MLN Connects®

National Provider Call Transcript

**Centers for Medicare & Medicaid Services**
**National Partnership to Improve Dementia Care and QAPI**
**MLN Connects National Provider Call**
**Moderator: Leah Nguyen**
**December 1, 2015**
**1:30 p.m. ET**

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**Operator:** At this time, I'd like to welcome everyone to today's MLN Connects® National Provider Call. All lines will remain in a listen-only mode until the question-and-answer session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

I'll now turn the call over to Leah Nguyen. Thank you, you may begin.

## Announcements and Introduction

Leah Nguyen: I am Leah Nguyen from the Provider Communications Group here at CMS, and I am your moderator today. I'd like to welcome you to this MLN Connects National Provider Call on the National Partnership to Improve Dementia Care in Nursing Homes and Quality Assurance and Performance Improvement, or QAPI. MLN Connects Calls are part of the Medicare Learning Network®.

This call will focus on nursing home providers as well as transitions of care between acute and long-term settings. A physician will share approaches to effectively manage high risk medications and a pharmacist will discuss the importance of drug regimen reviews and medication reconciliation. Additionally, CMS subject matter experts will update you on the progress of the National Partnership and QAPI. A question-and-answer session will follow the presentation.

Before we begin, I have a few announcements. You should have received a link to the presentation for today's call in previous registration emails. If you have not already done so, please view or download the presentation from the following URL, www.cms.gov/npc. Again, that URL is www.cms.gov/npc. At the left side of the web page, select National Provider Calls and Events. Then, select the December 1st call from the list.

Second, this call is being recorded and transcribed. An audio recording and written transcript will be posted to the MLN Connects Call website. An announcement will be placed in the MLN Connects Provider eNews when these are available.

At this time, I would like to turn the call over to Debra Lyons, a nurse consultant within the Division of Nursing Homes at CMS.

## Presentation

Debra Lyons: Thanks Leah. Hello and welcome. My name is Debbie Lyons, and together with my colleague Cathy Lawrence, we lead the Division of Nursing Home efforts around quality assurance and performance improvement, as well as adverse events. We've teamed up with the partnership on these calls in order to spotlight the importance of the systems approach when working toward quality improvement in any area vital to resident quality of life, quality of care, and safety.

The work of the partnership in improving the care for residents with dementia exemplifies many QAPI best practices. Through these calls, we hope to highlight some of these best practices as well as other high risk issues, such as adverse events.

I'm going to share some feedback from our September call. But first, I wanted to mention that, as you know, the comment period for the Notice of Proposed Rulemaking, or NPRM, for the Reform Of The Nursing Home Requirements closed on October 14th. Almost 10,000 comments were received, indicating a lot of interest in the proposed rule. CMS is busy reviewing and addressing the comments, and we'd like to thank you for taking the time to read the NPRM and submit any comments. CMS has up to 3 years to publish a final rule. Although we do not expect to take that long, a more specific timeframe is not currently available.

And now, I'd like to share some of the feedback we've received following the last call. First, we want to thank you for taking the time to respond to our polling questions. We read each of your comments and use them to improve future calls. And as you know, feedback from the front line is an essential element of QAPI. First, in our last call there were 1,751 people registered, of which nearly all were directly related to nursing and skilled nursing facilities. There was an overall 91.1 percent satisfaction rate for that call, which exceeded the 84.1 average satisfaction rate for all of 2014. And we're pretty proud of that, and we'll continue to try to meet your satisfaction.

Overall themes were respondents found that the presenters were engaged and passionate about their topics, which really held participants' attention during the presentations. Respondents said they appreciated hearing the speakers' experiences as they implemented initiatives and provided examples of best practices. And this has been a common theme over the last two calls and so we will continue to strive to find presenters who can share their experiences in taking a systems approach to improving the care and services in their facilities and share their innovative approaches and successes in dementia care. Respondents also considered the call informative and right on target, giving them ideas to try in their facilities.

So again, we thank you for taking the time to share your feedback. I hope you'll find today's call informative and helpful, as our presenters will share information on the role of the medical director in the management of high risk medications and on the importance of the drug regimen review and medication reconciliation.

And again, we look forward to your feedback after today's presentations. And now, I'll turn it back over to Leah for a keypad polling question. Thank you.

## Keypad Polling

Leah Nguyen: Thank you Debra. At this time, we will pause for a few minutes to complete keypad polling so that CMS has an accurate count of the number of

participants on the line with us today. Please note there will be few moments of silence while we tabulate the results. Holley, we're ready to start polling.

**Operator**: CMS appreciates that you minimize the Government's teleconference expense by listening to these calls together using one phone line. At this time, please use your telephone keypad and enter the number of participants that are currently listening in. If you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If they are nine or more of you in the room, enter 9.

Again, if you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If they are nine or more of you in the room, enter 9.

Please hold while we complete the polling. Again, please continue to hold while tabulate the polling.

Thank you for you participation. I'd now like to turn the call back over to Leah Nguyen.

## Presentation Continued

Leah Nguyen: Thank you Holley. I will now turn the call over to Michelle Laughman, coordinator of the National Partnership to Improve Dementia Care at CMS.

Michelle Laughman: Good afternoon. I would like to introduce Dr. Susan Levy. She is a geriatrician and the current president-elect of AMDA, the Society for Post-Acute and Long-Term Care Medicine, and she is also a consultant with CMS. Dr. Levy will provide information about effective management of high risk medications.

Dr. Levy, I turn it over to you.

### Effective Management of High Risk Medications

Dr. Susan Levy: Thank you Michelle. I hope everyone can hear me. Again, thank you for allowing me to speak on this topic today. I think we're starting at slide number 5. So if people are following along with the slides, we're on slide number 5 is where I actually start.

Just want to review some of the objectives, learning objectives. We really want to talk about the role of the medical director and prescribers in medication management in the long-term care setting and focus a little bit on QAPI efforts. And then particularly, kind of drill down a little bit on the use of some of the high risk medications, particularly anticoagulants and antipsychotics as examples of high risk medications.

So to start with, since we really — I really wanted to focus on the role of the medical director is certainly reminding everybody that we have F501, which really summarizes the role of the medical director based on regulations. Really, basically summarizing that their role is to implement resident care policies and coordinate medical care in the facility. And so, certainly that encompasses the role in oversight of medication management within the facility and working with other team members in that process.

Certainly in CMS surveyor guidance reviews, the intent — to really indicate what the role of the medical director should be in the nursing home setting. And — but also recognizes that their roles are separate. We recognize that in many facilities, the medical director may also be the attending physician. But it's important that anyone in a nursing home understand that those two roles really are somewhat distinct, even though it may be the same individual, and that the roles of the medical director focus much more globally on the facility, whereas the attending focuses much more on the individual care of a resident in the nursing home.

Also want to refer you to AMDA, which has done a lot of work around the role of the medical director, and more recently the attending physician long-term care. And a few years ago we actually updated this, but certainly really recognizing the role of the medical director, their roles and responsibilities. And there are several functions and then many taps under each function that have been identified, and I can refer you certainly do the AMDA website for more details. But clearly, medication oversight and management would fall under both the administrative and quality assurance functions that are outlined.

Again, more recently, we've identified competencies for both attendings — and by attendings we also really feel that includes anyone who's got prescriptive authority, both nurse practitioners and physicians assistants, and various domains that are listed, certainly on your — on slide number 11.

Basically though, I wanted to summarize what we can expect from a prescriber, what they really should be doing when they prescribe any medication. And, you know, basically their prescription, their use of medication, should be evidence-based. They need to balance the risks and benefits and the potential of adverse outcome and all the basic rights that we know about drug prescribing in terms of the right drug, right dosage, the appropriate duration, and certainly, particularly in our setting, listing the accurate diagnosis or condition for which a medication is being used.

## Areas to Focus QAPI Efforts and What to Monitor

So what keeps us up at night, and we have here on slide 13, you know, certainly, our concerns about oversight of med. management related to various types of errors that can occur. And certainly, particularly our concern about adverse events, whether those are just transient or they are much more serious events that can result in hospitalization, permanent harm, or, unfortunately, sometimes even in death.

We've got F329, and frankly, I'm always telling people, really read F329. And if you read both the regulation and the guidance, there's a lot of excellent information there that can help guide your oversight of medication management facility. And so we know, and I don't need to repeat everything that F329 says, but certainly that's listed on slide 14 in terms of the summary.

So if you're trying to decide what to do regarding med. management, where to focus, there's a variety of things that you can look at. First of all, you can look at some of the current national initiatives that are ongoing. We've talked about the CMS National Partnership to Improve Dementia Care, and certainly, that may give you some focus on the use of psychoactive meds, particularly antipsychotics in patients with dementia.

There's a National Action Plan for Adverse Drug Events, which is encouraged focus on some other high risk categories of medications, one of which we're also going to talk about, which is the anticoagulants. And certainly, there's been a big focus recently on the need to have antibiotic stewardship programs for nursing homes, so antibiotic usage would be another area to focus.

And then, obviously, to look internally at what's happening in your own facility. When you're looking at how to see what you should be looking at, your quality assurance program. Have you had any bad events in your facility? Yours, or if you've heard of others and are concerned that it may occur in your facility, might be an area to focus on in terms of medication management. Certainly, if you've had any survey issues, findings from your drug regime reviews — and you should be looking at those and summarizing those and seeing trends and patterns. So all of these are different ways to focus your efforts.

You could also just look at the Triple Aim and look at the patient experience quality cost issues related to medications and make your decisions about what you want to focus on around that area.

I think everyone who's on the call probably is familiar with the OIG report that came out in February 2014 regarding concerns about adverse events in skilled nursing facilities. The summary of that report is actually on slide 19. And I think many of us are well familiar with these numbers at this point — that 22 percent were actual adverse events, 11 percent of what was identified in residents in this study were temporary harm events. And of all events that were identified in the SNF OIG report study, 59 percent were found to be clearly or likely preventable. The preventable events, two-thirds of those were probably related to medication usage, and I think that that's important for what we're talking about today.

The basic categories that they identified, you know, within the study for adverse events and temporary harm events centered around things related to patient care, which would have been, for example, you know, pressure ulcers as well as infections, which

we've certainly focused on, in addition to medication usage. So those are three big buckets that they identified for harm events in the SNF study.

You know, one of the important things about thinking about this is actually on slide 20 is that this was an incredible cost. So adverse events, in general, and certainly in particular, even adverse medication events, are very costly in terms of repeated hospitalizations, need for more treatment. So it's important that we also focus on these adverse events for these reasons, also.

As result of the OIG report, CMS had a response, which is a Call to Action ,and certainly as a result of that, has had — not only had a stakeholder event in Baltimore back in September of 2014 but also has had subsequent calls and efforts to look at this issue regarding adverse drug events. Well, just adverse events, in general, but also more particularly, adverse drug events. Again, I think many of you, as is on slide 22, are familiar with the memo that was released in July related to medication-related adverse events.

And then, associated with that, on slide 23, just a sample from the adverse trigger event — Adverse Drug Event Trigger Tool that's also — was proposed and was out for comment. Again, to focus surveyors and to develop specific survey around adverse drug events because of the importance of this as a patient safety issue in nursing home residents.

So let's talk a little bit about some of the specifics. We said we were going to talk about anticoagulants. And so, what do we mean by anticoagulants? Well, we often forget that aspirin are antiplatelet agents and, in fact, actually are anticoagulants. But most of our concerns are also around the use of warfarin, as well as the new oral anticoagulants, the NOACs. Although I think Nicki is going to introduce and share with you the new term since there no longer new, they've been out on the market for a while.

And certainly, these are medications that are — have a variety of different indications. And as the indications have expanded somewhat, we're seeing more and more patients in nursing homes on these agents. In particular, we get concerned when we have duplicative therapies, which may be appropriate, for example, combinations for periods of time of antiplatelet agents. And one of the oral anticoagulants may indeed be appropriate, but certainly, concerns about adverse effect are going to rise with using two different categories of medications.

So what about the oral anticoagulants we're talking about? If you will, we'll still use the word NOAC vs. warfarin. So, yes, both categories of drugs are effective for preventing strokes, for treating venous thromboembolism, as well preventing thromboembolism. We have concerns about safety with all of these medications, particularly concerns about bleeding.

And that safety can also be impacted by changes in renal function, particularly with the NOAC, if you will. With the drugs, different comorbidities. There's concerns with the NOAC, although this may be changing in the future of no reversal agent. And also with the NOAC, there's a concern that there's a short half-life. So in settings where we have issues with patients complying, that can be an issue in terms of the individual — if they are missing doses, no longer being adequately — or anticoagulated. Unlike with warfarin, with a longer half-life, where they still will have some protection, even if they miss a dose.

So the effect is lost more quickly than with warfarin. Also about anticoagulants, why are we so concerned? Well, we're particularly concerned because of obviously, the concerns about safety, but this got a lot of press back in July, with the article in the Washington Post that, I think, many individuals are certainly familiar with.

And in that article, what they did identify is what we've already talked about, is that anticoagulants, and in this case it included not just warfarin but also heparin and the newer anticoagulants, that data from the first quarter of 2015 shows there's — although there's a significant variation State to State and region to region, that there is a significant usage of these medications, and we know that they're associated with a lot of risk.

In one particular State, North Carolina, if you look at this in terms of the medications causing adverse events, we realize that Coumadin, in particular, for serious events, tends to be, you know, fairly high on the list there. And drug categories we've already talked about regarding adverse events, you know, certainly are listed as very high here. We know that insulin is problematic. And we know that our pain medications, the oxycodones, the hydrocodones, also create significant numbers of adverse events. So again, these are reasons to focus in your QAPI program on these different categories of medications.

OK, so F329. Again, a lot of information, F329, particularly about Coumadin, and really gives you some guidelines and some things that you should really be looking at in terms of your program of anticoagulation management within your facility. Certainly, it talks about the need to monitor your prothrombin time, and certainly monitoring for adverse consequences and the potential for drug interactions.

Also goes through, and I'm not going into detail, but really, it does specify in terms of citations the different severity levels, based on some of the findings that a State surveyor might see, based on the elevation in the INR, and certainly the adverse consequences, particularly the bleeding that an individual may have. So these are what you might need to be concerned about and certainly tracking to make sure that some of these things are not occurring on a regular basis within your facility.

Also, the fact is that it's not just about unnecessary medications where you may have a problem if you're not doing a good job around managing, particularly Coumadin, but all of your anticoagulants. Is you may need to be looking at citations around physician supervision, physician visits, and, of course, medical director oversight. As I've already mentioned, it really is the medical director's role to help the facility develop appropriate programs to oversee the use of particularly high risk medications, such as oral anticoagulants.

**Managing Anticoagulant Medication**

So what do we need to know about anticoagulants in terms of medication management? You know, basically this is true for any medication, but certainly here with anticoagulation, making sure that you have a diagnosis that warrants the therapy. Establish goals of therapy. For warfarin, where do you want the INR to be? Decide on which agent you're going to be using. Explain and document the risks and benefits in the medical record, and initiate monitoring to meet the goals and limit the risks.

So we should be looking at your drug interactions. You should be looking at your lab monitoring, including not just your INRs for Coumadin, but also for all your anticoagulants, some periodic monitoring of hemoglobin or hematocrit, which may indicate problems with occult, you know, occult bleeding.

So what should happen? And again, this is what you should be thinking about in your facility, is that you have a program where you have someone coordinate and oversee the use of anticoagulants in your facility to make sure that there's, you know, essentially almost no — a virtual anticoagulation clinic, since we know from the literature that patients who are followed in those types of settings, is they have a much more rigorous approach to their monitoring and oversight, actually do better in terms of their clinical outcomes and have less problems with adverse events.

So again, some of the other things you should see in your building is that you should be assessing risk. You should be assessing risk for — venous thromboembolism. And you should be doing that whenever the patient is transitioning from one level of care to another to see if they still need medication or if things have changed and either it needs to be started or discontinued.

We do know from some recent studies that chronic immobility alone long term does not require long-term anticoagulation. So you need to be really thinking about that in terms of venous thromboembolism prevention in your facility. One of the other big indicators for chronic long-term anticoagulation is atrial fibrillation. And so you should be determining whether your facility, you're using some type of stroke risk assessment tool.

And right now we're actually on slide 38, so hopefully, some of you are keeping up. The initial score that tended to be used a lot with the CHADS2 score, and then subsequently,

on slide 39, you have the CHA2DS2-VASc score, which actually adds some other indicators and is probably a little more sensitive in terms of predicting individuals that really are probably going to benefit most from full anticoagulation if they have atrial fibrillation.

And so, you should be determining whether at some point somebody with atrial fib. in your facility is having their risk for having a stroke assessed. And then the counterpart to that is also, are you evaluating their bleeding risk for using Coumadin?

So if you're using particularly warfarin on a long-term basis, these are examples of some of the risk-assessment tools. And I think Nicki is going to go into this in a little bit more detail, so I'm not going to talk about that much more.

The role of the medical director, I think that is hopefully already started to impress on you, is that the medical director really should be looking at the drug regimen review reports and identifying if there's any trends or patterns regarding the use of anticoagulants. Are patients' risks being assessed? Are their adverse events being assessed? Are the medications being used appropriately?

They should be meeting regularly with their pharmacy consultant and the director of nursing to talk about issues, particularly around anticoagulation management. Were there any issues relating to getting the blood test results back, getting the medication appropriately dosed, working with the pharmacy, nursing, and the prescribers to make sure that all of this works seamlessly and minimizes any risk to the patient. And certainly, should be reviewing all the policies and procedures in helping and providing input into those, not just responding to those passively.

And in terms of QAPI, I mean, again, a number of things that you can look at, including what's listed around the fourth thing down there on slide 42, which is the time in therapeutic range, which the expected standard for at least warfarin, is that the patient should be in therapeutic range probably at least 60 percent or more of the time. So you could really actually work with you consultant pharmacist and your lab and trend those results and see what happens there.

## Managing Antipsychotic Usage

We'll switch now a little bit of talk about antipsychotic usage and the CMS National Partnership to Improve Dementia Care. And I think most people on the call, or many people on the call, are familiar with, I think what have been really strong results in reducing antipsychotics since the initiative started and should really be happy, although I think there is more — certainly more work to do. I think the last report on the end shows that nationally, we're down from 18 percent, and we were almost in the mid-20s when the initiative started — so real significant improvement.

The next slide, which is slide 44, tells us a little of the reason why we're concerned is because, again, we identify that the risk/benefit ratio with utilizing these medications really had shifted. And that there is actual harm, and significant harm use — related to the use of antipsychotics with probably not that significant a benefit, and certainly not in all patients.

So what should be happening around antipsychotic usage in your facilities? What should the medical director's role be? Well, again, it's about communication and collaboration between the medical director, the prescribers, the consultant pharmacist, in this case, also the mental health provider, who may be available in the facility. You know, are they talking, meeting, and sharing data, just like you should do for other of potential high risk medications.

AMDA, I'm going to refer to again back when the partnership was initiated, really came out with a number of recommendations regarding the role of the medical director as related to dementia care. And again, this is not just about medication usage but also about improving dementia care in our facilities, which has a lot to do with better education of staff, better education of the prescribers regarding dementia care.

So we're at slide 47 now, and what I just wanted to point out is some of the things that you can be looking at it, and I'd be surprised if most people are not looking at antipsychotics at this point in our QAPI program. But besides just looking at the actual rate, you can be looking at other variables that improve your management of dementia as well as your utilization of many of these medications.

So you've been tracking your rate of gradual dose reduction, your success rate for that. You can be talking about some process indicators about — do you — have you really, you know, done what you needed to around getting consent — permission from family members or residents themselves about the usage of these medications? So a number of things that you can look at, a number of indicators for your QAPI program.

You know, some other things are, you know, looking at, you know, are you actually complying with the individualized care plans? That should be happening. Are the care plans truly individualized?

So, a number of things that you can look at, you can look at hospitalizations and emergency room transfers for problems of behavior. So you can also look at the resident-to-resident, resident-to-staff altercations — all of these can be tracked through your QAPI program. And you can also look at, as we mention on slide 49, the use of other medications, and look to make sure that you're not just shifting one drug to another for — just because you want to take them off an antipsychotic but you just replace it with another medication.

Another area that you can look at is your fall rate, since we know that most of these medications are associated with an increased risk of falls. And then certainly with falls, we're concerned about potential for injury.

## Medication Issues and Transitions of Care

And transitions — obviously, what we want to look at is issues that surround hospitalization. I think Nicki is going to talk some more about transitions. Are you really doing a thorough medication reconciliation? Are your discharge summaries being reviewed? Are we making sure that we're not missing any medications? And that can be a complicated process, and I think she's going to get into that a little bit more.

OK. I think you should be able to look at your facility and really have policies and procedures around transitions of care and your use of probably all medications, but certainly high risk medications. You should be able to identify who's doing the reconciliation, making sure that you're reconciling at some point both home medications, hospital medications, and the medications the patient's getting in the nursing home. And certainly, make sure yourselves when you're discharging patients to the community that you're again are doing a thorough medication reconciliation, and that that's part of your discharge process.

Some of the rules of thumb I've always had in terms of transitions of care: You should spend twice as much time discharging a resident as you do admitting them. And that frequently we're very hurried and rushed at the time of discharge and we don't take the time that's necessary to make sure that we certainly have an educated patient. We need to utilize the methods of teach-back, and we should do it once again just to make sure that everyone, both the family and the patient, understand. Make sure they have contact information and are able to have someone they can call if they have any questions about their medications, particularly high risk medications, such as Coumadin that the patient may go home on discharge and wanting to make sure that they are getting the appropriate followup and lab monitoring for that.

So with that, I guess it's time to turn this over to Nicki, Dr. Brandt.

## Drug Regimen Review and Medication Reconciliation

Dr. Nicole Brandt: Thanks Dr. Levy. Great job, and I really appreciate the setting the stage of high risk medications. So, I think we're on slide number 53 now, and talking about the importance of drug regimen review and medication reconciliation from a pharmacist's perspective. So I want to just get into basic learning objectives for everybody on the line, and just as noted, just understanding the roles and responsibilities of the pharmacist.

It's always a pleasure to work with physicians like Dr. Levy in the trenches, who really appreciate the interdisciplinary team. And you're going to hear from my presentation

the importance of the pharmacist on that team, because the medication regimens are becoming increasingly more complex.

And though we're focusing on high risk medications, it's imperative, as in the principles within F329, to look at all medications. So, we're going to talk a little bit about that. I'm going to talk also about the differences between medication regimen review, which is a mandatory service that's provided by pharmacists in the SNF nursing home setting, and differentiate that from the term medication reconciliation. Though there are some similarities, there are also very distinct differences. And then I'm going to talk about the application to a case.

So Dr. Levy, Susan, just went through a lot of information, but let's relate this to a case, and again, how that interprofessional team needs to work together, focusing on these high risk medications, such as anticoagulants and antipsychotics.

So, before we get into that, I want to kind of give a pictorial of the process. Oftentimes when I'm talking with family members and explaining to them the system, they don't really understand that there's not a pharmacy onsite necessarily. Most nursing homes don't have a pharmacy onsite. There are some exceptions to the rule, but they may not. They may not also be aware that there's not always a doctor onsite all the time, too. So understanding the medication use system, understanding the different providers at the setting is important. So you heard about the roles to the medical director, you heard about the roles of the attending physician.

Slide number 55 goes into kind of the various roles when it focuses on the medication use process. So, the first one is prescribing, obviously it's a prescriber, whether it's a nurse practitioner, a physician who's prescribing the medication, is evaluating the resident, and determining if meds are indeed needed. A lot of attention is being given to appropriate medication, and that's where it's important to look at the indication for use, the dose, the duration, and just as an aside, they've updated medication — potentially inappropriate medication list with the Beers criteria recently, which got additional attention with prescribing and potentially inappropriate meds.

So prescribing is a big domain, and looking at the quality of prescribing is important for a facility to be doing that on a regular basis. As Susan mentioned, not just focusing on these high risk medications but also the principles of antimicrobial stewardship, too.

The next thing is documenting and transcribing. You know, we know that we're evolving in the post-acute long-term care segment to more of an electronic media, and we know with transitions, whether it's transitions in care or transitions in systems, there's always the opportunity for potential for errors. So I think it's really important to look at your systems of how orders are being documented, how they're being transcribed, what kind of media are we using to, again, reduce medication errors, or potentially transcription errors, and then ultimately dispensing.

So dispensing. Oftentimes, the model is the pharmacy's offsite, medication is dispensed, then they're sent over to the facility. There may also be onsite emergency kits at the facility that also have to be overseen to ensure that they're being used appropriately. So dispensing of a medication, we hear of dispensing errors, something also we need to look at as well.

And the other thing is administering. We know that this is a big role of the nursing, as well as the nurse aides, and the other teams. Not just administering medicines, but monitoring medications. So looking at medication administration records, if they're in electronic format, really critically thinking through the drug burden, what time they're being administered, and, of course, looking at the right medication, the right dose, the right rate, at the right route, at the right time, to the right patient. For all those nurses that are out there, so important but very time consuming, and then recording the administration of the medications in a timely fashion.

And I just go through this process because we focus on these medications, but the administration, the monitoring, all these various steps are really imperative to look at when we're looking at the process. And your pharmacist can be one of the major team members that can help you in improving your medication use process and systems.

And the last one is monitoring. If you look at some of the existing literature out there by Dr. Gurwitz out of Boston, this is an area where we often fail is in monitoring. And it could be because we're not checking an INR, as Dr. Levy mentioned. Our patient refuses it, or it didn't get transcribed to be ordered, or it could be that the nursing staff is not aware that it's a new oral anticoagulant agent or a target-specific oral anticoagulant agent that just came out on the market, and they're not aware of the bleeding side effect with it.

So again, monitoring is imperative and ongoing, and one of the big things in long-term care and chronic care that we have to do a lot more work with — monitoring. And this is assessing again, the patient's response to the medication, reporting and documenting outcomes, making sure that we keep these adverse events or side effects of medications documented so that we don't put our resident, our patient, at greater risk for having another event. And again, the pharmacist can be very really important here in helping with the monitoring of medications. And Susan mentioned, the virtual anticoagulation clinic because this has been a high risk medication where pharmacist-directed anticoagulant services have really excelled in maintaining patients within the therapeutic window and minimizing adverse events.

So kind of setting the stage for understanding, the pharmacist can be involved in many, many steps in this medication use process equation, whether they're the clinical consultant pharmacist that's onsite, at the building, or they're the pharmacist who's dispensing the medication that's ensuring that is the appropriate dose, at the appropriate time, that there's not significant drug-drug interaction. And it really takes a

team. I just can't stress enough, it really takes an interprofessional team when we're looking at medication use, especially in light of increasing complexity.

**Medication Safety Procedures**

So let's talk a little bit about the processes that go on out there to ensure and improve medication safety. So, as stated in the State Operations Manual, the definition of the medication regimen review is a thorough, and I'll repeat, thorough evaluation of the medication regimen of a resident with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, errors, or other irregularities, and collaborating with other members of the team. So, the key thing is this is thorough, comprehensive looking at the patient's medical conditions, looking at all of their medications, looking at the timing, looking to see everything's being treated appropriately, or, you know, maybe they don't need treatment anymore. So it's really a thorough review of all their medications.

A medication reconciliation is a process of comparing medication orders to all the medications that the patient has been taking. So developing a list, reconciling it against the list that's being prescribed, and then, making decisions based on this comparison, and then communicating that to the appropriate caregivers, patient, and other members of the interprofessional team.

So where I look at the distinction between the two — yes, there are similarities in terms of comparison and the importance of medication reconciliation, but the medication regimen review takes it one step further and looking at, should we be putting a patient on something like Vitamin D to prevent, you know, or improve bone health, or is this medication really needed? It's not just reconciling two lists, but a really thorough assessment. And again, a medication regimen review is conducted by a pharmacist, where a medication reconciliation can be conducted by various members of the team.

But what we do know is that when we look at medications — well, I think all of you on the phone definitely know, more work needs to be done. There's inconsistent protocols across the settings of care. When we look at medication reconciliation, and the Stratis report that got published last fall, in 2014, I think articulated it really well. And it's a good review, an easy read in terms of a paper.

But as Susan already mentioned, when we're looking at what we can do better at our facility, we need to implement interventions that assure indications. We know why we're giving these medications. We can't assume anything and we have to understand the diagnosis. So, for instance, if we're talking about using antibiotics, what are we treating, what is the source of the infection? And that's going to drive how long we need to be put on an antibiotic. And then, documenting this for all prescribed medications, not just these high risk medications that we're talking about. They may become the

initial focus because of the greater risk of having adverse drug events, but really looking at all prescribed medications.

And then what we saw from this Stratis report, and I didn't write this, but I was very happy with its recommendations, is really increasing pharmacy's role in medication reconciliation during these transitions in care. Looking at their fill patterns, looking at the medications they're taking from outpatient to inpatient, inpatient to the post-acute, sub-acute, long-term care settings, to maybe back to home. And really letting them know, because too often than not — I practice in the community and in the post-acute long-term care setting — patients, and more importantly, caregivers are even very confused about all the medications they have at home, and really going through a thorough review. And then working during these transitions in a very timely matter to ensure they have the appropriate medications and they understand why they're giving them.

OK. So continuing on, and we're on slide number 58 When we look at the F tags, and we look at the consultant pharmacist's role here. The obvious one is looking at F329, as we've talked about already. And being biased and having worked on F329 with individuals like Dr. Levy, we know that it's really important to look at medications as part of the care process.

And we can't stress this enough. There is another OIG Reports looking at care plans lacking real attention to some of these high risk medications that we've talked about, such as the antipsychotics, but ensuring that there's an indication for use. And indication, again, will drive potentially how long we need to be on them, which gets that duration.

Looking at dose, and as we get older, we have more likelihood for having chronic kidney disease and impaired renal function, which can compromise the excretion or elimination of medications, putting, again, our older adults at greater risk. We need to look at efficacy, how do we know if the patient's having the positive effect from it. As Susan mentioned, looking at the therapeutic window and making sure our patient's in that targeted window with warfarin, because if they're not at a therapeutic dose or at a therapeutic level on a regular basis, oftentimes these medications are no more beneficial than using nothing at all.

So — and efficacy is a really important point. Adverse effects, and we know one of the things that we always train students and practitioners is any new side effect or any new symptoms should be considered a drug side effect until proven otherwise. Because oftentimes our older adults are not well studied per se or put into clinical trials, so looking for adverse effects and the importance of ongoing monitoring.

And then, what's unique but shouldn't just be unique to the post-acute long term care segment, but every practice setting, is the philosophy of gradual dose reductions, or

what I like to call some pharmacologic debridement or deprescribing, really reevaluating, are medications still clinically warranted? What are the goals of therapy? What are the patient's wishes when it comes to goals of therapy? And more patients than not, usually like to have less medications than more. Of course, there's always an exemption to the rule. But generally speaking, most of the patients I've worked with prefer to have less medications than more.

And then we look at the overarching pharmaceutical services. And so, as we talk about kind of procedures and we talked a little bit about framework and process, this is our policies and procedures. So at your facility, what kind of procedures are in place, what kind of policies are in place to look at anticoagulants, to look at antimicrobials, to look at antipsychotics, and to look at, maybe, from your own QA initiatives, what other medications, such as insulin or opiates, might your facility having difficulty with? And then, what can you do from education to clinical reminders to help with administration? And again, working with your interprofessional team, working with your nurses, working with your pharmacists and physicians, to really look at this takes a team effect.

So as we move on to slide number 59, oftentimes when we see a deficiency in unnecessary medications, a companion deficiency might be medication regimen review. Does a pharmacist pick up on this during the review? How do they communicate with the prescriber, with the nurse to ensure followup? And if there is a change in condition, this is another time to signal the medication's being looked at as well. Medication storage, labeling, control drugs is another area under F431, making sure there's systems in place.

There's been a lot of attention given to the inappropriate use, but as well as the diversion of control substances across all settings of care. And how are we looking at that system within the post-acute long-term care setting? How we are ensuring there's continued need, and how are we ensuring appropriate not just storage but also disposal of these medications. So what kind of policies and procedures do you have in place to look at that?

And then ultimately, many of initiatives that Susan talked about are also captured under F309. In terms of quality of care, looking at the dementia care, looking at pain management, looking at behavioral management, and we know the connection between maybe less than optimal pain control in terms of behavior manifestation. So there's a lot of work when we're looking at, again, medication use, nonpharmacologic approaches, as well as the interprofessional team monitoring our patients. And the pharmacist is really important in that equation.

## A Case Example

So let's bring this to an example that maybe some of you can relate to, so an application of some of the concepts we talked about.

An 88-year-old woman who's being reviewed — so this is a patient who I have seen in our facility whose using's reviewed. So the attending provider asked, you know, I'm concerned about warfarin management. We seemed to have labile INRs, that means erratic up and down INRs. So they wanted to look at some of our cases and see, you know, with this particular individual, and then looking at a system perspective, you know, would these agencies target specific oral anticoagulants, also known as NOACs, novel, not as novel anymore, because they all do have a little bit subtle differences in terms of where they target within the coagulation cascade. But comparing them to warfarin, would she be a candidate?

She has a past medical history from what we know of atrial fibrillation, so we'll use some of those tools that Susan mentioned about in terms of calculating risk for an event, as well as calculating risk for adverse events, such as a bleed. And she's currently taking warfarin. From the medical record, we see she has atrial fibrillation, she has a history of edema, nonspecific ideology, hypertension, anxiety, and dementia.

When we look at our medication administration record, she's on Risperidone (Risperdal), also known as an antipsychotic, twice a day for dementia, so that was the indication. Digoxin, which is a rate-controlling agent for atrial fibrillation, also known as Lanoxin. She's on Donepezil for her dementia, a cholinesterase inhibitor, Furosemide (Lasix) once a day for her edema, Icy Hot patches for her pain, Valsartan for her high blood pressure, Verapamil for her high blood pressure, and as we talked about using warfarin in combination with 2 milligrams and 5 milligrams, through two separate tablets to get to total daily dose of 7 milligrams a day. And she has a bunch of different as needed medications for treatment.

So now I'm going to go in to slide number 62, which talks about risk calculations, so as we go through the process of looking at all medications, looking at that risk/benefit. So the CHAD VAS, the one that Susan mentioned, was calculated at about 5 — because of her age being greater than 75, she gets 2; female, she gets 1; hypertension and based on her medication, the implication of her having heart failure, getting at additional 1. So she's 2 or greater. So she definitely needs an anticoagulant. And so you start looking at, OK, which anticoagulant and why. If you look at the bleeding risk assessment tool, the HAS BLED, she got 2 because her age is greater than 65 and her INR, based on the readings here, one could argue they're labile, so it puts her at a greater risk for, again, potentially a moderate risk for bleeding. So if you look in various calculations and calculators that are out there, if you look at two patients for 100 patients years, it's the risk of bleeding, so kind of a moderate bleed risk.

And so the other thing, just giving you objective data, so as we're looking at bringing this back, looking at the INRs, and typically, if you look at the literature, we look at about a 6-month window back if you can to see how often, you know, is the patient actually in that therapeutic range. And more than not, she was subtherapeutic, one could argue, the 1.6 and 1.9 — I think the 1.6, you definitely see as therapeutic. So we bolded out

where she definitely was between 2 to 3. And the other ones were not at those goals for looking at where she was in terms of her targets.

So when we continue on, some of the other important information to look at when we're looking at what sets the stage for potentially having adverse drug events, we need to look at her serum creatinine. So pharmacist should be calculating creatinine clearance. And we can see, based on her serum creatinine, her weight's not reported here, but her creatinine clearance is about 23 ml, so she has compromised renal function, and there are specific warnings and concerns with the dosing, with these new agents, these new oral anticoagulants, in terms of the dosing, and we're going to talk a little bit more about that.

So we're going to come back to the case, but it already kind of sets the stage: A patient that's commonly seen in a post-acute long-term care setting, having multiple comorbidities, multiple medications, impaired renal function, and what are some other things we need to consider?

So as pharmacists, and I'll put in my plug for the American Society of Consultant Pharmacists as their current president, we, like AMDA, have position papers out there and just want to highlight one of the position papers focusing on antipsychotics.

So we know that our patient here is also on an antipsychotic. We focused a lot on the risk/benefit discussion with the anticoagulants and warfarin, but we have to have that same discussion when we look at antipsychotics.

So the position paper here, ASCP strongly believes that the use of antipsychotics in nursing home facility residents should include, again, an appropriate indication for use. So based on what you know from this case is she has dementia. It doesn't get into expansive amount of what our target symptoms are, how long she's been on it, what are her goals of therapy, because that should be mentioned as well.

And then, based on the very limited information within the case, does not discuss, you know, how are we monitoring the patient over time? Are we looking to see, you know, are they more somnolent? Are they having extrapyramidal symptoms or Parkinsonian symptoms, in terms of looking at adverse effects and presence of adverse effects? There's just some to kind of highlight, but, again, ongoing monitor is critical with these medications in order to definitely justify a successful gradual dose reduction, and ideally, potentially getting a patient off of these medications if not clinically warranted.

And what we do know from the literature that's been out there published is, use a medication only for the duration that's really needed at the lowest effective dose, because there are well-designed trials, studies out there, looking at dose-related side effects with these medication, as well as the exposure in terms of time and duration with these medications, as well.

So again, antipsychotics are a drug class of attention. A lot of initiatives have been going on to focus on not just the medication-related aspect, but the nonpharmacologic approaches, as well. So I wanted to focus, because I feel that this is — this is always a seesaw or a balancing act when we talk about anticoagulants. And I've been doing a lot of education as a pharmacist at facilities and with prescribers about looking at this balance of bleed and stroke. So — and the same kind of conversation with families when we talk about care planning and understanding that risk/benefit. So we don't want to cause a bleed, and we don't want to have a stroke.

So let's look at these different agents, because when we think about where the new oral agents have really fit in is trying to minimize the risk of bleed as well as still being as effective as warfarin.

Now we know that this is a moving target when we look at the target specific oral anticoagulants, no pun intended. But they do have varying indications for use, and I took this from the package insert. But you can see that they're all indicated for stroke prevention and atrial fibrillation. Some of them have extended venous thromboembolism prevention, and some of them also have after a knee replacement or a hip replacement, and that's what a total knee replacement, total hip replacement, THR, is.

So they're not all created equal in terms of their indication for use, and we know that there's been attention being given using medication off label without an indication for use that can become a concern.

We also know, and there is some italicized areas at the bottom, that looking at the timing of these medications, with respect to transitioning from warfarin or other parenteral anticoagulants, and there's even additional requirements among some of the medications looking at weight, looking at serum creatinine, and making sure we dose adjust.

So step number 1, when we think back to the care process indication for use, do these agents have the indication for use that we're treating? And then next, as we go down to get to slide number 66, what is our treatment dose, and how do we compare these agents when we look at efficacy as well as potential for toxicity?

So what this particular trial and slide went into is all the different landmark trials that are out there looking at the data to support from an efficacy perspective of the Dabigatran, Rivaroxaban, Apixaban, and Edoxaban. So try to say that 10 times fast right now.

But you can see there's a fair end with them. And when we look at the patient breakdown, the studies do include those over the age of 75 and 80. And some of them have a higher end in there, and I would defer to the clinical trial to look at them. You can

also see the treatment doses and the time within that therapeutic window with warfarin. So as Susan mentioned, that benchmark of greater than 60 percent, some of these studies had even a little a bit higher that patients were within that therapeutic window.

We also — the used the CHADS2 vs. CHADS VAS in terms of scoring, but you can see that these patients were at risk — an indication for an anticoagulant. When we looked at efficacy vs. warfarin, they were either superior or noninferior, meaning, again, they are both working.

Intracranial hemorrhaging, which is a concern in terms of ultimate bleed risk, was reduced. And I think that's one of the big advantages when we look at the new agents that are out there. And if you looked also at some of the major bleeding, it was either similar or reduced, and Apixaban and Edoxaban have some lower side effects in terms of bleeding and major bleeding. And, again, similar or reduced in terms ischemic stroke, so as the data showed, superior and noninferior.

So kind of getting that back, when we think about the medication, we think about the risk/benefit. We look at OK, what's the data that support its indication for use? How long do we treat based on that indication for use? What is the appropriate dose? And needing to look at the patient's renal function, needing to look at their bleeding risk, and some of the data that support that.

So with renal impairment, as we saw with this particular case, she has impaired renal function, and the — still the gold standard to be using is the creatinine clearance. There's also oftentimes debate regarding GFR, which is calculated by labs, but in terms of drug dosing and drug handbooks, they're still using creatinine clearance cutoff. And what we saw in terms of case studies is that if patients weren't appropriately renal dosed, it did put them at greater risk for having bleeds, and there were some extreme cases of death because of in appropriate renal dosing. So – and Dabigatran is mentioned here in particular.

When we look at bleeding risk, which get us slide number 68, again, this risk/benefit, and this is oftentimes one of the big factors that dictates how aggressively we treat with oral anticoagulants.

So again, if patient's renally impaired, depending on what their creatinine clearance is, you may need a reduce dose or not to use, but we do know that all the TSOACs do different in their bleed risk and types of bleed. But generally speaking, they have less risk of intracranial hemorrhaging. But the GI bleeding can be increased, and has been increased in some of the higher doses, especially if they're not taking into a constant renal dosing.

So when we look at our checklist approach in terms of safety, bleeding risk is going to be a continued concern. When we look at some of these clinical trials, they may have excluded populations that had severe renal impairment. They may have excluded patients on certain other coexisting medications. And we know it's not just our anticoagulants that can increase the risk for bleeding, that's why the importance of looking at a comprehensive medication regimen review — because other agents, like prednisone, aspirin, could put our patients — antidepressant — may put our patients at greater risk for bleeding. So we need to look at these in combination on top of everything else, and just some consideration.

So let's go back to the case, because I've got to make sure I'm cognizant of time here, too. So let's apply the concepts we just discussed to the case.

So again, this is an 88-year-old woman who's being reviewed for that risk/benefit of looking at TSOACs compared to warfarin. So during this review, there is many medication-related considerations, but anticoagulants. So she does have an indication for atrial fibrillation to be on an anticoagulant. The concern with her renal impairment and her creatinine clearance, about 23 mls per minute, we have to be concerned about the safety.

And currently, there is an approved antidote for Dabigatran out there, but would not be — I would be very concerned with using Dabigatran in her renal impairment. But she does need to be on something, and so the question becomes is would we switch her to a newer oral anticoagulant?

We actually kept her on the Warfarin and just improved the monitoring and watched for drug-drug interactions. But it becomes a big discussion, an important discussion with family and care planning in terms of monitoring at this time.

Regarding the antipsychotic medication, as we got to know her more, again, it wasn't a clear clinical indication. And we did have the opportunity to gradually dose reduce. As you remember, she was on the Risperidone twice a day. We were able to gradually dose reduce to once a day, and then completely off through stabilizing her environment, getting her involved in activities, and working with the staff in terms of nonpharmacologic interventions. But it takes — the imperative is documentation, the team approach and monitoring the patient over time.

So those are kind of the take home points from my section. It really takes a team. And I'm going to then turn this back over, I believe, to Michelle to go into the partnership updates and closing questions in Q&A. Thank you.

## National Partnership to Improve Dementia Care Update

Michelle Laughman: Thank you Nicki. We'd now like to share some updates related to the partnership. Our work on the 2015 Focused Dementia Care Survey effort has ended,

and we are currently developing a final summary report, similar to what was distributed for the 2014 pilot. And we anticipate that the report will be released in early 2016. Additionally, in response to feedback from the stakeholders and partners of the National Partnership, we're very excited to tell you about the release of a recent survey and certification memo 16-04 last week, which included the revised survey materials developed for the 2014 pilot and the 2015 focused dementia care expansion effort.

The focused dementia care surveys were specific, targeted survey effort conducted in several States that reviewed the practices of dementia care. And we hope that by releasing this information, facilities will use these tools to assess their own practices in providing resident care.

Attachment 1 of the S&C memo includes questions that are related to facility practice. They are not resident-specific. The tool assists in determining the nursing home's philosophy on dementia care, which includes policies, leadership, staff training requirements, as well as documentation.

And it also includes a section related to the nursing home's Quality Assessment and Assurance Committee. This section investigates whether the nursing home has a QAA Committee, and if so, whether or not the required staff participate at least quarterly. It also focuses on whether or not the care of residents with dementia is monitored through the QAA Committee.

The second attachment is resident-specific, and it is completed for each resident in the sample of the focus survey. And the tool assists in the observation of dementia care, whether it be positive or negative. It also provides some possible situations and relationships that surveyors would evaluate during the focus survey, but can be used by nursing homes themselves to look at quality improvement.

Interviews are used primarily to provide additional evidence for what the surveyor has observed or gleamed from the record review, but may, in some cases, also substitute for direct observation to support a citation of physician practice.

We encourage every nursing home to review these tools and to use it as an opportunity to assess your dementia care practices and implement appropriate changes to ensure that the necessary care and services for a resident with dementia and to support his or her highest practical level of physical, mental, and psychosocial well-being are being provided.

Additionally, we wanted to share some information on a national survey to assess the adoption of person-center care practices in nursing homes across the United States. The Rothschild Foundation in collaboration with Perkins Eastman Ideas Institute and the Beryl Institute has developed the 2015 State-of-the-Art of Person-Centered Care Survey.

This is an opportunity to explore new person-centered care concepts and practices and also to share the changes that you have been making. The 2015 State-of-the- Art of Person-Centered Care Survey will be available online. It was beginning November 1st and through December 31st, and it can be accessed at www.IDEASinstitute.org/2015pccsurvey. And we'll put that on — we'll link that when we post the slides, so that that's — use that for everyone.

Additionally, recent data from the partnership was shared in October, and we've now seen 24.8 percent reduction in the rate of antipsychotic use in long stay nursing home residents. The partnership has engaged the nursing home industry across the country around the reduction of antipsychotic medications with momentum and success. And we thank you for your participation in today's call and look forward to continued partnership.

I just want to mention that our next call is scheduled for Thursday, April the 28th. And I'm now going to turn it over to Leah and Holley for the question-and-answer session.

## Question-and-Answer Session

Leah Nguyen: Thank you Michelle. Our subject matter experts will now take your questions. But before we begin, I would like to remind everyone that this call is being recorded and transcribed. Before asking your question, please state your name and the name of your organization.

In an effort to get to as many of your questions as possible, we ask that you limit your questions to just one. If you would like to ask a followup question or have more than one question, you may press star 1 to get back into the queue, and we'll address additional questions as time permits.

All right, Holley, we are ready to take our first question.

**Operator**: To ask a question, press star followed by the number 1 on your touchtone phone. To remove yourself from the queue, please press the pound key. Remember to pick up your handset before asking your question to assure clarity. Please note your line will remain open during the time you are asking your question, so anything you say or any background noise will be heard in the conference. Please hold we'll be compile the Q&A roster.

Your first question comes from the line of William Simonson.

William Simonson: Yes, thanks Dr. Levy and Dr. Brandt, very nice presentation. Regarding Dr. Levy's slide 49, she mentioned looking for a class shift from antipsychotics to other drugs. I'm particularly interested in the use of Nuedexta. There seems to be a lot of attention to using it as opposed to antipsychotics; however, it is not indicated for

behaviors of dementia. Is this a concern? Is it better because it's the lesser of two evils compared to antipsychotics or does it decrease the focus on nondrug management of behavior? How do we handle that?

Dr. Susan Levy: Hi, it's Susan Levy. Well, you know, I think the first principle, and hopefully, the first principle I think Nicki would support and myself, is that, whenever possible, you know, we want to use nonmedications. And so I think the alternative to drugs is you should be looking at other behavior interventions.

The whole concepts around patient-centered care, and I think what most facilities have identified who have been successful in reducing their use of antipsychotics — it's not that they're replacing it with other medications. They're replacing it with better education of their staff. Knowing their patients better and being able to understand the behaviors better. And I think that that's one of the key issues.

I think in terms of shifting to other medications, I, you know — first of all, I'm always concerned if anyone's, you know, using anything, you know, off-label, as they certainly are very comfortable with using the medication and, you know, feel that it is indeed warranted.

So, you know, I know that there's been concerns about switching some facilities to other medications, not just that, but, you know, again, that's largely, my first effort is to move away from, you know, use of any medications at all.

Dr. Nicole Brandt: An aside, Dr. Simonson, just to kind of follow up on Dr. Levy's comments, I wholeheartedly agree. What I tend to find though is Nuedexta got a lot of — and those who you — who may not be familiar with the brand name, Nuedexta is the combination of dextromethorphan and quinidine — two very older agents, if we think about it. And it got a lot of attention when the publication came out about a month and a half ago, now in JAMMA, looking at the effect of it on agitation in patients with Alzheimer's disease dementia, which is a really early — I think it was a phase 2 clinical trial. It was really early on in the study, and, you know, just with any of the studies, if we pull them apart, you know, there was definitely concerns. And we know with the combination of dextromethorphan and quinidine is the potential for drug-drug interactions, especially amongst our older adult.

So, wholeheartedly agree with Dr. Levy in terms of going to the basics of behavioral management. But I know, you know, family members as well as caregivers are often asking question about new medications when they see them come out in the media. And then I think the important role of the interprofessional team with the involvement of the consultant pharmacist is to look at the evidence, right? to look at the evidence to support the risk/benefit of these medications.

So, it has gotten a lot of attention, and I think by the attention, people are looking for alternatives. They're always looking for, you know, a potentially new medication because it's not an antipsychotic, by it does have its own constellation of potential adverse effects and significant drug interactions in my mind.

Leah Nguyen: Thank you.

**Operator**: You're next question will come from the line of Mary Gracey-White. Mary, your line is open.

Mary Gracey-White: Hi, good afternoon. I'd like to thank you for the presentation. It was very informative. And just a quick question, just to go back to something that Dr. Levy said in the presentation regarding consent for the use of antipsychotic meds. That is a recommendation, because I don't know that that's an actual regulation.

Dr. Susan Levy: Yes, hi, it's Susan Levy. There's no requirement that you have a formal signed consent. There's always a requirement that you inform patients and/or their responsibility — responsible parties about medications.

Mary Gracey-White: Yes, um-hum.

Dr. Susan Levy: So that should be documented somewhere. So to me, in reality, it's maybe a little bit of wordsmithing issues, that's a form of consent. I mean, it's not a formal form that you've completed, although there are some facilities who've chosen to go that route ...

Mary Gracey-White: Right.

Dr. Susan Levy: ... to make sure that they have the documentation. But frankly, you know, good policy is generally to document somewhere that the family's been informed, and if they've been informed to the risks and benefits. To me that's a form of consent, but it's not formal consent.

Mary Gracey-White: Right.

Dr. Susan Levy: So, I hope that that clarifies.

Mary Gracey-White: Yes, it does. Thank you very much, appreciate it.

**Operator**: Your next question will come from the line of Dane Meyer.

Dane Meyer: Good afternoon folks. Thank you very much for the presentation, I appreciate that. My question's directed — well, actually, I'm a registered nurse working with a Medicare-funded project called OPTIMISTIC in Indianapolis. And we've been

dealing both with the polypharmacy issue as well as the elimination of Beers criteria medications. But should we also be looking at the idea of gradual dose reductions on certain long-term maintenance medications, given a very aging geriatric population?

Dr. Nicole Brandt: Susan, I can take this one. I think – it's Dan, correct? This is Nicki. I think it's important to look at all medications, especially, you know, with the recent publication with Simvastatin in patients towards end of life. And I guess, you know, though we can never predict, but I think as patients, you know, may change their goal of therapy, looking at chronic use of medications is important. So, statins have got attention in terms of some of the end of life literature and patients with 6 to 12 months to live, you know, is there really any clinical utilizations still needed?

So, I think it's important, and I think there's certain classes of medications where it's really important to gradually dose reduce, because either there might be a disease exacerbation or a drug withdrawal event.

So I tend to find as we — with every medication, there's a great paper out there by Mike Steinman out of California which gives a framework for medication monitoring and deprescribing. And one of the things is to educate the staff. As we start medications, we monitor. But as we stop medications, how do we monitor, and what do we need to monitor for and what's our backup plan?

So, you know, I think the philosophy is — with all medications — is that discussion of risk/benefit. Is there still clinical need, you know, what are the patients, and as well as oftentimes the family's, wishes in terms of goals of therapy? And that could mean an open discussion and reevaluating some of those chronic medications.

Dr. Susan Levy: Yes, hi. I actually think that's an excellent — those are excellent points. Just a couple of additional comments. You could certainly, if you're — in your quality program, you could look at the Beers list. You know, I looked at a number of ways, I had to decide what to look at, but certainly looking at that list. Again, I'm a believer in using things as indicators. You know, I think that there are often exceptions to many rules for when you might use a medication that's, you know, not certainly supposed to be used in someone of this age group.

You need to have a lot of very good documentation today, you know, certainly around that. But that's, you know, that's another criteria you could use for developing some of your quality programs. What you're doing is looking at compliance with Beers list, you know, medication. So, I think, that certainly is very good.

I think there are efforts for people to look at the overall drug regimen a patient is on and really try to make determinations on a regular basis as to whether people need lower doses, maybe no longer are benefiting. Frankly, part of your visit as a physician should be looking at the medications you're prescribing, certainly at any visit, but particularly at

your regulatory visit, and making a determination as to whether the patient's still benefiting from all those medications. I think that really is part of that process, in addition to support from your consultant pharmacist.

Leah Nguyen: Thank you.

Dane Meyer: Thank you.

**Operator**: Again, if you would like to ask a question, please press star then 1 on your telephone keypad. To withdraw a question or if your question has been answered, you may remove yourself from the queue by pressing the pound key.

Your next question will come from the line of Ken Capron.

Ken Capron: Thank you, excellent presentation. I think my — I'm looking at slide 71, there's under antipsychotics, and there's a line that says "nonpharmacologic approaches to care." I'm very interested in — what is in that category from your point of view? I often try to encourage patients to self-advocate, and medications are one area which they just get lost. There's no way that they can really understand the paradigm. So, what nonpharmacologic approaches have been discussed or are included in that bullet point?

Dr. Nicole Brandt: Sure, this is Nicki. So in terms of nonpharmacologic approaches, there's been some great systematic reviews out there. And I think, you know, people may criticize some of the nonpharmacologic data, but we know that it has to be individualized.

So, with this particular patient, in terms of nonpharmacologic approaches, having a structured schedule, having consistent staff was an approach. We used some music therapy as another nonpharmacologic approach because she enjoyed that. Increased activities with the structure was also very helpful. Regular routine, activities throughout the day, led to her sleeping better at nighttime, which is sometimes — we know with sleep deprivation, of poor sleep hygiene, can lead to poor sleep, which aggravates behaviors.

But I think, if you look in the literature, there's so many nonpharmacologic approaches out there. I know there's — some more coming out of the group in Pennsylvania, with Donna Six's group to look at nonpharmacologic approaches in dementia patients. Some of the resources we have through our Advancing Excellence campaign that we've done work with have a whole bunch of indices on different nonpharmacologic approaches.

I know that Susan, we're both here in Maryland, has done work with some of our psychiatric facilities who have even more nonpharmacologic tactics, such as Snoezelen room, light therapy. And they've done different things inpatient which they then shared

with the outpatient, post-acute long-term care setting, so the caregivers, in term of nonpharmacologic approaches.

So, I find that there's not one-shoe-fits-all when it comes to nonpharm, it's got to be very individualized. And it's having a better understanding of that person's needs. So, and that's from a pharmacist's perspective. So, I am not a nonpharm expert. I'm going to give that caveat, but I've just read so much of the literature. And from my almost 20 years of experience, it really is so individualized when it comes to nonpharmacologic approaches.

Leah Nguyen: Thank you.

**Operator**: Your next question will come from the line of Lisa Tomm. Lisa, your line is open.

Lisa Tomm: Good afternoon. Thanks so much for the presentation, very informative. I'm calling with — just to seek your thoughts on the end of life and hospice care population. You know, we very typically use antipsychotic medications, not just Haldol and Thorazine, for nausea, vomiting, and hiccups. They're still considered antipsychotics though and have run into some trouble in nursing facilities that feel that they cannot use them blanket, across the board, which, of course, is not the case. I'm just looking for both of you, and your thoughts on that.

Dr. Susan Levy: Yes. Hi, it's Susan — Susan Levy. You know, I know that's been a concern for a long time. You know, first of all, you know, many of our patients are not on hospice all that long or need those medications that long. And, I think, regardless of whatever the initiative is or any of this, is that this is not just about the regulations, this is doing what's right for your patient and documenting and being able to explain the reasoning for that.

So, if the medication is appropriate for the patients, and that's what — and that's what's benefiting them, that certainly is what they need. Honestly, even with the behaviors, if you were to stop medications where the patient was clearly benefiting from the medications, and weren't addressing the fact that, you know, they needed medications — regulators are as concerned about that, as they are about giving antipsychotics.

So, I mean, the issue is about doing things appropriately and doing what's right for the patient. So, I know that there's been a lot of concern. There's also, again, whenever there's initiative, you know, there are sometimes individuals who don't get the full message, and the message that comes out is that, you can't put anybody on antipsychotics for any reason. That's not the message of the partnership. The partnership was about — there are alternatives to medications. The medications are not benign and that we need to really think about other alternatives. In the case of

nausea/vomiting, I know, that's been a concern. You know, the medications can be, you know, and certainly are effective as antiemetics.

So, you know, I think that's real. I think people at CMS understand that. There are other, you know, there are other alternatives but, you know, the Haldol, you know, is certainly effective. Other antipsychotics are effective as antiemetics.

Dr. Nicole Brandt: And I just want to piggyback — yes. I'm just going to piggyback that. This is Nicki. I think Susan's right on there. I think the other concern is sometimes we're seeing where there's just implemented protocols with standard order sets on everybody. And, I think, the key thing is to look at, you know, ensuring that there's an indication for use for the medications, such as the antipsychotics or other types of agents. So, yes, so, I think those are just another kind of pearl to add to the discussion.

Leah Nguyen: Thank you.

Lisa Tomm: Thank you both very much.

Leah Nguyen: I think we have time for just one final question.

**Operator**: OK. Our final question will come from the line of Pat Whitacre.

Pat Whitacre: Yes, I just wanted to make sure I understood. I thought Nicki said something about Dabigatran has a reversal agent, is that correct?

Dr. Nicole Brandt: So, the company, Boehringer Ingelheim is coming out with an antidote. I haven't used it myself yet in terms of accessibility but, yes, there is a reversible agent for that. I have no experience with it. I'm reading up on it and learning myself a little bit more about it, but, I know the concern with that particular — with Dabigatran is you've got to be very conscientious of the dosing and the renal dosing, and some of the pharmacokinetic modeling and the implication it has in terms of the efficacy. But it does — it is one of the new agents that does have an antidote that just got announced.

Pat Whitacre: OK, cause I think one of the deterrents with trying to use NOAC or even doing a medication review with the pharma — or with the physician is when I talk about NOACs and say, "You know, instead Coumadin, can we take a look at those, you know, take a look at the risks and everything?" Many physicians that I have spoken with will say, "As soon as there's a reversal agent, I will consider it".

Dr. Nicole Brandt: Yes.

Pat Whitacre: And so I think sometimes that really does put a damper on people being able to use the NOACs vs. the Coumadin.

Dr. Nicole Brandt: Now, just know it's only for Dabigatran, and, you know, so you've got to look at that. And I think the other thing, too, is we talk about cost and effectiveness and safety and access. We have to look at that as well.

So, I know that, I just got announcement of it over the last couple of weeks. So, we're looking into it, but, yes. So I would say, definitely, you know, evaluate it and consider, you know, as a possible. But I know that with post-marketing data with the Dabigatran, I work on the Beers criteria. We're still concerned about the safety implications with that particular agent and some of the inferences in terms of the reduced dose and the efficacy.

So, you know, I won't give my impression, but there's definitely — got to look at the effectiveness, safety, and the whole package when you consider then the availability of an antidote for that agent.

Pat Whitacre: OK, thank you very much.

Nicki Brandt: No problem.

Leah Nguyen: Holley, actually, could we take one more question.

**Operator**: At this time, there are no further questions.

## Additional Information

Leah Nguyen: OK, thank you. An audio recording and written transcript of today's call will be posted to the MLN Connects Call website. We will release an announcement in the MLN Connects Provider eNews when these are available.

On slide 74 of the presentations, you will find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you will take a few moments to evaluate your MLN Connects Call experience.

Please join us again for a future MLN Connects Call. We'll have two calls coming out next week on Medicare Quality Reporting Program and the End Stage Renal Disease Quality Incentive Program.

Again, my name is Leah Nguyen. I would like to thank our presenters and also thank you for participating in today's MLN Connects Call on the National Partnership to Improve Dementia Care in Nursing Homes and QAPI.

Have a great day everyone.

**Operator:** This concludes today's call. Presenters, please hold.

This document has been edited for spelling and punctuation errors.

**-END-**