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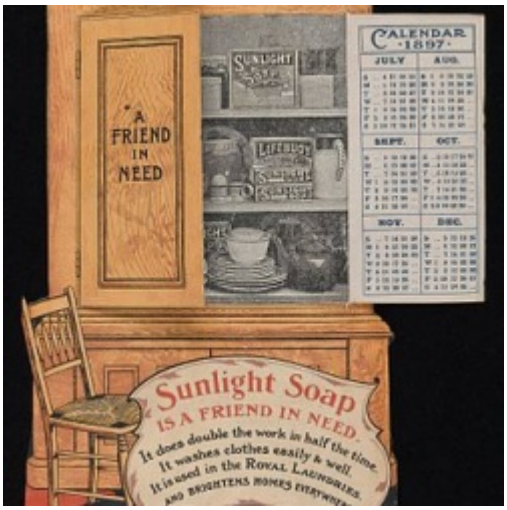
Pre-Diabetes: Medical Risk or Market Segmentation?

By Chuck Dinerstein, MD, MBA — March 8, 2019



Courtesy of the Wellcome Trust [1]

Charles Piller has written a very interesting article on pre-diabetes, the link is at the bottom, and is worth the 10 minutes. Pre-diabetes describes a measure of glucose metabolism, usually, the HgA1c that provides a measure of glucose's chronic blood level, that is below the diagnostic range, but "out of an abundance of caution" bears watching. In a similar way, we have seen the hurdle for having high blood pressure drop over time down into ranges once considered "normal."

"**How 'pre' is pre-diabetes?"**

It turns out that this is a multi-million dollar question. Some studies report 15-30% of "pre-diabetic" patients develop clinically significant diabetes within five years; other as low as 2%. As far as I know, pre-diabetes remains a gateway, and no study has demonstrated that patient's with these slightly elevated glucose values suffer greater complications of diabetes than a diabetic patient who never was diagnosed with the "pre" form of the disease. At best we might say that being told your glucose metabolism is impaired somewhat is an opportunity for a lifestyle course correction.

Preventative maintenance

I choose maintenance over care only because I feel care implies some treatment, but feel free to think preventative care, the American Diabetes Association(ADA), pharmaceutical companies and doctors, use that term. It should come as no surprise that a nutritious diet, watching one's weight and exercise are the initial suggestions, much as my mother would offer chicken soup – of course, chicken soup was in many instances, more productive. And it is not that those initial suggestions are ineffective, it is just so hard to put down the pizza and pick up the kale or walking over driving, especially in our car-designed suburbs.

But a looming fear requires action. Aggressive action, like prescribing pills. Two thoughts, how

often do you hear aggressive and pills in the same sentence? Usually aggressive is associated with my clan, the surgeons, nice to see my fellow internists being recognized. Second, the act of prescribing a pill turns a possible problem into a MEDICAL CONDITION – and that opens up a lot of opportunities, not just to prevent disease, but sell stuff. What stuff you ask, well besides the off-label recommendation for medications, you can buy self-help books or glucose monitors, and there can be labels affixed to particular foods, like “natural sugar substitutes.” The marketing opportunities are endless.

Conflicts of ideologic interest.

Now, the article does call out pharmaceutical companies for seeing an opportunity and funding research to show that some medication, especially a 25 year old one, like metformin, may slow pre-diabetes. Of course, slowing would imply an understanding of the natural history of prediabetes as a risk, which we do not. But Big Pharma’s motivation, divided between patients and investors, is well known; and the FDA recognizes that treatment goals are “hazy” so they are dragging the bureaucratic feet, a slow roll would be too fast a description.

The conflict of ideologic interest begins within the ADA whose leadership coined the term pre-diabetes to convey urgency to “complacent” physicians and the public that did not heed their Chicken Little warning. An ADA board member, in her role as the CDC’s chief of diabetes prevention, brought the term to the CDC. Now, these organizations fund a lot of research, just like Big Pharma. And the more people who are now “increasingly at risk for developing diabetes” act as greater leverage and make the ADA’s representation that much more important. ADA guidelines, which increasingly include calls for aggressive prevention, are not intentionally misleading, they lead through eminence. The same way legacy admissions to the Ivy League work – merit, or scientifically demonstrated value, is but one of many considerations.

To be fair, experts attract research funds and research creates experts – that is a tight knot to untangle. The ADA committee to write the guidelines include these experts, rightfully so I might add. But the ADA feels there was no conflict of interest when "tainted" research funds were received more than a year before the guidelines were written, or when the payments were less than $10,000. But where is the consistency? ProPublica says that doctors are swayed by sandwiches and chips, they are, of course wrong, but $10,000 buys about three years worth of lunches. And to ignore a relationship because there hasn’t been funding in more than a year suggests a very cynical attitude about researchers and their funding sources – a “what have you done for me lately” type of approach.

> *“Mission creep is the gradual or incremental expansion of an intervention, project or mission, beyond its original scope, focus or goals, a ratchet effect spawned by initial success.”*

Mission creep is not limited to military engagements; it is alive and well in healthcare. It does not require evil intent, just a loss of focus and a chance to have a “greater impact,” academically or financially.

Charles Pillar, his collaborators, Jia You, and Megan Weiland, and Science deserve a lot of credit for bringing the story forward.

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