Closer Look

AACE/ACE Consensus Conference on Glucose Monitoring

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Executive Highlights

Greetings from the second day of the AACE/ACE Consensus Conference on Glucose Monitoring, which followed the packed first day of the meeting. The culminating day's agenda featured illuminating breakout sessions that brought together four "pillars of support" (medical, scientific, and educational societies; patients; government and payers; and industry) to debate the merits of the conference's four key questions (see below). Big picture, we heard lots about the importance of bills HR. 1074/S. 539 that would create a National Diabetes Clinical Care Commission - there is a clear urgency to get this legislation passed as it bridges the interests of patients, payers, and industry. We continued to hear a push for greater Medicare coverage of CGM, aligning with our biggest takeaway from day one of the conference.

The FDA was again a positive bright spot, though it became clear that current post-marketing surveillance and inspections are highly sub-optimal, particularly in foreign countries. A major open question is whether FDA actions again sub-par products will results in changes in payer coverage - there was no clear answer on that, even from the CMS representative that came to a few hours of today's sessions.

The event closed on a positive note with powerful testimonials from two distinguished patient advocates, Mr. Manny Hernandez and Mr. Jeff Hitchcock. Their stirring words brought the audience to their feet as they drove home the need for consensus on issues of quality and safety. Stay tuned for a summary of the final consensus document to be presented at a Congressional briefing tomorrow morning - we'll be in attendance and eager to see how the writing committee connects today's dots.

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POSITIVES

1. Bills HR. 1074/S. 539, which would create the National Diabetes Clinical Care Commission, represented a driving AACE priority on the second day of the conference. As background, this legislation seeks to establish a commission comprised of diabetes experts (endocrinologists and other specialists, patient advocates, and reps from the federal agencies most involved in diabetes) to streamline federal investments, improve coordination, and boost outcomes for people with diabetes and prediabetes. This is completely no-brainer legislation in our view that is supported by every diabetes organization, would require no new funding, and is already cosponsored by 165 House and 21 Senate members (although the upcoming election will change that at least a bit). If it was already in place, it's possible that none of the mess around glucose monitoring would currently exist. As we understand it, this will be a major focus of tomorrow's Congressional briefing and meetings, and rightly so - we couldn't think of anything more uncontroversial and more positive for patients, HCPs, industry, and the healthcare system. Failing to pass this very tame legislation would represent an abject failure for diabetes advocacy, and we salute AACE for championing it so heartily.

2. Children with Diabetes founder Mr. Jeff Hitchcock received major kudos following his emotional and very personal presentation on "Why we do diabetes." Using family photos from the past 25 years, Mr. Hitchcock illustrated the story of his daughter Marissa's diagnosis at two years old ("Happy second birthday. You have type 1 diabetes."); milestones from her teenage years with diabetes (prom, driving

for the first time alone); graduation from high school and college (she's now a registered nurse); marriage; and recent birth to a healthy baby boy. One tear-filled anecdote in particular emphasized the true importance of accurate glucose meters and sensors - Marissa avoided a truly severe low at home alone thanks to an accurate CGM alarm - said Mr. Hitchcock, "Without accurate data, without a sensor, who knows what would have happened?" He summarized the talk with a slide of Marissa dancing on the beach at a CWD Conference: "Look at the smile on her face. She is loving life. We do diabetes, we do all these hard things, we use the tools that industry makes, so that we can do this. My grandson is a year old. This is why things like accurate meters matter. She spent 12 months doing diabetes harder than anyone I've ever seen. She had an A1c of 5.2% and gave birth to a healthy, normal weight baby. She has no complications after 25 years with type 1 diabetes. The data is important; the numbers matter."

3. Following Dr. Courtney Lias' positive talk on behalf of the FDA yesterday, she continued with a patient-centered, solutions-oriented spirit today - "It is our belief that sub-standard glucose monitoring technology does harm patients." Dr. Lias was outspoken in the breakout sessions and made it clear that the FDA is working hard to improve the current state of affairs despite significant regulatory and enforcement handicaps (see #3 below). She seemed quite positive on DTS' post-marketing surveillance program ("If a manufacturer has cut corners, you would know [with this program]"), indicating that this data would be useful to the FDA in targeting company inspections and identifying sub-standard products. The agency is working diligently on the draft guidances on BGM - in particular, she mentioned that the lot release criteria received "lots of negative comments from industry" and "lots of positive comments from patients." It will be interesting to see if the final guidance changes on this front, as well as the more controversial accuracy guidelines that tighten ISO 2013 standards. Dr. Lias also emphasized that adverse event reporting is highly variable and highly underreported, a point we also heard from Dr. Anne Peters at EASD. By Dr. Lias' estimates, only about 5% of adverse glucose monitoring events are actually reported to the agency.

4. Mr. Manny Hernandez's Q&A remarks strongly commended AACE, the FDA, and private payers, and appropriately excoriated CMS: "As a patient advocate, I truly commend AACE for putting together this unprecedented event and bringing together all the stakeholders. It showed us why continuing to advocate for HR. 1074/S. 539 is so necessary. There is no coordination at the federal level. Everyone made great efforts to be here on a Sunday. And I want to give special recognition to two groups we have been particularly critical of. One is the FDA. They have stood up, spoken, and are a champion for us. They have things to improve on, but they deserve recognition. That deserves to be heard at the Congressional hearing tomorrow. The other group is the private payers that were here yesterday and have remained here today. They are a key part to this issue and it's great to see them in the room. At the same time, I want to express my profound disgust - I have no other word - over the lack of representation from Medicare. It is unacceptable. It is an insult to everyone's time and effort. They are a public service. I don't care what they had to do yesterday. We all were here. It should be known at the Congressional hearing tomorrow that they were not present yesterday or for most of today, besides the breakout session." Other patient advocates called for greater infrastructure support for patients, including better reimbursement of their doctors and nurses.

5. A breakout session featuring members of medical, educational, and professional societies drove to a general consensus on frequency of testing for type 1s (7-10 strips/day), type 2s requiring insulin (7-10 strips/day), type 2s on orals (4-6 strips/day), and type 2s on lifestyle intervention (2-4 strips/day). Many advocates, including Dr. Aaron Kowalski (JDRF, New York, NY) and Dr. Bob Ratner (ADA, Alexandra, VA), expressed apprehension regarding the specificity of this guideline - in their view, the definition plays into Medicare's "one-size-fits-all" approach to treatment, undermining a personalized approach to care. However, participants were more fearful that the lack of a definition would ultimately facilitate a reduction in CMS test strip coverage - in the words of Dr. David Klonoff (Mills Peninsula Health Services, San Mateo, CA) "if left to their own devices, CMS would pay for none of this." In our view, we see the value of both perspectives - unfortunately, the need to sacrifice ideal guidelines for practical ones speaks to the nuance of dealing with CMS. It's increasingly a world of influencing payers, and we're glad to see such notable names thinking hard on this front.

6. Yesterday's momentum to obtain Medicare coverage of CGM continued today. Said one Consensus summary of a breakout session: "CMS must change its policy against covering CGM for

older adults, which appears to be age discrimination." We believe this is a matter of when and not if, and expect to see strong language on this front coming out of the consensus conference. As a reminder, there are now bills in the House and Senate on this front. Meanwhile, Dexcom is working on obtaining an insulin-dosing claim for CGM (see Dexcom 2Q14), a key Medicare objection to covering the technology.

NEGATIVES

1. It is currently unclear if FDA actions against poorly performing meters will result in payers eliminating coverage, especially CMS. Dr. Lias emphasized that this is currently an unknown and more Agency dialogue with payers would be highly valuable. Specifically, since it's "pretty much impossible" for FDA to unclear/unapprove a device, the agency has limited options when it discovers poorly performing meters (e.g., discovered through a post-market surveillance program): warning letters, seizures, court injunctions, border checks on imported devices, recalls. However, most of these enforcement options require investigations, evidence collection, court cases, and significant time - they are not the short-term solution anyone wants. The transparency of a post-market, independent testing process could help identify poorly performing meters, but it remains unclear if payers will even care about the data or restrict coverage accordingly. We hope to see greater Agency dialogue with payers going forward (especially CMS), particularly if the DTS Surveillance Program gets off the ground.

2. It was positive to see CMS Medical Officer Dr. William Rogers present for the government/ payer breakout session, though his comments evaded most important issues, including coverage of CGM, competitive bidding, and poorly performing meters. "We really cannot say anything. We're the biggest insurance company in the world, and the only insurance company in the world managed by Congress. Congress has taken away our decision-making power." To add authority to his remarks, he brought a large red book up to the breakout session stage, pointing to the specific clause in the Social Security Act that mentions coverage of "medically necessary" products - "We have to cover things that meet that definition," he said, "and we are forbidden to cover things that don't meet that definition. We have a very scientifically robust process to determine what to cover; right now, our coverage decisions are the product of that process. We have nothing to say about that unless you want us to go through the coverage process."

- **Dr. Rogers defended the competitive bidding program,** noting that it was an idea of Congress, has been successful ("Congress loves it"), and is here to stay. He said that from 2013-2022, taxpayers will save $26 billion through the program, and Medicare beneficiaries will save $17 billion (we find this hard to believe). Meanwhile, "The number of complaints has not been overwhelming." Since Congress has not received a lot of backlash on the program, the "political reality is that it's here to stay" and "Medicare beneficiaries have largely adapted." This was a patient advocacy failure not to see the impact of competitive bidding clearly enough; we are working to make sure it does not happen again.
- **Regarding inaccurate meters, it was somewhat unclear what CMS would do if data was published from a testing program.** At one point, Dr. Rogers implied that "hard outcomes" linked to accurate vs. inaccurate meters would be necessary to pull meters from coverage (e.g., a DCCT-like trial of an accurate vs. an inaccurate meter). However, he backed up from that ludicrous statement in subsequent comments, which made his actual view fairly unclear. Still, the implication was that as long as a meter is FDA approved, CMS will cover it, and there is no obligation to remove it from the market. What remains a gray area is if FDA takes enforcement action against an inaccurate meter - would CMS yank coverage?

3. Said Dr. Lias about foreign BGM manufacturers, "We play whack-a-mole with some of these companies." The lack of FDA resources to do foreign inspections was a clear theme in her remarks, and represented one of the most depressing and most alarming comments of the day. For example, one manufacturer in Taiwan - following an FDA inspection - shut down and reestablished operations somewhere else. FDA can follow the company and even issue warning letters, but the process takes significant time, particularly in foreign countries. In addition, the FDA can go into US manufacturers unannounced, while

companies in Asia know about inspections well ahead of time (i.e., part of the country agreements) - as a result, they can prepare for the FDA visits and clean up any deficiencies.

4. DTS' post-marketing surveillance program was mentioned throughout the day, though the major outstanding question - who will fund it - remains unanswered. Dr. Klonoff confidently pitched the program in Q&A as an asset to the FDA, payers, and HCPs, though his remarks did not share any finer details or point of clarification on what it will take to truly get it off the ground. Many attendees expressed support for this to become an FDA program, though the Agency made it clear that it does leverage outside surveillance/quality programs in other areas (e.g., the NGSP hemoglobin standardization program).

KEY QUESTIONS

Q: Will DTS' Post-marketing surveillance program obtain funding to actually begin testing in mid-2015? Will it eventually become an FDA program? Will FDA use the data?

Q: Will Congress past the National Diabetes Clinical Care Commission Act (Bills HR. 1074/S. 539)?

Q: How long will it take for Medicare to cover CGM?

Q: How would payers respond to FDA enforcement action against substandard meters?

Q: What will emerge as the strongest issues in AACE's consensus statement?

--by Adam Brown, Varun Iyengar, and Kelly Close