

DIABETES CLOSE UP

Diabetes Close Up, V2, #26
November 13, 2003
World Diabetes Day Eve

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 2. **And back in the US, Tommy Thompson speaks.**
 - a. **The fact sheet is greatly improved**, full stop. That said, gaps remain (see below).
 - b. **What are the market implications?** In my view, multiple companies should benefit: the addressable market has increased for insulin, drug, insulin pump, syringe, pen, and blood glucose manufacturers due to new definitions of expanded groups living with diabetes as well as a drive toward more aggressive treatment trends.
 - c. **“So wait, back up. Give me more finesse on what’s changed, please.”**
 - d. **Complications abound:** Most people have seen most of these numbers, but here are a few lesser-known ones.
 - e. **“What did I not like about the new fact sheet? And what did I like?”**
 - f. **Overall it’s an awesome new resource.** Obviously a huge amount of work went into amassing this data and hopefully it’ll provide rich fodder for the press and for companies and for patients.
 3. **Help! Reimbursement editorial.**
- Appendix 1: NHANES Poster, ADA 2003 – How treatment paradigms have changed.**
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1. **World Diabetes Day-In addition to all the U.S. focus (see below), significant concern exists across the planet:**
 - a. **WHO (World Health Organization, a UN agency)** now estimates (look for announcement Friday) that in developing countries, the number of diabetes cases could double over the next 30 years, from 115 million in 2000 to 284 million in 2030. Sedentary behavior and poor diets were cited as the main culprits. Not sure what global strategy can stem this, but stay tuned.
 - b. **The Associated Press will report tomorrow that the former Soviet republic of Kyrgyzstan is running out of insulin.** Big pharma has(ve) apparently suspended shipments because the country is \$700,000 behind in payments.
 - c. **The piece also noted that the EC said today that it would spend nearly \$14 million between now and 2008 on research focusing on obesity.**
2. **And back in the US, Tommy Thompson speaks:** The official news was released today by Health and Human Services that the estimate for US patients with diabetes has now reached 18.2 million, as of the end of 2002, up from 17.0 million, as of the end of 2000¹. Look for the press release/new fact sheet at www.hhs.gov/news/press/2003pres/20031113.html and www.cdc.gov/diabetes/pubs/factsheet.htm.
 - **The fact sheet is greatly improved**, full stop. That said, gaps remain (see below). Before we get to the issues with the fact sheet, let me share some of the critical stats and findings:
 - **Diagnoses improve: 13 million Americans are estimated to have diagnosed diabetes**, with 5.2 million undiagnosed. Although new cases rose to 1.3 million in 2002 from 1.0 million in 2000², we’re making headway on the diagnostic front – an estimated 5.2

¹ I could’ve sworn this 17 million stat only came out a year ago. If anyone can clarify, please let me know. Are they releasing these stats annually now?

² I’m a big confused on this – the fact sheet says there are 1.3 mm new cases per year, but isn’t it half that (given the two year span)? I have deposited my query at diabetes@cdc.gov, which I have found remarkably responsive over the last few years.

million of current patients with diabetes are undiagnosed – or 29% of the total, down from 5.9 million or 35% of the total in 2000.

- **Geez, but – growth in patients with diabetes continues to increase, from an ever-higher base:** The 2002 estimate of 18.2 million is up from the 2000 increase of 17.0 million and the 1998 increase of 15.9 million. The 1998-2000 growth rate, for those that don't want to do the math, was 6.9%, while the 2000-2002 growth rate was 7.1%. A tenth of a percent represents 10,000 people.
- **What are the market implications? In my view, multiple companies should benefit: the addressable market has increased for insulin, drug, insulin pump, syringe, pen, and blood glucose manufacturers due to new definitions of expanded groups living with diabetes as well as a drive toward more aggressive treatment trends³.** And that market doesn't even *count* this whole pre-diabetes population. As I see it, new US guidelines lowering the acceptable level of blood glucose, to 100 mg/dL from 110 mg/dL for pre-diabetes will drive more people faster into the diabetic bucket. (see DCU V2, #24). It's harder to bury one's head in the sand with all this press.
- **“So wait, back up. Give me more finesse on what's changed, please.”**
 - **Updated treatment stats show increased insulin use, more drugs, and more combo therapy:** The fact sheet shows the following treatments for adults with diabetes – when you compare this to the numbers below, you see that overall, insulin use has increased (31% compared to 27% in latest survey) and less reliance on diet/exercise (now 15% compared to 20% in latest survey)⁴:
 - **Insulin only** - 19%
 - **Insulin and oral drugs** - 12% take insulin and oral drugs,
 - **Oral meds only** - 53%
 - **Diet only** - 15%
 - **NHANES data shown at ADA⁵** this summer showed how treatment changed for Type 2 patients from 1988-1994 to 1998-2000:
 - **Insulin only** – 16% (down from 24% in first NHANES survey)
 - **Insulin and oral drugs** – 11% (up from 3%)
 - **Oral meds only** – 53% (up from 45%)
 - **Neither insulin nor oral agents⁶** – 20% (down from 27%).
 - **Combination therapy gains steam:** Among thought leaders it seems more common that when Type 2 patients are switched to insulin, they are kept on at least a couple of oral drugs. Monotherapy seems more and more out of favor, and most patients on one oral drug are probably on at least a couple. Daily costs of patients that switch say to Lantus may be understated – most estimates I see assume the TZDs, etc. go away and I think this is less and less common. I was listening to a tape from last year's ADA⁷ where highly regarded endocrinologist Matt Riddle noted that many Type 2 patients go on insulin and stay on drugs – even though a decade ago, this would've been considered "a big ploy by big pharma to get us to spend more - now it's very accepted")
 - **Updated subgroup stats underscore worrisome trends, particularly among ethnic minorities:**
 - 14.9 percent of American Indians and Alaska Natives who are at least 20 years old and receive care from IHS have diabetes. On average, American Indians and

³ Editor's note: hopefully this visibility will translate into a negative for McDonald's and PepsiCo, etc. etc., so that they will do more to fight obesity. Simplistic? Probably. We've got to make them believe this'll be a great investment.

⁴ I have to say – it seems weird that since NHANES is used as a big source for this fact sheet that these numbers are off. It may be that the data for the fact sheet was cut a bit differently – I've got a query in, but in the meantime, I think it's an interesting comparison.

⁵ See Appendix 1 for copy of Poster 956-P1

⁶ They used to call this bucket “diet and exercise” but now it is “neither insulin nor oral agents.” Small nuance perhaps but I imagine they changed it because a number of folks are taking no drugs and doing no exercise *and* eating badly. Not all! But some. Diet/exercise implies people are working hard, but in reality, this is could often be untrue.

⁷ I'm a little behind in tape listening – but I never underestimate the huge potential to learn from these. Last week I purposely drove to Santa Barbara rather than flew so I would be shut in a car alone for twelve hours with four tapes from the recent Canadian meeting. In today's case, I was listening to a tape where two endos put forward opposing views regarding whether Type 2s should be put on pumps. Fascinating.

- Alaska Natives are 2.3 times as likely to have diabetes than non-Hispanic whites of similar age.
 - 11.4 percent of non-Hispanic blacks aged 20 years or older have diabetes. On average, non-Hispanic blacks are 1.6 times as likely to have diabetes than non-Hispanic whites.
 - 8.4 percent of non-Hispanic whites aged 20 years or older have diabetes.
 - 8.2 percent of Hispanics aged 20 years or older have diabetes. On average, Hispanic Americans are 1.5 times more likely to have diabetes than non-Hispanic whites.
 - Native Hawaiians and Japanese and Filipino residents of Hawaii aged 20 years or older are twice as likely to have diabetes as white residents of Hawaii.
 - **Updated stats on age-related prevalence:**
 - 8.3% of people over 20 have diabetes
 - 18.3% of people over 60 have diabetes
- **Complications abound:** Most people have seen most of these numbers, but here are a few lesser-known ones:
 - **Heart disease and stroke:** 2-4 times higher risk for adults with diabetes versus adults without. 73% - seventy-three percent! – of people with diabetes have blood pressure over 130/80 mm Hg or use hypertension drugs.
 - **Blindness:** Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness each year.
 - **Kidney disease:** Diabetes accounts for 44% of new cases of ESRD. In 2001, nearly 143,000 people with ESRD were living on chronic dialysis or with a kidney transplant.
 - **Amputations:** In 2000-01, about 82,000 non-traumatic lower-limb amputations were performed annually among with diabetes. Severe forms of diabetic nerve disease are a major contributing cause of lower-extremity amputations.
 - **Complications of pregnancy:** Poorly controlled diabetes 1) before conception and during the first trimester of pregnancy can cause major birth defects in 5% to 10% of pregnancies and miscarriages in 15-20% of pregnancies; and 2) in the second and third trimesters of pregnancy can result in excessively large babies, posing a risk to mom/kid.
 - **Dental disease:** Almost one-third of people with diabetes have severe periodontal disease with loss of attachment of the gums to the teeth measuring 5 millimeters or more.
 - **Other complications:** Oh, and other. Uncontrolled diabetes often (often?) leads to biochemical imbalances that cause acute life-threatening events such as diabetic ketoacidosis and hyperosmolar (nonketotic) coma. To boot, people with diabetes are more susceptible to many other illnesses and once they acquire such illnesses, frequently have worse prognoses. For example, they are more likely to die with pneumonia or influenza than people who do not have diabetes.
- **“What did I not like about the new fact sheet?”**
 - **Blood glucose monitoring is not mentioned once in the 8-page overview, although the importance of self-management education is stressed, which is key.** A1C stats are given, which is a great start, but I think it would be helpful to explain what goes into an A1C. Pumps are also mentioned for the first time I can remember (“*To survive, people with type 1 diabetes must have insulin delivered by injections or pump*”), but no benefits of either are given. While I realize it isn’t the mandate of fact sheets like this to offer opinions of various treatments, I think it’s appalling that the ADA guidelines for blood glucose monitoring aren’t even cited - evidence-based medicine has shown the power of these tools, after all.
 - **Lifestyle – for how many can this be a real strategy?** I don’t know whether to put this in the “like” or “dislike” bucket. So the fact sheet emphasizes the power of the diabetes prevention trial where there were such great results from the lifestyle arm – the development of diabetes was reduced 58% in the “lifestyle” arm. The sheet is specific in saying this can be done with as little as 2.5 hours of walking per week. GREAT! Great to get people out there. But it’s also important to realize these patients in the trial that were at risk for diabetes had huge support and I think that should’ve been mentioned – sort of a

full disclosure thing. While I believe using lifestyle to reduce risk of complications is eminently important, the big concern of course is how reproducible this is in real life.

- **And what did I like about the new fact sheet?**
 - **A few specific things –**
 - **Great that the fact sheet mentions the increased diagnoses of diabetes in kids and teens** – and that they discuss increase in type 2 diabetes in these populations in particular
 - **Pre-diabetes stressed** – 21% of adults 40-74 are estimated to have prediabetes. Oddly, the old 110 mg/dL is used, not the new 100 mg/dL – so with the new, that's probably even higher. But the main point is that the dots are starting to be connected
 - **Lots of tie – in** between importance of controlling cholesterol and blood pressure and they make it clear that those with pre-diabetes and diabetes are at much higher risk for other adverse outcomes. AND (this is the part I liked), the fact sheet also offers hope by emphasizing that complication risk can be reduced by good control (naturally, I think next time it would be great if they could be more actionable about how to get there.)
 - **Overall it's an awesome new resource.** Obviously a huge amount of work went into amassing this data and hopefully it'll provide rich fodder for the press and for companies and for patients.

3. **Help! Reimbursement/coverage editorial:**

- a. **I knew reimbursement was a nightmare** but I had no idea it was *this* bad. So get this. Medicare starting reimbursing for insulin pumps four years-ish ago. Typically a warranty for a pump is 4-5 years.
- b. **However Medicare doesn't honor warranties** – it has this policy of ONE insulin pump per person, period. I just learned this today. Apparently for DME (durable medical equipment), this is common but a pump is a little different story from other devices.
- c. **So if a patient on Medicare wants a new pump when their current pump warranty expires**, they are simply out of luck, with only the prospect of mountains of paperwork for the doc as a potential save.
- d. **Also. Not only won't Medicare reimburse after a normal warranty period ends, they won't automatically reimbursement even if the pump life ends!** Pumps are amazing but no way are they going to last a lifetime. (Do cars? PCs? Cell phones?)
- e. **You know how there's a lot said about how pump penetration won't expand beyond early adopters etc?** First of all, I don't believe it and I think there are many trends continuing to drive pump therapy (better smarter pumps, the advent of continuous, etc.) I'm starting to think that the reason penetration hasn't expanded even further stems more from behavior of doctors – many GREAT doctors – than from patient behavior. Getting patients on pumps has so much required paperwork – even outside the Medicare sphere – that this has served as a disincentive for some docs. Now there of are COURSE amazing centers like UCSF that have incredible training and put together amazing courses – but they are by no means making money on this and it's only because they are so committed that this continues.
- f. **Back to Medicare.** Docs are required to send in paperwork ad nauseum when a pump stops (meantime the patient returns to syringes) and to try to manufacture a "*change in medical condition to warrant an upgraded model.*" Sometimes this is possible, sometimes not, but why put specialists through this?
- g. **In the worst instance, all this paperwork required prompts productivity to plummet** and makes even the best endos incredibly frustrated. No matter this specialty is dwindling.
- h. **This stands as quite a worrisome issue. Educating the rule-makers in DC appears a major challenge.** But it must happen, for anything to change. If they took away my pump, my life would become unglued. Why should I not have to worry about that just because I am lucky enough to have Blue Shield and not Medicare? This 1-2 year time horizon (their version of ROI) is ridiculous. The ROI is good, they've got to understand. Let's use me as an example (I know, something new and different : > I'm only one data point, but I don't think my experience is uncommon.)

- i. **Health system savings on KLC: \$62K!** My insurance has spent \$15,120 for me to wear a pump for the last seven years⁸ (and I've got a year left!). In the seven years before I got a pump, I was taken to the emergency room eleven times for hypoglycemia (venues ranging from Joslin to New York Hospital to UCSF). Multiply by \$7,000 every time the ER gave me OJ – “you do the math” as they say - \$77,000. So not to be too reductive, but seems one could argue the system has saved \$62,000 on me over this time – how is that not meaningful? Oh, and to say nothing of letting me have my life. I am so happy I don't wake up with the lights whirring every few months anymore and that I haven't seen a paramedic since '97!
- ii. **Now, I'm the first to say that the insulins have improved dramatically since the days when I was on unstable NPH** – more than likely I wouldn't be in the ER so much were I on Lantus – but with variable basal rates, no way would that work nearly as well. Pumps are so much more physiological, they address the dawn effect, they allow us not to wake up at the same time every day 24/7/365 – they make us feel real.

4. Upcoming diabetes/obesity-related conferences

- a. **November 14, Designing an Accelerated Cure for Type 1 Diabetes: Integrating Biology with Bioengineering.** Symposium at Sunsun, Santa Barbara.
- b. **December 14-15: Consensus Development Conference on Inpatient Diabetes and Metabolic Control, Washington DC.** www.aace.org. This is one of those under the radar screen conferences that is going to be top rate and terrifically interesting and will read on the industry direction - amazing faculty. If you'd like an agenda, please let me know.
- c. **February 6-8, 2004, ADA 51st Annual Postgraduate Course.** San Francisco, CA <http://www.diabetes.org/main/professional/conferences/default.jsp>
- d. **April 28 – May 2: AACE, Boston, MA.**
- e. **May 1-4, 2004: Pediatric meeting,** San Francisco, CA.
- f. **June 4-8, 2004: ADA,** Orlando, FL.
- g. **August 11-14, 2004: AADE,** Indianapolis, IN.

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⁸ That's \$5000 for the first pump, \$5500 for the second pump, \$1200/year for supplies, minus my co-pay.

Abstract Information

Abstract Number: 956-P

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Results: We explored differences in oral antidiabetic agents (OADs) and insulin usage and associated glycemic control rates (HbA1c < 7%) for the years 1988-94 to 1999-00 in the US diabetic population. We identified two adult samples one each from NHANES III (n=1215) and NHANES 1999-00 (n=372), which reported a diagnosis of type II diabetes and had data on diabetes medication and HbA1c. We defined four therapeutic regimens: diet, insulin, OADs (monotherapy or combination), or OADs plus insulin. We compared the age-adjusted (NHANES 1999-00 adjusted to NHANES III diabetic age distribution) and age-specific (20-44, 45-64, and 65+ years old) glycemic control rates for each regimen between the surveys. We used logistic regression to compare glycemic control between the two surveys adjusting for medication, age, gender, ethnicity, BMI and duration of diabetes. Compared to NHANES III, diabetic individuals in the 1999-00 survey were younger (61.3 and 59.0 years old, respectively), included more males (44.5 and 51.0%) and fewer non-Hispanic whites (74.4 and 60.8%), had a higher BMI (30.4 and 32.3 kg/m²) and a longer disease duration (9.3 and 11.9 years). Diabetic individuals treated with diet decreased between the surveys (27.4 and 20.2%). Likewise, those using insulin decreased (24.2 and 16.4%), while those on OADs (45.4 and 52.5%) and OADs plus insulin (3.1 and 11.0%) increased. These pharmacological changes were most pronounced in the 45-64 and 65+ age groups. Age adjusted glycemic control rates declined from 44.5% in NHANES III to 35.8% in NHANES 1999-00. Control rates declined from 15.8 to 13.3% in 20-44 years old, and from 44.3 to 38.9% in the 65+ age group, but increased from 39.9% to 47.7% in those 45-64 years old. The adjusted odds of glycemic control was 21.5% lower in the more recent survey compared to NHANES III (Odds Ratio = 0.78, p<0.0001). These findings suggest that glycemic control remains inadequate in US diabetic individuals and that early aggressive therapy is warranted in order to achieve glycemic goals.

Category: Epidemiology