CLINICAL ENDPOINTS: Fat Mass vs. Body Mass Index

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Given that this eclectic mix of fact and opinion challenges longstanding beliefs and practices, please know that opposing points of view are expected and respected.

The overwhelming majority of obesity medicine specialists monitor fat mass expressed as a percentage of total body mass (%FM) because neither weight alone nor the weight and height-based Body Mass Index provides the clinically relevant information needed in order to determine how much of a patient's weight (total body mass) is fat tissue.

Body Mass Index, originally known as the Quetelet Index, is a rudimentary weight/height^2 ratio developed in 1832 by Belgian statistician and sociologist Adolphe Quetelet as a statistical reference for sociological (not health-related) population studies. During the late 19th century, life insurance actuaries began to find the statistical correlation between population-based weight-height data and life expectancy to be compelling enough for them to start factoring these data into their risk calculations. This mathematical tweaking started benignly enough. Using population data along with individual data to estimate risk is, after all, fundamental to mortality risk modeling. During the latter years of the 20th century, however, life insurance actuaries began to assign too much weight (mathematical weight) to population-based weight-height data and overstep the bounds of their professional qualifications by labeling individual applicants as "obese."

Case in point: In 1989, when all four of my children were under the age of 10, it was extremely difficult for me to find an affordable life insurance policy because insurers had pegged me as "obese" based on what they called my "weight-height ranking." After independently confirming that my %FM was clearly in the healthy range at 12%, I initiated several failed attempts to challenge the insurers' flawed assessment of my mortality risk. And in spite of what the defenders of Body Mass Index (BMI) as an individual health assessment metric would have you believe, the truth is that I was not a "rare case." I was a 37-year-old suburban dad with a gym membership, healthy eating habits and lab reports that had my primary care doctor giving me a high five every year.

To this day, I do not understand how a life insurer could have labeled me as obese 6 years before an "official" definition of obesity (BMI ≥30) was first proposed by a World Health Organization (WHO) Consultation Group. The entire world unfortunately went on to adopt this population-based metric (BMI) as the standard benchmark for ***diagnosing*** obesity after the WHO Consultation Group report was published in 1995.

Physiologist Ancel Keys, who is credited with "rebranding" the Quetelet Index as

Body Mass Index in 1972, acknowledged its limitations and used BMI only for population data-gathering and analysis, not for individual health assessments.

Indeed, the evidenced-based view of BMI as a data point for population studies and not as a key metric for individual health evaluation purposes is rapidly finding favor among clinicians, academics and allied health professionals. As important as population data insights are for clinicians to remain cognizant of, pushing population data too deeply into the domain of individual health evaluation often clouds clinical judgment and sabotages patient-centered, personalized care. Worldwide use of BMI as the standard metric for defining obesity is clearly one of the most egregious examples of allowing population data to be injected much too deeply into the scope of individual health.

Having established that %FM is far more clinically relevant than BMI, let's take a look at body composition testing. Various forms of testing are used to estimate %FM, some more accurately than others. Among the many different body composition testing methods available, there is no universally recognized "gold standard" method of body composition testing that is used to evaluate the accuracy of all other methods. MRI and CT scanning devices are generally considered to be the most accurate body composition testing devices, but one should not assume that the reported values are highly accurate simply because they were derived from MRI or CT images. The condition, the calibration and the technological sophistication of the actual scanning device, the capabilities of the software and the encoded algorithms that are used to process and analyze the images and the imaging data inputs, whether the whole body or a specific region or targeted site was imaged, and the patient's hydration status (yes, even with MRI and CT) are all factors that affect the accuracy of the reported body composition values.

Quality and accuracy variability between and among different methods is an issue not just for imaging-based methods but for all body composition testing methods, most of which are far more practical, affordable and accessible than MRI and CT scanning. The common thread here is that they are all data input-based methods that are used to estimate %FM with varying degrees of accuracy.

Body composition devices, whether they are hardware devices, software devices or hardware devices with companion software for data processing and analysis, that are not intended to be used for medical purposes are not medical devices. So-called smart scales, nonmedical digital devices with body composition claims and other "body comp" devices that are not designed for or marketed for clinical use can generally be viewed as innocuous items of interest that should never be used for medical decision-making.

Among body composition testing devices that are designed for and marketed for clinical use, since the accuracy pecking order is open to debate, there is an obvious need for the FDA to evaluate the performance of clinical body composition testing devices in order to determine whether any given device should be cleared or authorized to be marketed as a medical device in the United States.

Unfortunately, however, clinical body composition testing was effectively downregulated to an exempt device indication by the FDA in 2015. Although the FDA guidance that was published during the summer of 2015 called for the exemption to apply only to devices labeled "Not intended to diagnose or treat any medical condition," body composition testing devices that are intended to guide medical treatment decisions were ultimately regulated as exempt devices as well, reportedly based on an erroneous belief that using body composition test results to inform obesity medicine treatment decisions is a "low risk" treatment-related use of a device. Nothing could be further from the truth, but whatever this misguided decision was based on, with all clinical body composition testing devices suddenly being exempt from 510(k) premarket notification requirements in 2015, the manufacturers of these devices were no longer required to complete the safety and effectiveness studies that had been required by the FDA in order to evaluate the safety and performance of these devices.

The FDA's dismissive view of the risks associated with obesity medicine treatment might actually be based on a biased and disproven view of obesity as a behavior choice rather than the chronic, relapsing, multifactorial disease that it is. In view of the fact that the most prevalent and comorbidity-associated chronic disease in the United States (obesity) was classified as a disease by the National Institutes of Health in 1998, the first of many obesity medicine fellowships was established at Harvard in 2007, the American Board of Obesity Medicine was founded in 2011, the American Medical Association officially classified obesity as a disease in 2013, and clinicians routinely use body composition test results to inform prescribing decisions that are fraught with risk in the absence of proper monitoring, the 2015 exemption of clinical body composition testing devices is entirely inconsistent with the FDA's public health protection mission.

This lack of FDA oversight has opened the door for any manufacturer of a "body comp" device, such as a smartwatch purported to "measure" body composition, to register with the FDA, list the device with the FDA and market it as an "FDA-listed" medical device. Allowing devices with unproven performance characteristics to be marketed as medical devices is risky enough to begin with, and given the seriousness of certain anti-obesity medication (AOM) warnings and adverse effects, allowing untested test results to inform AOM prescribing decisions clearly exposes patients to a risk of substantial harm.

The FDA was in the midst of what Harvard Professor Daniel Carpenter called "a deregulatory moment" as Margaret Hamburg was nearing the end of her 6-year tenure as FDA Commissioner. When Stephen Ostroff officially stepped into the role of Acting Commissioner in April, 2015, there was certainly nothing on his to-do list about second-guessing device regulators. And when Robert Califf was confirmed as FDA Commissioner in early 2016, he was clearly devoid of any motivation to ask the FDA Center for Devices and Radiological Health to revisit regulatory exemption decisions.

So here we are now, 9 years later, with device manufacturers marketing their new clinical body composition testing devices in the United States with far less FDA regulatory scrutiny than a monitoring test for a disease of such high prevalence and far-reaching public health impact should be subjected to.

It is certainly worth noting here that while clinical body composition assessment procedures were routinely referred to as body composition tests prior to 2015, body composition testing device manufacturers have generally shied away from referring to their products as testing devices ever since the FDA downregulated body composition testing as a device indication. It is also worth noting that clinical body composition testing procedures have always been used for screening and monitoring purposes, and unlike BMI, never used for diagnostic purposes.

That may change if the FDA ever adopts a more clinically relevant standard for defining obesity, but for the time being and the foreseeable future, we're stuck with BMI and an entire category of medical testing devices that are unfortunately exempt from the FDA premarket notification requirements that might elevate their status enough to effectively argue for %FM to be factored into the clinical standard by which obesity is defined.

To be clear, this regulatory exemption no longer applies to all body composition assessment devices. Software used and intended to be used as an independent device to analyze digital images for medical body composition assessment purposes is regulated as Software as a Medical Device (SaMD) that must be reviewed by the FDA before it can be legally marketed as a medical device in the United States.

SaMD was not specifically excluded from the 2015 exemption because no SaMD had yet been submitted to the FDA for a body composition analysis indication as of 2015. But when the FDA received a submission for an MRI image-analyzing SaMD with a body composition analysis indication in 2017, the regulators decided that SaMD built to analyze digital images for medical body composition assessment purposes is not exempt and does require a full FDA regulatory review.

Key takeaway: The exemption detailed above unfairly places the burden on obesity medicine clinicians in the United States to ensure that the exempt body composition testing devices they're using to inform medical treatment decisions are safe and have been properly validated with performance evaluation studies. Clinicians who are using an FDA-exempt device that has been certified by European medical device regulators, however, have the assurance of knowing that the safety and performance of the device have been reviewed by a competent regulatory body.

The European Medicines Agency and Notified Bodies in the European Union regulate all body composition testing devices that are used (and are intended to be used) to inform medical treatment decisions as Class IIa medical devices. Such devices must meet specific safety and performance standards in order for a Medical Device Regulation certificate to be issued and for a CE mark to be legally displayed on or in the device and its labeling.