Empowering patients

Real-world data should drive obesity drug use

The race is heating up with published and upcoming anti-obesity trials, but where is the long-term evidence for sustained patient benefit?

Obesity is a global health concern. The European Federation of Pharmaceutical Industries and Associations recently published an EQVIA report indicating that adult obesity rates have doubled since 1990 and one billion people or one in eight globally are living with obesity. Given the magnitude of the problem and the numerous new therapeutics being developed to address this complex disease, it behooves us to understand the long-term effects of new therapeutics in a condition where poor diet and sedentary lifestyles are significant contributors.

There are cultural considerations when discussing obesity. In some cultures, being overweight is seen as a sign of prosperity while in others a sign of lower socio-economic status. Characterising the impact of obesity, regardless of culture, requires an objective lens on the impact of therapies in the real world. Real-world data is the foundation for generating evidence providing longitudinal data, helping inform decisions on health, reimbursement and unanticipated effects of a therapy. Without quality evidence, there is a risk that as a society we will question the benefit of these therapies.

Evidence generation starts very early in the life of a compound, well before first-in-human trials. Natural history studies provide a lens into the patient journey, followed then by Phase 1 to 3 trials. While this is the norm, obesity defies any one particular disease as it is a constellation of conditions that manifest as a complex problem. The etiology of obesity is not due to a single factor, as environmental, behavioural and genetic factors all contribute. The primary treatment for obesity are lifestyle and dietary interventions, but as this approach is not universally successful coupled with the increasing incidence and prevalence of obesity globally, the need for effective alternatives including medications has increased over the last decade.

There are over 120 novel pharmacotherapeutics in pre-clinical and clinical development for obesity, some of which are also used to treat some of the comorbid conditions associated with obesity, such as, diabetes and moderate to severe obstructive sleep apnoea. The most common assets right now are GLP-1 agonists, GLP-1/GIP dual agonists, and amylin agonists in clinical pipelines, with new therapeutics designed to reprogramme metabolic pathways, providing potentially disease-modifying therapeutic impact for high quality, sustained weight loss. However many of these marketed therapies do not have the data on long-term effects on weight loss that would be considered sustainable.

The complexity of obesity and the various mechanisms of action create a challenge in determining which outcomes should be captured and how to weigh the impact of one desired outcome versus another. The most recent FDA guidance, issued in January 2025, provides direction on the design of obesity studies that look at the impact on comorbidities. The FDA proposes a diversity plan to include individuals whose race or ethnicity places them at higher risk of obesity. Yet these may be the very same people who may not have access to drugs given the payer landscape, particularly in the US. Real-world data has to consider the same diversity globally.

Historically, regulators and manufacturers have not considered the need for long-term evidence, when evaluating novel therapeutics. However, what experience has taught us is that while providers and patients are eager to incorporate new therapies, judicious use and follow up are equally important.

Patient preferences and the impact of a drug on their weight loss, disease control and quality of life will likely provide the best real-world data to help inform the effectiveness of these new anti-obesity products. Being able to capture these data are limited by the fact that there are no ongoing registries that provide a lens into the impact on a patient's quality of life as well as his or her ability to sustain ongoing weight loss. While the FDA and EMA have defined sources for real-world data, such as electronic health records, the most reliable source will likely be the patients themselves.

The limitations of data access globally from health institutions and the lack of consistent measures for obesity and certain comorbidities, point to the patient as a viable source of data. Only then can we better characterise short term and long-term effects of these therapies. There is an inherent bias in this approach as not every patient may be willing to provide information. Having said this, most people who start weight loss journeys are motivated to assist, given the difficulty with behavioural change.

Real-world data and evidence generation require patient registries that are company agnostic and funded by consortia to limit bias. Ideally multiple data sources can be curated and harmonised to provide a more global view of the comorbidities, the impact on weight loss and the consumption of health care resources. The investments being made by companies like Novo Nordisk into AI platforms to identify which molecules to take forward into trials, relies upon patient datasets. These real-world data tools will serve a dual purpose to support trial design and help us learn more about how people tolerate drugs and what benefit is realistic in managing obesity, a very complex disease.

Given the global prevalence of obesity, generating high quality long-term evidence will ultimately be the only way to shift the payer landscape. Patient-reported data is a key source of quantitative data, but more importantly qualitative data.

This article was written by Femida Gwadry-Sridhar, PhD, founder and chief executive of Pulse Infoframe Inc, a real-world evidence generation platform company.