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How to navigate the problem of *inconsistent access* to obesity management medications

Conflict of Interest Disclosure

- **Receipt of honoraria or consultation fees:** Johnson & Johnson, Nestle HealthScience, Reshape HealthSciences, iNova Pharmaceuticals, Novo Nordisk, Eli Lilly
- **Participation in a company sponsored speaker's bureau:** Nestle HealthScience, Fit for Me, Reshape HealthSciences, iNova Pharmaceuticals, Novo Nordisk, W.L.Gore & Associates, Merk Sharp & Dohme, Johnson & Johnson, FitForMe, Medtronic
- **Receipt of travel grants/attend conferences:** Novo Nordisk, UGI Research Foundation
- **Gratis Australian medical advisory work:** Pharmaceutical Benefits Advisory Committee, Ministry of Health, NSW Health, Royal Australian College of General Practitioners

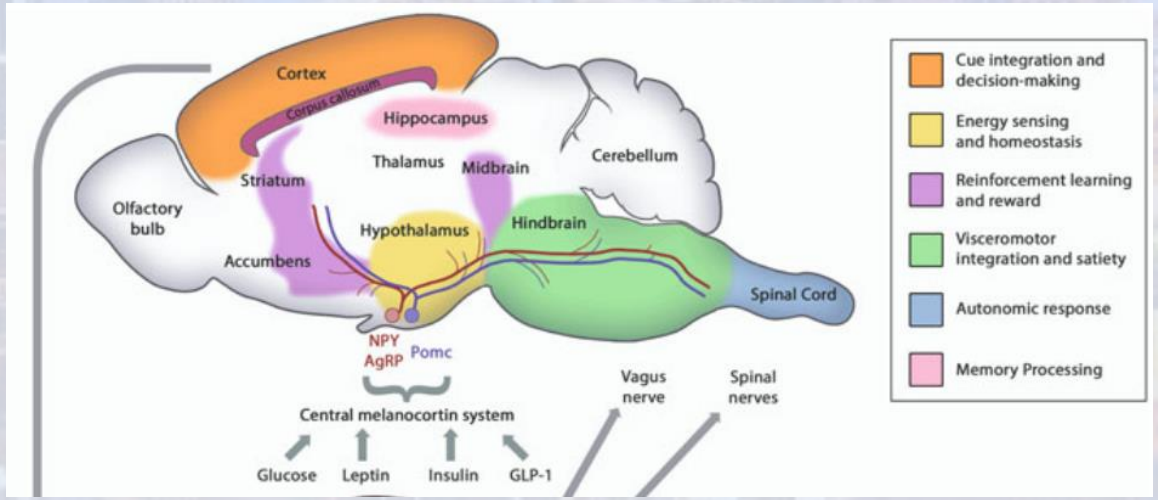
Lessons learned thus far

Safety
Tolerability
Efficacy
Acceptability
Accessibility

Table 4
Historic Adverse Consequences of Past Drug Treatments for Obesity. Since the 1800s, multiple therapies used to treat obesity have encountered unacceptable adverse side effects. Table lists historic discontinued anti-obesity therapeutics and their adverse health consequences [7,123–125]. None of these are currently indicated to treat obesity.

Year	Drug	Consequence
1925 - present	Thyroid	Hyperthyroidism
1933 - 1938	Dinitrophenol	Cataracts/Neuropathy/Fatal hyperthermia
1947 - 1979	Amphetamine	Addiction
1965 - 1968	Aminorex	Pulmonary Hypertension
1973 - 1997	Fenfluramine/Dexfenfluramine	Valvulopathy
1976 - 2000	Phenylpropanolamine	Strokes
1920 - 2004	Ma Huang (ephedra)	Heart attacks/stroke
2006 - 2007	Ecopipam (Dopamine)	Depression/Suicide
2006 - 2009	Rimonabant (Selective cannabinoid-1 receptor antagonist): Never approved in the US	Depression/Suicide
1997 - 2009	Sibutramine	Cardiovascular disease risk
2012 - 2020	Lorcaserin	Cancer signal (e.g., lung and pancreas)

Where are we heading?



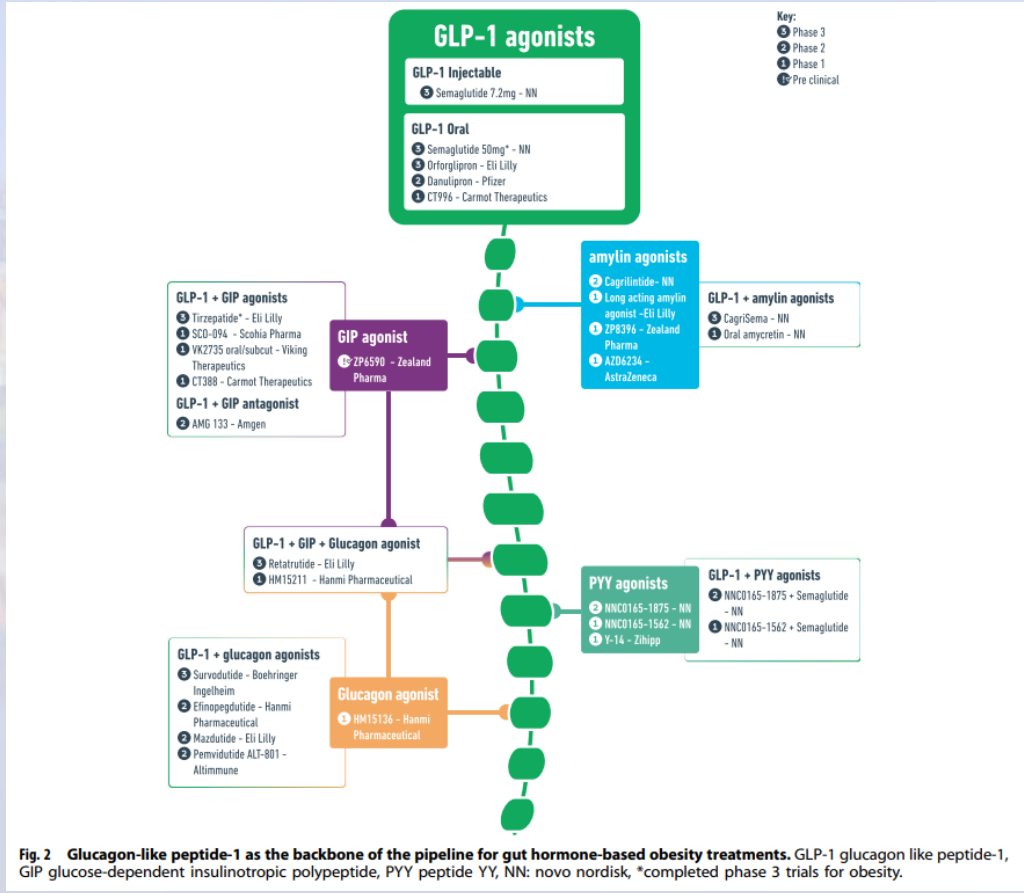
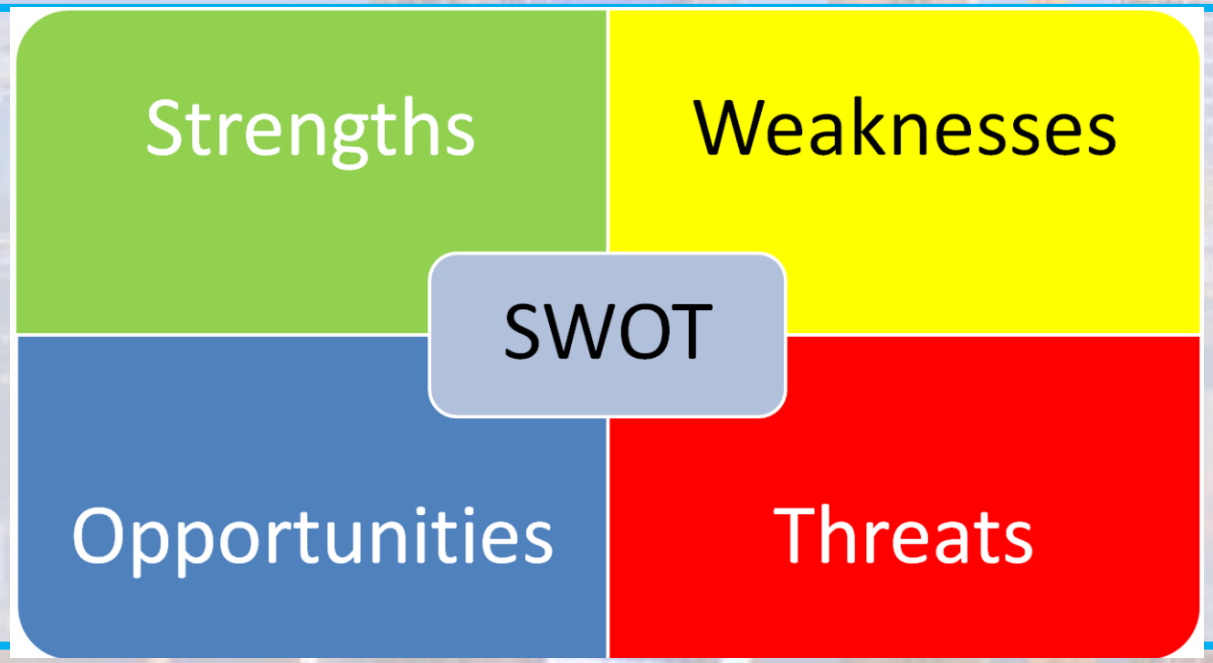


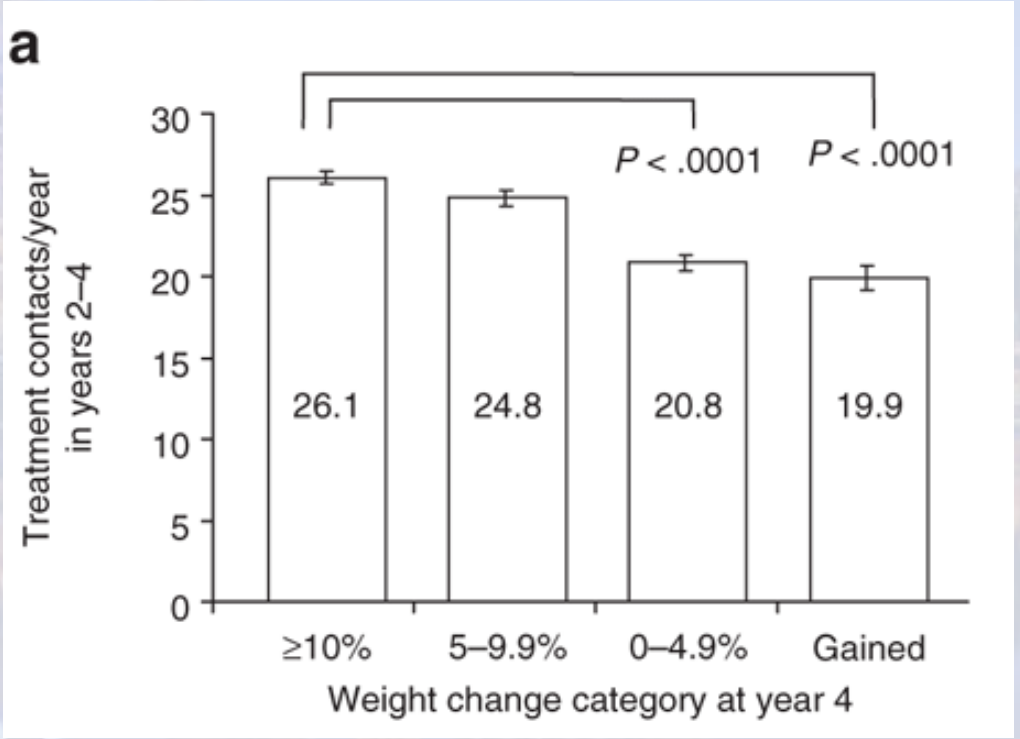
Fig. 2 Glucagon-like peptide-1 as the backbone of the pipeline for gut hormone-based obesity treatments. GLP-1 glucagon like peptide-1, GIP glucose-dependent insulinotropic polypeptide, PYY peptide YY, NN: novo nordisk, *completed phase 3 trials for obesity.

Problem of inconsistent access



Strengths:

- Regular clinical touch points with HCPs (in person +/- virtual)
- Patient support networks



Wadden et al; Four-Year Weight Losses in the Look AHEAD Study: Factors Associated With Long-Term Success Obesity 2012

Behaviors associated with maintenance of lost weight:
Mean number of total treatment contacts per year (for years 2–4).

Strengths:

- Newer generation of OMM:
  - lowest effective dose +/- increase dose prn eg menstrual cravings etc then step down OR
  - lowest effective dose +/- small dose of a different OMM prn
  - consider the half-life of the OMM & feedback from patient

Strengths:

- Earlier generation of OMM still available and effective
  - lowest effective dose +/- increase dose prn eg menstrual cravings etc then step down OR
  - lowest effective dose +/- small dose of a different OMM prn
- Combination therapy: OMM + VLED

Strengths:

Please note sibutramine was **WITHDRAWN** and no longer approved for obesity management

Table 2. Proportions of Patients Maintaining ≥100%, ≥50%, or ≥25% of Weight Loss Following a Very-Low-Calorie Diet

	Endpoint†		Month 6		Month 12	
% Weight Loss Maintained	Sibutramine (n = 81)	Placebo (n = 78)	Sibutramine (n = 73)	Placebo (n = 68)	Sibutramine (n = 55)†	Placebo (n = 45)
≥100%	60 (74%)**	32 (41%)	65 (89%)*	46 (68%)	41 (75%)**	19 (42%)
≥50%	75 (93%)*	59 (76%)	72 (99%)*	59 (87%)	52 (95%)*	33 (73%)
≥25%	78 (96%)*	65 (83%)	72 (99%)	65 (96%)	53 (96%)*	36 (80%)

* $P < 0.01$, ** $P < 0.001$, comparison versus placebo.

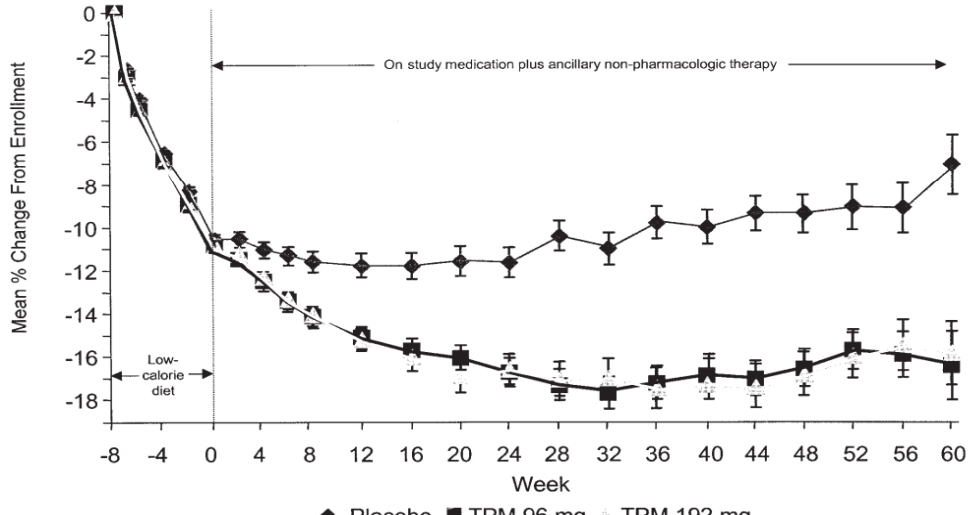
† Endpoint indicates the end of the trial, or the last available measurement carried forward. See methods.

‡ Includes one patient who had withdrawn from the trial but had an assessment within 6 days of last dose of trial medication and had taken trial medication for 338 days.

Apfelbaum M, Vague P, Ziegler O, Hanotin C, Thomas F, Leutenegger E. Long-term maintenance of weight loss after a very-low-calorie diet: a randomized blinded trial of the efficacy and tolerability of sibutramine. Am J Med 1999;106:179–84.

Strengths:

Please note topiramate is **NOT** TGA approved for obesity management

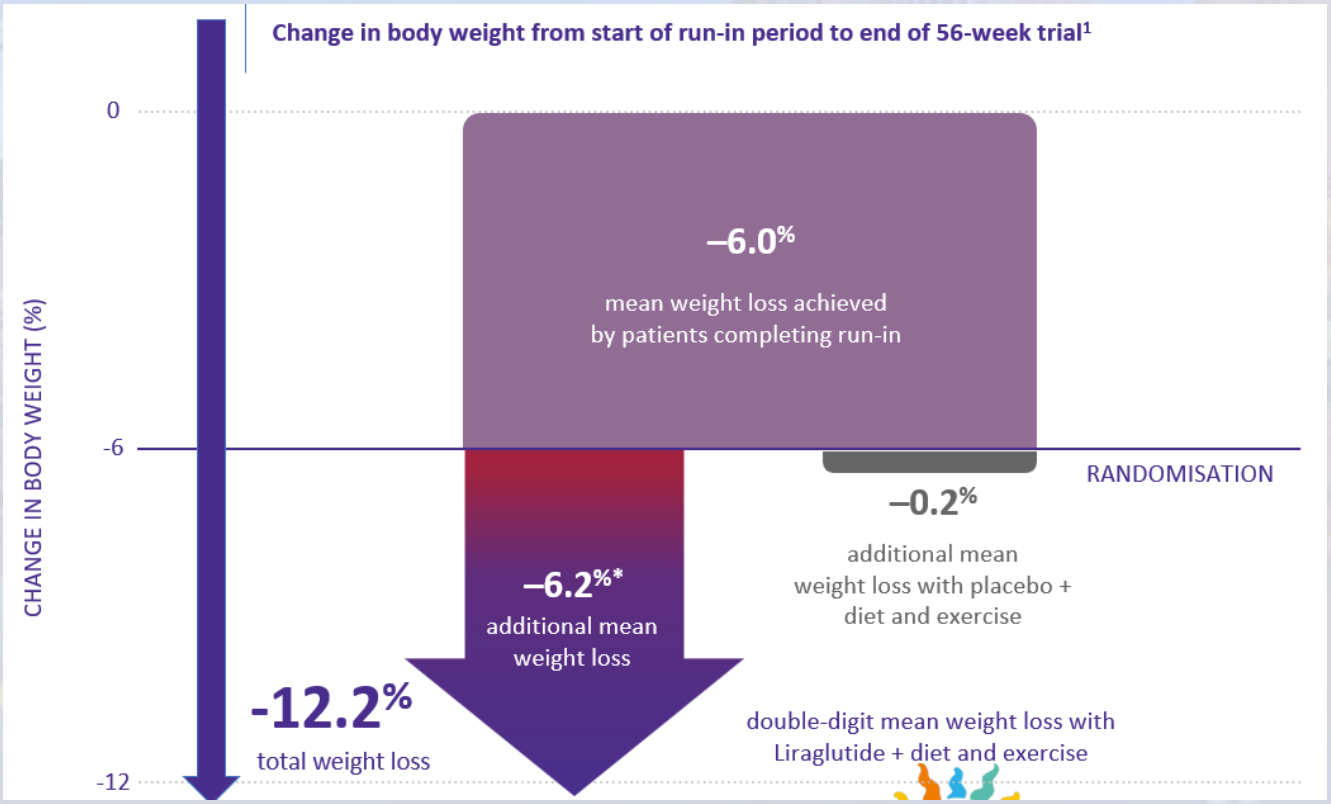


Number of Subjects																
Placebo	99	99	95	93	95	94	88	84	82	86	84	80	80	70	57	51	28
TPM 96 mg/d	96	96	87	84	84	85	79	76	70	71	68	69	67	62	56	48	30
TPM 192 mg/d	98	98	97	93	89	84	83	83	78	79	75	77	76	70	60	50	30

Figure 4: Mean percentage change from enrollment body weight over time to week 60. Includes the 8-week low-calorie diet phase. Each time-point uses all nonmissing observations at that time-point (observed MITT population). Because of the gradual attrition (withdrawals) that occured during the course of the trial, the number of subjects (and nonmissing observations) decreased at each subsequent time-point. The plot also includes data from subjects who had received therapy beyond week 44 when the decision was made to terminate the study. After week 44, the number of observations rapidly decreased.

Astrup A, Caterson I, Zelissen P, Guy-Grand B, Carruba M, Levy B, Sun X, Fitchet M. Topiramate: long-term maintenance of weight loss induced by a very low energy diet in obese subjects; OBESITY RESEARCH Vol. 12 No. 10 October 2004; 1658-1669

Strengths:



Data are observed means using LOCF. *P<0.0001 vs placebo.[1]
LOCF: last observation carried forward.

1. Wadden TA, *et al. Int J Obes (Lond).* 2013;3(11):1443–51.

Weaknesses:

Inequity in access

Cost prohibitive

PwO often report feeling “desperate” & “anxious” with inconsistent access [fear of relapse]

Tachyphylaxis

Threats to the PwO:

PwO hoarding when they can source the OMM- further exacerbating the inequity in access

Perceived “fat tax” by PwO= discriminatory

PwO charged $600+/month from chemists importing newer Gen OMM [prior to global supply issues, cost was $140/month]

Compounding chemists: what are PwO actually receiving ?

Pharmacists advising PwO to multi-dose from vials lacking preservatives

Virtual tele-clinics: vulnerable patients, sub-optimal care

Threats to HCPs:

Compounding chemists: responsibility lies with HCP signing the Rx

Regulatory authorities “advising” HCPs to prioritize PwT2DM over PwO

Medical indemnity insurers refusing to indemnify HCPs for the above

Pharmacists advising PwO to “ask their doctor for a higher dose”, so they can multi-dose

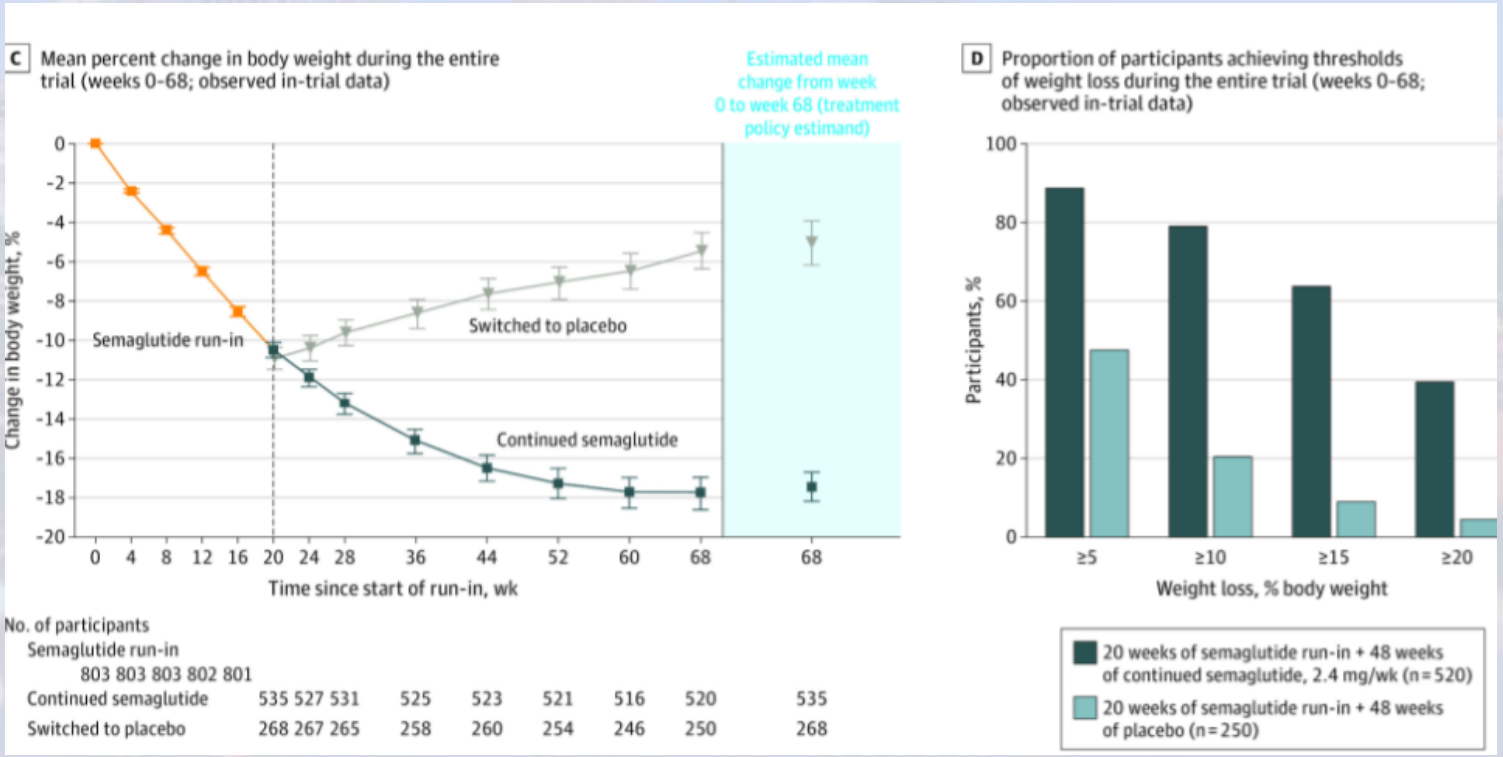
Virtual tele-clinics following “algorithm” & not necessarily seeing the patient; they also “seemed” to have access to stock

Opportunities:

Patients start to “believe”

-that OMM work

-obesity is a chronic Dx



Rubino D, et al. Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults With Overweight or Obesity: The STEP 4 Randomized Clinical Trial. JAMA. 2021 Apr 13;325(14):1414-1425. doi: 10.1001/jama.2021.3224. PMID: 33755728; PMCID: PMC7988425.

Opportunities:

MDT review:

-dietary review eg adequate protein, fibre etc

-talking therapies

-physical activity multitude of health benefits

-stress

-sleep hygiene

-“other” medication review: ensure not likely to stimulate appetite

Opportunities:

ICD-11
International Classification of Diseases 11th Revision
The global standard for diagnostic health information

World Health Organization

Audit our clinical practice

eg patient Electronic Medical Record

Q: Are we entering the diagnosis code?

Q: Are we entering the management code?

ICD-11 Coding Tool Mortality and Morbidity Statistics (MMS) 2024-01

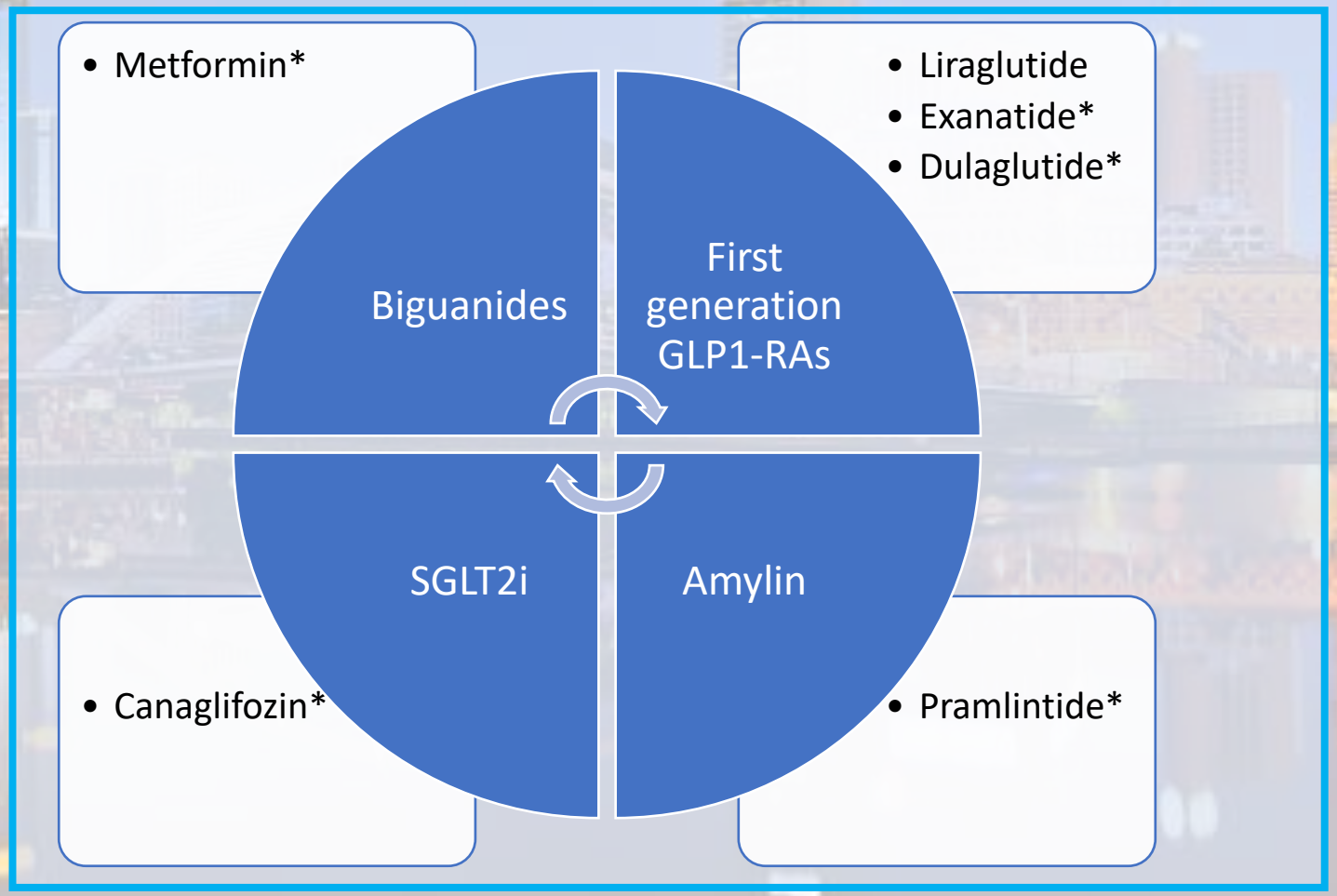
obesity

Related words...

Word list (sort: Relatedness/repetition)	Destination Entities	
class	5B81.Z	**Obesity**, unspecified *
endocrine	5B81.Y	Other specified **obesity**
severe	5B81.1	Drug-induced **obesity**
drug	5B81.01	**Obesity** in adults
glandular	5B81.01&XS2B	**Obesity** in adults with BMI greater than or equal to 40.00 kg/m²
familial	JA65.2	Excessive weight gain in pregnancy
simple		maternal **obesity** syndrome
nutritional	5A61.Y	Other specified hypofunction or disorders of pituitary gland
constitutional		Pituitary **obesity**
endogenous	5B81.01&XS6N	**Obesity** in adults with BMI 35.00-39.99 kg/m²
exogenous	5B81.01&XS3Y	**Obesity** in adults with BMI 30.00-34.99 kg/m²
morbid	5B81.00	**Obesity** in children or adolescents
medicament-induced		
pituitary		

Opportunities:

Please note * signifies, **NOT** TGA approved for obesity management



Please note:

- I am note endorsing the use of off-label prescribing
- This is an acknowledgement of reported HCP practices

Opportunities:

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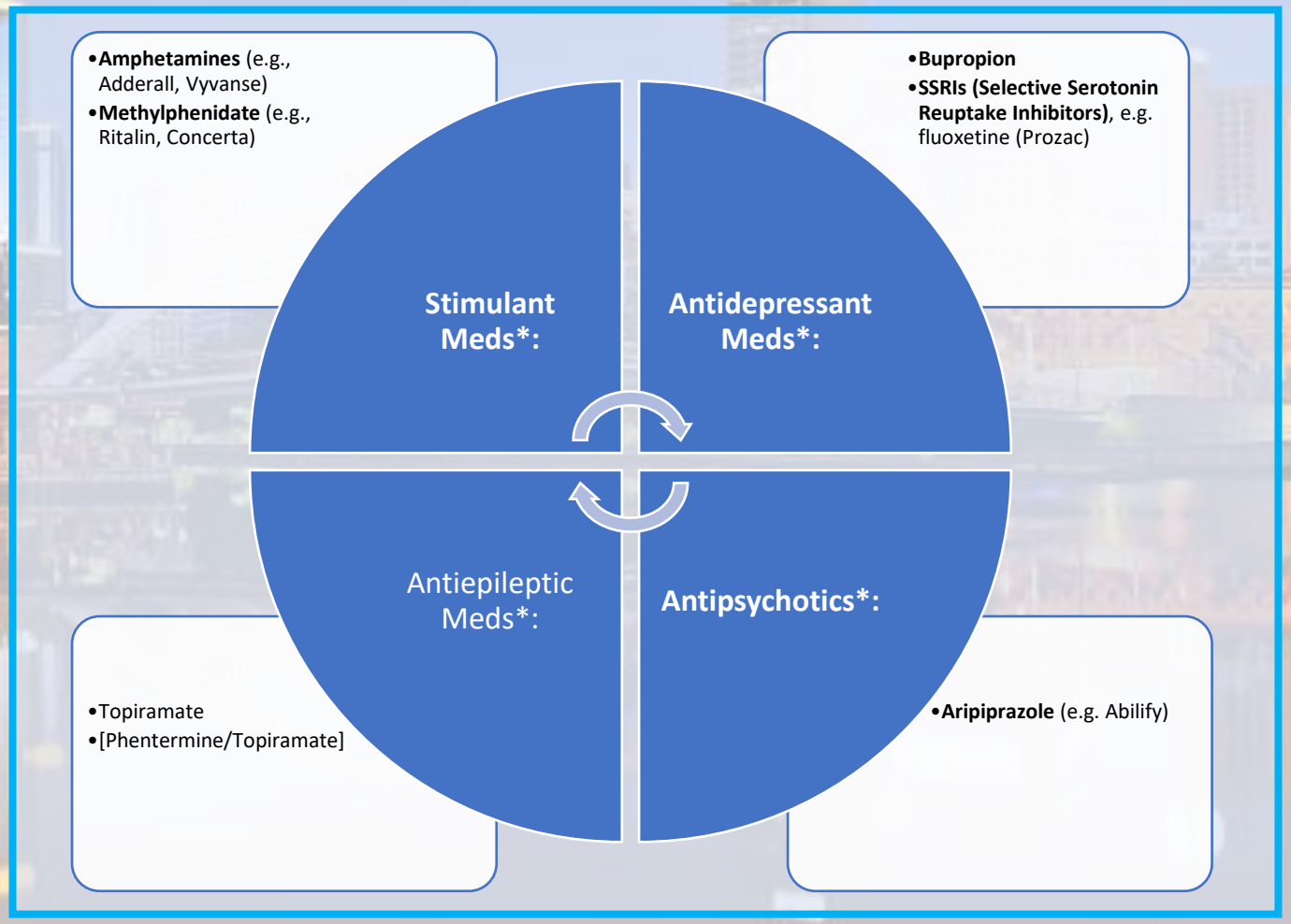

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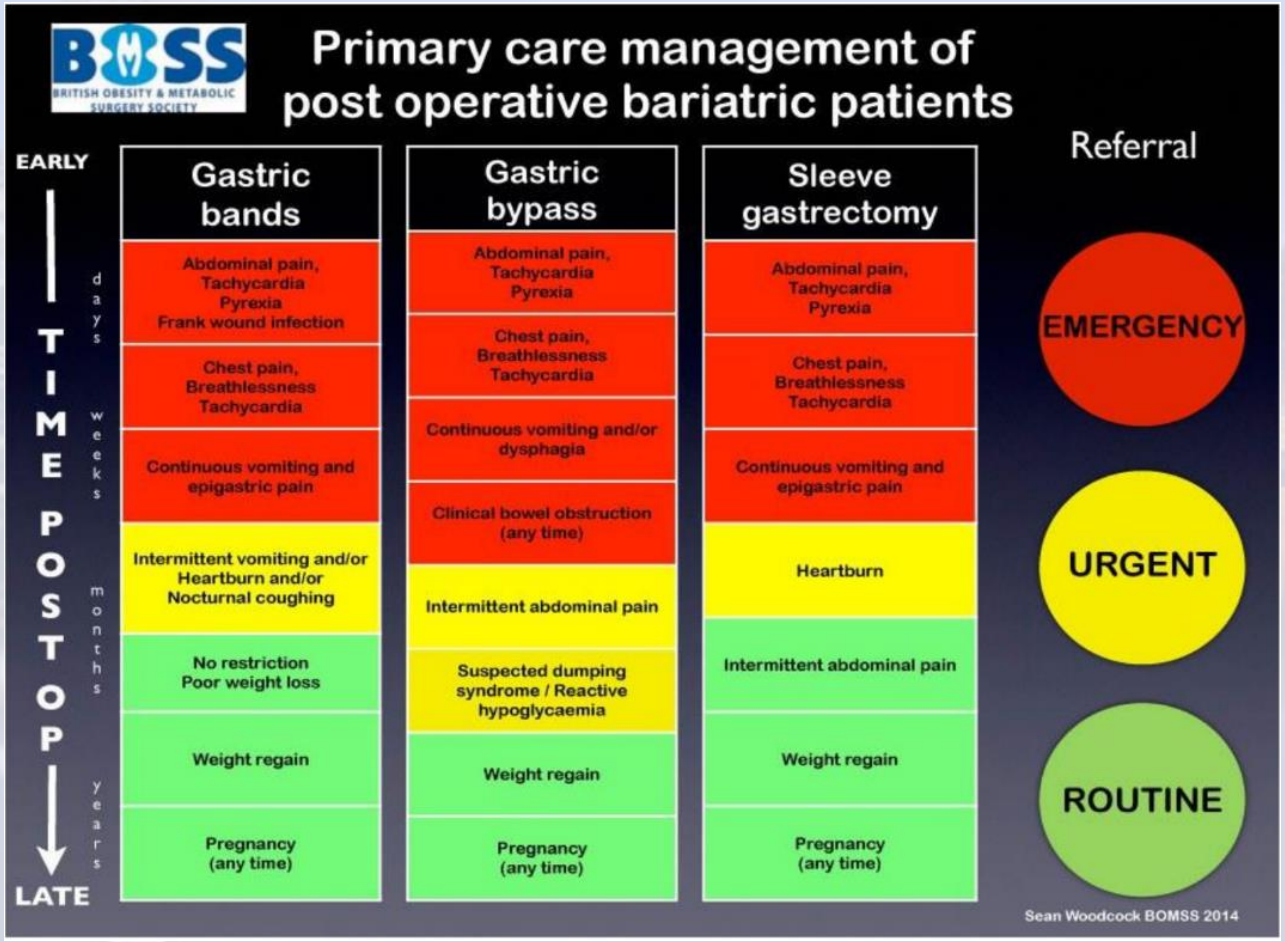
Opportunities:

Develop an

ACTION PLAN

with the PwO



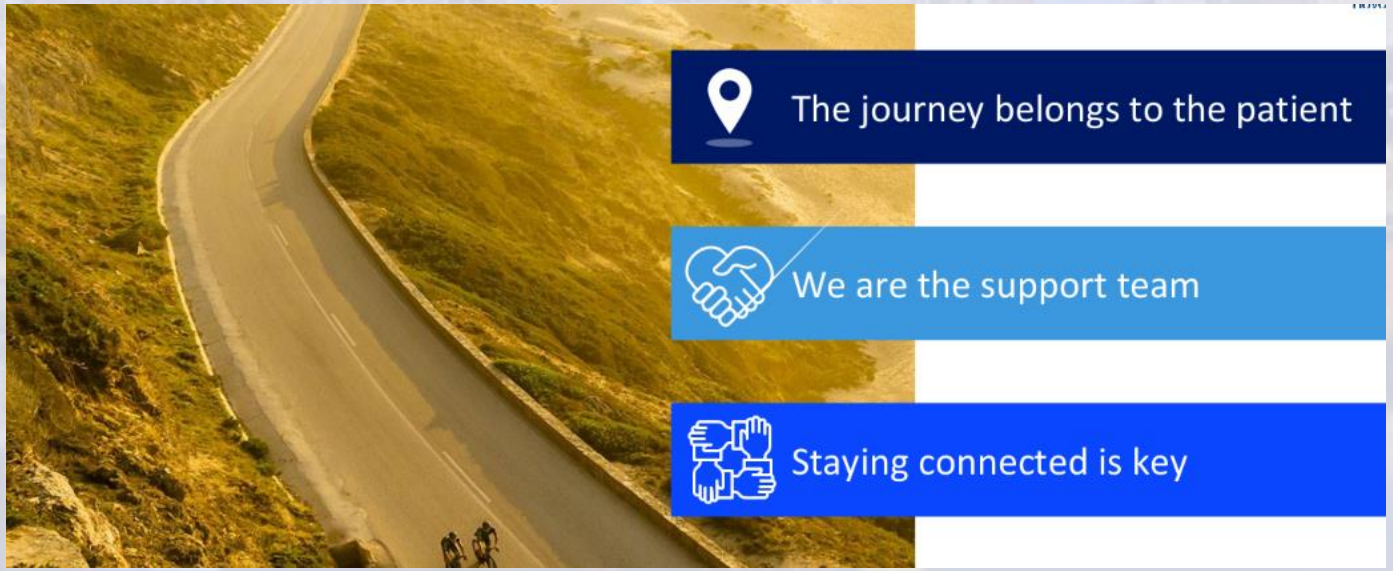
Opportunities: Advocate

1.Founder of RACGP Obesity Management Specific Interest Group 2014
2.Represented RACGP ast the National Obesity Summit, Canberra February 2019
3. &4. Advocated for equitable access to OMM & MBS, Parliament House Canberra, August 2024

Closing remarks

We need a better understanding
of the heterogeneity of obesity from:
-presentation to
-response to treatment

Future research & development of OMM:
-reduce adiposity but ALSO
-correct adiposopathy



Questions?

Thankyou

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