

**HIT Policy Committee  
Quality Measures Workgroup  
Transcript  
June 3, 2013**

**Presentation**

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thank you, good afternoon everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's Quality Measures Workgroup. This is a public call and there is time for public comment on the agenda and the call is also being recorded so please make sure you identify yourself when speaking. I will now go through roll call. Helen Burstin?

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

I'm here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks, Helen. Terry Cullen?

**Theresa Cullen, MD, MS – Veterans Health Administration – Director, Health Informatics**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks, Terry. Chris Boone? Tripp Bradd?

**Tripp Bradd, MD, FAAFP – Skyline Family Practice, VA**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks, Tripp. Russ Branzell?

**Russell P. Branzell, FCHIME, FACHE, FHIMSS, CHCIO – Poudre Valley Medical Group**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks, Russ. Cheryl Damberg? Timothy Ferris? Letha Fisher? David Kendrick? Charles Kennedy? Karen Kmetik? Saul Kravitz?

**Saul Kravitz, MD – MITRE Corporation – Principal Health IT Engineer, Center for Transforming Health**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks, Saul. Norma Lang?

**Norma Lang, PhD, RN, FAAN, FRCN – University of Wisconsin – Professor of Health Care Quality & Informatics**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks, Norma. David Lansky? Marc Overhage? Eva Powell? Sarah Scholle? Cary Sennett? Jesse Singer? Paul Tang. Kalahn Taylor-Clark? Aldo Tinoco?

**Aldo Tinoco, MD, MPH – National Committee for Quality Assurance – Physician Informaticist**  
Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks, Aldo. Jim Walker? Paul Wallace? Mark Weiner?

**Mark G. Weiner, MD – Perelman School of Medicine - University of Pennsylvania Department of Medicine**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Ah, great, thanks, Mark. Olivier Bodenreider?

**Olivier Bodenreider, MD, PhD – National Library of Medicine – Staff Scientist**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks, Olivier. Niall Brennan? Ahmed Calvo? Carolyn Clancy? Westley Clark?

**H. Westley Clark, MD, JD, MPH, CAS, FASAM – Substance Abuse & Mental Health Services Administration**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks, Wes. Kate Goodrich? Dan Green? Peter Lee? Marsha Lillie-Blanton? Michael Rapp? Steven Solomon? Tony Trenkle? Jon White?

**P. Jonathan White, MD – Agency for Healthcare Research & Quality (AHRQ)**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks, Jon. And, any ONC staff members on the line if you can identify yourself please?

**Jesse C. James, MD, MBA – Office of the National Coordinator**

Jesse James is on the line.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thank you, Jesse. Okay, with that I will turn the agenda over to you Helen.

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

Great, thanks, MacKenzie, hi everybody, we have a packed agenda. So, we're delighted today to have an opportunity to hear from the Federal Interagency Workgroup on ADEs. I think that everybody should have received the slides they were sent out earlier today, but if not they'll be projected on the webinar. I guess with that I'm going to turn it over to Yael Harris. Yael are you with us?

**Yael Harris, PhD, MHS – Health Resources and Services Administration**

Thanks, so much Helen, thanks everyone. We just want to thank you for this opportunity to share some of the great work that has been done here in developing a national action plan for adverse drug events and how Health IT can help us achieve some of the goals that have been identified. If you can go to the next slide? This has actually been a cross federal initiative which includes all HHS agencies as well the VA and DoD who have been active participants. Next slide. So, next slide.

I just wanted to give a quick overview. Adverse drug events are a major public safety concern and they're frequently related to uncoordinated or poorly managed use of prescribed medications. Next slide. As you can see they're associated with high levels of mortality and morbidity resulting in unnecessary use of healthcare services as well as high cost in the healthcare system. Next slide.

According to the Office of the Inspector General about two-thirds of adverse drug events in the inpatient setting can actually be ascribed to three major drug classes, anticoagulants, opioids and diabetic agents, and among these about 50 percent can actually be prevented. Next slide.

And they're not just limited to inpatient settings, in the outpatient setting it's estimated that approximately 100,000 emergent hospitalizations each year just within the Medicare population are attributable to these same three drug classes. Next slide.

They're especially common during transitions of care and it is estimated that two-thirds of post discharge complications actually results from adverse drug events and half of these are preventable. Next slide. This table just shows the extent of the impact they have on our healthcare system resulting in serious medical harm as well as avoidable cost. Next slide.

As a result of this data the Assistant Secretary for HHS determined that the nation needed a national action plan to coordinate across federal efforts to address this immense safety issue. Next slide. So, basically a steering committee was pulled together and identified that in order to have the greatest impact the action plan should focus on the three drug classes that are associated with two-thirds of the adverse drug events in America anticoagulants, diabetic agents and opioids. They decided that within each of these drug classes the effort should focus on four main categories. Next slide.

The focus should be on surveillance, evidence-based prevention, incentives and oversights, and additional research needs. Throughout the dialog of these three Workgroups it became apparent that Health IT was a major tool and resource that could be used not only to measure adverse events but to help prevent them, incentivize appropriate management and help identify and evaluate new information to support future efforts in this field. Next slide.

Currently Stage 2 includes a number of measures that are actually related to adverse drug events and you can see those here. However, there is still a great deal more that can be done to help measure and prevent these serious patient errors. Today's presentation will focus on recommendations identified by members of the cross federal steering committee to leverage Meaningful Use and Health IT.

The recommendations support the initial intent of the HITECH Act which aimed as using Health IT to increase patient safety, better coordinate care and focus on person-centered care to result in improved quality and overall cost savings. Next slide.

The Federal Interagency Workgroup recommended several actions that they thought could be useful to use Health IT to promote improved health care with an adverse drug event. The first is additional data elements that could be captured and collected with an electronic health record either to be used in patient panels or at least used by the doctor to track these conditions.

They also agreed that there are some existing measures that are already in Meaningful Use that could be retrofitted to reflect the most recent scientific evidence. There could also be new adverse drug event measures that are already being used across different parts of the federal government and lastly you could use clinical decision support to help apply existing knowledge for real-time prevention of these ADEs at the point of care.

So, you will hear from each of the Federal Interagency Workgroups who have spent months reviewing the literature, evaluating current models of care and learning about health practices across the federal space to inform their recommendations to you today. I'd like to start first with the recommendations from the anticoagulant group, which will be presented by Dr. Nadine Shehab from CDC.

**Nadine Shehab, PharmD, MPH – Centers for Disease Control and Prevention – Senior Service Fellow**

Thank you; this is Nadine Shehab, thank you Yael and thanks to ONC and the Quality Measures Workgroup for the opportunity to present to you. So, I will be discussing the recommendations that were made by the Federal Workgroup that addressed anticoagulant adverse drug events and you will see here – sorry, next slide. You will see here a summary of the recommendations that we felt could be targeted at outpatient settings or eligible providers. Next slide, please and next slide.

What you should see in front of you now is a slide that summarizes anticoagulation safety and the current national measures that address this. So, the approach that our workgroup took to selecting our targets, we looked to see what currently exists in terms of nationally recognized clinical guidelines targeted at optimizing anticoagulation management or what current nationally recognized quality measures exist and that was our approach to try to bring those first into EHR incorporation.

And, so a lot of the recommendations that you'll see addressed here are based in part on the National Quality Forum's currently endorsed measures NQF 555 and NQF 556 one that recommends monthly INR monitoring and one that recommends an INR retesting three-to-seven days after a new anti-infective medication for a patient receiving an anticoagulant.

And also we looked at the nationally recognized chest guidelines and we saw that there are also recommendations there for INR testing frequency and there are also recommendations for avoiding certain anti-infectives with anticoagulation. So, previously slide, please. I'm sorry to jump around.

So, one of the first recommendations that we made is for a patient list, this is a list of patients that would print out for the provider of patients on warfarin stratified by time since their INR test and the EHR would be able to provide a list that would inform the provider when the last INR test was 30 days, 60 days, 90 days, over 90 days. The justification being that this allowed the provider to re-evaluate the need for follow-up INR testing based on the individual's needs.

And we chose this approach rather than recommending sort of a strict cut off where the EHR would have to tell you, you know, in 30 days or 90 days or whatnot because as you can tell, if you can move to the next slide please, the current recommendations, the current national recommendations are now somewhere between four and 12 weeks and what we heard from clinician, SMEs and what we are understanding is that it really requires that each patient be evaluated to determine which is the INR monitoring interval that's most appropriate to them. So, given that we wanted sort of to optimize the utility of EHRs to allow the provider to have that information so that they could re-evaluate whether the patient required re-testing of the INR.

We also – next slide, please, we also put this as a quality measure concept and we recommended a measure a percent of patients on anticoagulants with an INR test 17 to 14 days following an out of a range INR. The justification for this was that the evidence suggests that anticoagulation control is measured by time in therapeutic range, is improved by prompt retesting after out of range INR values.

So, given that there was a very – the evidence suggested a very close correlation between when a provider noticed an out of range INR and followed up on it and that patient is doing better essentially keeping that INR within range for future tests, we felt that the EHR could be leveraged here to remind the provider that there is a need to essentially get a retest or we could be measuring how many providers are getting a retest as a quality measure-type concept.

We recommended two clinical decision support sort of recommendations I guess, one was a reminder to assess the INR, re-assess the INR test on patients on warfarin therapy to remind the provider that they've not had one for 30 days and again at that point they can evaluate whether that's appropriate for that patient or that's not. And this is what a proposed CDS display would like. Next slide.

As you can see here the CDS display would let the provider know what the INR goals are, what the last INR was in terms of date and the dose that the patient is receiving. It would also guide the provider through what is appropriate to do or what will the provider do, it will collect that information, should the patient be re-evaluated, should they schedule an INR test for another date or should they do something else. Next slide.

The second clinical decision support recommendation that we made was a notification when a patient is on warfarin or is prescribed a new interacting anti-infective medication and you would have seen that this stemmed from the NQF and chest guidelines recommendations for patients receiving anti-infectives and oral anticoagulants. This would be essentially a CDS-type reminder to let the provider know that initiated treatment with anti-infective medication has been made in a patient on chronic warfarin therapy and that there is an action that needs to happen and to see – sorry next slide.

The action, the possible actions that the CDS could help the provider sort of walk through is to instruct the patient to hold the warfarin dose, to change the anti-infective medication, to notify the anticoagulation provider, to schedule an INR retest to determine if the anti-infective medication has had any deleterious effect on the INR.

So, that was it for the outpatient-based recommendations. We also wanted to make recommendations for the inpatient settings where anticoagulants are also a very frequent cause of harm among hospitalized patients. And this was a bit of a challenge because there was really a paucity of national quality measures and national recommendations to pull from and even current clinical guidelines such as the chest guidelines are more a way towards community-based or outpatient care than they are inpatient care and as we discussed this among our workgroup members and our subject matter experts, and our clinician consultants, and presenters really what came to fruition was this concept that what – given the acuity and complexity of patients on the inpatient setting, given how fast things change and the complexity of how we use parenterally administered anticoagulants in the inpatient setting really what was most useful is having an EHR that could provide real-time linked laboratory pharmacy data that could be used by the provider to help guide anticoagulation management so that things aren't static so that there is an active surveillance, an active responding to problems in the inpatient setting.

And also this recommendation, which seems rather general, actually came out of the fact that we didn't feel comfortable with just singling out one single agent in the inpatient setting. There is less concurrence here in terms of the literature and there is variability in lab testing standards across hospitals in the United States for the parenteral anticoagulants. So it's more complicated than one would think in the inpatient setting, but almost resoundingly what came to sort of the surface in our discussions was this idea of real-time monitoring, real-time surveillance, link lab and pharmacy data for the complex and acutely changing or quickly changing acutely ill patient.

And we had examples of sort of private vendors being able to do this and so we felt that this was something that was doable, being used and it could be made as a requirement and implemented in sort of a vendor neutral way if possible and this is – sorry, next slide. This is an example of what an anticoagulation and flow sheet would look like.

This is sort of a very static example I don't think it can sort of mimic the robustness of what exists right now in terms of what vendors are doing, but it would be something that would essentially reflect the whole of the anticoagulation profile of a patient not unlike what we would now do for when we are doing antimicrobial stewardship for patients that are able to see their white blood cell count, what anti-infectives they're on, if they've had any bumps in their serum creatinine, so on and so forth. And being able to translate that to anticoagulation was something that we heard sort of resoundingly in our discussions. Next slide.

So, you might have noticed that our recommendations for the outpatient setting were sort of heavily weighted towards warfarin and in the inpatient setting they're rather general, but this was not because that's sort of the most ideal right now especially given the advent of new oral agents that are going to be used heavily in the outpatient and inpatient settings.

But we didn't feel right now that this is the best time to come out with de novo measures that have not yet been critically reviewed by folks, you know, like at the National Quality Forum or other organizations that haven't been – that have not yet been taken up by national clinical guidelines to address all the other areas.

Ideally we would like to see an EHR address in the future and so some of these areas were newer oral anticoagulants. Here, although we struggled we would have liked to provide something in terms of recommendations for EHR and newer oral anticoagulants this is still a very much evolving and early science. We're still learning about what the quality metrics here are and there weren't really any national quality measures yet to pull from. But in the future we would love for EHRs to address issues to do with dosing adherence and transitions from warfarin on these agents. These seem to be the critical areas –

**Jesse C. James, MD, MBA – Office of the National Coordinator**

I'm sorry to interrupt I think we need to advance one slide, thanks.

**Nadine Shehab, PharmD, MPH – Centers for Disease Control and Prevention – Senior Service Fellow**

Oh, sorry, for the agents right now. Sorry, I'm having a hard time keeping track because I can't see the –

**Jesse C. James, MD, MBA – Office of the National Coordinator**

Okay.

**Nadine Shehab, PharmD, MPH – Centers for Disease Control and Prevention – Senior Service Fellow**

So, for the other agents the parenterally administered agents in the inpatient setting we felt that EHRs needed to address very pertinent laboratory monitoring parameters for example heparin is a parenterally administered agent in the inpatient setting. We would like to see some laboratory monitoring parameters addressed in EHRs but right now, like I mentioned, the lack of consensus and uniformity across hospital sites and we're still trying to figure out what the best laboratory parameters are for the various parenteral anticoagulants that we use.

And in terms of outcomes-based metrics you'll notice that a lot of our measurements were process-based that's because actually anticoagulant related bleeding is extremely hard to measure in a most sensitive and specific way. We can capture it but whether we are actually capturing all of anticoagulants and bleeding and capturing in a specific way is a much bigger question.

And so right now there are limitations in what ICD-9 and procedural codes can tell us about anticoagulant bleeding and until we learn a little bit more about that that's what makes the outcomes-based metrics a bit challenging even though this is the outcome we'd like to prevent and we are targeting essentially EHRs to monitor, survey, prevent, this is a challenging thing right now to do with diagnostic codes. It's done but we don't fully know the sensitivity and specificity.

And of course transitions of care related metrics, as mentioned by Dr. Harris, transitions of care is an important area where we worry about anticoagulant follow-up and follow-up for other medications, but to the extent that a lot of these metrics have to do with communication and handoff between providers we're really struggling here with what can an EHR capture in terms of communication and handoff, it's a very complex process metric.

That's not to say all of these four areas we would love to see addressed we didn't purposely exclude them we thought a lot about them but we struggled with them and we'd really like to move forward in terms of EHRs being able to address them, explore them, see if they are appropriate for EHR incorporation, but in sort of the timeframe that we have and the scope of our Workgroup we didn't want to come up with anything de novo that hadn't yet been nationally endorsed in these areas. And with that I'll end.

**Yael Harris, PhD, MHS – Health Resources and Services Administration**

Next slide, please. At this time we wanted to see if there are any questions and answers specific to the anticoagulant recommendations before we move on? All right Nadine do you want to introduce the next speaker?

**Nadine Shehab, PharmD, MPH – Centers for Disease Control and Prevention – Senior Service Fellow**

Yeah, sure, Dr. Len Pogach from the VA and Cindy Brach, and Dr. Andrawis from CMS will be presenting on recommendations from the diabetes agents, ADE Workgroup.

**Leonard M. Pogach, MD, MBA, FACP – National Program Director for Endocrinology & Diabetes – Department of Veterans Affairs**

Thank you, first slide please. I'd like to first off thank the committee for the opportunity to present, we've been, on behalf of our FIW, we've been influenced by the HIT Policy Committee transmittal letter back in August 2011 regarding patient safety and hopefully some of our comments today hopefully will be reviewed as a response to that.

The evidence for hypoglycemic safety has evolved since the ACCORD advanced NVADT there is no doubt now all the major guidelines within a number of about the past 5 months now recommend against intensive therapy defined by an A1c less than 7 for people who are older, have chronic co-morbid conditions and decreased life expectancy.

In fact the American Geriatric Society in collaboration with the American Board of Internal Medicine Foundation in choosing wisely have gone so far to state that most seniors over 65 should not be on medications to lower A1c less than 7.5 unless that is metformin and recommend 8-9 percent is appropriate for many. So, this is now consistent with the American Diabetes Association, the VA and the DoD.

So, in the beginning it was not anticipated that we would be so aligned throughout the entire country private and federal sectors as we are today. Our general EHR recommendations are quite consistent in approach to the Coumadin approach and is also consistent with the National Quality Safety Plan developed by HHS; specifically we have a major emphasis on co-morbid conditions that drive the risk of hypoglycemia.

We want to stratify patients both by lab values, certain risk factors as well as co-morbid conditions. We will have a concept measure for an overtreatment measure as a balancing measure that has been proposed by your group as well as other groups and finally clinical decision support, which emphasizes shared decision support with the patient. Next slide, please.

So, most of the elements that we need to accomplish there are already in existing data elements the one exception would be hypoglycemia which would need to be built in, this is usually self-reported by the patient.

We recommend that lists of patients be put together by key risk factors this could be partly at the decision of the plan or the patient office. Key ones include cognitive impairment, advanced diabetes complications and especially even early chronic kidney disease has been proved to be an important risk factor for hypoglycemic events based on post hoc analysis of the ACCORD Study. Other conditions including cardiovascular complications or an NACQA measure for less than seven in people less than 65, limited life expectancy, alcohol substance abuse where you should discharge from prior hypoglycemic reaction. Next slide.

I should note that these are data that we have developed first in a VA resource funded to my group that try to look at the magnitude of the problem, are patients being over treated, potentially over treated? We found that out of about 1.1 million veterans in the VA identified as being on oral agents, sulfonylureas and/or insulin, we found that a number of categories of risk, if you just look at the one labeled A, which is age over 70, serum creatinine over 1.7 and cognitive impairment or dementia that are clearly evidence-based on all the guidelines, I don't think anybody would disagree, we found about 44 percent of all of our patients, who by the way represent 10 percent of all Medicare male patients in the United States had A1c's 48 percent had A1c's less than 7 percent and about 27 percent had A1c's less than 6.5 percent and this was 44 percent of the population. Depending on how many risk factors you want to include certainly the majority up to about 71 percent of veterans in the VA maybe at higher risk for a hypoglycemic reaction or its consequences. Next slide.

So, our concept measure is the percent of patients on sulfonylurea and/or insulin therapy who have what we call an out-of-range A1c which would be less than – which would be evidence of intensive control as a possible overtreatment measure and our numerator/denominator remained to be more fully developed and obviously all these risk factors are evidence-based based upon grade B evidence and it's a matter of sensitivity and specificities for coding as to what would go into such a measure. We would exclude younger patients those who are not on hypoglycemic agents and those who didn't have specified co-morbid conditions. Next slide.

Clinical decision support could be done even in lieu of a measure and this would identify patients as high risk that would result in action steps. Next slide. And this would be one example of proposed display that would ask the providers and patients to put down what the individualized target would be as opposed to an arbitrary target that was not negotiated together consistent with modern perceptions of shared decision making. Next slide.

And that this would then be how to measure shared decision making would be a more difficult issue, it might eventually involve survey information that is done on a more general basis for CAHPS and other surveys, but this would be the ultimate goal. Next slide.

In the VA we have 21 networks for those who are familiar with the VA hierarchy and VISN 12, which is in the Midwest, is already piloting examples of clinical decision support by putting up our guidelines for targets and then checking the target within a range for the patient clearly indicating that this has been discussed with the patient though obviously this relies on the provider to complete. Next slide.

We also feel, as with Coumadin, there needs to be an action step as to what to do should a patient have risk factors that may put them at risk for serious hypoglycemia, next slide. And this would again be an example of what could be done to document that at least the possible over treatment in the context of the particular patient was addressed. Next slide.

So, finally, before we go onto patient engagement I would comment on one other issue, as with our colleagues from Coumadin we don't quite know the incidence of serious hypoglycemia in the ambulatory care setting – from the distance study from Kaiser Permanente found that 59 percent of patients on insulin had a serious hypoglycemic reaction and recent literature suggests that even it goes well beyond the event itself but is strongly associated with depression, anxiety and even withdrawal symptoms in some of the routine activities of life. So, we feel that ultimately we will need survey information to really capture the impact of hypoglycemia upon people with diabetes. I'd like to turn this over to Ms. Brach now for comments on health literacy.

**Cindy Brach, MPP – Senior Health Policy Researcher – Agency for Healthcare Research & Quality**

Hi, thanks very much Len, unfortunately I'm not on the webinar so I'm going to assume that you are looking at the health literacy related recommendation number one and this is the idea that to meaningfully use EHRs you would select patient education materials that follow health literacy principles that meet language needs and confirm understanding of those materials.

And some of this was informed by some case studies that we did at the Agency for Healthcare Research and Quality that providers were doing a lot of searching through long libraries of materials that did not necessarily match patient's need. We need those materials to be understandable in terms of not using jargon or vague language and actionable in terms of breaking down action steps into manageable explicit steps.

And we know that a large proportion of patient education materials really aren't at the level that most Americans can understand and act upon. We have a population where over 1/3 have limited health literacy 8.6 percent are speaking English less than very well. So, you know, we really need to do a better job of matching our patient education materials and how we explain those to patients with their levels and that can be actually any person whose health literacy level may drop when they're sick, when they're agitated, when they're worried.

The last piece of this is around confirming understanding which has been actually shown to be associated with an increase in glycemic control, so not only, you know, didactically giving information but really checking the comprehension of patients. Next slide, please.

We have a second recommendation also stemming from some of the same work where the ideas that lab results should be presented, structured, trended and with links to interpretive information so that you can understand what those results mean and one of the things that we heard from providers very consistently was how powerful these graphic images were to patients where they could see their own performance and, you know, look at it over time, compare it to benchmarks and in fact these could help overcome some of language or literacy barriers that some patients present. And now I will pass the baton to Mary to go with our next recommendation.

**Mary Andrawis, MPH, PharmD – Centers for Medicare & Medicaid Services – Health Insurance Specialist**

Excellent, thank you so much, hi everybody and thank you again for the opportunity to present to this Workgroup I'm really grateful. I'll walk us through the inpatient recommendations so if we can go to the next slide. So, this is kind of a summary just like we had before and if you go to the next slide we'll start with the data display recommendation.

So, this is basically a recommendation to make or to pull together certain elements to be presented as a flowsheet on a single page. We know that the Workgroup is aware that frequently patients are subject to recurrent hypoglycemia because the data is not available in kind of one location in one place in the medical chart or in the medical records where a nurse or a physician can easily go and monitor the patient's blood sugar, so this is an attempt to pull that together and display that data in one flowsheet kind of format.

So, if you go to the next slide we have an example of what that would look like, what a proposed flowsheet could look like, again, including not just the actual blood sugar reading but looking at other lab values or A1c, their kidney function and what medications they are on insulin or oral hypoglycemic agents or steroids even and then other very crucial information such as nutritional intake and if they are on a tube feeding and if that's been stopped and that kind of thing, and the Workgroup felt very strongly that this would be an important way to prevent hypoglycemia that often is caused because of nutritional interruptions or feeding interruptions when a patient has been already given long-acting insulin. So, this was our first recommendation.

If you go to the next slide this recommendation is for the quality measure concept. Number one, so we have four total, I'm sorry, yes, four total, so the first one, this one here is for severe hypoglycemia and this is the rate of hypoglycemic events when a patient is on an anti-diabetic agent and here hypoglycemia being defined as less than 40, I should say severe hypoglycemia.

So, if you go to the next slide, this one is for hyperglycemia and the Workgroup was able to have the input of several subject matter experts and actually the second expert panel of CMS that's been working on the previous concept that we just heard about in severe hypoglycemia and there was a very strong recommendation from the Workgroup to include a balancing measure of hyperglycemia with that metric and the data shows that when a patient or I should say when a hospital or a setting has good glycemic control then they should do well on both of these measures. So not only would they not have hyperglycemia but they would not have hypoglycemia. So it's an indicator of strong and good glycemic control protocols overall. So, those two metrics kind of go together.

If you go to the next one, concept number 3 is for mild hypoglycemia that would be defined as less than 70, sorry this slide is not – there we go, so that would be less than 70 instead of less than 40 and this is kind of the idea that patients often or nurses, or providers often are not aware of patients that are becoming hypoglycemic until it's too late.

And then the very last one, concept number 4 on the next slide is for recurrent hypoglycemia and unfortunately many patients that experience hypoglycemia it's usually a recurrent event and so that is where the Workgroup is coming up with this very important measure concept.

And then the last recommendation is for, on the next slide, is for clinical decision support and that relates to the metric that we just talked about on recurrent and repeated hypoglycemia. So, this would be – our proposal here is that a provider would be notified and be kind of forced to document when a patient experiences hypoglycemia in more than two readings or values that are less than 70. So, first of all the provider would be notified and second of all that they would need to document that they did something about it or that they're aware of this and that there is a reason that they're not taking action if no action is taken.

You'll see a screenshot of kind a proposed display for that on the next slide, so you can see there would be a list of, for example, what the cause is, the provider would need to document why the patient is hypoglycemic and then the second piece would be to report whatever action is being taken to mitigate that or to address that or to explain why no action has been taken. So, those are the recommendations on the inpatient side.

Again, we're grateful for the opportunity to present these recommendations and I think we have now some time for questions and answers before we move onto the very last section for opioid safety.

**Yael Harris, PhD, MHS – Health Resources and Services Administration**

Any questions from the Workgroup?

**Theresa Cullen, MD, MS – Veterans Health Administration – Director, Health Informatics**

This is Terry I had, Terry Cullen, I had one life expectancy, I think I saw on a slide that you guys define that as a diagnosis of cancer, end-stage liver disease is that right? I mean, do you have a –

**Leonard M. Pogach, MD, MBA, FACP – National Program Director for Endocrinology & Diabetes – Department of Veterans Affairs**

Yes, this is Dr. Pogach, so we – some of the definitions still would need to be flushed out. There are a lot of definitions of limited life expectancy floating around the universe including a recent JAMA paper. We tried to bring it down to the clinician level by trying to pick some conditions that would suggest that patients are likely to be quite ill and on a whole have a limited life expectancy of less than 10 years, which is sort of the cut point that's been used in many of the guidelines and papers.

**Theresa Cullen, MD, MS – Veterans Health Administration – Director, Health Informatics**

Okay, I think what I'm concerned about is figuring out what's the code, the standard terminologies that we use to say you have a limited life expectancy. So, it's a little different than just doing chart reviews so I don't know if you guys have pushed into that at all?

**Leonard M. Pogach, MD, MBA, FACP – National Program Director for Endocrinology & Diabetes – Department of Veterans Affairs**

We had one article in which our definition of limited life expectancy was by Pogach in the American Journal of Managed Care 2007, our definition of life expectancy had a 5 year mortality of about close to 50 percent, but, again, I think the concept generally was to pick a number of conditions for which there would be general agreement that patients were very, very sick and in danger of dying, but agree that needs to be flushed out and made more operational no disagreement whatsoever.

**Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration**

Okay, and I think I have the same concerns about the last CDS stuff about control. I think we're going to – I don't disagree at all with conceptually where to go with that, I guess I'm concerned about how to translate that into an e-Measure.

**Leonard M. Pogach, MD, MBA, FACP – National Program Director for Endocrinology & Diabetes – Department of Veterans Affairs**

By control you're meaning the...by how we pick less than 7 or less than 6.5?

**Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration**

No, no the hypoglycemic or the hyperglycemic so 70 –

**Leonard M. Pogach, MD, MBA, FACP – National Program Director for Endocrinology & Diabetes – Department of Veterans Affairs**

Oh, I'm sorry, that's from Mary.

**Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration**

– more than, you know –

**Mary Andrawis, MPH, PharmD – Centers for Medicare & Medicaid Services – Health Insurance Specialist**

Yes, so are you asking where the thresholds came from?

**Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration**

No not where the thresholds came from. So, I'm fine with anything that's an alphanumeric but it's trying to run the diagnostic decision support quickly through a system and maybe it's not an issue, but I just think we need to be cognizant of how difficult it is to – what are the two – are you using the ACCU-CHEK are you using a bedside, are you using a LOINC code? What are you doing to figure that out and then how do we document that the provider responded? So, a lot of that just is not in standard terminology yet.

**Mary Andrawis, MPH, PharmD – Centers for Medicare & Medicaid Services – Health Insurance Specialist**

Yeah and we tried a very – I appreciate that, this is Mary, we did try our best to put that into the appropriate terminology but if you have – if there is a way that we can make this better packaged for the Workgroup, you know, we'd be happy to do that. Yeah, no I appreciate that maybe the terminology is not exactly right, but we were very focused on looking at the evidence and looking at, you know, what the guidelines support and what is available now. So, if there is a way that we can make these more – these concepts more usable for you, you know, we'd be happy to try to support that.

**Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration**

No, I actually really appreciate what you've done and what I think it calls out to us, Helen, on a much larger scale is where are the gaps in standard terminology that we should be kicking to the Standards Committee to look at. So, for instance when a provider responds in a hospital are there only 5 ways the provider responds? They respond, they initiate an action, they don't initiate an action and they explain why not. It's really; really important work and I just don't think we are at that level yet with this.

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

That's a really good suggestion, Terry. Well, given the time we probably should move onto narcotics and see if there is time towards the end –

**Mary Andrawis, MPH, PharmD – Centers for Medicare & Medicaid Services – Health Insurance Specialist**

So, I think I will actually turn it over to my colleagues Dr. Perfetto from AHRQ and Dr. Kern from the Department of Veterans Affairs.

**Deborah G. Perfetto, PharmD – Agency for Healthcare Research & Quality**

Great, thank you, Mary. Hello and thank you for the opportunity to share our measures with you today. I am Debbie Perfetto I'm one of the Co-Chairs of the Workgroup and I work in the Center for Quality Improvement and Patient Safety at AHRQ and also we have on the line today Dr. Robert Kerns from the VA. Bob, would you like to introduce yourself?

**Robert D. Kerns, PhD – National Program Director for Pain Management – Department of Veterans Affairs**

Yes, hello, I'm Bob Kerns I'm the National Program Director for Pain Management in VA and I'm happy to Co-Chair this group with Debbie I'm inconvenienced today so Debbie is going to do the presentation but I'll be available for Q&A.

**Deborah G. Perfetto, PharmD – Agency for Healthcare Research & Quality**

Thank you, Bob, and we also have two technical experts on the line to answer any questions that you have about some of the measures, we have Dr. Jodie Trafton from the VA and Debbie Krauss from the CMS Office of Clinical Standards and Quality. Jodie and Debbie if you're on the line if you would like introduce yourselves as well? They may be joining us in a few moments.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

They might be on the non-speaker line so I'll make sure they get transferred over, so it's Debbie Krauss and who else?

**Deborah G. Perfetto, PharmD – Agency for Healthcare Research & Quality**

Jodie Trafton and Debbie Krauss.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Okay, thanks.

**Deborah G. Perfetto, PharmD – Agency for Healthcare Research & Quality**

Thank you. With that we can go ahead and get started. Like the other groups we worked to develop a series of recommendations for Stage 3 Meaningful Use that will help reduce adverse events related to opioids. Next slide, please.

We started with developing measures for eligible providers, as we went through the process we developed a list of data elements including data elements that are already collected in EHRs and recommendations on data elements that we need to collect in EHRs to incorporate our recommended quality measure concepts. We developed seven recommendations for quality measure concepts for provider eligible EHRs and we developed clinical decision support rules based on those quality measure concepts that we proposed. Next slide, please.

We started the same process as the other groups but because of the differences in the direct classes we ended up using a different strategy for developing our measures. We started with an environmental scan for existing measures related to opioid safety, unfortunately, there were no NQF endorsed measures related to opioids.

Opioids are a little different than anticoagulants and diabetic agents in that we don't have any surrogate markers we can look at such as INR, A1c so because of that we took a different approach and tried to identify the process measures related to reducing opioid overdose risk factors that could be measured. So, to do this we identified the risk factors that most strongly correlated with opioid overdose and developed measures around those processes and guidelines recommended to prevent those risk factors.

One important thing to note is that our group decided to focus on patients on long-term opioids for chronic pain because this is the patient population that has been largely responsible for the dramatic increase in prescription, opioid prescribing overdose in the past decade.

We evaluated the literature and compared opioid prescribing guidelines for consensus and we identified the risk factors listed above as the ones that our measures should target, those included the high opioid daily dose, co-prescribing of CNS depressants, significantly untreated mental health disorders, active history of substance abuse in multiple prescribers. Next slide, please.

First we decided to identify what information the EHRs already capture and identify what information needs to be collected for opioid quality measure concepts. As you can see the data that is already captured in EHRs are medication list, results of tox screen, results mental health screening, history of drug abuse, family history of drug abuse, some of this information is recorded in current EHRs, but we will need the systems to make more robust use of the data than they currently do.

The new data elements that need to be captured in EHRs are working equivalent dose, a way to record if a patient is on a long-term opioid therapy and a way to document the date and results of the most recent PDMP data, the written opioid treatment plan with treatment goals to identify the primary opioid prescriber and the results of opioid risk assessment. Next slide, please.

As I mentioned earlier, we developed seven quality measure concept for provider eligible Meaningful Use and we targeted the long-term care or long-term opioid use, because of that the denominator and exclusion criteria are going to be the same for each of the quality measure concepts we proposed.

The denominator will always be the number of patients on less opioid therapy which we defined as patients with active opioid prescriptions for greater than 90 days. We have more specific definitions around the denominator in the recommendations package that we submitted.

The exclusion criteria for all these measures are patients on palliative or end-of-life care. For these patients the risk/benefit assessment is a little different than the patients in the general population. Also, we want to note that we considered including patients with cancer pain in the exclusion criteria but we decided that cancer pain is no longer a terminal illness so there is an entire group of cancer survivors that are treated for cancer pain that are at the same risk of opioid overdose as patients treated for non-cancer pain.

With that I will briefly go through our quality measure concepts. Our first measure is to measure the percent of patients on a high daily dose of opioids. The literature shows that there is an increased risk of opioid overdose for patients on a high daily dose of opioids. All guidelines recommend or agree that 200 mg of morphine equivalent per day is a high daily dose so we used that as our initial recommendations until there is more evidence that might be available. Next slide, please.

As I mentioned above, we developed clinical decision support around the quality measure concepts that we developed. So, for this CDS tool we recommended an alert for prescribers to use caution when prescribing more than 200 mg morphine equivalent doses per day in patients that are on long-term opioid therapy. Next slide, please.

Our second quality measure concept is to measure the percent of patient's co-prescribed opioid and CNS depressants, especially benzodiazepines. The rationale for this measure as the literature says that co-prescribing opioids and CNS depressants is associated with opioid overdose deaths. All the opioid prescribing guidelines recommend against co-prescribing opioids and CNS depressants. This measure is based on a measure that is already in use in the VA system. Next slide, please.

The related clinical decision support is an alert for prescribers to use caution when co-prescribing opioids and CNS depressants. We have provided the VA list of CNS depressants in the appendix of our recommendations that were submitted as an example. Next slide, please.

Our third quality measure concept is also based on measures that are already in use in the VA system. This measure is a percent of patients that receive a toxicology screening prior to initiating long-term opioid therapy and for those that receive a tox screen at least once a year when they are on long-term opioid therapy. The recommendations that we submitted have detailed definitions for initiating and ongoing use.

The rationale behind this measure is that most guidelines recommend the use of tox screens for patients on long-term opioid therapy to identify aberrant drug behaviors such as illicit drug use or identify patients that may be diverting their medications as shown in patients that are negative on their tox screens. Next slide.

As you recall the measure concept is also based on measures that are already in use in VA. The measure is the percent of patients that receive a tox screen prior to initiating long-term opioid therapy and for those that receive a tox screen at least once a year when they are on long-term opioid therapy. The recommendations that we submitted have detailed definitions for the initiation and ongoing use.

The rationale behind this measure is that most guidelines recommend the use of tox screening for patients on long-term opioid therapy to identify drug behaviors such as illicit drug abuse or identify patients that may be deferring their medications. Next slide, please.

The supporting clinical decision support would be a reminder for a physician to get a tox screen when there is no tox screen on record or if the toxicology screen on record is out of date. Next slide, please.

Our fourth quality measure concept is one that we are particularly excited about but we recognize that a big part of it will be based on how the PDMP is developed. This measure is the percent of patients that are checked in a PDMP prior to starting on long-term opioid therapy and checked at least once a year for as long as they are on long-term opioid therapy. Again, this recommendation we had submitted – we have detailed definitions for initiating and ongoing use.

We recognize that PDMPs are the perfect opportunity to improve interoperability and data exchange between systems and there may be a day when EHRs are able to readily assess the data from PDMPs. This measure is meant to be a precursor to that so we are encouraging prescribers to access and use that information from PDMPs. Next slide, please.

The supporting clinical decision support provides two alerts for this measure; first there is an alert if there is no PDMP data recorded or if the PDMP data is out of date. Next slide, please.

**Jesse C. James, MD, MBA – Office of the National Coordinator**

I'm sorry to interrupt this is Jesse from ONC, we should leave time for public comment and for any questions or comments from the Quality Measures Workgroup.

**Deborah G. Perfetto, PharmD – Agency for Healthcare Research & Quality**

Okay, the clinical decision support provides an alert based on the data entered and notifies the prescriber if there are multiple opioid prescribers identified. Go to the next slide, please. And the next slide, quality measures concept. Our fifth quality measure concept measure is the percent of patients that have evidence of a written care management agreement. Next slide, please.

The related clinical decision support would be an alert if the patient doesn't have an opioid agreement on record. Okay, the last clinical decision support is an alert to the prescriber when there is no mental health assessment on record. Next slide, please.

And we also developed two quality measure concepts for eligible hospitals. Next slide, please. For the data elements EHRs should already have captured their sedation score, pulse oximetry and respiratory rate. We also need to capture morphine equivalent doses and record if the patient is opioid naïve. Next slide, please.

Our first quality measure concept is based on measures that Deborah Krauss's group is working on in CMS. Next slide, please. And our second quality measure concept for eligible hospitals is a percent of opioid naïve patients that are started on high dose opioids in the inpatient setting and next slide, please.

The screen clinical CDS provides an alert when opioid naïve patients are started on greater than 60 mg MED of opioids. Next slide. Next slide. And the final clinical decision support is an alert for prescribers that titrated dose by increasing more than 50 percent at a time. Next slide. With that we'll go to Q&A. Bob would you like to moderate the Q&A for us, please?

**Robert D. Kerns, PhD – National Program Director for Pain Management – Department of Veterans Affairs**

Be happy to if there are any questions?

**Deborah G. Perfetto, PharmD – Agency for Healthcare Research & Quality**

Thank you everyone, I will turn it back to Dr. Harris.

**Yael Harris, PhD, MHS – Health Resources and Services Administration**

Thanks, next slide please. We just wanted to point out several key things that are relevant to the Workgroup's discussion. First of all a number of these measures are already in existence and therefore could be re-tooled at a relatively low cost with a quick turnaround time.

We also have talked to the National Quality Forum and they indicated that they are going to have a new call for measures for medications in 2014, calendar year 2014, so this is on their radar that a lot of their current measures maybe outdated and that there are new medication measures that need to be considered.

We have also talked to Dr. Gerry Ostrov who has a contract with ONC for the CDS for a new contract and he shared with us his worksheet which is on the next slide and recommended that they also be used to help identify the best clinical decision support for each of our recommendations as well the fact that a number of these are currently being used by Dr. Greg Maynard of UCSC and have been submitted for funding to various entities.

Lastly, we know that some providers already have patient panels that have been created to address high risk ADEs for example diabetics at risk for hypoglycemia, so this would not be relatively new science it would just need to be sort of standardized across EHRs as required in the certification rule. Thank you.

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

Great, thanks Yael, any general questions for the team? I realize we're out of time Jesse so we may want to have some broader discussion about some implications for our work going forward to a later discussion but defer to you and MacKenzie.

**Jesse C. James, MD, MBA – Office of the National Coordinator**

No, that's fair. I think, we can on our one hour follow-up call have a conversation about – that the Workgroup is especially interested in, if there are a group of measures or a clinical area that the Workgroup is especially interested in recommending to the Health IT Policy Committee we will leave time for discussion at another date on what those measures might be.

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

Sounds, good, so public comment, MacKenzie?

**Public Comment**

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Sure, operator can you please open the lines for public comment?

**Caitlin Collins – Altarum Institute**

If you are on the phone and would like to make a public comment please press \*1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press \*1 to be placed in the comment queue. We do not have any comment at this time.

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

Great, thank you MacKenzie. I think with that we'll wrap it up; perhaps we can invite our federal partners to come back at the start of our next call to see if there is any further discussion. Thanks, everybody that was a wonderful discussion.

**Jesse C. James, MD, MBA – Office of the National Coordinator**

Thank you so much.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks, everybody.

**Helen Burstin, MD, MPH, FACP – National Quality Forum – Senior Vice President, Performance Measures**

Bye.