs are identified and evaluated. A couple of them were things we talked about during the presentation like the FDA FARES voluntary reporting system, the prescription drug monitoring programs, medication therapy management program which are usually driven by Medicare party insurers are looking for potential adverse drug events such as drug interaction and therapeutic duplications and working with patients to manage their medications so they may identify adverse drug events. There is also patient safety organization which are organizations that institutions can confidentially report events that occur to them so that they can do root cause analysis and identify causes or problems and then put interventions in place to improve safety. But there is no one unified repository or reporting place that goes across care settings or across institutions and that sort of thing.

Laurie: We do have another question, it asks “If a patient on warfarin has an INR that is “out of range” is it considered an adverse drug event?”

Nicole: That's a very good question and that is something that has actually it may vary depending on the project or depending on the setting but based on the definition of ADE in the national action plan my interpretation is no it is not an ADE so long as they have not had any symptoms associated with that INR such as bruising or bleeding or if it is elevated or clot, if it's too low that could be attributed to the out of range lab value. If an INR is out of range but there is no other symptoms that would be potential ADE. There is a potential that a bleed could occur if the INR is not connected, let's say.

Laurie: Our next question asks “On performing record reviews for ADE what is the first document of the medical record where the medication orders are reviewed?”

Nicole: I am not sure, we are talking about a hospital chart? I would say in the, well you know you have somewhere in the chart there is a list of the person's medications. Also there is the medication administration record where you know a nurse would sign when medications are given or denote electronically when medications are given. I don't know if that answers the question but I hope I’m getting close.

Laurie: Chris Gatlin, I unmuted your line if you wanted to add on to Nicole’s answer for that question.

Chris: Yes can you hear me?

Laurie: Yes.

Chris: Okay, great. It's been my experience that a lot of places that they look for is the admission order set to see if they are carried out in comparison to the medication order sheet. I know a lot of hospitals have moved to electronic medication records. So this is another place to look. The other thing is that a lot of hospitals will either use a 12 hour or a 24 hour chart review and this is where you can catch if there is an ADR or potential ADR that happens like the ICUs typically use at every 12 hours whenever they change shifts or lots of time it could be a 8 hour if they change shifts but this another place where you'd look in to see if orders that are signed or carried out or if there is discrepancies there. Also don't forget about the patient you know the patient has a lot of signs and symptoms that they tell you and this is another way to start you know the light bulb should go off you know "Hey probably an adverse drug event has happened based on the symptoms that the patient is reporting." Hope that helps your questioner.

Nicole: Thank you Chris.

Chris: Thank you ma'am.

Laurie: And Nicole I am going to go ahead and unmute all of our panelists so they can weigh in on these questions as well.

Nicole: Okay then since you are doing that then I would like to take the opportunity to give a shout out to a couple of people I know who are on the line today. I know that Ruth Marietta, the Vice President of the New Jersey pharmacists association has tuned in and I was just wondering if you had a comment Ruth at this time or a question.

Ruth: Yes, thank you Nicole, my comments are communication is key and engagement with the patient is so important especially when we are trying to prevent adverse drug events. I represent New Jersey Pharmacists Association, I am also a community pharmacist. I am passionate with my patients, I engage as much as I can with them. I call them up, I ask them how they are doing, I provide health test, I do blood pressure checks. During those times I take the opportunity to ask them about their medications and if they have any questions. We provide MTM services, we have demonstrations for insulin devices and inhalants. We check the PMP, we counsel patients as much as we can. I can't emphasize how important this is to the community and the health of our patients. Also last year New Jersey Pharmacists Association had performed a study on the impact of pharmacists in discharge planning and we found out that the pharmacist are utmost important in counseling patients on discharge. We had just to read off we looked at the group health cooperative in Washington State that gave us statistics that financial savings of 100 patients who received medical reconciliation was an estimated $35,000. Of the patients 80% had at least one medication discrepancy upon discharge. So it is very important in all settings in pharmacy what we do provide counseling to our patients and we gather that information to prevent adverse drug events. That's all I have for now, thank you.

Nicole: Thank you so much Ruth, we appreciate those very, very important comments. And we also have from the Ernest Mario School of Pharmacy at Rutgers University, Clinical faculty Dr.

Rolee **Das** is on with us as well and she is not only working with students in the School of Pharmacy, she is also in clinical position at St. Josephs Medical Centre in New Jersey. Don't want to put you on the spot but if you have got any particular comment to add or question or anything we would like to give you the opportunity to do that at this time.

Dr. Rolee: Thank you very much. It is actually very valuable presentation I think just to outline the preventative measures. I just also wanted to reiterate that we do at St. Joseph's Medical Center. I am involved in the monitoring adverse drug events for the hospital and I definitely see through the monthly monitoring of ADEs the potential for prevention through patient and provider education. So I think that patient education of course is key, also provider education you know as the nurses and the physicians and other prescribers and the pharmacists are kind of there when we are able to identify the opportunities and to reiterate the importance of following the guidelines and standards of care and as pharmacists we are kind of in a position to be able to iterate the impact of some of these events on patient quality of life. Whereas sometimes often hypoglycemic event is seen as a number by somebody who is not the bedside, nurse might be able to discuss with us, with the group the critical nature of that value and really draw attention to what we could do moving forward to not have another patient affected.

Nicole: Thank you. So what I am hearing is that patient and provider education can help prevent events and to look at the impact on the patient as well and how it impacts their quality of life and not just look at numbers. So all very insightful and very good advice. Thank you so much for commenting in today we really appreciate that because I don't think everyone wants to hear my nasally sniffly voice the whole time, so I am glad to have some other people charming in with their expertise. Laurie do we have any other questions through the chat or elsewhere that we can address at this time?

Laurie: Yes, we have another question, it asks "If I want to start an ADE project in my community who might be included on the team?"

Nicole: Well that's a good question and I guess it would depend on where the intended intervention is going to take place. If its health system or hospital based obviously the hospital would be involved but again if you are putting across setting intervention in place that is going to impact the patient as they go out of the hospital or into another care setting or home and into the community you want to have the hospital, the nursing home, pharmacy, social work is key. Other community based organizations that can provide support to the patient such as the area agency on ageing or home health can all play a role and you know one example is in New Jersey we have one care transition group that's doing an intervention in the Elizabeth, New Jersey area through Trinitas hospital and Holy Redeemer and they have RN health coaches on their team. They have care transition social worker, they are working with a local food bank to provide frozen meal deliveries to people when they go home from the hospital so that we know that they have food and then they are also putting in that care transition pharmacist piece where the pharmacist is going to be making not only telephone follow ups but home visits to the home as well. So that's one example of what a community team might look like.

Laurie: Okay another question asks “What would be some examples of interventions that have been implemented to reduce ADEs and how would pharmacy and pharmacists be involved?”

Nicole: Okay well I just give an example of how an intervention and how a pharmacist would be involved and what one of the things they are going to be doing as the study that Ruth Marietta from New Jersey Pharmacist Association quoted is they are going to be monitoring all the medication reconciliation errors or omissions that they see. They are also going to be monitoring any potential address adverse drug events and actual adverse drug event that they identify and tracking over time to hopefully see improvement. But other examples some of the things that we mentioned during the patient like eliminating sliding scale insulin, using optimizing anticoagulation monitor through anticoagulant clinics or self-monitoring or self-testing protocols for dosing of the new oral anticoagulants, Bell protocols for patients on opioids to prevent some of the side effects associated with opioid drugs. We of course worry so much about overdosing on opiates and respiratory depression and loss of consciousness and things like that but you know some of them more inconvenient day-to-day side effects of opioids such as constipation and bowel obstruction and things like that can be just as troublesome to the patient, require healthcare intervention and can be costly as well. So sometimes it could be a simple intervention like that that can help and some of the things that Christ Gatlin my colleague from Louisiana mentioned about ways to make sure that the medication order upon admission are carried out properly when the person moved into the health care setting and then again on the back end when a person goes out doing that same type of medication rec and then 24 hour review to make sure nothing was missed and that sort of thing.

Chris: Nicole this is Chris from Louisiana there was a question about asking about being proactive in Louisiana and I am sure this is true in other coastal communities. We have a high intake of seafood and in Louisiana there is a crawfish season where there is an increased consumption of this seafood and it’s high in Iodine which affects the patients who are on [indiscernible][0:58:01] and there PT and INR. So in recent years there has been articles in the newspaper that “Louisiana Cardiologist Gear Up For Crawfish Season” so proactively they educate the patient to watch your intake of seafood. So I am sure the same is true of other coastal communities.

Nicole: That's very interesting and it just goes to show you how an intervention can be very community specific and inland community may not have the same issue but I know here just in my own practice I have seen similar things with other foods like one patient in the outpatient clinic that I used to work in had trouble with their INR going down, couldn't figure out why and it was the end of the summer the beginning of the fall and we found out that the person who was an avid gardener and had grown lots of spinach and was eating spinach salads every single day. So again those education points are so important.

Laurie: We have another question “Can you give some examples of how to reach out to the pharmacy in the community to get them involved?”

Ruth: I can talk about that, this is Ruth Marietta. It is important to get involved in your state and local associations and even collaborate with some other associations like American Heart Association. Just become a little more involved in that that will help you in education and practicing and teaching your patients and community settings and hospital settings and wherever you practice and just apply whatever you can learn. I hope that answers the question.

Nicole: Thank you so much.

Laurie: That was great we do have one more question that just came in. “What are some examples of the symptoms that can actually be medication related events?”

Nicole: Okay that's a good question and that comes up a lot when we are monitoring adverse drug events and also looking at potential events. Well you know do I count this, do I count that, how do I know it’s from the drugs things like that but just in general some examples are things like falls, restlessness, confusion, loss of memory, constipation as we mentioned, sleep disorders, weight loss, bowel changes, incontinence, dizziness those are often symptoms that are often side effects of medications and can actually be caused by medications. But if you we overlook that and don't recognize that then we may look for another medical cause or layer on another drug to treat that symptom without realizing that it is actually drug that is causing that so we should modify the causative drug rather than adding on another agent. So those are some of the things that we look for and some of the things that we want to think about.

Laurie: Alright those are all the questions that have been entered into the chat feature if anybody has anything out state like to ask please type it in now.

Nicole: Okay while we are giving people just a last chance to type I just wanted to point out I don't know if all the participants can see it but in answer to the question about the diabetes self management programs that we spoke of earlier and particularly someone was asking about Louisiana if you go to the qualityinsights-qin website that's up on the screen now and you click on the initiatives tab and then go down to diabetes care you should get some more information about that and then again on our events page which looks like a calendar, all the currently scheduled programs are listed there but we are always adding more. So don't hesitate to reach out to your state contact and to get more information and in Louisiana it happens to be Chris Gatlin who is on the line with us today. And in some of the other state if you are not sure you should be able to find it on the website, if you are not sure who to reach out to you can always reach out to one of us and we will point you out in the right direction.

Laurie: Okay we did get another question and it asks “Is a package insert an expected side effect in ADE?”

Nicole: Can you read that again?

Laurie: Yes “Is a package insert expected side effect an ADE?”

Nicole: That's a good question, I would say yes, an event that occurs from the medical use of a drug would be considered an ADE but in the course of if you are monitoring, if you are trying to improve medication safety there are certain events associated with, particularly the high risk drugs that we have mentioned which are preventable and modifiable. You may not be able to prevent a rash or a headache from a drug which would be listed in package insert but when you are talking about the high risk medication some of these best practices and interventions in safety protocols we have been talking about for example with anticoagulation you can improve for a person on warfarin you can improve the time in the therapeutic range. You can educate them on drug interactions and dietary interactions and those can prevent adverse drug events. And in diabetes you can prevent hypoglycemia and you can educate on sick day management and even with other diabetic drugs you can do other dose correctly and educate to look for other side effects such as you know pancreatic issues and things like that. So I think if you are looking to reduce adverse drug events and you are looking to improve patient safety you are really going to want to look at those ADEs that are preventable and modifiable with proper clinical protocol and best practices. Yes all those things listed as package inserts may be considered as adverse drug event but they may not be predictable or modifiable some of those other things.

Laurie: Okay, I am not seeing any further questions being answered. So Nicole did you want me to open up the phone lines or how do you want to proceed?

Nicole: We do have till 3:15 before we get kicked off the phone line so to speak so yeah I will say let's go for it, let's open up the phone lines now and see if anybody wants to comment. Just remember that because all the lines will be open if you have got background noise where you are listening then we are going to hear that and it may be a little difficult to modify if you know a lot of people try to speak up at once but we will do the best we can because we do want to give people an opportunity to speak especially those people that may not be in front of the computer and may only be listening on the phone. So let's go for it and give it a try, if it gets really noisy folks we may have to try to cut you off. So we will do the best we can.

And while we are giving people moment to have the courage to speak Laurie why don't you let people know about the post webinar evaluation.

Laurie: Yes, there will be a very brief evaluation at the close of this session. We are asking that you all just take a brief moment to complete it. Your input helps us to plan future programming, so the evaluation will pop up on your screen when you close out of this session and there is only a couple of questions so if you could take a moment to answer those we would greatly appreciate it.

Chris: Nicole this is Chris again, I wanted to make a comment on something that Laurie posted about in case of an actual ADE most places use an incident report or an event reporting form and in legal documentation if you are in the hospital or nursing home and I worked risk management for a long time, you should never document that an incident report was

completed on blah blah blah. This makes it legally discoverable if somebody were to sue a hospital or an entity if you write that in a document then it opens the door for their whole incident reporting system which a lot of times they try to make anonymous to encourage reporting but it makes it discoverable. So for most people it is recommended that you just document what you observed or what you found or what you reported and then leave the entire incident reporting system as a separate entity and a separate reporting process.

Nicole: Thanks Chris for that comment I am hearing that a lot of people are starting to log off so I would like to get the evaluation up there.

Laurie: Okay that will only show up once the session ends.

Nicole: Okay I will give everybody one more minute to speak up or forever hold your peace and then we are going to let you evaluate us. I am not hearing anyone jump in so let's go ahead and get that evaluation up there. I want to thank everyone for participating today and listening in and our commenters and my colleagues across the 5 states and Dr. Das and Ruth Marietta thank you so much for your informed comments and we hope that you will join us again soon for the next program.