BroadcastMed | Grand Rounds: Evaluation of diabetes care quality and value: Role of Optum Labs in patient-centered health care delivery research

GLENN SMITH: Good afternoon and welcome to CTSA or CCaTS Grand Rounds. I'm Glenn Smith. I'm the associate director for education in CCaTS, and I also have the privilege of being in the education leadership in the current center for this science of health care delivery. So it's a special treat to get to introduce our speaker today whose credentials amaze and astound me.

Dr. Rozalina McCoy did undergraduate training at Harvard, and then attended medical school at Johns Hopkins where she was at the top of her class. And has since, fortuitous for us during this training program doing your internal medicine residency and now in adult endocrinology fellowship at Mayo Clinic. She's been in the clinician investigator training program for portions of this training, and was also one of our delivery systems science fellows through the Academy Health program in 2013 and 2014.

Her research focuses on the development evaluation and improvement of care delivery models for treating patients with diabetes and other chronic conditions. So a true scholar of delivery science, and we're fortunate to have her present today, Dr. McCoy.

ROZALINA MCCOY: OK. So, I want to make sure this is working. Well, thank you everyone for coming, and for listening to what I think is an important topic, not only because we'll be speaking about chronic disease management of specifically diabetes, but because it can allow us to demonstrate how big data, and in this case specifically, Optum labs data, can be used to study patients with chronic conditions, and improve the quality and the value of care that we provide to our patients.

So I'm a fellow and had absolutely no disclosures. So, our learning objectives for today will be to speak about the role of big data in health care delivery research, and patient centered [INAUDIBLE] research focusing specifically on Optum labs. Where we review trends in diabetes treatment intensification practices, compare second-line agents for diabetes therapy, and ultimately appreciate the prevalence of over-testing and over treatment among low risk patients.

So we all hear about big data. That's a result of the fact that there's just a lot of it out there with the Health Information Technology for Economical Clinical Health Act in 2009. There's been a proliferation of electronic medical records and health information exchanges. And that CMS HR incentive programs, and ultimately meaningful use, have mandated us to use this information in a meaningful way. So what does that actually mean, and why is that not happening to the degree that we like? Well, part of the problem, and I know the clinicians among you will appreciate this, is the fact that all of this patient information is buried in multiple different clinical applications. In order for EHRs to be useful for research and proactive patient care, it has to be accessible and useful in real time. We have to be able to interrogate that data and correlate it, and ultimately, to use the findings from that information to improve patient care through translation and implementation.

In the ideal world, this big data, or patient related clinical and administrative, this patient related information, can be used to guide and generate a learning health system where the power of advanced analytics could be combined with the multi-dimensional health related data from EHRs to facilitate data driven discovery and allow for current and actionable knowledge to be generated. Examples could be comparative effectiveness research, identification of waste inefficiencies, individualization of the patient experience, population based care delivery models. They can inform clinical practice for the clinicians, and improve the provider's financial health overall.

So my experience is using the Optum Labs. So I know a lot of you have heard of Optum Labs, but for those who haven't, it's a partnership between Optum, a subsidiary of United Health Group, the insurance company, and Mayo Clinic, that was formed in January of 2013. And the goal is for Optum to give us a lot of data, and Mayo Clinic, and ultimately later partners who joined, to use that clinical data to improve patient care. The partners that are part of the Optum collaboration include not only Mayo Clinic, but agencies such as AARP, Pfizer, Tufts, University of Minnesota, Harvard Medical School, Merck, Medica. So bringing together a diverse array of experience and questions, that together can work with the data provided by Optum, as well as the partners, to improve patient care.

Patients included in the Optum Labs population, between 1994 and the present, includes 7.5 million commercial or private insured enrollees, nearly 41 million of whom have both medical and pharmacy coverage. In addition, there's almost 4.5 million Medicare Advantage enrollees, such that this is the largest data set of commercially insured Medicare patients available for research use. There are patients from every single state in the United States, though due to the insurance companies who provide this information, the greatest representation is in the south and Midwest US.

As an example, in 2013 alone, you'll see that there's near 31.7 million commercial enrollees, representing 16% of all commercially insured people in the US. All ages are represented, but of course the young and working age adults are most prevalent. And there are people there from every state.

Finally, as you can appreciate, looking at how much longitudinal information we have, there's a substantial number of people with one, two, three, four years of continued enrollment, allowing us to look at longitudinal information. Why these percents may not be high, remember, we're starting with 32 million people. For Medicare Part C, in 2013, there were more than 3 million individuals, or 20% of Medicare Advantage patients, again representing all ages, states, with longitudinal information available for a very vast number of people.

This, even though it's a commercial plan, we do have people of all ages, including people over age 65, as well as the young, less than 18. And these are people who have typically not been included in clinical trials, as well as observational studies, due to accessibility of their information. A pretty equal split of men and women, and a relatively good mix of racial groups.

There's a lot of information. But just to give you a glimpse of what information is out there, because I think this is a very useful tool that all of you can use for your research as well, there's information about patients. So type of health plan and they have, their gender, age, their family unit, everything that providers and pharmacist bill for. The medications that they fill, when they fill them, allowing for cancellation of adherence rates. How much co-payment was paid, or co-insurance, for medications or clinical encounters. Who was the doctor that they saw? What was their specialty? What hospital were they cared for? What were those hospital characteristics? What lab tests that they have done? And for about a 30% subset of individuals, what was the result of that lab test? There's income, education, race, and house ownership for every patient. A subset have clinical or EHR information. We can read their notes, even including natural language processing. Health risk assessment, height, weight, tobacco use, PHQ-9s.

Mortality data is currently not reliable, because it's not available for every patient, depending on the state. So importantly, all of this is completely deidentified, so patient data can be used for research. But unfortunately, it cannot be linked to other data sets, such as Medicare or survey information. So having access to this vast amount of data will really help us to conduct research and individualize and improve patient care.

So thinking about the IHI triple aim of health care, patient experience, population health, per capita costs. Or the IOM accommodations for high quality care, making it safe and effective, patient centered, timely, efficient, equitable. Keeping this in mind, and having this vast amount of information, gives us a lot of opportunities to do research, and which made me very excited about it.

So I know I'm preaching to the choir, but we all know the burden of diabetes in the US and worldwide. It affects 9% of the US population, including 7% of adults in Olmsted County. We know that poor glycemic control increases risk of diabetes complications and impairs quality of life. And as a result, there are publicly reported performance metrics aimed at improving glycemic control. And those involve, first, measuring the hemoglobin A1C, or a measure of average blood sugar over the span of three months, and ultimately treating patients to lower their hemoglobin A1C to below 7%.

Now, what is the best way to treat type 2 diabetes? Metformin is accepted as first line therapy, and it's currently recommended by clinical practice guidelines. But ultimately, patients require additional medications as their glycemic control deteriorates. Multiple studies have implicated failure of treatment intensification in being associated with poor glycemic control and greater risk for complications. There are many patient factors that can be associated with failure to intensify, but the provider factors as well, referred to as clinical inertia.

So there are two seminal studies that looked at this. In 2003, a national survey of adults with multiple chronic conditions found that among diabetes patients specifically, only 45% receive recommended care. And that was defined as a composite of 13 indicators, including counseling, treatment, and follow up. This really called attention to clinical inertia, and a drive by clinicians to be better at it.

Yet in 2006, 34% of patients with diabetes in a Kaiser study, who had high hemoglobin A1C above 8%, did not have their treatment intensified, despite that fact, calling yet again, our focus on clinical inertia. So one of our first questions working with this was, has this improved? So we looked at treatment naive patients with type 2 diabetes, who were initiated on that metformin monotherapy, between 2002 in 2007. There were more than 75,000 people who met this inclusion criteria. And we looked at their time to treatment intensification, as well as the choice of second line therapies. While metformin is recommended as the first line agent, the specific second line therapy, there are no recommendations for which one is best.

So ultimately, what we found is that time to treatment intensification decreased over time, from patients started on metformin in 2002 or 2003, 2004 and 2005, and 2006 and 2007. And we really looked at these breakpoints to mimic the two seminal studies that were done, calling attention to clinical inertia.

Now looking at the likelihood of treatment and intensification, adjusted for age, sex, race, income or education, co-morbidity level, we found that the odds of intensification did increase over time. There was no difference by sex or by ethnicity. Importantly, patients who were sicker were more likely to be intensified. It kind of goes against guidelines, which say that patients with limited life expectancy should not be intensified, and we thought that this was observed in other studies, and we thought that it represented just increased access to providers. Sicker patients see doctors more often, and are more likely to have another drug added on.

In terms of the choice of second line agent that was used as an add on to metformin, we saw some changes over time. Sulfonylureas were are consistently most common, but they're use decreased over time. As expected, thiazolidinediones use plummeted after they were found to potentially increase risk of heart failure and mortality around this time.

New medications, of the incretin class, so DPP-4 inhibitors and GLP-1 receptor agonists, really took off. And by 2006 and 2007, were more than a quarter of all second line agents, despite limited long term data surrounding their efficacy and safety. And finally, insulin use increased as well.

So keep in mind, this says administrative data, and there are limitations. We have no laboratory data for this patient population. And ultimately, the type of pharmacy benefit could contribute to the choice of second line therapies. These are all privately insured adults.

Now, we saw that there was this change in second line agents over time. So we asked, are newer agents really better? So there are 12 classes of diabetes medications currently approved. The ones listed here are most commonly used, and you saw them on the slide before. So which one is better?

We looked at a slightly different patient population, again, all from the national Optum data set, treatment naive type 2 diabetes patients started on metformin, 1995 until 2010. Because we were interested in hard outcomes, we required that they have at least five years of continued enrollment after metformin initiation. There were 37.5 thousand adults who met our inclusion criteria. And we compared these four treatment regimens after metformin. What is best? Sulfonylurea, DPP-4 inhibitor, GLP-1 receptor agonist, or, as some suggested should we go straight to insulin?

We used the population based glycemic control model based on a Markov chain, and the outcomes that we were interested in were expected life years, and quality adjusted life years, and cost of treatment, until a first diabetes complication, which, congruent with the randomized control clinical trials, were defined as a composite end point of ischemic heart disease, stroke, blindness, renal failure, amputation, or death. An additional secondary outcome was the expect the time to insulin initiation, because it's a patient important outcome. How long can they remain off insulin?

So looking at these different regimens, remember, sulfonylurea, DPP-4 inhibitor, GLP-1 receptor agonist, and insulin, men and women, we found that the expected life years until the first diabetes complication was similar, in terms of life years and quality adjusted life years for all regimens. However, the expected cost per quality adjusted life year was much lower for the sulfonylurea pathway. Mean time to insulin use was much longer with the sulfonylurea pathway, compared to all other pathways.

Importantly, I'll call your attention to the [INAUDIBLE] are comparable, because those include hypoglycemia, weight gain, cardiovascular events. So the adverse events that have been linked to sulfonylurea therapy, those are included in the quality adjustment. So even when you control for that, take that into consideration. The sulfonylurea agents of course still appear to be more cost effective compared to DPP-4 inhibitors and GLP-1 receptor agonists.

There is controversy among clinicians in terms of what is the best target for hemoglobin A1C in patients with type 2 diabetes. And we conducted sensitivity analyses looking at the different targets as recommended by different practice guidelines. So 8% 7% and 6.5%. And we modeled the quality adjusted life year to the event versus cost for all the regimens and the different glycemic targets. So you want your patient to be treated with a medication that's kind of closest to here, longest time until event at the lowest cost. So the closer you are to here, the better.

And you can see that no matter what glycemic target, the sulfonylurea regimen performs a lot better. The other thing that you note it is that the last seven to 6.5 target appears to be the best as well. Keep in mind these are recently diagnosed patients with type 2 diabetes, who did not have any of these cardiovascular events at baseline. So these are not the high risk patients that were included in ACCORD and ADVANCE studies. These are newly diagnosed patients who are looking at treatment identification. For women, years are different, but the findings were exactly the same.

So again, this is observational data and we used information from real patients to develop our Markov model. As a sensitivity analysis, we used clinical trial data, but the results were exactly the same. There are benefits to observational data, and the fact that it reflects real world treatment effects, real world rates of hypoglycemia and weight gain, and real world adherence.

Now while it is also a Markov model, rather than true observational data, and it is limited by the fact that we could only put into our models the side effects, [INAUDIBLE] effects of medications that are actually known, it is malleable, and can be improved, as there is new evidence about drugs and their risks. There's also empiric evidence that is forthcoming. The GRADE randomized controlled clinical trial just started, funded by the NIH, that is asking exactly the same questions. Same four regiments. It is expected to last 10 years, so probably 10 to 15 years from now, we're going to know the results. Hopefully the medications used will not be obsolete, but they might be. But it'll be great to see how those results compare to what we got in our model. We're also now doing an empiric study similar to this, using Optum Labs data. So looking at the results prospectively, rather than using a model.

Now we talked about, how should we treat our patients with diabetes. What about the other part of managing them? How often should we monitor them? And that really drives at reducing waste and inefficiency and patient burden. So how often should hemoglobin A1C be checked? We all know what to do for our not controlled patients, or patients at risk for deterioration of control, women who are pregnant, type 1 diabetics, or patients on a pump. But what about adults with stable, controlled disease, no history of complications such as hypoglycemia or hyperglycemia, and no indications for intensive treatment and monitoring, like pregnancy.

So current guidelines say, anywhere between 12 and six months. AACE does not say how often to check the low risk patients, but it does say that if you're not stable, it should be every three months, suggesting that once you are stable, it is probably less, though they don't explicitly state that. So how often is it actually checked, and does testing impact the treatment practices? Is there more to testing frequency than just patient burden, an extra poke, and an extra charge?

So here, I'll actually present data both from the national Optum Labs data set, as well as our own employee community health population. We looked at low risk adults, and truly as low risk as we could define them. Over 18, no insulin use, not pregnant, no documented hypoglycemia or hyperglycemia. And to demonstrate the fact that their hemoglobin A1C is not only controlled, so less than seven, but also stable, they had to have two consecutive A1C measurements that were less than seven.

So we found those patients, and we followed them prospectively for 24 months. We defined testing, we broke down testing frequency into what is recommended by the guidelines, one or two times a year; what is not guideline concordant in this population, but makes physiologic sense, so three to four times a year; and a frequency that in this population does not make physiologic sense, more than five times a year, or less than three months apart. Recall, hemoglobin A1C is a measure of average blood sugar over three months, so we should only be checking, once steady state is achieved, every three months. It is reasonable to check sooner people who have high hemoglobin turnover, or who are not at steady state or stable, but all of those patients were explicitly excluded from our study. So in our patient population, this does not make physiologic sense.

So first we wanted to define the scope of the problem, and later to look at the impact on diabetes treatment. For this we could only do it in the national data set, because Mayo Clinic AHR does not allow for reliable estimation of medications used. And we looked at things that have been linked, or suggested, as potential precipitants of excessive use, such as fragmentation of care, or specialty care, as well as panel testing, which been proposed as a way to decrease redundancy. And we looked at regional variability as well.

So what did we find? So in the national Optum data set, there were 33,000 people who met our very strict inclusion criteria, compared to 1800 patients at Mayo Clinic. Now this should demonstrate to you the power of Optum Labs. We can get sample sizes that are unparalleled if we were to look at single center studies, even with inclusion of all of our primary care clinics, and even multi-center studies.

So how often were these patients tested? Nationally, only 39.5% were tested as recommended by the guidelines. 55% were checked quarterly, and nearly 6% were checked less than three months apart. The Midwest was actually the least bad of them all. You see the numbers here. The highest prevalence of excessive testing here was in the Northeast, and that's consistent with what Dartmouth Atlas has found. We were very happy to find that we were better. Very few patients were tracked more often than five times a year. Half were checked quarterly, and about half were checked once or twice a year.

How does that correlate with what their A1C was? So are these patients all teetering at the edge of losing control, so providers are anxious? Well, not really. So breaking down by A1C, in the whole data set, a third were 6.5 to 7, 57% were 5.7 to 6.4, and 10% had a hemoglobin A1C less than 5.6%. This does not even meet criteria for the diagnosis of diabetes, suggesting very intensive treatment. Importantly, about a third were not on any medications. They were just diet controlled.

And yet looking at the testing frequency, it seemed not to really matter how low your A1C was, or how many medications you're on. The prevalence of excessive testing, and this high frequency testing, was pretty comparable. So again, the higher your A1C, the more often you were tested, and the more medications you're on, the more often you're tested. But the numbers are still remarkable for how often these stable, low risk patients are being sent to the lab. Now again, at Mayo Clinic, our A1Cs were generally higher, and the testing frequency, again, increased as the A1C rose.

Now who's ordering these tests, thinking about the role of specialty care? Well, ultimately, most patients do have a test ordered by primary care. Now the denominator for these percents is the number of patients, and because we're looking at the numerators, the number of tests. So they don't add up to 100 because of the redundancy of testing. But ultimately the extra tests, so looking at who is in these two groups, the extra tests are primarily driven by specialty practice, primarily endocrinology and nephrology. Now this is Mayo Clinic numbers, but the national numbers look very similar.

What is the role of panel testing, and does getting a hemoglobin A1C simultaneously with other diabetes labs, so lipids, creatinine, urine microalbumin, does that decrease the likelihood of excessive testing? In the national population, it does. So about half of the patients were checked just the A1C on that day. The other half it was checked together with other diabetes studies. Excessive testing was a lot more common among those who had the A1C checked alone, such that the odds of excessive testing with panel use was 80%. Now at Mayo Clinic, we probably reached the point of maximal return, because there was no difference in the odds of excessive testing, whether the A1C is checked by itself or with other labs, but 80% of our tests are done with something else, with a panel. So we may have reached the point of maximal return.

Finally, looking at coordination of care, thus involvement of multiple providers, and specifically multiple providers ordering the same tests, does that impact excessive testing? So we found that it does. So for patients whose A1Cs are ordered just by primary care alone, nobody, basically, is getting checked this often. 43% are checked quarterly. For patients who have tests ordered both by primary care and specialty, 3% are checked five or more times a year, and 61% are checked quarterly. Patients managed by specialists only, and this is a very tiny number at Mayo Clinic, they're somewhere between.

Now nationally, only 12% of patients are actually managed just by primary care. 84 percent have both, a primary care provider and a specialist. And the rates of excessive testing are higher, because they were higher overall, but they follow the same general principle. Lowest for primary care only, intermediate for specialists only, and the highest for primary care and a specialist, suggesting a role of not only specialty care in excessive testing, but also fragmentation of care.

Now does testing ultimately lead to changes in treatment? So here we only looked at the national Optum population, and we found that patients who are over tested are more likely to have their treatment intensified, so either by addition of another drug, or transition to insulin, despite the fact they all, by definition, had hemoglobin A1C less than 7% at goal. Now when we looked at who was most likely to be intensified, it was the patients whose hemoglobin A1C was between 6.5 and 7, as well as those managed by endocrinology.

The only predictor of deintensification, or having a medication removed, was being on three or more meds at baseline. Having a hemoglobin A1C of let's say 5.5% did not significantly increase your odds of being deintensified. So this raises the question of the other side of clinical inertia. Your patient is doing well. Their A1C is very low. They're on, let's say, two drugs, so we won't rock the boat. But is that really the best practice? Just food for thought.

Now, putting aside the burden of poly pharmacy, and extra visits to the lab to have your A1C checked, what is the cost? So nationally, if we were to tell providers to check hemoglobin A1C in this low risk population once a year, that would save $1.2 million dollars. Two tests a year, which many believe is still too much, but is reasonable, is $340,000. At Mayo Clinic, having one test a year would save us $56,000 a year.

Now this may seem like a small number, but we think that this is just the tip of the iceberg. Because remember, 80% have other, multiple tests done at the same time. How often should a lipid panel be chucked in these low risk patients? Probably not every three months. So when you would add everything up together, the costs would probably, well, would likely be a lot higher.

Now it is a highly restrictive patient population, so we expect that excessive testing is actually a lot more prevalent, if you were to expand it to everybody who really should not be checked that often. We do not know all of the follow up hemoglobin A1C values, so we don't know if maybe they went up or down. We don't know the specialty of providers who were ordering the tests in Optum labs. That's why I showed you the data for Mayo. And we don't know the treatment regimens in Mayo, so I showed you the data for Optum labs.

Now we see that there may be evidence of overt testing. What about over treatment? So the current guidelines say, your A1C should be targeted to less than seven. If you're very low risk, you haven't had any low blood sugars, 6.5 is reasonable. The elderly, and those with hypoglycemia, or with co-morbidities, less than 8%.

We know that poly pharmacy is associated with increased risk of adverse drug reactions, patient burden, cost, and it can cause hypoglycemia. So we looked at exactly that same population, so low risk adults with controlled type 2 diabetes, no prior hypoglycemias, no insulin use, not pregnant. We stratified them by whether they're treated with any medications, or they're diet controlled, and we looked at, well what happens to their treatment regimen when they have that A1C that is less than seven?

So a lot of information, but I'll point out the key things here. So at baseline, these are people who are not on anything at baseline. They've got diabetes, but they're diet controlled. This is the A1C that you have in front of you, What would you do? So most patients, fortunately, are not standard on anything, but many are. If you look at patients with an A1C between 6.5 and 7, 18% have one drug started, or are started on two drugs. Even patients with 5.7 to 6.4, 8% percent are started on a drug. 2% are started on two or more drugs at the same time.

The medications that are started are similar to what prior studies have shown when they look at first line therapies for diabetes. Even though metformin, so biguanides, are recommended as first line therapies, that's not what is started in everyone. It's started in the majority, so 70% overall, but 21% are started on sulfonylurea, 16% were on thiazolidinediones, DPP-4 inhibitors, GLP-1 receptor analogs.

Now what about patients who are already on a diabetes medication? So first of all, at baseline, how many medications does it take to keep them at their goal? So for people whose A1C is between 6.5 and 7, half were on one drug, a third were on two drugs, 15% were on three or more drugs. That's fine. You're keeping them at goal. But what about people who are treated intensely? So 5.7 to 6.4. It takes-- so 11% are on three or more drugs to keep them at these high targets. These seemingly dangerous targets require poly pharmacy in 10% of patients as well. These are people who should probably be deintensified, because the lower your A1C, the higher the risk of hypoglycemia. Moreover, while we know that-- well, evidence is fairly good that having A1C at around 7 does reduce your risk of micro vascular complications, and potentially macro vascular complications, there's really no data that shows that the lower you go, the better. In fact, the lower you go, the higher your risk of death and of cardiovascular events.

Now what happens, so putting this aside, what happens to them once they have this A1C checked? Well, overall, 6% are intensified even further, despite their normal hemoglobin A1C. And very few are deintensified, so among this high risk group, only 18% are deintensified. So 82% are continued on their medications, despite a very low A1C.

So where we're taking this data next is looking at, how does that impact outcomes? Are the patients who are intensified potentially inappropriately, or not deintensified, are they going to have hypoglycemic events? What is going to happen to their A1C? They're controlled now, but followed long term, who's going to deteriorate? Who is going to get their A1C that's going to be above 9? So who are the patients we should be watching closely? They're all low risks now, but how do we know who will not be low risk in the future? Because those are the patients that need frequent monitoring and interventions. So we're going to use novel analytic techniques to identify patient subtypes who are at risk for deterioration of glycemic control, and hypoglycemia and hyperglycemia.

So know I presented a lot of information, and hopefully we'll have time for questions. But just to summarize what we found using Optum Labs, and how, for us, it has been a very useful tool. We found that there's been a small improvement in treatment at intensification rates over time. There's also been a change in second line agents used to treat diabetes. Less older drugs, sulfonylureas, and a lot more incretin agents. And yet we found that it is the sulfonylureas that are most cost effective, particularly in low risk, recently diagnosed patients. We found a relatively high prevalence of redundant testing among low risk patients, and over testing leads to over treatment. And finally, we found evidence of over treatment, and potentially inappropriate treatment intensification, in a population of patients previously not looked at, yet who make up about 60% of all diabetics nationwide.

So how has this changed clinical practice? So as a caveat, we've only been doing this for about two years. So in terms of translation to clinical practice, we're lagging a bit behind, appropriately so. But this data has been used for diabetes medications decision support, in order to work with patients to make the best decisions about what medication should be used when metformin fails. And we're now working on a multidisciplinary effort to reduce redundancy of hemoglobin A1C testing our own population, working with order entry tools to decrease redundancy, EHR prompts, potentially redesigning panel tests, and working with laboratory medicine to see what they can do from their end as well.

So this is a lot of information, because it's a team effort. And I really want to thank people here, as well as those not mentioned, in mentoring me guiding me and working with me on this. So thank you again for your attention, and this whirlwind of information. And hopefully we'll take any questions now.

[APPLAUSE]