# Access to Transplant: Worth the Weight (Loss)

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#### Conflicts of Interest

I do not have any relevant disclosures. Off label indications will be discussed.



#### Learning Objectives

- 1. Describe the importance of weight management in the transplant setting.
- 2. Review weight management drugs including mechanism of action, side effect profile, and patient-specific factors.
- 3. Discuss successes and barriers for implementing weight management strategies for patients in the transplant setting.



#### Case Study

BG is a 67 yo M with a PMH of ILD 2/2 hypersensitivity pneumonitis, OSA, and osteopenia. He requires 6L of oxygen at rest. Pertinent labs and vitals are as follows:

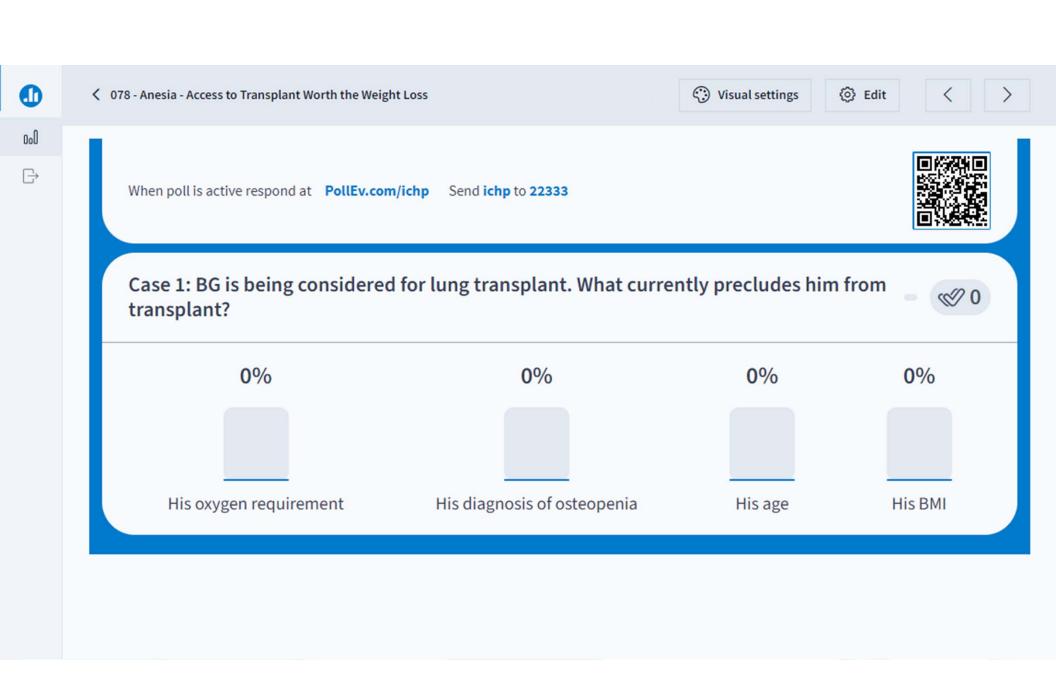
• HgbA1c: 5.2%

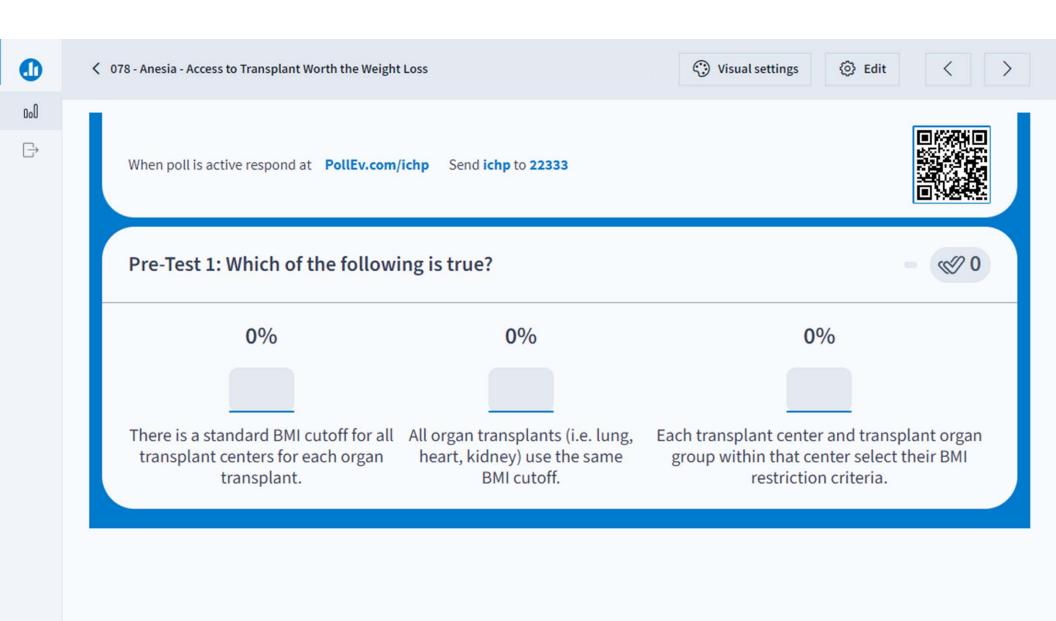
• Total Cholesterol 95, HDL 29, LDL 52

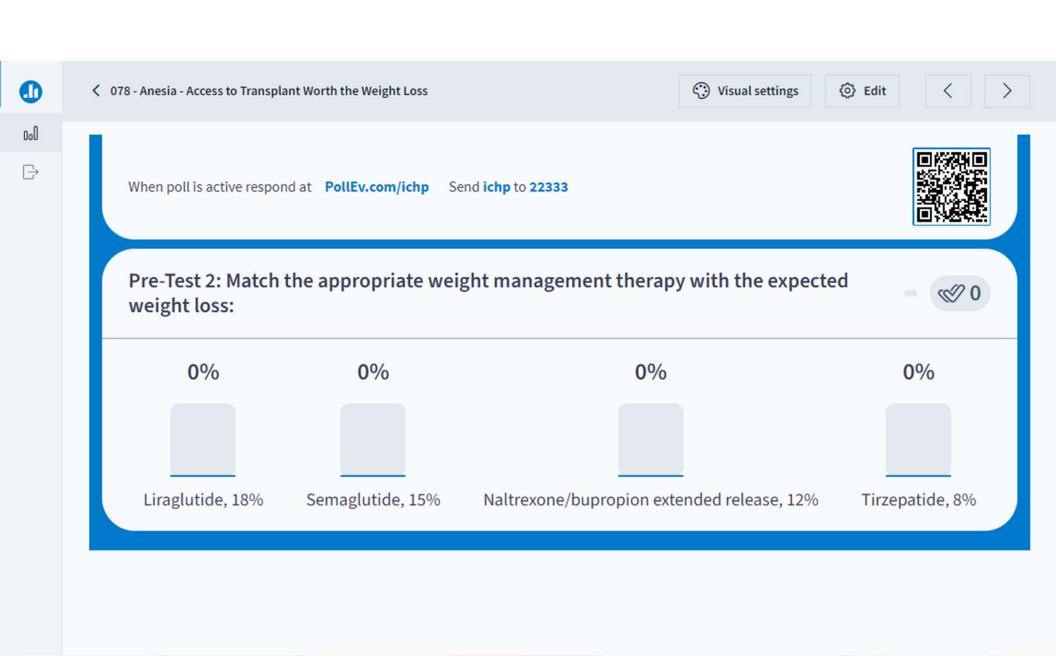
• Weight: 215 lbs

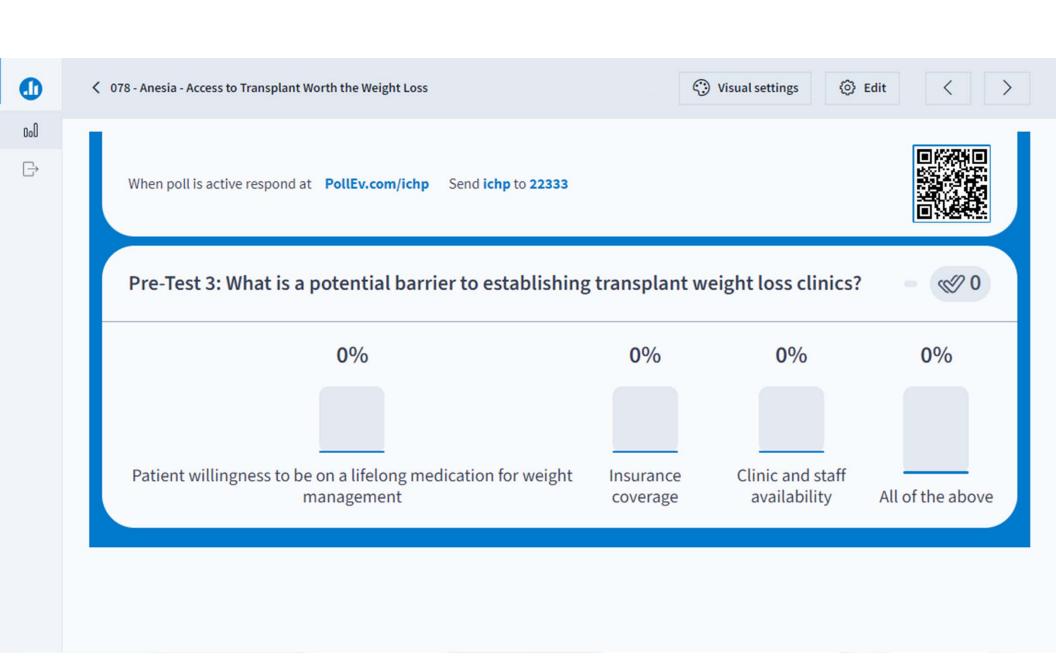
Body Mass Index (BMI): 33.81 kg/m<sup>2</sup>





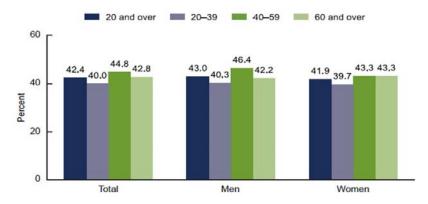




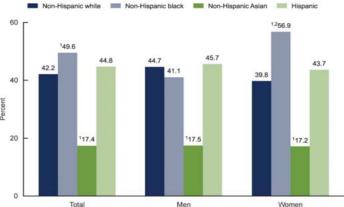


#### Obesity in the General Population

- Nearly 1 in 3 adults (30.7%) are overweight (BMI 25-29.9 kg/m²)
- More than 2 in 5 adults (42.4%) have obesity (BMI 30- 39.9 kg/m²)
- About 1 in 11 adults (9.2%) have severe obesity (BMI > 40 kg/m²)



Age adjusted prevalence of obesity among adults ages 20 and older by sex and age, U.S., 2017-2018



Age adjusted prevalence of obesity among adults ages 20 and older by sex, race, Hispanic Origin, U.S., 2017-2018



#### Factors Leading to Increasing Rates of Obesity

 Worldwide prevalence of obesity nearly tripled between 1975 and 2016





#### Obesity and Chronic Disease

 Obesity is an independent risk factor for many chronic diseases that lead to end stage organ disease

Obesity exacerbates complications from existing conditions



## Indications for Transplant and Rates of Obesity

#### Kidney Transplant

- Hypertension: 41%
- Diabetes: 55%

#### **Liver Transplant**

- Alcohol-related liver disease:20%
- Metabolic dysfunctionassociated Steatohepatitis (MASH): 81%

#### **Lung Transplant**

- Idiopathic Pulmonary Fibrosis: 34%
- Chronic
   Obstructive
   Pulmonary
   Disease (COPD):
   15%

#### **Heart Transplant**

- Valvular disease: 10%
- Cardiomyopathy 32%



#### Transplanting Obese Patients

- Surgical/technical considerations
- Increase in inflammation and potential link to rejection
- Mobility post transplant
- Lack of standardization of BMI requirements
- Short term and long term morbidity and mortality
- Concern for resource utilization



#### Transplant Center Specific Approach

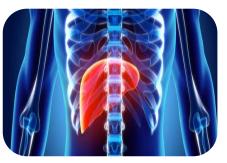
- American Society of Transplant Surgeons 2012 Kidney Transplant Survey:
  - 66 of 67 centers had BMI criterion
  - Upper limit for evaluation: BMI 35-45 kg/m<sup>2</sup>
  - Inconsistent BMI for listing

- Thomas Jefferson 2014 Liver Transplant Survey:
  - » 46 centers
  - » 70.5% centers had BMI criterion
  - » 55% reported BMI cutoff of 45 kg/m²
  - » 25% of centers reported any BMI was acceptable

# Transplanting Obese Patients- UCMC Limits



 $BMI > 40 \text{ kg/m}^2$ 



No BMI restriction



BMI >35 kg/m<sup>2</sup>



 $BMI > 30 \text{ kg/m}^2$ 



#### Obese Recipient Risk: Kidney Transplant

- Skin and soft tissue complications
- Anastomotic complications
- Delayed graft function
- Increased rejection
- Decreased graft survival
- Increased risk for sepsis, readmissions, new onset diabetes



#### Obese Recipient Risk: Liver Transplant

- Difficulty defining obesity with weight alone due to sarcopenia, fluid overload/ascites, and malnutrition
- BMI > 40 kg/m² → decreased 30 day, 1 year, and 2 year post operative survival
- Overweight and mild obesity → protective effect
- Higher risk of recurrent hepatocellular carcinoma

#### Obese Recipient Risk: Heart Transplant

- Decreased 1 and 5 year survival with BMI >35 kg/m<sup>2</sup>
- Increased risk of dialysis post transplant
- Increased risk of new onset diabetes, chronic dialysis, and post transplant coronary artery disease

#### Obese Recipient Risk: Lung Transplant

- Increased risk of primary graft dysfunction with BMI >30 kg/m<sup>2</sup>
- Increased risk of post transplant mortality with BMI > 30 kg/m<sup>2</sup>
  - 22% greater mortality rate compared to those of BMI 18.5-24.9 kg/m<sup>2</sup>
- Poorer long term outcomes with BMI > 35 kg/m<sup>2</sup>



#### Historical Approach to Obese Transplant Candidates

Pt referred to transplant center



IF BMI unacceptable: pt instructed to call for scheduling when BMI is within eval range



IF BMI acceptable: eval scheduled



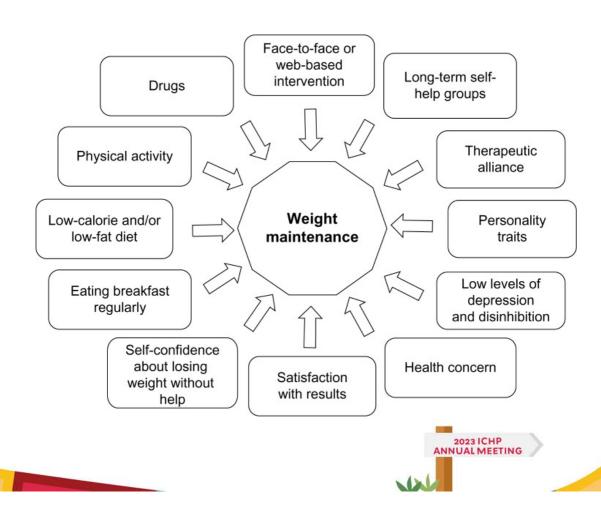
Eval completed and pt instructed to lose weight & call back when BMI is below cutoff



#### How Hard Is It to Lose Weight?

• 3-5% weight loss seen with lifestyle changes

 More than half of the weight is gained back in 2 years and 80% in 5 years



#### What Can We Offer These Patients?

- Referral to bariatric surgery
  - Only 1% of currently eligible population undergoes surgical treatment
  - Can consider at time of abdominal transplant
- Anti-obesity medications
  - Greater and more sustainable weight loss when paired with lifestyle modifications

# Oral Anti-Obesity Medications

Medication	Drug Class	Indication	Dosing	Common Adverse Effects
Phentermine/topiramate extended release (Qysmia™)	Combination sympathomimetic amine anorectic/anti-epileptic analogue	Chronic weight management in adults with a BMI ≥30 kg/m² or ≥27 kg/m² in the presence of weight related comorbidity*	3.75 mg/23 mg capsules: 1 capsule PO daily x 14 days then titrate. Max dose 15 mg/92 mg PO daily	Paresthesia, dizziness, dysgeusia, insomnia, constipation, dry mouth
Naltrexone/bupropion extended release (Contrave™)	Combination opioid antagonist/aminoketone antidepressant	Chronic weight management in adults with a BMI ≥30 kg/m² or ≥27 kg/m² in the presence of weight related comorbidity*	8 mg/90 mg tablets: 1 tab PO daily x 1 week then titrate. Max dose 16 mg/180 mg PO twice daily.	Nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth, diarrhea
Orlistat (Xenical™ or Alli™)	Lipase inhibitor	Chronic weight management in adults with a BMI ≥30 kg/m² or ≥27 kg/m² in the presence of weight related comorbidity*	60 mg capsule or 120 mg capsule: 120-180 mg three times daily with meals that contain fat	Oily spotting, flatus with discharge, fecal urgency, fatty/oily stool



#### Oral Anti-Obesity Medications

- 3-10.8% total body weight loss seen with oral pharmacotherapy when partnered with lifestyle modifications
- Phentermine/topiramate shows greatest weight loss (~10%), but increased cardiovascular risk
- Unique patient populations from these agents can benefit beyond weight loss



# Advent of Glucagon-like Peptide 1 Receptor Agonists (GLP1 RAs): The Injectable Anti-Obesity Medications

Chelsea Handler, Kyle Richards and More Celebrities Who've Spoken About the Ozempic Weight Loss Trend

By Kaitlin Simpson August 14, 2023





Former UK prime minister Boris Johnson stopped taking semaglutide because he said it made him feel ill.



#### "The worst-kept secret in Hollywood"

In the last several months, Ozempic has exploded onto the scene, with everyone from Elon Musk to Chelsea Handler talking about taking versions of the drug.



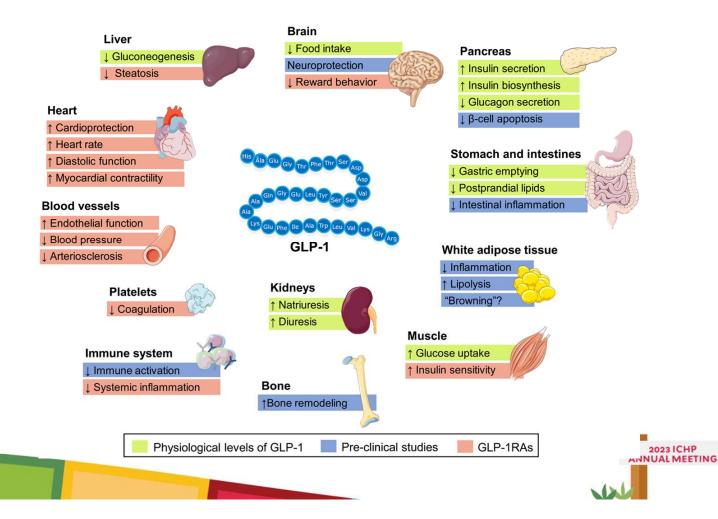
#### Available GLP-1RAs

- Exenatide (Byetta®)
- Dulaglutide (Trulicity®)
- Liraglutide (Saxenda®)\*
- Semaglutide (Ozempic<sup>®</sup>, Wegovy<sup>®</sup>\*, Rybelsus<sup>®</sup>)
- Tirzepatide (Mounjaro®)

\*approved for weight loss



#### Benefits of GLP-1RA Pharmacotherapy



### Liraglutide

- Dose titration every week
- Contraindications:
  - Personal or family history of medullary thyroid carcinoma
  - Patients with Multiple Endocrine Neoplasia syndrome type 2

Medication	Available Doses and Frequency	Indication
Liraglutide (Saxenda®)	0.6, 1.2, 1.8, 2.4, 3.0 mg SQ; given once daily	Chronic weight management
Liraglutide (Victoza®)	0.6, 1.2, 1.8 SQ; given once daily	Type 2 diabetes



# Data Supporting Use

Source	Design and Study Population	Results
Pi-Sunyer et al. 2015 (SCALE)	<ul> <li>Double blinded, randomized 2:1</li> <li>3731 pts with BMI ≥ 30 kg/m² OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>56 weeks of liraglutide 3.0 mg q day vs placebo</li> </ul>	<ul> <li>Mean change in body weight from baseline to week 56 was -8% in the lira group vs2.6% with placebo</li> <li>Percent of pre-diabetics found in the lira group after 56 weeks was 30.8% &amp; the percent of pre-diabetics found in the placebo group after 56 weeks was 67.3%</li> </ul>



#### Semaglutide

- Dose titration every 4 weeks
- Use in caution in patients with history of pancreatitis
- Contraindications:
  - Personal or family history of medullary thyroid carcinoma
  - Patients with Multiple Endocrine Neoplasia syndrome type 2

Medication	Available Doses and Frequency	Indication
Semaglutide (Ozempic®)	0.25, 0.5, 1, 2 mg SQ; given every 7 days	Type 2 Diabetes
Semaglutide (Wegovy®)	0.25, 0.5, 1, 1.7, 2.4 mg SQ; given every 7 days	Chronic weight management
Semaglutide (Rybelsus®)	3, 7, 14 mg PO; given daily	Type 2 Diabetes



# Semaglutide Data

Source	Design and Study Population	Results
Wilding et al. 2021 (STEP 1)	<ul> <li>Double blinded, randomized 2:1</li> <li>1961 pts with BMI ≥ 30 kg/m²</li> <li>68 weeks of semaglutide 2.4 mg q week vs placebo</li> </ul>	<ul> <li>Mean change in body weight from baseline to week 68 was         <ul> <li>14.9% in the sema group vs2.4% with placebo</li> </ul> </li> <li>Sema group with greater improvement in cardiometabolic risk factors and pt-reported physical function</li> </ul>
Davies et al. 2021 (STEP 2)	<ul> <li>Double blinded, randomized 2:1</li> <li>1210 pts with BMI ≥ 27 kg/m² AND type 2 diabetes</li> <li>68 weeks of semaglutide 2.4 mg q week vs semaglutide 1.0 mg q week vs placebo</li> </ul>	<ul> <li>Mean weight change was -9.6% in sema 2.4 mg vs7.0% vs3.4% in placebo group</li> <li>More patients on sema 2.4 mg than sema 1.0 achieved slightly better glycemic control, reductions in cardiometabolic risk, and improved physical function</li> </ul>
Wadden et al. 2021 (STEP 3)	<ul> <li>Double blinded, randomized 2:1</li> <li>611 pts with BMI ≥ 30 kg/m² OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>68 weeks of semaglutide 2.4 mg q week vs placebo + low calorie diet x 8 weeks + intensive behavioral therapy</li> </ul>	<ul> <li>Average weight reduction was 16.0% with sema vs. 5.7% with placebo</li> <li>At least a 5% reduction in bodyweight was met by 86.6% (sema) versus 47.6% (placebo).</li> </ul>
Rubino et al. 2021 (STEP 4)	<ul> <li>Double blinded, randomized</li> <li>803 pts with BMI ≥ 30 kg/m² OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>20 weeks of semaglutide 2.4 mg q week then randomized 2:1 to 48 weeks of continued semaglutide vs placebo</li> </ul>	<ul> <li>Patients lost average of 10.6% of weight in first 20 weeks</li> <li>Pts who continued on sema after randomization lost an additional 7.9% of their bodyweight, on average, to give a total 17.4% weight loss over the whole trial, whereas those who switched to placebo regained an average 6.9%, giving a total weight loss of 5.0%.</li> </ul>



# Semaglutide Data cont.

Source	Design and Study Population	Results
Garvey et al. 2022 (STEP 5)	<ul> <li>Double blinded, randomized 2:1</li> <li>304 pts with BMI ≥ 30 kg/m² OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>104 weeks of semaglutide 2.4 mg q week vs placebo</li> </ul>	<ul> <li>Mean change in body weight from baseline to week 104 was -15.2% in the sema group vs2.6% with placebo</li> <li>Demonstrated weight loss was seen through week 60, and then maintained until week 104</li> </ul>
Kadowaki et al. 2022 (STEP 6)	<ul> <li>Double blinded, randomized 2:1</li> <li>401 Asian pts with BMI ≥ with BMI ≥ 35 kg/m² with one comorbidity OR BMI ≥ 27 kg/m² + two comorbidities</li> <li>68 weeks of semaglutide 2.4 mg q week vs semaglutide 1.7 mg q week vs placebo</li> </ul>	<ul> <li>Mean weight change was -13.2% in sema 2.4 mg vs9.6% vs2.1% in placebo group</li> <li>Sema associated with significant reduction in abdominal visceral fat and a significant reduction in hemoglobin A1c in patients with diabetes</li> </ul>
Rubino et al. 2022 (STEP 8)	<ul> <li>Open –label, double-blinded, randomized 3:1</li> <li>338 pts with BMI ≥ 30 kg/m² OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>68 weeks of semaglutide 2.4 mg q week vs. liraglutide 3.0 once daily</li> </ul>	<ul> <li>Mean weight change was 15.8% with sema vs. 6.4% with liraglutide</li> <li>Higher rates of discontinuation in liraglutide (12.6%) vs. sema (3.2%) vs. placebo (3.5%)</li> </ul>

SELECT trial not yet published but reported 20% reduction in risk of major cardiovascular events

#### Tirzepatide Data

- Dose titration every 4 weeks
- Use in caution in patients with history of pancreatitis
- Contraindications:
  - Personal or family history of medullary thyroid carcinoma
  - Patients with Multiple Endocrine Neoplasia syndrome type 2

Medication	Available Doses and Frequency	Indication
Tirzepatide (Mounjaro®)	2.5, 5, 7.5, 10, 12.5, 15 mg SQ; given every 7 days	Type 2 diabetes
Tirzepatide (brand name pending)	5, 10, 15 mg SQ; given every 7 days	Pending FDA approval



# Tirzepatide Data

Source	Design and Study Population	Results
Jastreboff et al. 2022 (SURMOUNT 1)	<ul> <li>Double blinded, randomized 1:1:1:1</li> <li>2539 pts with BMI ≥ 30 kg/m² OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>72 weeks of tirzepatide 5 mg vs 10 mg vs 15 mg q week vs placebo</li> </ul>	<ul> <li>Mean change in body weight from baseline to week 72 was -15.0% (5 mg), -19.5% (10 mg), and -20.9% (15 mg) tirzepatide group vs3% with placebo</li> <li>Co-primary endpoint of the proportion of people attaining at least a 5% reduction in their baseline bodyweight: 85% (5 mg), 89% (10 mg), and 91% (15 mg) versus 35% (placebo)</li> </ul>
Garvey et al. 2023 (SURMOUNT 2)	<ul> <li>Double blinded, randomized 1:1:1:1</li> <li>938 pts with type 2 diabetes AND BMI ≥ with BMI ≥ 35 kg/m² with one comorbidity OR BMI ≥ 27 kg/m² + one comorbidity</li> <li>72 weeks of tirzepatide 10 mg vs 15 mg q week vs placebo</li> </ul>	<ul> <li>Mean weight change was -12.8.% (10 mg) vs14.7% (15 mg) vs3.2% in placebo group</li> <li>Co-primary endpoint of the proportion of people attaining at least a 5% reduction in their baseline bodyweight: 79% (10 mg), and 83% (15 mg) versus 32% (placebo)</li> </ul>

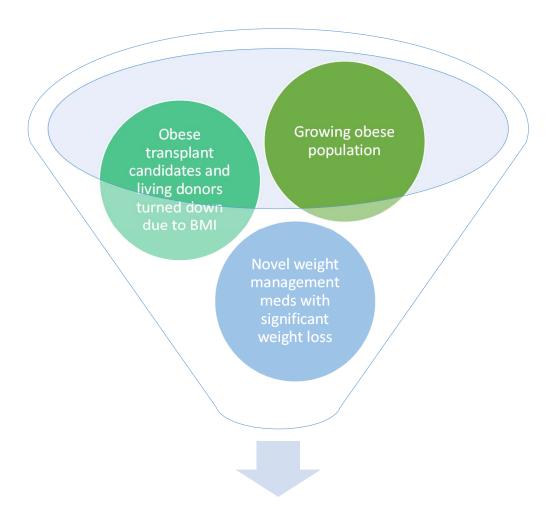


#### **GLP1RA Trials Summary**

- Greatest medication-assisted weight loss seen
- Varying degrees of weight loss seen (8-25%) with different agents
- Trials did not include patients on dialysis or with chronic end stage organ disease
- Majority of trials include mostly Caucasian and female patients (~70%)
- More data needed comparing GLP1RAs

#### Clinical Approach to Obesity

- The Obesity Society/American College of Cardiology/American Heart Association joint guidelines last published in 2014
- Many other organizations publishing guidelines: American Association of Clinical Endocrinologists, American Gastroenterological Association
- All obese patients: comprehensive lifestyle intervention program
- Pharmacological intervention indicated BMI ≥ 35 kg/m<sup>2</sup>
- Bariatric procedures for pts with a BMI ≥40 kg/m<sup>2</sup> or a BMI ≥ 35 kg/m<sup>2</sup> with weight-related complications

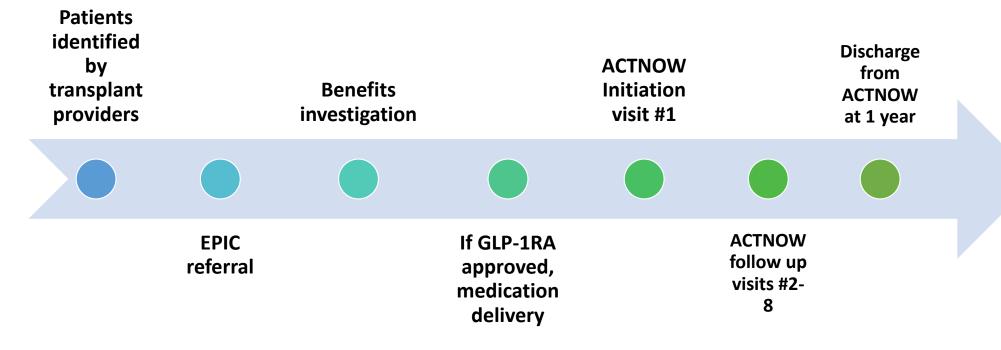


The birth of a transplant weight loss clinic

2023 ICHP ANNUAL MEETING Access to
Transplant
through Novel
Approaches to
Weight Loss
(ACTNOW) Clinic:
March 2023



## Workflow Chart



2023 ICHP ANNUAL MEETING

## Patient Selection

## **Appropriate Patient Population**

- Patients in need of an organ an unacceptable BMI For surgery
  - Lung: BMI  $> 30 \text{ kg/m}^2$
  - Kidney: BMI >  $40 \text{ kg/m}^2$
  - Heart: BMI >35 kg/m<sup>2</sup>
  - Pancreas/islet: BMI >32 kg/m²
  - Liver: surgeon discretion

### **Excluded Patients**

- Pts w/ incomplete psychosocial and medical work up
- Pts w/ malnutrition
- Pts already on GLP-1RAs
- Pts w/ personal or family history of medullary thyroid carcinoma, multiple endocrine neoplasia syndrome type 2



# Referral & Benefits Investigation

- Referral made by transplant team after transplant work up is complete
- GLP-1RA coverage checked prior to first visit done by specialty pharmacist
  - Ensure coverage of induction + maintenance dosing
  - Prior authorization + appeal attempted
  - Assessment of financial assistance needs
- Patients only scheduled if active coverage for GLP-1RAs and receive med prior to visit



## ACTNOW Visit #1

NP visit

• Physical exam
• Medical and family history
• Assessment of readiness and motivation

PharmD Visit

• Medication counseling (expectations, ADRs, administration)
• Movement counseling

• Assessment of eating habits
• Individualized dietary modification counseling



# Lifestyle Modifications

- Movement goals
  - Assess starting point
  - Attainable, modified goals
- Dietary goals
  - Access to food
  - Mediterranean diet
  - Protein supplements





### Beginner Friendly Yoga Postures



Sit back on your heels and place your knees out as wide as possible. Either rest your forehead on your mat or, if that's uncomfortable, stack your fists under your forehead and rest upon them.

Benefits: stimulates digestion, regulates blood pressure, promotes relaxation, alleviates lower back pain

### Low Crescent Lunge



Bring your front foot to the outer edge of the mat. Place hands in front of you for support. Sink hips to floor. May lift the back knee off of the floor or leave down for added support (place blanket underneath knees if there is any discomfort).

Benefits: stretches leg, hip and groin muscles; alleviates lower back pain; promotes balance; opens chest and shoulders with arms lifted



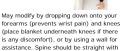
Seated upright, bend one knee and set foot down close to the seat. Inhale to lengthen the spine, exhale to twist towards the bent knee. May aid in twist by holding the knee with the opposite hand. Flex foot of straight leg.

Benefits: stimulates digestion; improves posture, alleviates back pain, strengthens back muscles: boosts mood

Plank Pose







shoulders over wrists (or elbows).

### SAN DIEGO SPORTS MEDICINE

### Seated Resistance Routine

For resistance band movements, anchor the band to a sturdy door/door handle.

#### Scated Row

Face toward the door. Holding the band in each hand, squeeze shoulder blades back while pulling elbows alongside your body.







#### Chest Press

Face away from the door. Holding the band in each hand, place the resistance band around your mid back and under the arms. Extend both arms until they are straight, pulling the band with them. Lower back to starting position.

Repeat: 10 times Perform: 2 times daily





### Stir the Pot

Stand sideways to the door, pulling the band to full tension directly in front of you. Form a circle in one direction, making sure only to use your arms, keeping your body still. Perform 5 reps and switch directions.

Repeat: 5 times each direction Perform: 2 times daily





Stand sideways to the door, pulling the band to full tension directly in front of you. Lift the band up to eve level, then down to waist level. Return to starting p Repeat: 10 times

Perform: 2 times daily









AT THE FOREFRONT UChicago Medicine Transplant Institute 5841 S. Maryland Ave Chicago, IL 60637 ACTNOWclinic@uchicagomedicine.org

### **Visit Topic List**

Mediterranean Diet Date of Visit:



The Power of Protein Date of Visit (virtual):



Grocery Store/On the Go Guide Date of Visit (virtual):



Eating the Rainbow: How to add more fruits/vegetables



Proper Portion Control Date of Visit:



Exercise for Energy Date of Visit:



Maintenance Mode Date of Visit:





# Follow Up Visits

Visit Number	Week since Initiation	Scheduled Appointments
Visit #2	Week 4	Virtual: PharmD, RD
Visit #3	Week 8	Virtual: PharmD, RD
Visit #4	Week 12	In person: NP, PharmD, RD
Visit #5	Week 24	In person: NP, PharmD, RD
Visit #6	Week 36	In person: NP, PharmD, RD
Visit #7	Week 52	In person: NP, PharmD, RD



# PharmD Specific Visits

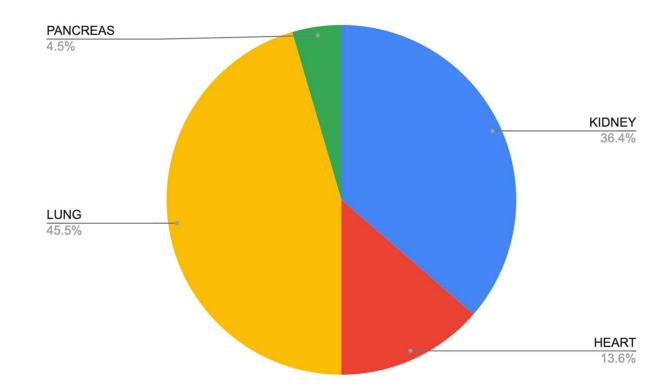
- Assessment of adverse effects
- Adherence
- Changes in concurrent medications
- Dose titration
- Goal setting



# Results to Date: Patient Population

• Referrals: 37

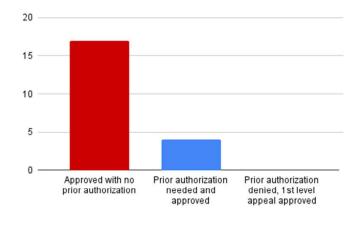
• Active patients: 22



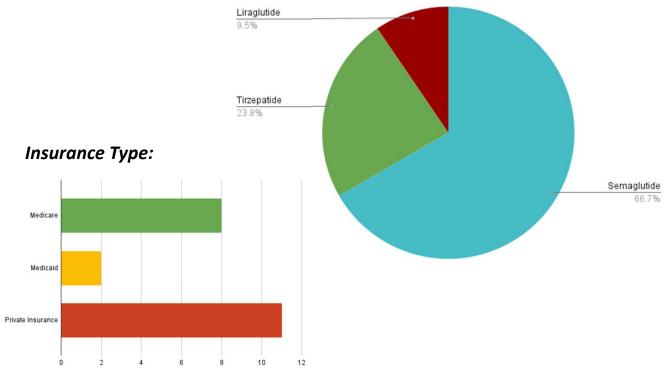


## Results to Date: Medication Access

### **Medication Approval Process:**



### **GLP1RA Selected:**





# Results to Date: Weight Loss

- First patient seen 3/24/2023
- Of the 12 patients who have completed at least 8 weeks of ACTNOW, average weight loss is 14.2 lbs. (ranging from 5-23 lbs.)
- All patients are losing weight
- No discontinuations
- 3 patients have reach goal weight and 2 patients subsequently listed!



## Potential Limitations of Clinic

Formulary changes

Equal access across insurance providers?

Therapy continuation peri-transplant?

Transitions of care when discharging from ACTNOW



## **Future Endeavors**

- Expanding access to living donors
- Chicagoland outreach
- Potential partnerships with GLP-1 manufacturer to expand access
- Publish ACTNOW data



## Conclusions

- Obesity is a growing epidemic that poses significant problems to the pre-transplant population
- Obesity and high BMIs limit patients' access to transplant
- GLP1RAs provide significant weight management benefits compared to conventional therapy and weight loss benefits vary dependent on selected agent
- The ACTNOW Clinic is an innovative service that expands access to transplant to obese patients with end-stage organ disease

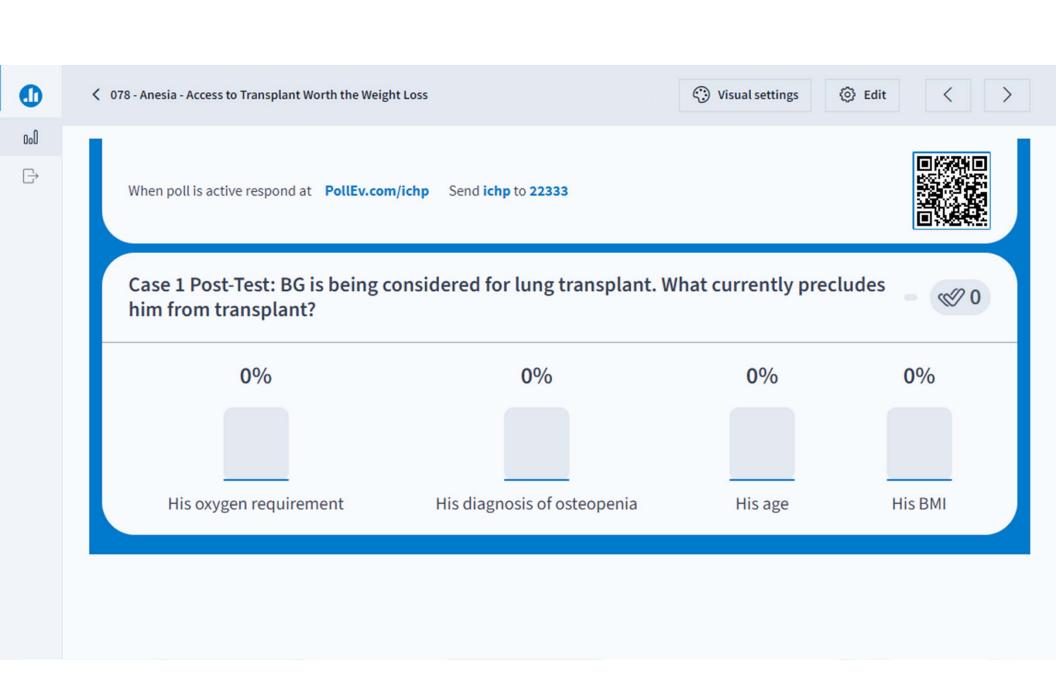


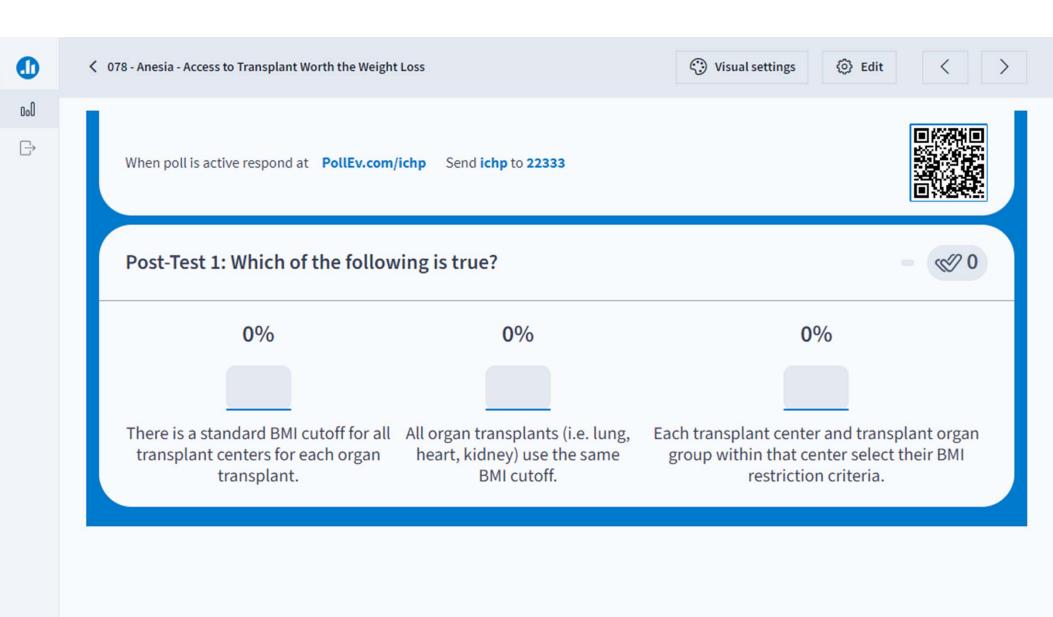
# Case Study

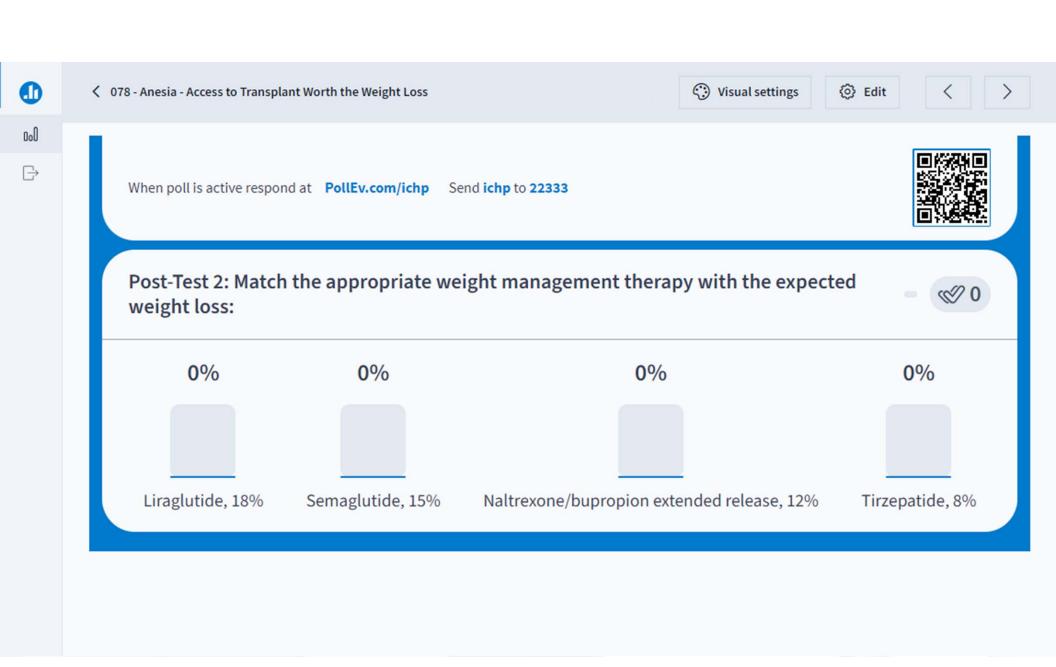
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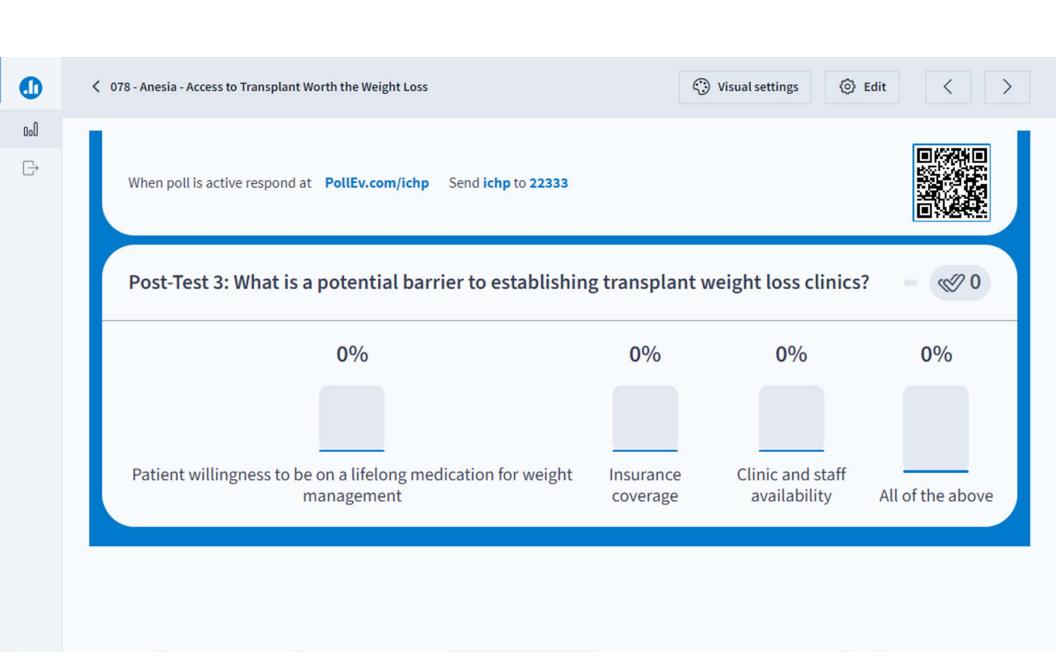
- HgbA1c: 5.2%
- Total Cholesterol 95, HDL 29, LDL 52
- Weight: 215 lbs
- Body Mass Index (BMI): 33.81 kg/m<sup>2</sup>

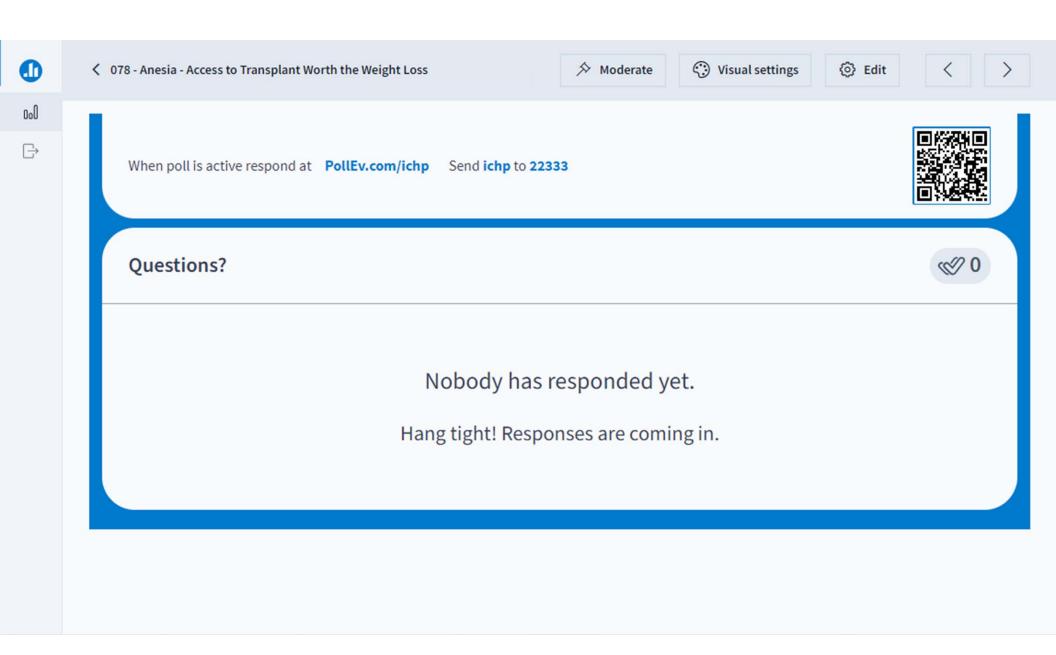












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