CMS 2012 MEDICARE PRESCRIPTION DRUG BENEFIT SYMPOSIUM

MARCH 20-21, 2012
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Clinical and Safety Outcomes
Erwin Jeong, Pharm.D.

Good afternoon -- and good morning to my West Coast friends since I'm from the West Coast. We have a three-hour time difference, so I'm a little bit jet lagged. Today what I wanted to present is just our experience at Kaiser Permanente in California with our outcomes that we've been reporting on. So I have no disclosures. As far as the learning objectives, there's two that's listed here; one is to determine what outcome measures could be used for a Medicare MTM Program, the second one is to identify clinical and safety outcomes to determine the quality of your Medicare MTM Program.

So this is a polling question. I just wanted to get to know the landscape of my audience as far as what they're currently doing, who's primarily responsible for managing your MTM Program. So if you can get your response card out: (a) would be pharmacists; (b) would be physicians; (c) would be nursing; or (d) would be other health care members. So you have ten seconds. I guess I can start singing because there's no music – the Jeopardy song.

Okay, so the majority of the audience primarily has pharmacists that are doing the management of their MTM Program. And for our program at Kaiser in California, our program is primarily run by pharmacists.
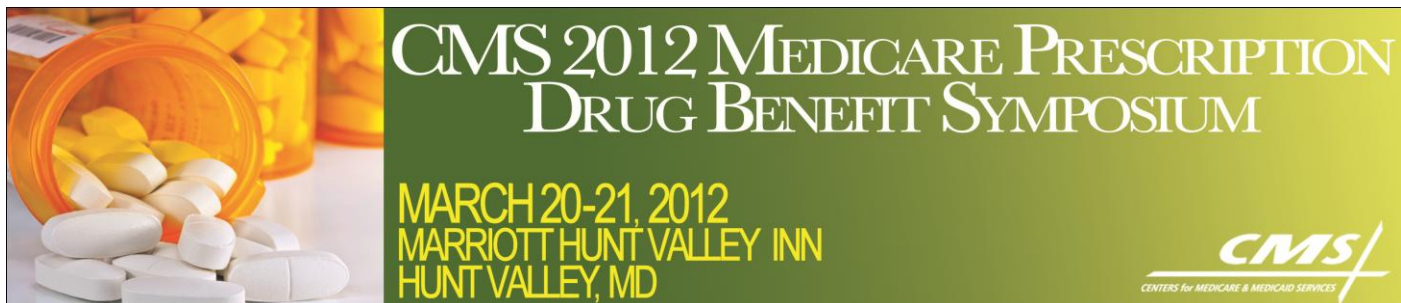
So the Medicare Modernization Act in 2003 had their goal as for a Medication Therapy Management Program was to optimize the therapeutic outcomes through improved medication use and to reduce the adverse effects for our patients that we manage. In 2006, when MTM first started, there was not a lot of specifics as far as how to conduct that MTM program. So that led to a lot of innovations and best practices. And eventually in 2010, CMS released the Call Letter that standardized the programs and made those processes a little bit more uniform across the different programs; but it still didn't really specify outcomes that our MTM Program should be reporting on.

The American Pharmacists Association had done environmental scans for the past four years. These are some of the outcomes that they have listed in the 2010 release, where you have outcomes that are associated with medication use – either them being underuse or drug interactions. There is some cost-related outcomes that are associated with medications for health care costs. Then you have the quality outcomes such as HEDUS, the high-risk medications; utilization-type measures on generic and formulary utilization; then you have others on medication adherence and satisfaction.

So what I wanted to talk about today is briefly go over what our program involves and how our program operates at our facility in California. We have two regions – Northern California and Southern California. Our system is an integrated system, so we are composed of both the health plan side (the hospital) and then the medical group – which we have the physicians employed by the Permanente medical group.

We service 6.8 million members; of that, about 800,000 is Medicare. There's 35 hospitals, and we employ about 12,000 physicians, all linked together by one Electronic Medical Record. And then we do own our own outpatient pharmacies and staff, so the operations for pharmacy is all internal.

Our descriptions are briefly for 2010, we are looking at patients to have at least three multiple conditions. The conditions are listed on this slide, and they're primarily cardiovascular risk conditions. There's a condition that I omitted and it should be in there, which is hypertension. So if you could just make a note that we do target the hypertensive patients. And also, as far as the Part D drugs, they have to have at

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least five medications. And again, those medications are mostly the cardiovascular-type meds. And in 2010, the drug cost threshold was greater than or equal to $3,000. Our pharmacy staff that does the management of our MTM Program consists of ambulatory care pharmacists; and we do have support staff, either technicians or population management support coordinators, that run the program. Our program is – the majority of the cases is telephonic.

Our pharmacists work under collaborative practice agreements with our physician groups. So that allows them to do titration of medications, both increasing/decreasing doses; discontinuing doses and ordering necessary labs for those patients if the physician approves the pharmacist to work on their protocol. If the physician doesn't send authorization or does not agree with the pharmacist working on their protocol, then we just make recommendations to that physician.

Our pharmacy and staff works together with the medical groups – so with the physicians, the nurses, the care managers – by placing the patient in the center to improve the outcomes for that particular patient. And just some examples of how our process works is we will identify our patients on a quarterly basis, and this is based off of our MTM description and inclusion criteria. The next step would be that those patients are paneled out to the respective pharmacy teams, which is the pharmacist and the support staff based on the primary care provider's location. So we have 32 medical centers across the state in California. They're divided amongst those medical centers, and that team works on management of that particular population.

Centrally we send out our offer letters; and in that offer letter is a questionnaire that does ask the patient for their list of medications. And if they have particular questions that they want to address with our pharmacy staff that is made and noted. The patient sends that back in. We get a copy that's scanned into the system, and we can see it electronically. Then once that occurs, our pharmacists go to work calling the patient and performing the CMR.

And since when we first started MTM there was a lot of questions as far as how to operate this program, because MTM is more of like a generalist-type of program – it's not specific where you have a particular disease state that you're managing. It's pretty much all a primary care. So what we wanted to do was determine how best to manage these patients to improve their outcomes. So when you're looking at a patient's medical record or a patient's drug list, there's questions as far as where do you start from all those medications that those patients are taking.

So what we did was we've used pharmacy data and medical data from our integrated system and our Electronic Medical Record and determined flags as far as to determine which populations to focus in on or have the pharmacists focus in on. So, for instance, there's a hospital discharge flag that flags a patient if they were recently discharged from the hospital. There's a flag for patients that are taking high-risk medications or drugs to be avoided in the elderly. There's medication adherence flags that will flag, say, certain chronic medications. And then there's a couple lab monitoring – which is the LDL and the A1C – that if they're not at goal, these flags will pop up on them. We have a cardiovascular risk care gap flag. This particular flag will look at the absence of, say, aspirin, ACE inhibitor or an ARB or a statin on these patients. If patients have deteriorating renal function, we have a flag on certain medications that require dose modifications. And then lastly med monitoring, which is a HEDUS metric where we're looking at the ACE/ARB, the diuretic and the digoxin and making sure that there's a potassium or serum creatinine drawn within the year.

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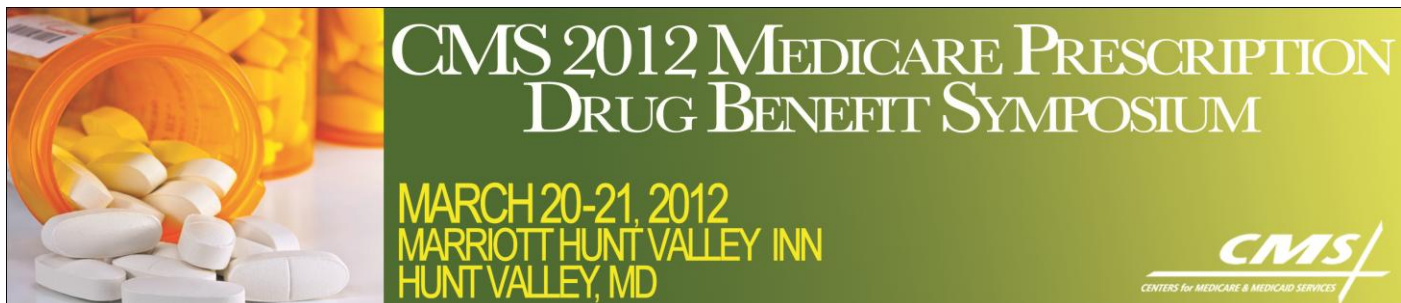
So, where do you start with reporting on, as far as your particular program? Well, there's information that most programs collect – the demographic information. So you could look at your age, your gender, your race; and I'll talk about that in the next slide, about what we did looking at our demographics.
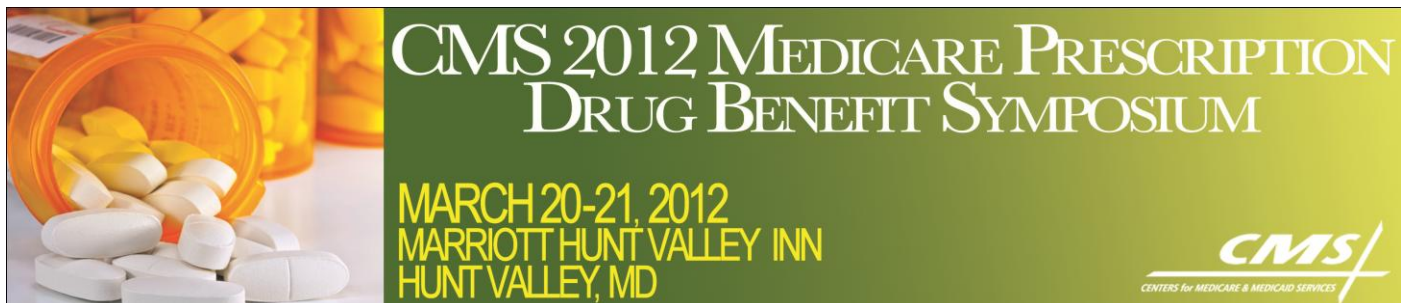
There's also enrollment or process measures that are well-defined by CMS since we have to report on these on an annual basis. We provide this information, and it was recently due at the end of February. And then, finally, the outcomes. So looking at our demographics, there is a study that was published in the health Service Science Research. What they did was Wang and colleagues – they looked at a population to determine if there was any racial or ethnic disparities in meeting MTM eligibility in 2006. So what their findings was that the Hispanic and the African American populations were less likely to meet MTM eligibilities. Then CMS communicated in April of 2011 to have programs take a look at their program to see whether or not any disparities exist in their racial or ethnic backgrounds.

So what we did within Kaiser is we pulled our demographics information, primarily looking at the ethic/racial flags for our 2010 program. And then we had about, say, three-quarters of the patients that had a designation of their ethnicity. What we did was we looked at three groups (similar to what the Wang and colleagues did) which were the African American groups, the Hispanics and the Whites. We looked at their eligibility to see whether or not they were eligible or not for the MTM Program or not eligible; calculated a percent eligible – which you'll see here. For Blacks, it was 11.6%; for Hispanics, 10.1%; and then the Whites was 7.4%. We calculated an odds ratio for the respective groups, comparing it to the reference value for Whites, and found out for Blacks we had a 1.63% odds of being eligible for our MTM program compared to Whites; and the Hispanics had a 1.4% odds of being eligible for our MTM Program. So in conclusion, we did not find any disparities between those two particular races – the African Americans and the Hispanics -- on being eligible for our MTM Program.

So what else besides demographics can be measured? I mentioned earlier that there's process measures that we submit to CMS on an annual basis. Those may include the eligible population, how many patients disenrolled, how many CMRs we offered and how many CMRs received. Also in that submission on an annual basis, we submit the patient level file that contains a wealth of information, including how many Long Term Care patients you have, how many prescriber interventions, how many interventions that you made that resulted in a medication change.

So what you want to do is evaluate your program and determine, *What population are you managing?* So within our Kaiser California population are mainly looking at the cardiovascular-risk patients. And the other question would be, *What are common interventions that are being performed by your staff?* So some of those for us was looking at LDL control, A1C control, and making sure patients weren't on high-risk medications in the elderly and also trying to intervene on those patients that were recently discharged from the hospital.

So as far as a process measure, what we did here was we do collect data on our eligible population and the number of patients that we did a CMR on. So what you have here in this particular measure is being proposed by CMS as an MTM measure, where their calculation of the percent of your eligible population that got a CMR. So over the past four years, once we started looking at this data, we've shown an increase as far as the percentage of these members is eligible populations getting a CMR. And that, again, is driven by us setting certain targets. So, for instance, in certain years we've set targets to be at a certain percentage; so that sort of drives performance amongst our staff. So currently, last year we are at about a 67% CMR rate for eligible population.

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So now on to the outcomes -- the MTM description template has a list of outcomes that are available to be selected at the end of that particular template, and they're listed here. I won't go over in details with that, but you could read them. So what we did was over the beginning portion of our program once we started in 2006, the outcomes that we had measured primarily was cardiovascular-related, so it involved LDL control and A1C. But we wanted to look at more in-depth as far as what extra or additional outcomes we should be looking at. So we participated with the America's Health Insurance Plans (or AHIP), and then we piloted several measures for them. This particular program was a pilot that involved about 10 or 12 health plans, both PDPs and MAPDs. We looked at program demographics on the number of CMRs that were being done, also number of patients that entered the coverage gap. We also looked at the utilizations of generic medications, adherence to statins and oral hypoglycemics; we looked at a couple safety measures; and then several clinical measures, which I'll go over later.
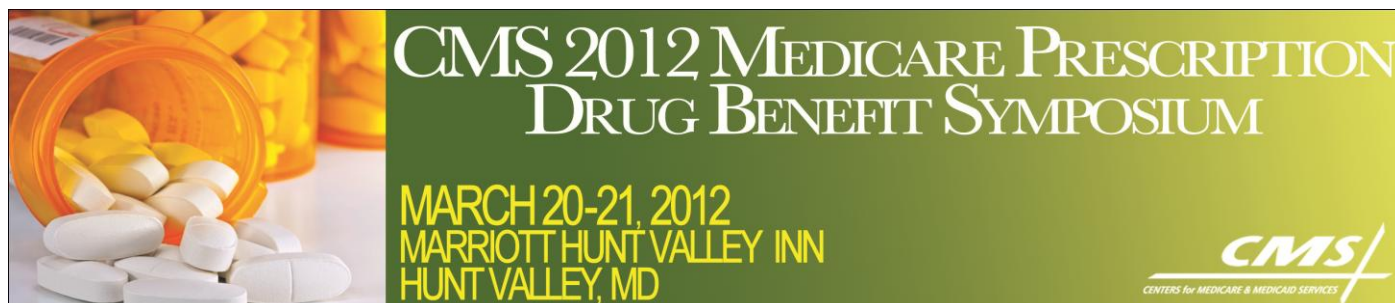
Then in 2010, we were involved with the Pharmacy Quality Alliance, where they asked us to pilot four of the measures that were being proposed. So we got involved with looking at CMR percentage, the use of high-risk meds in the elderly, ACE/ARBs in the diabetic hypertensive population, and controller use in the asthma population.

So, on to safety outcomes -- this is the safety outcomes on the high-risk medications in the elderly. So this particular one looks at the percentage of the MTM patients that are greater than or equal to 65 and received at least one high-risk medication in the elderly. And that list – you could look and get that high-risk medication list from the NCQA website. But the main outcome here is to try and minimize the adverse effects of these medications for our elderly population. So over the past four years that we have listed here, this particular measure – you want the number to be lower the better because this is the number of patients filling a high-risk medication. So the less patients filling it, the better off. So we started at about 36%; and currently, last year were at about 14%.

Another method to measure that high-risk medications involves looking at that CMR or that intervention to see whether or not that intervention that that pharmacist did has any impact on reduction in the high-risk medications. So this measure, similar to the previous one, is looking at the members that are greater than or equal to 65, they got a CMR from the pharmacist, that discontinued or did not fill that high-risk medication in a post period. We chose 120 days as that post period, and our results – you want the number here to be larger, as opposed to the previous measure. So our results for the past couple years, we have in 2010, 69%; and then 73% for 2011.

For another safety measure, we're looking at those patients that had diabetes or hypertension and whether or not they are on an ACE inhibitor or an ARB. This particular measure, again, is looking at medications as proxies for those two conditions instead of diagnosis. In this particular case you want the number to be lower because we're looking at those patients that do not have a prescription for an ACE or an ARB. Our results from last year are 16%.

Now on to the clinical outcomes -- so what we're doing here is in these particular cases are using diagnosis coding (or ICB9s) to determine the diabetic population and looking at how many of those patients have LDLs less than 100. So what we do here is we use our data – both medical claims and pharmacy claims – to determine what that percentage is. And we have slowing increasing our amount to at the last year it's about 82% of our patients with diabetes having an LDL of less than 100.

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Looking at that same population of the diabetics, we wanted to see whether or not the A1C was less than 9, so a similar type of methodology here looking at the labs. And we've stayed pretty consistent – about 90% of our population having an A1C less than 9.

Looking at coronary artery disease, that particular diagnosis, and whether or not they had an LDL less than 100. Our results are listed here, where we started at about 70-something percent and are now at 81% with that particular measure.
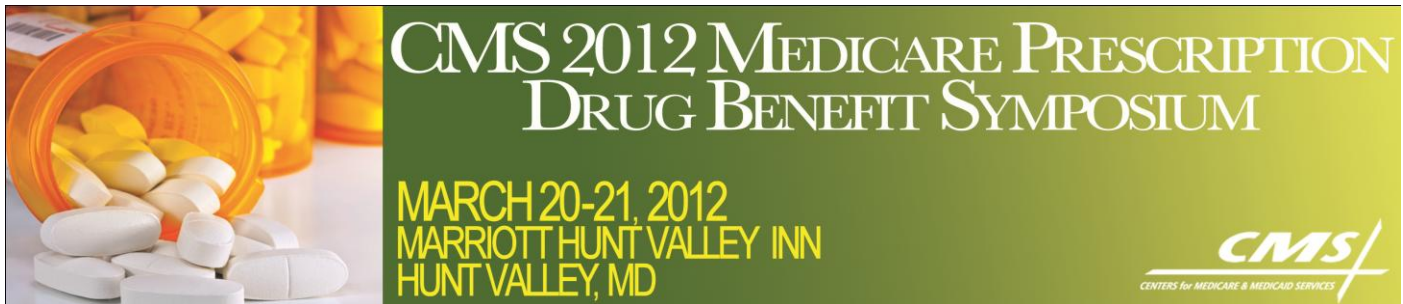
So with all these safety and clinical outcomes, we wanted to find out whether or not the pharmacists' work was having an impact on the overall health outcomes of the patient. So what we did was we pulled hospitalization and ER data from our systems. We have the hypothesis listed that states that our MTM patients that get a CMR would have less utilizations of these resources. We looked at a six-month period in our 2010 program year. The MTM group were those patients that had a CMR, and then we had a comparative group which did not get a CMR. So these patients were either disenrolled from the program or were inactive, not having any interaction with the MTM pharmacists. So we looked at – similar to the previous presentation – the CMR date was the anchor date -- and we looked 12 months forward for any ER use or hospitalization. For the comparative group, which was the PCP group or those patients that didn't have a PCP visit; we looked 12 months from that first PCP visit to see if there was any ER usage or hospitalization. The number of patients in our 2010 year was about 40,000; of that, we had 24,000 that got a CMR; the comparative group – 16,000 that did not have a CMR; and further breaking that down, we see about 14,000 that had a PCP visit and 1,800 that did not.

The results here, primarily the MTM group as far as the age is about, say, 75 years. The PCP groups range from 75 to 78 years of age. The number of active medications that were in the MTM or CMR group was about 14 active meds; for the PCP groups, between 14 to 15 medications. The mien number of hospitalizations for our MTM group was 1.97; for the PCP group, 2.16; and then for the ones that did not have a PCP visit, 2.28. The mien number of ER visits for our MTM group was 2.67; for the PCP group, 2.97; and for the ones without the PCP visit, 2.69.

So when we looked at the incidents as far as how many received a hospitalization, our MTM group we had about a 30% of that population having some type of hospitalization – the mien number. Now again, our 2010 program, since we're subselecting out these high-cardiovascular-risk patients that are using high medication drug costs, that's something to consider. The PCP group, as far as their percentage on hospitalization, was 36%. And then the ones that didn't have a PCP visit was 42%. So when you look at this, the difference between MTM versus PCP ranges between say 5% to about 12% reduction in hospitalization.

When you look at ER utilization, our MTM group, we had about a 48% use; the PCP group, 52%; and then the no-PCP, 52%. So the percent change or the reduction was between 3% to 4% compared to our MTM group.

When we looked at the odds ratio of the two cohorts on hospitalization and ER visits, when we compared the CMR group with our comparative group, the odds ratio for the hospitalization was 0.767% or that particular group the patients that got a CMR from the pharmacist had a 23% less hospitalization when you compared it to the comparative group. When we looked at ER visits, we had an odds ratio of 0.813% or 19% less ER use when compared – your patients that got a CMR compared to those that did not.

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So this just summarizes that there was a lower incidence of hospitalization and ER usage that I just went over.

So some takeaways as far as what should be done is what you want to do is assess your population and determine who you're targeting or who you're focusing in on; and from the outcome work that Kozma and Reeder have done where they've used the ECHO model (where you have the "E" standing for economics, "C," clinical; "H," humanistics) -- we've added in another "S" for safety as another outcome. So under the economics, you could look at anything that's cost-related; so say, generic utilization, the drug cost PMPM, resource utilization, hospitalization, ER utilization. And for the clinical pieces – those quality pieces or surrogate markers – you can look at LDL control, A1C and blood pressure control; also adherence measures.

Then the humanistic side would be anything satisfaction-related; so, getting the responses from your patients or providers on the satisfaction of your service; then the two safety measures that I went over – which is the high-risk medications in the elderly and the use of ACE inhibitors or ARBs in the diabetic hypertensive patients. So once you evaluate your program, what you want to do is start measuring those particular outcomes and then set program goals to achieve those particular targets.

So another thing to consider is that a lot of the programs that is not similar to Kaiser, which is an integrated model, may not have a lot of this data available or readily available to look at what the hospitalization rate is, what the ER rate is. So one of the questions that I have for our CMS folks here is if possible – and I know that it was mentioned earlier in our symposium that more data will be made available to us – but what we're trying to do is just see whether or not we can get the data from the health plans – so for instance, their hospitalization rates – and then compare it to the MTM data that we submit to come up with some type of measure to assess how effective your particular MTM Program is. So doing that – I think using that, say, team approach similar to how we manage our patients in Kaiser where we work collaboratively with our medical group – if we have the plan's data available to the pharmacist that's actually doing the MTM work so they could see what the effects are of their particular interventions are on the ultimate outcome of the patient, that would be much helpful for us to evaluate the worth of our particular program.
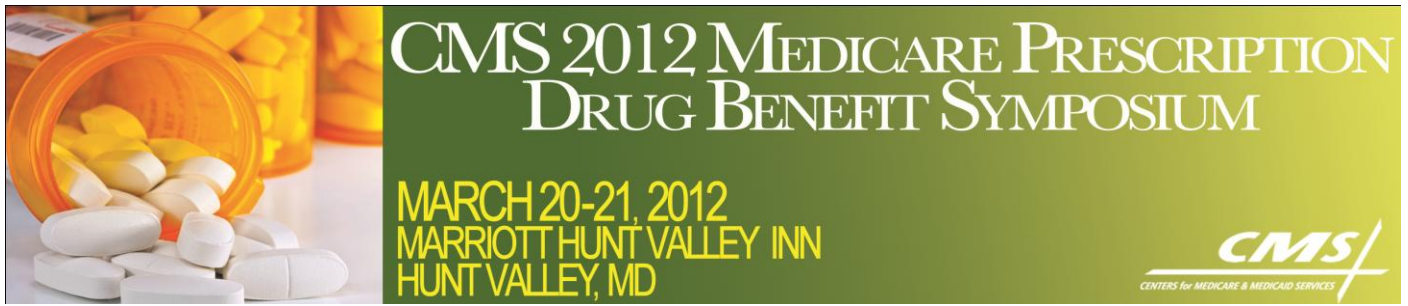
So I have the assessment questions; so if you can get your automated response available.

So questions – next slide – okay, thank you.

So the first question is, *What outcomes measures can be used to assess a Medicare MTM Program: (a) medication adherence rates; (b) clinical measures affecting management of chronic conditions; (c) safety measures to prevent harm from medication use or non-use; or (d) all of the above?* So you'll have ten seconds.

Okay, so looks like mostly everybody got that correct, which is (d) all of the above. So no one was falling asleep during my presentation.

Next question, *Which of the following clinical outcomes can be used to assess the quality of a Medicare Medication Therapy Management Program: (a) LDL control in patients with coronary artery disease; (b) A1C control in Type 2 diabetics; (c) blood pressure control in patients with hypertension; or (d) all of the above?*

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Okay, all right. Just one person didn't get it right. So the answer is (d), all of the above.

Okay, thank you.