Will a Direct-to-Consumer Promoted Treatment Work for My Patients?
A GLP-1 Example Using Existent Patient-Powered Technology

Modified from a Poster Produced by Eliza Hearst BA and Adam Schwartz, MD

Most published RCTs enroll a narrow spectrum of patients and follow them for a short period of time. Direct to consumer (DTC) marketers often generalize the findings and leave it up to doctors to decide whether the results apply to their patients. Trials of GLP-1 are no exception.

Dr. A.S. has had an internal medicine practice for two decades so its obese patients are older. Dr. A.S. wonders how helpful are GLP-1 medications are for an older population?

Method Overview:

To estimate the selection bias of an influential randomized controlled trial (RCT) of a GLP we examined archived data from an existent online health assessment technology (HowsYourHealth.org) to compare the needs, risks for subsequent costly care, and quality of life of obese patients who would have fit selection criteria. 22118 patients fit the simulated RCT enrollees and FIGURE ONE illustrates the distribution of their needs and risk for future costly care. The needs and risk score is based is on the sum of five responses: i) to inadequate health confidence, ii) bothersome pain or iii) emotional problems, iv) polypharmacy, or v) possible adverse medication effects. The sum, called a what matters index (WMI), is strongly associated with patient-reported quality of life and risk for future use of hospital or emergency services. (1)

Over two months we then asked patients who had been prescribed GLP-1 medications by Dr. A.S.'s practice to use the same patient assessment technology that additionally asked them how helpful the medications had been: namely "not helpful (little weight loss)", "somewhat helpful (10-15% of my weight)", "very helpful (more than 15% of my weight)", or either of these responses " I had to stop because of side effects" or "I stopped it but the weight is back." For validation obese patients not in that practice who self-selected to complete an on-line health assessment were asked the same questions about GLP-1 effectiveness.

Results: Based on the online patient assessment technology, when FIGURE ONE is contrasted with FIGURE TWO, the widely cited randomized study's selection criteria result in a population that has relatively lower needs, lower risk for future hospital and emergency care, and a higher quality of life.

FIGUE TWO demonstrates major differences between Dr. AS's patients and the self-selected respondents. Despite these differences in respondent age, financial status and gender, both samples reported similar rates for GLP effectiveness (89% vs 84% somewhat

or very helpful) and GLP effectiveness was influenced adversely by the WMI score even after accounting for differences in age, gender, and poverty rates. (FIGURE THREE)

FIGURE ONE

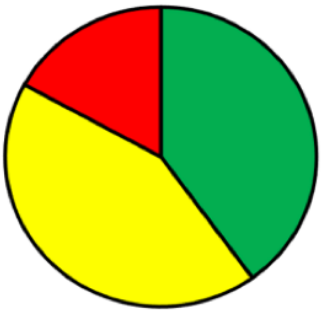
Simulation of Patients Enrolled in a Widely Cited Controlled Study of GLP-1 Effectiveness for Weight Loss*

No Diabetes, Few Emotional Problems, Likely to Follow Protocol, Not Poor

FIGURE TWO

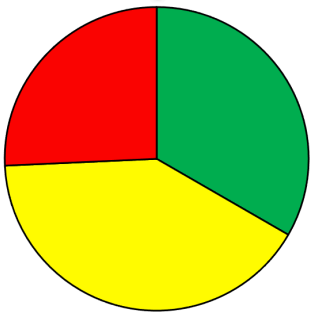
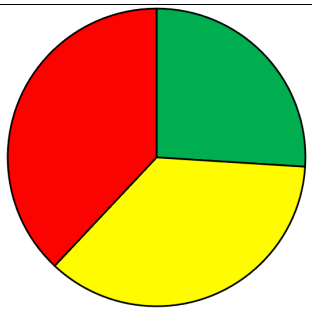
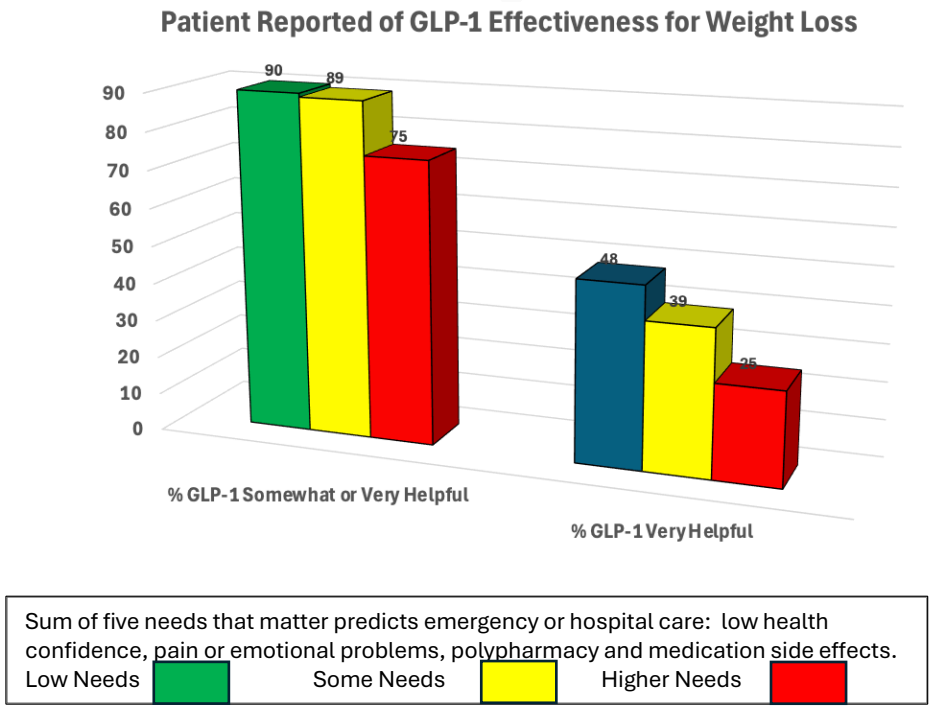
Patient Characteristics	GLP Helpfulness for Weight Loss in a Practice	Self-Selected Respondents from Across the United States Report of GLP Helpfulness for Weight Loss
		
	Older (92% 50+) Low Income (2%) Female (35%)	Younger (45% 50+), Low Income (29%) Female (63%)

FIGURE THREE



An additional survey about the benefits and bothers of GLP-1 medications in Dr. A.S.'s practice revealed that:

- Most patients benefitted and 61% cited three or more benefits. Most commonly, decreased appetite, less “food noise”, and weight loss.
- Many patients reported side effects: 47% had two or more -- most commonly nausea and constipation.

The sample size was too small and the mix of GLP-1 medication types too large to see any trends toward benefits and bothers for different formulations of prescribed drugs.

Summary: We conclude that despite a reduced patient need and risk profile in an influential GLP-1 study, respondent patients in this internal medicine practice and outside of this practice confirmed that most benefit in many ways from GLP-1 medications albeit with the frequent side effects of nausea and constipation. Although our results are derived from a limited number of patients in a single practice, they are bolstered by the fact that self-selected respondents from GLP-1 users outside the single practice reported similar benefits.

Of note is the decrement in GLP-1 effectiveness when two of more of the following WMI problems are present: to inadequate health confidence, bothersome pain or emotional

problems, polypharmacy, or possible adverse medication effects. Doctors should pay attention to these needs and problems before GLP-1 medication is prescribed.

The fact that we were able to gather this data using existent technology in a brief period with little effort and no cost demonstrates that our approach can be useful for rapidly investigating the benefits and bothers of other primary care therapies. Physicians can easily learn about the value of new treatments from their patients. When coordinated across many practices to increase the number of respondents, conclusions about interventions for a variety of "real world" patients and practices should be efficiently and quickly attainable.