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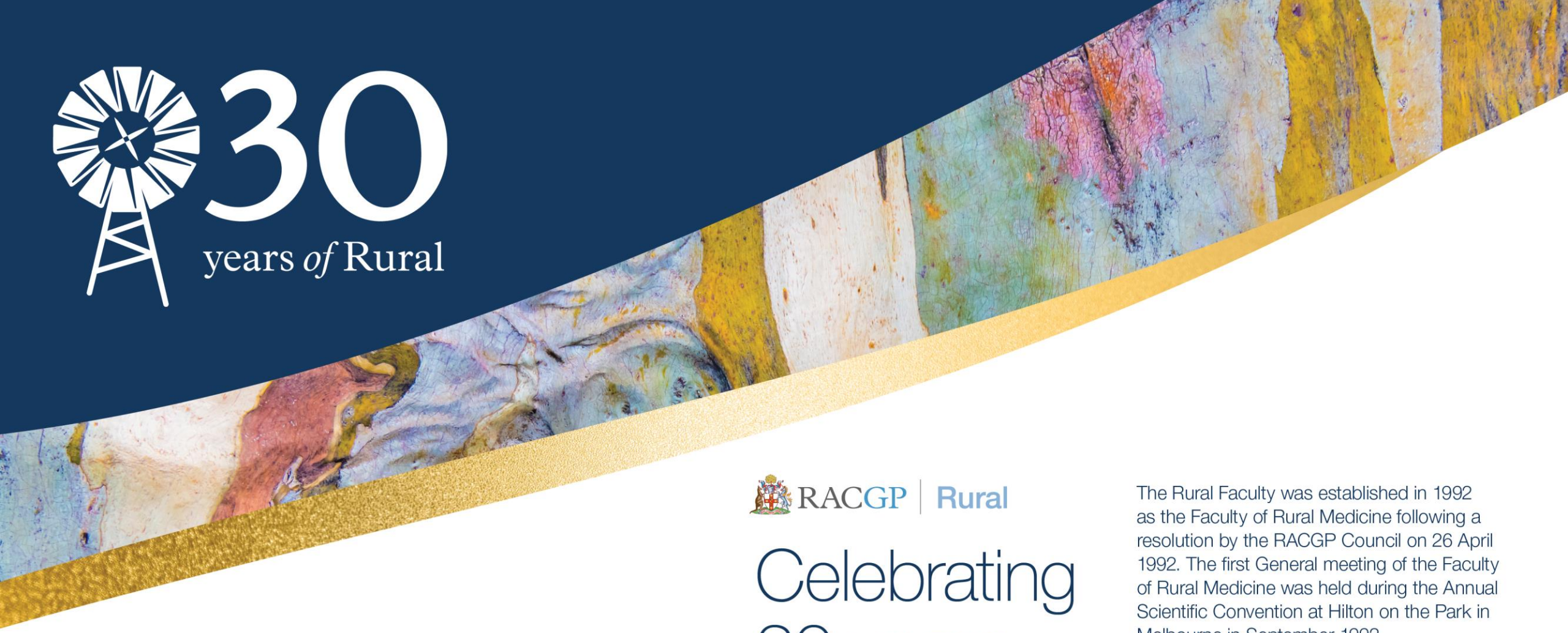

30 years of Rural

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Celebrating 30 years

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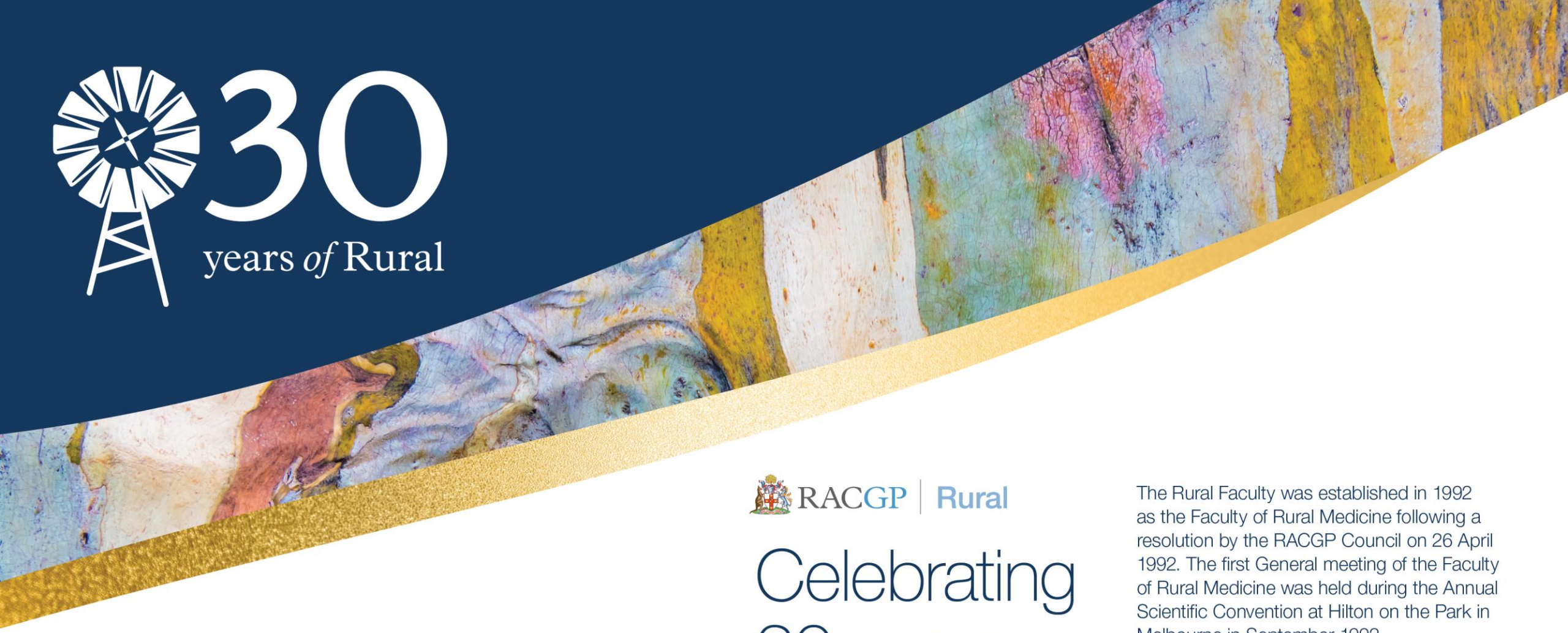
2020
22



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2020
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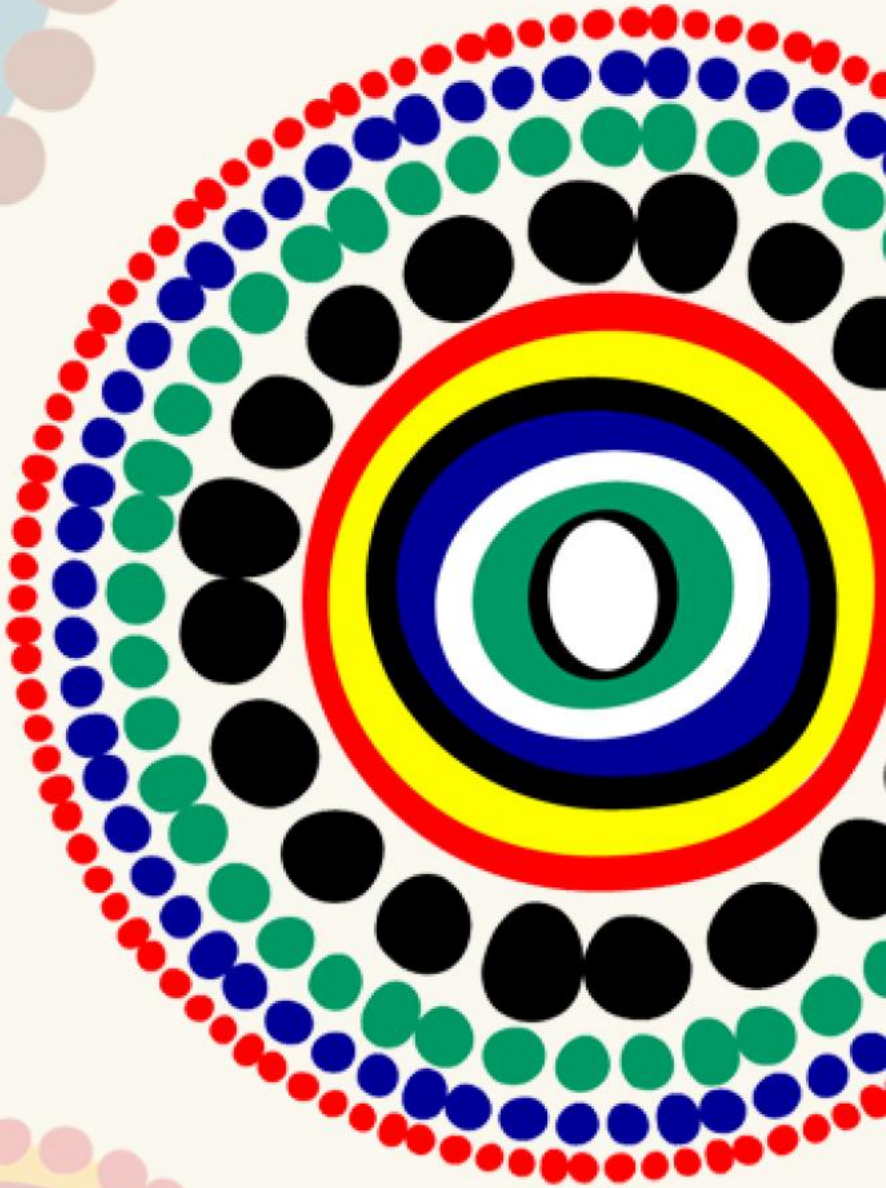
NACCHO



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After six years of diabetes check-ups, you notice that pigmentation on her cheek.

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Welcome to tonight’s webinar

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Safely navigating the management of T2D patients with the GLP-1RA shortages

Dr Gary Deed
Chair, RACGP Diabetes Specific Interest Group

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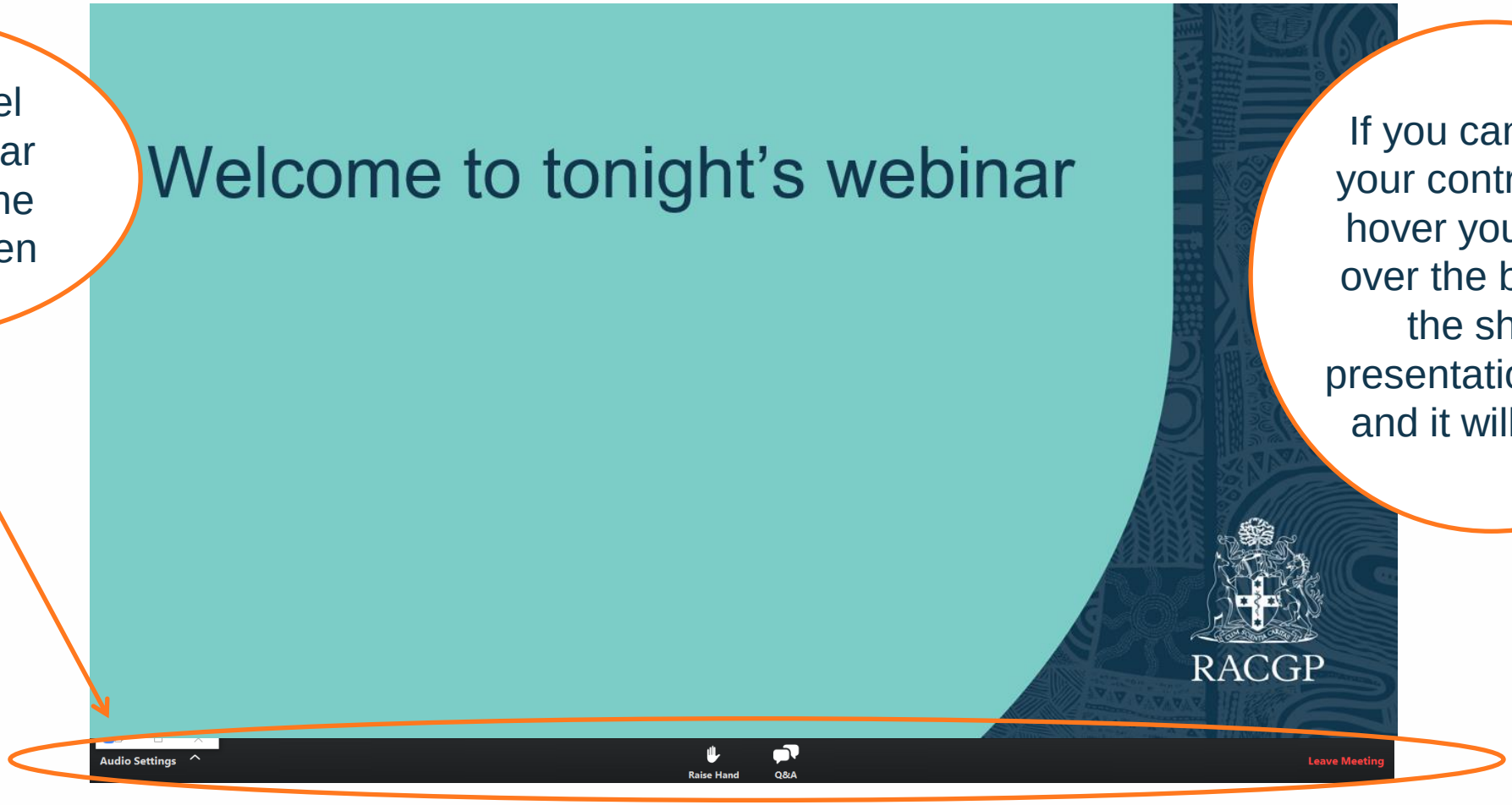
Where is my control panel?

Your control panel will appear as a bar at the bottom of the presentation screen



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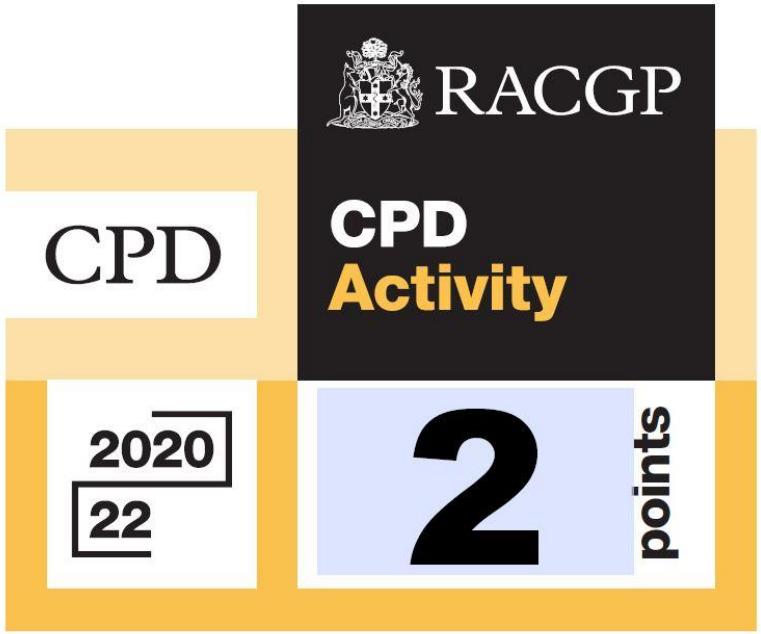
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points

Dr Gary Deed

Chair, RACGP Diabetes Specific Interest group

RACGP Specific Interests

Healthy Profession.
Healthy Australia.

Acknowledgement of Country

I would like to acknowledge the traditional owners of the lands from where each of us are joining this webinar today.

I wish to pay my respects to their Elders past, present and emerging.

Agenda

- The GLP-1RA shortage: what are the issues
- Guidelines to assist choosing
- Case study
- When and how to step up to insulins
- Summary

Disclosures

- Member of the Australian Diabetes Society. He is a GP in a multidisciplinary practice at Coorparoo in Brisbane, He has been a member of National and International advisory boards in diabetes and educational development and delivery: AstraZeneca, Abbott, Boehringer Ingelheim, Inova, Lilly, Nevro, Novartis, Novo-Nordisk, MSD, Sanofi.

- He is a member of an NHMRC funded research team based at Monash University for STAREE; a JDRF funded research team based at Sydney University for National Screening for type 1 diabetes; and a co-investigator of the START trial with George Institute

- He has no other financial or other conflicts to disclose with respect to the content of this talk

GLP-1RA shortages

- Weekly GLP-1RA
  - Semaglutide “Ozempic” – no stock till April 2023
  - Semaglutide “Weygovy” - not released yet – different pen device and doses
  - Dulaglutide “Trulicity” – variable stock available till early 2023

- Daily GLP-1RA
  - Liraglutide “Victoza” (T2D) – available – Non PBS
  - Liraglutide “Saxenda” (Obesity) – available – non PBS
  - Exenatide “Byetta” twice daily – withdrawn

Characteristics of weekly GLP-1RAs

- Injectable once weekly dosing
- Single one dose/use device – Dulaglutide (Trulicity)
- Titratable multi-use device – Semaglutide (Ozempic)
- Other GLP-1Ra's are daily - liraglutide(Victoza) or BD exenatide (Byetta)
- Potent HBA1c lowering, low risk of hypoglycaemia unless used with sulphonylureas or insulin
- Weight loss aspects
- Insulin dose sparing
- Nausea/vomiting GIT upsets as a risk. Rare gallbladder/pancreatitis issues

PBS/Prescribing issues

- Advice is to NOT INITIATE NEW PRESCRIPTIONS AT THIS STAGE
- SEEK ALTERNATIVES FOR PATIENTS
- GLP-1RAs have restricted PBS access – must be utilized with metformin and/or sulphonylurea (unless SU contraindicated)
- Can be combined with insulins (with metformin)
- Not to be used with DPP4 I, or SGLT2i or combinations
- Alternative choices in diabetes management have less restrictive PBS criteria

Clinical Decision making if GLP – 1RA's are not available

"Review"

Audit those prescribed GLP-1RA's (PDSA)

Lifestyle and weight management, plus review adherence and re-assess clinical parameters for T2DM goals.

- E.g: Is HBA1c at goal on current therapy, could additional weight management support be provided.
- Generate a appropriate Team Care plan incorporating dietitian and CDE reviews

Do not initiate any new prescribing of weekly GLP-1RA's

Those identified as existing patients: Consider replacement options as GLP1-RA's may not be available for some months

Reference Key Australian Guidelines

AUSTRALIAN TYPE 2 DIABETES
GLYCAEMIC MANAGEMENT ALGORITHM

This Type 2 Diabetes Glycaemic Management Algorithm should be read in conjunction with the Living Evidence Guidelines in Diabetes (please click here).

All patients should receive education regarding lifestyle measures: healthy diet, physical activity and weight management. +

Determine the individual's HbA1c target – commonly ≤53 mmol/mol (7.0%) but should be appropriately individualised (refer to ADS position statement).

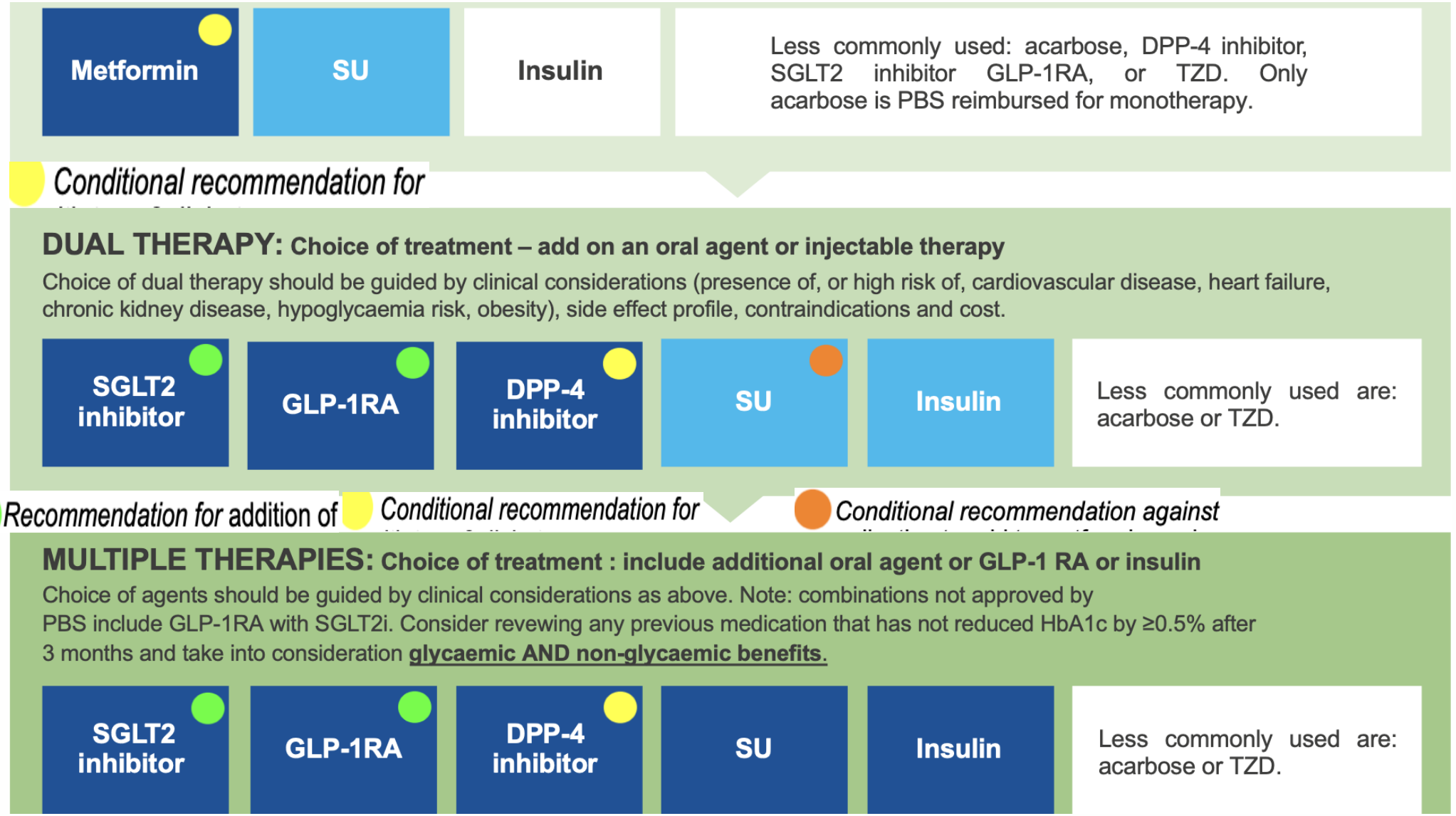
+ Weight loss of ≥10% will likely allow a reduction or cessation of glucose lowering medication. Consider intensive weight management options including:

- Low energy or very low energy diets with meal replacements
- Pharmacotherapy
- Bariatric surgery.

Click here for the Australian Obesity Management Algorithm

Review treatment: if not at target HbA1c or if presence of cardiovascular/chronic kidney disease –

- Check patient understanding of self-management including drug treatment
- Ensure current therapies are clinically appropriate including comorbidities/ therapies impacting glycaemic control
- Review medication adherence
- Assess tolerability, adverse effects and risk of interactions


Metformin
SU
Insulin
Less commonly used: acarbose, DPP-4 inhibitor, SGLT2 inhibitor GLP-1RA, or TZD. Only acarbose is PBS reimbursed for monotherapy.
Conditional recommendation for
DUAL THERAPY: Choice of treatment – add on an oral agent or injectable therapy
Choice of dual therapy should be guided by clinical considerations (presence of, or high risk of, cardiovascular disease, heart failure, chronic kidney disease, hypoglycaemia risk, obesity), side effect profile, contraindications and cost.
SGLT2 inhibitor
GLP-1RA
DPP-4 inhibitor
SU
Insulin
Less commonly used are: acarbose or TZD.
Recommendation for addition of
Conditional recommendation for
Conditional recommendation against
MULTIPLE THERAPIES: Choice of treatment : include additional oral agent or GLP-1 RA or insulin
Choice of agents should be guided by clinical considerations as above. Note: combinations not approved by PBS include GLP-1RA with SGLT2i. Consider revewing any previous medication that has not reduced HbA1c by ≥0.5% after 3 months and take into consideration glycaemic AND non-glycaemic benefits.
SGLT2 inhibitor
GLP-1RA
DPP-4 inhibitor
SU
Insulin
Less commonly used are: acarbose or TZD.

Living Evidence in Diabetes Guidelines

Metformin as first line monotherapy followed by:

*If the patient also **has CV disease, multiple CV risk factors* and/or kidney disease**:*

Add SGLT2i

If SGLT2i is contraindicated or not tolerated

Add GLP-1RA

If SGLT2i or GLP1-RA is contraindicated or not tolerated

Add DPP4 inhibitor

SU not considered as first choice add on to metformin due to risk of severe hypoglycaemia

*If the patient **does not** have CV disease, multiple CV risk factors* and/or kidney disease and is unable to achieve goals for glycaemia:*

Add SGLT2i or GLP-1RA or DPP4 inhibitor

Recommendation for

Conditional recommendation for

Conditional recommendation against

**Multiple CV risk factors – men aged ≥55 years or women aged ≥60 years with T2D who have ≥1 additional traditional risk factors, including hypertension, dyslipidaemia or smoking*

Healthy Profession. Healthy Australia.

Clinical Decision making if GLP -1Ra's are not available

"Maximise" remaining oral therapy options and dosages adjusted to clinical assessment.

- **Metformin dose to optimal** 2 grams XR a day, or reduced with decreased renal function.
- **SGLT2i dose optimization** – empagliflozin 10mgs -> 25mgs. Dapagliflozin is single dose 10mgs
- **Remember fixed dose combinations** – SGLT2i/DPP4i (HBA1c lowering is greater than individually[1]) e.g empagliflozin/linagliptin - Multiple doses 10mg/5mgs or 25mgs/5mgs ; or dapagliflozin/metformin or other combinations.

Fixed dose combinations (FDCs)

- FDCs can improve medication adherence when combination therapy is used, and may help achieve glycaemic targets more rapidly[1]
- FDCs also provide potential benefits in terms of convenience and cost saving

SGLT2i with Metformin		
Empagliflozin + metformin (**Jardiamet**)	Dapagliflozin + metformin **(Xigduo)**	Ertugliflozin + metformin **(Segluromet)**
SGLT2i with DPP4i		
Empagliflozin + Linagliptin (**Glyxambi**)	Dapagliflozin + Saxagliptin (**Qtern**)	Ertugliflozin + Sitagliptin (**Steglujan**)
DPP4i with Metformin		
Linagliptin + metformin (**Trajentamet**)	Saxagliptin + metformin **(Kombiglyze)**	Sitagliptin + metformin **(Janumet)**

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1. Davies MJ *et al. Diabetes Care* 2018 Oct 4. pii: [Epub ahead of print]

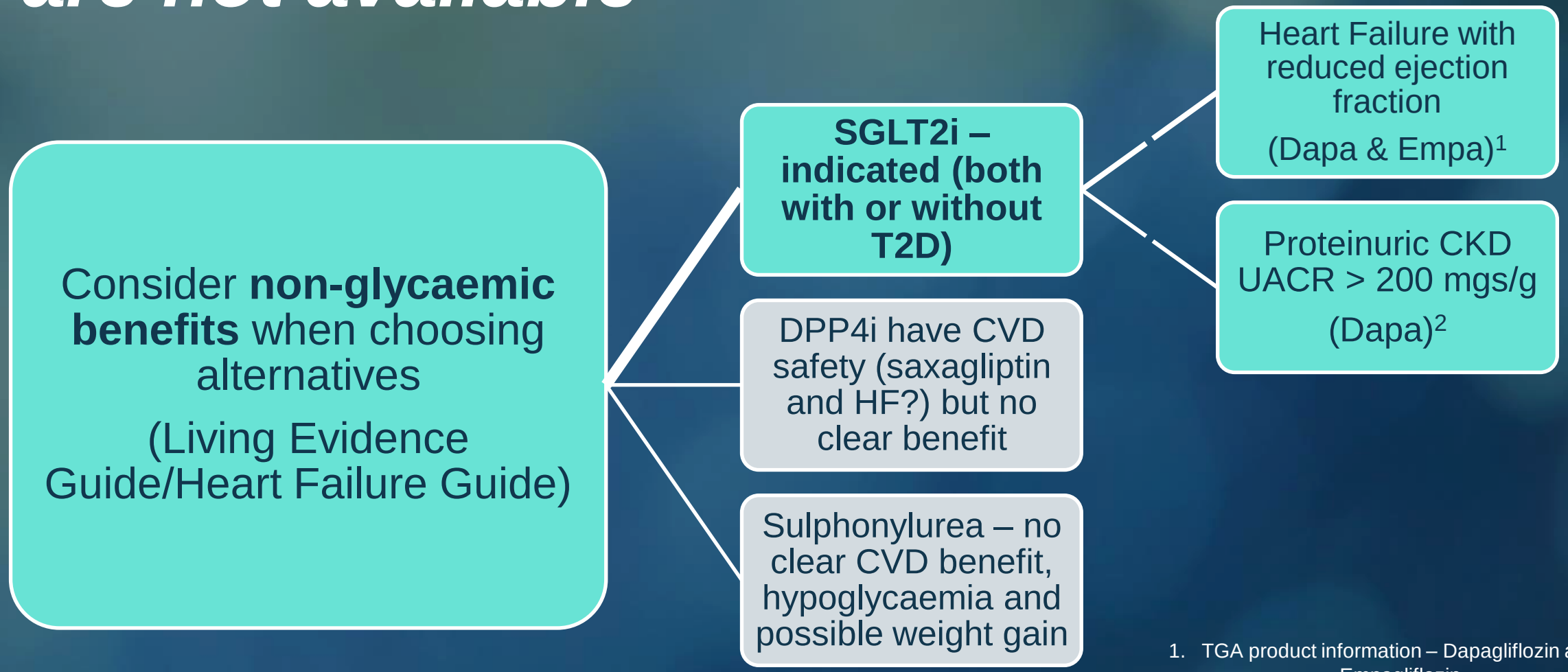
Fixed-dose combinations (FDCs)

1. (SGLT2i with DPP4i) + Metformin; OR

2. (SGLT2i with Metformin) + DPP4i; OR

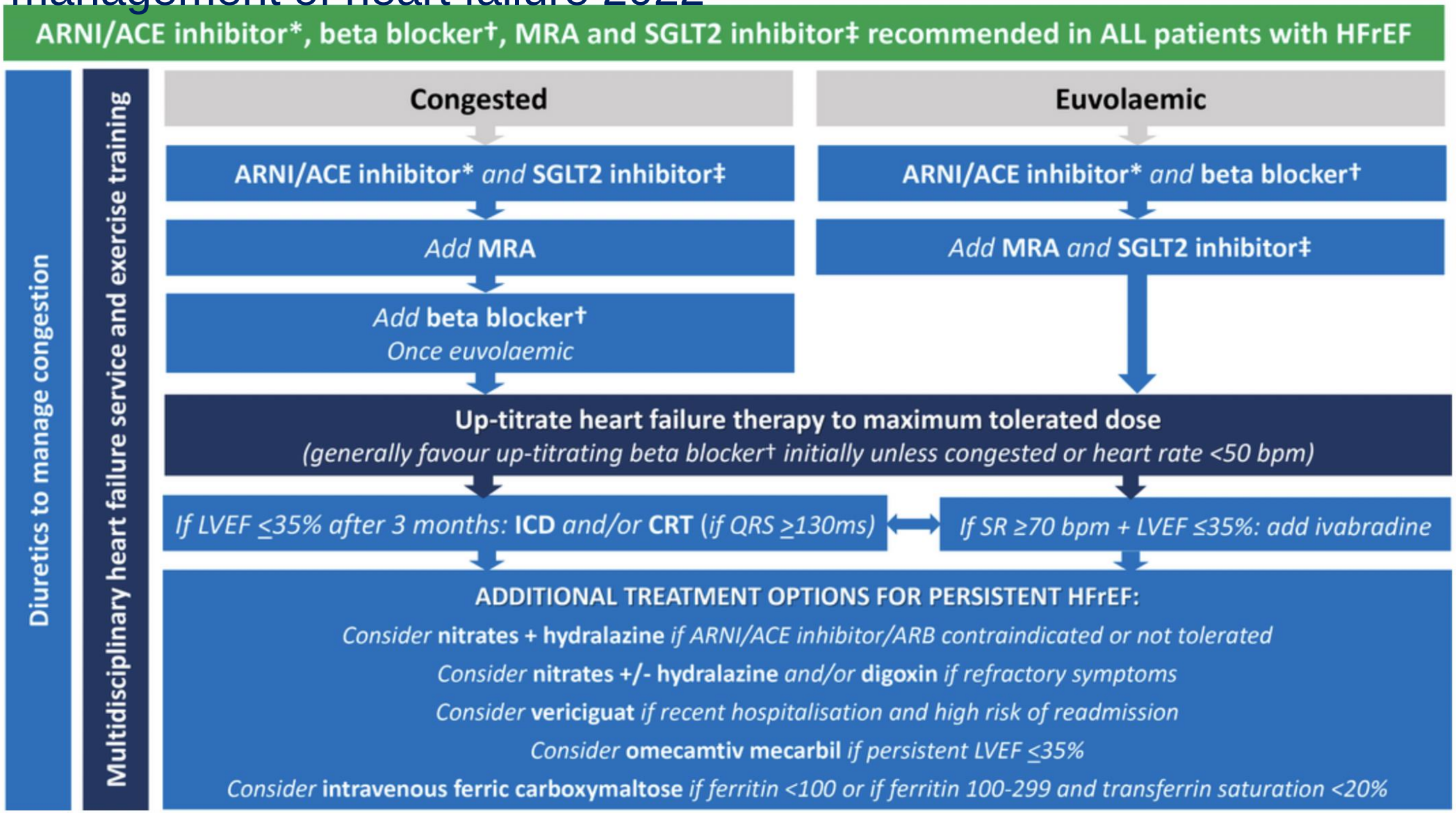
3. (DPP4i with Metformin) + SGLT2i

Clinical Decision making if GLP -1RA's are not available



1. TGA product information – Dapagliflozin and Empagliflozin
2. TGA product information – Dapagliflozin

Consensus statement on the current pharmacological prevention and management of heart failure 2022



Case Study - Angela is a 62 year old teacher – wants an "Ozempic" script repeat

Patient information:

Age 62 years – T2D for 11 years. Past GDM. Never smoked

Hyperlipidaemia and hypertension

No established CVD

HbA_{1c}: 7.8 %; was 7.1% six months ago

Current treatment:

Metformin 1g BD

Gliclazide MR 60mg QD

Semaglutide 1mg weekly

Telmisartan 40 mg QD Rosuvastatin 20 mg QD

Examination:

BP: 130/72 mmHg

BMI: 36kg/m^2

Cardiac/respiratory examination normal

FPG: 11 mmol/L

TC 4.5 mmol/L

LDL-C 2.4 mmol/L

HDL-C 1.1 mmol/L

TG 2.2 mmol/L

eGFR: 55 mL/min/1.73 m^2

UACR: 25.5 mg/mmoL(n<3.5)

Key Clinical Questions: How can we safely and effectively advise Angela?

Managing T2D should include minimising risk and maximising benefits

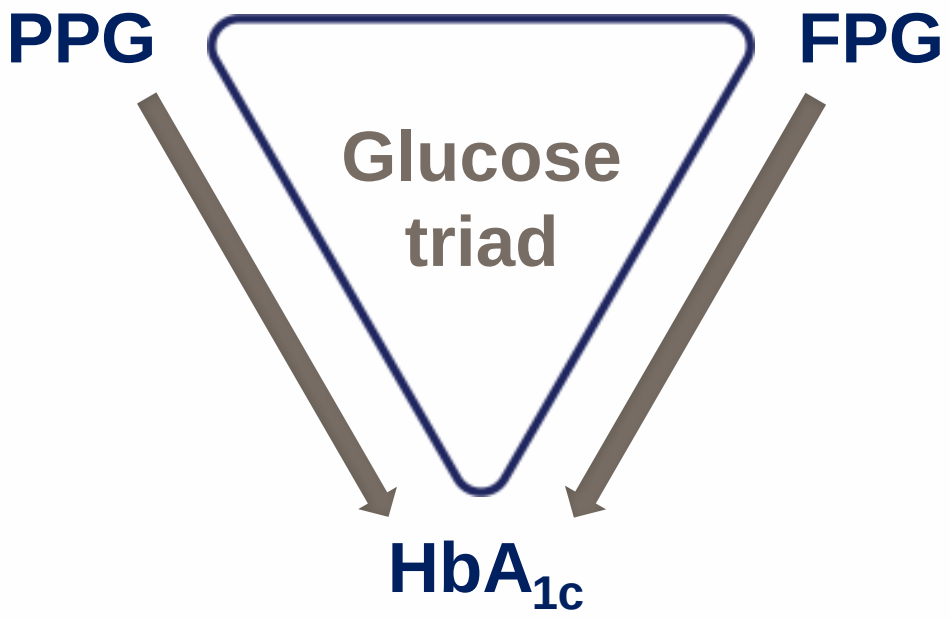
What are Angela's:

- Personal concerns?
- Short-term risks
- Longer-term risks?
- What support can we provide?
- Sick day Management Guidelines [1].
- Perioperative Guidelines for SGLT2i [2,3]

IN THE ABSENCE OF GLP-1RA's – What would you choose?

HbA_{1c} control: need for INSULIN

Both fasting and mealtime glucose contribute to HbA_{1c}



Clinical evidence suggests that reducing postprandial glucose (PPG) excursions is as important as reducing fasting plasma glucose (FPG) for achieving HbA_{1c} goals[1,2]

FPG, fasting plasma glucose; **HbA_{1c}**, glycosylated haemoglobin; **PPG**, postprandial plasma glucose.

1. Monnier L, *et al. Diabetes Care.* 2003; 26(3): 881-5. **2.** Ceriello A, *et al.* International Diabetes Federation (IDF), 2011. Guideline for Management of PostMeal Glucose in Diabetes.

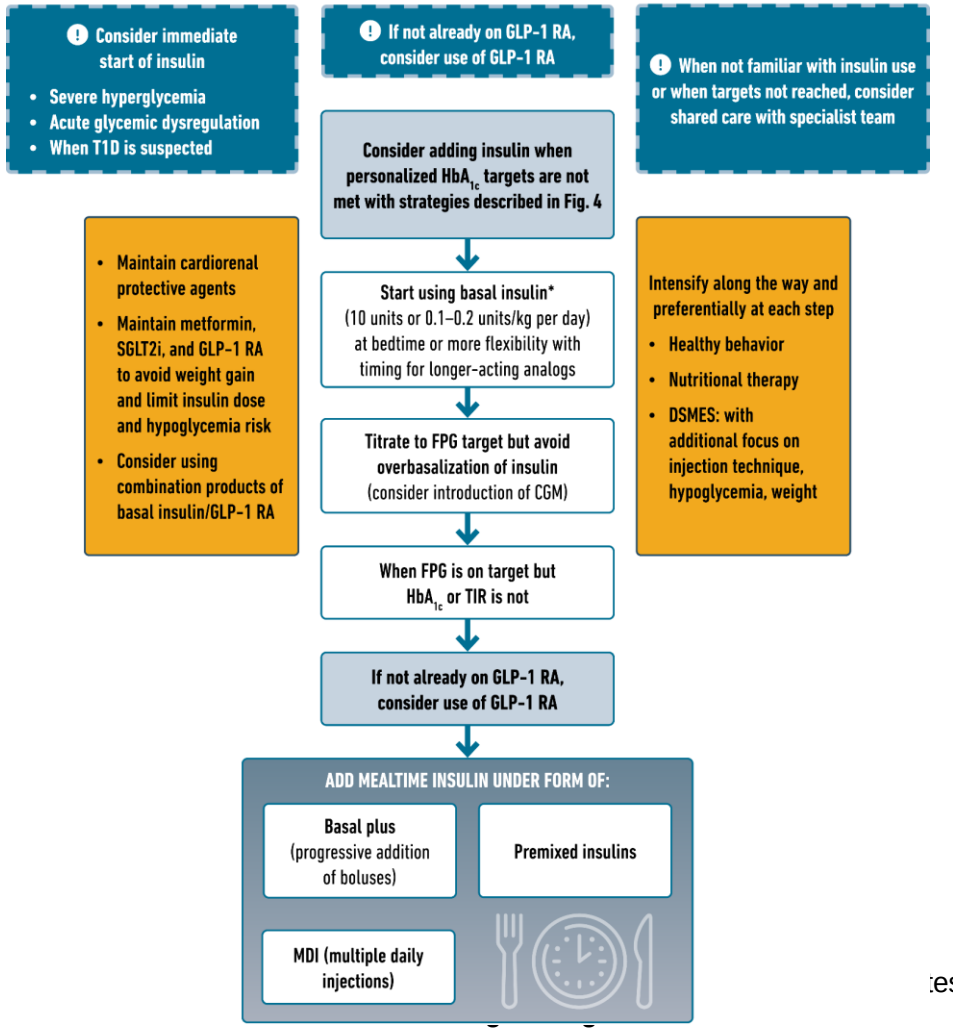
Clinical Decision making if GLP -1RA's are not available

Insulin should be considered as a replacement if on Triple oral therapy and no longer at goal

- Insulin is ***ADDED*** to oral therapies where tolerated
- Starting dose is usually 10Units/day but if symptomatic hyperglycaemia 10-15 units may be considered
- The effective dose if never usually this dose – It needs to be titrated to targets

From: **Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)**

PLACE OF INSULIN[1]



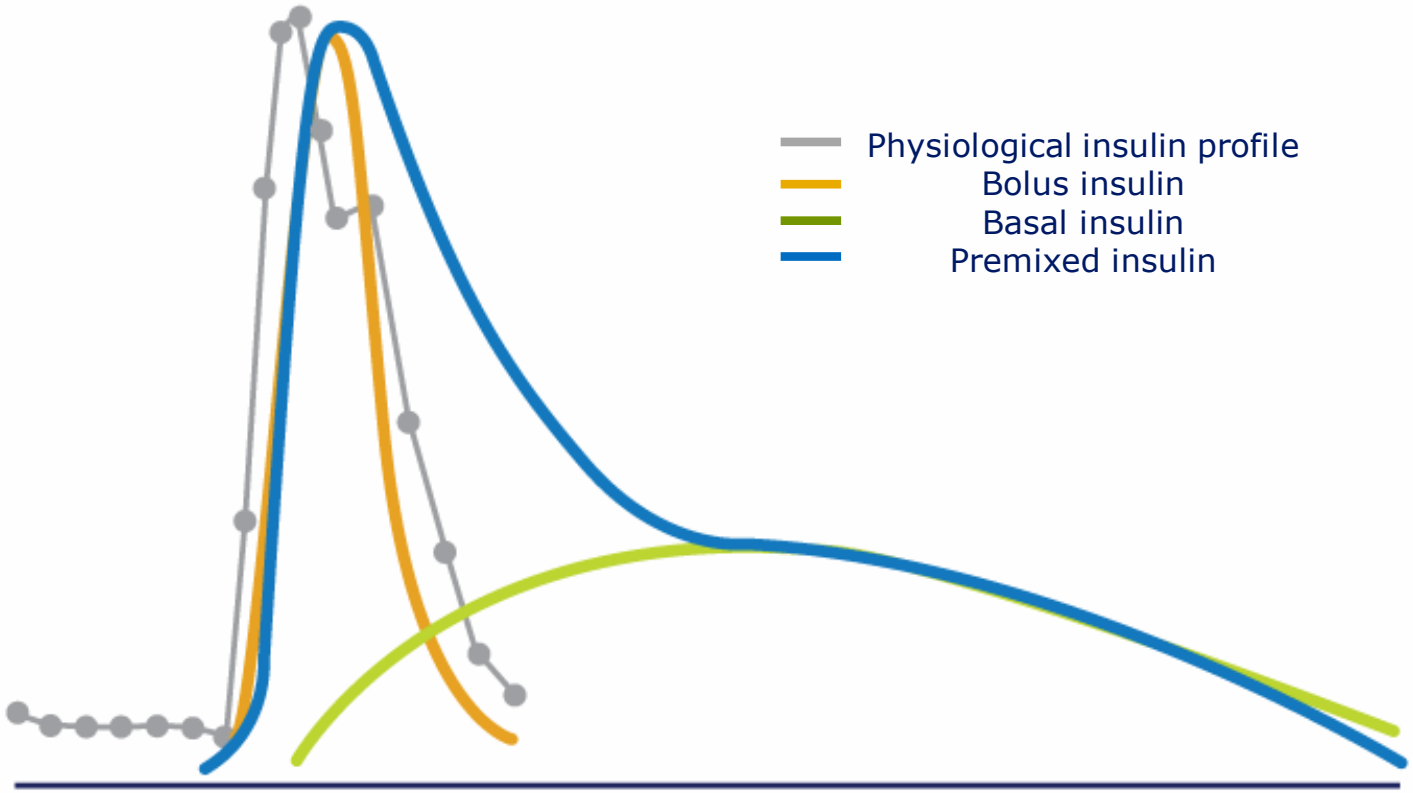
:es Care. 2022;45(11):2753-2786. doi:10.2337/dci22-0034

Place of insulin. *NPH insulin or preferably analog to reduce nocturnal hypoglycemia risk. [1]More details can be found in Davies et al. (12) and “Pharmacologic Approaches to Glycemic Treatment” in Standards of Medical Care in Diabetes—2022 (16). CGM, continuous glucose monitoring; DSMES, diabetes self-management education and support; FPG, fasting plasma glucose; GLP-1 RA, glucagon-like peptide 1 receptor agonist; SGLT2i, sodium-glucose cotransporter 2 inhibitor; T1D, type 1 diabetes; TIR, time in range.

Making the switch?

EFFECT	GLP-1RA	INSULIN
Moderate to high glucose lowering	YES	YES
Hypoglycaemic risks	Low	Moderate to high
Weight loss	Moderate	Nil or gain
Titratable dose	YES with semaglutide NO with dulaglutide	YES
Requires structured glucose monitoring	Not routinely	Routinely
Can be combined with oral agents:		
DPP4i	Not on PBS/contraindicated	YES
SGLT2i	Not on PBS	YES
Metformin	YES	YES
Non-Glycaemic effects	MACE benefits	No clear benefits/No Harm

Limitations of premixed insulins and a basal-plus insulin regimen



Physiological insulin profile comprises a basal component with meal-related peaks[1]

Limitations of a basal-plus insulin regimen:[2]

- Burden of multiple injections
- Complex titration schedule

Limitations of premixed insulins due to protamination:[2]

- Variability in glycaemic control
- Incomplete 24-hour basal coverage
- Need for re-suspension

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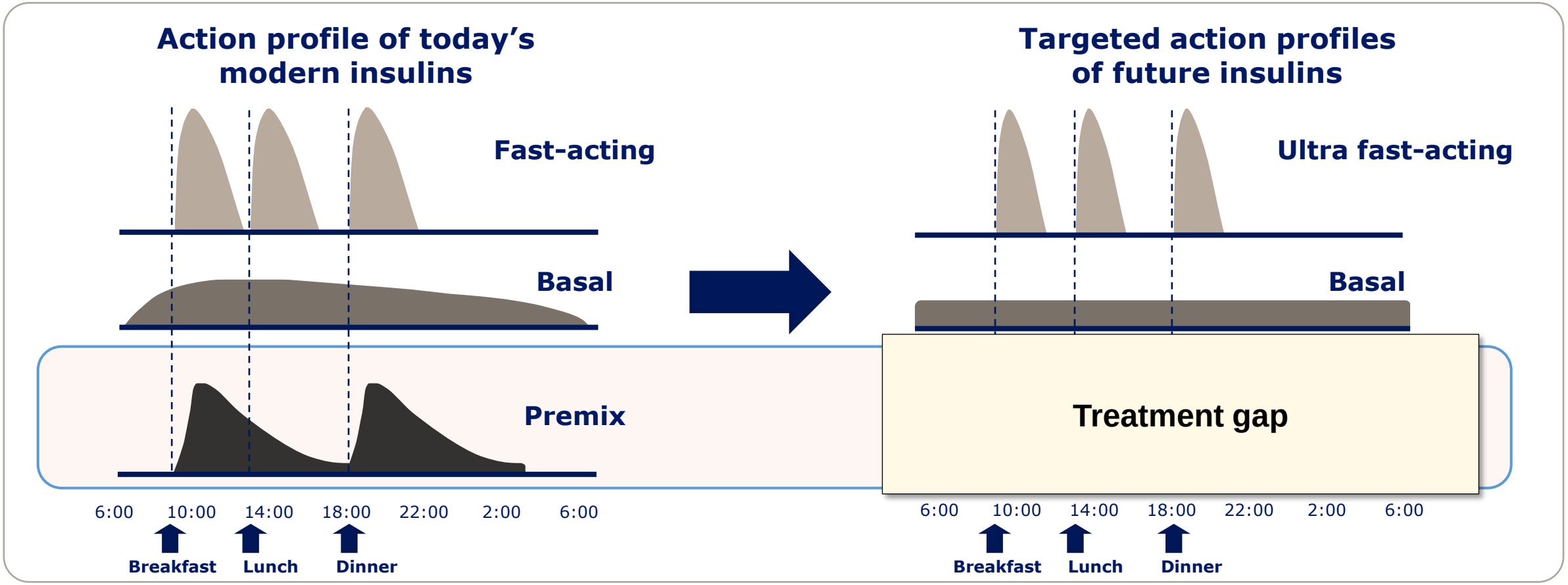
For illustrative purposes only (adapted from multiple sources).[1,2]

1. Kruszynska YT, *et al. Diabetologia.* 1987; 30(1): 16–21. **2.** Atkin S, *et al. Ther Adv Chronic Dis.* 2015; 6(6): 375–88.

Target profiles for new insulin analogues

Mimicking physiological responses



For illustrative purposes only.

Pharmacological differences between insulin co-formulations and premixes

Co-formulation

Involves mixing two biologically active solutions together in a fixed-ratio combination[1]

e.g.: Insulin degludec and IAsp

Mimics physiological insulin secretion closely

Avoid the "shoulder effect" and variability of protaminated premixed insulins, thereby reducing the risk of hypoglycaemia

Simplify the insulin regimen without requiring resuspension and lower the injection burden

VS

Premixes

Involves a suspension of one biologically active solution with an insoluble biologically inactive precipitate in a fixed-ratio combination[2]

e.g.: Biphasic human insulin and protaminated IAsp

Limitations of premixed insulins due to protamination[2]:

Variability in glycaemic control

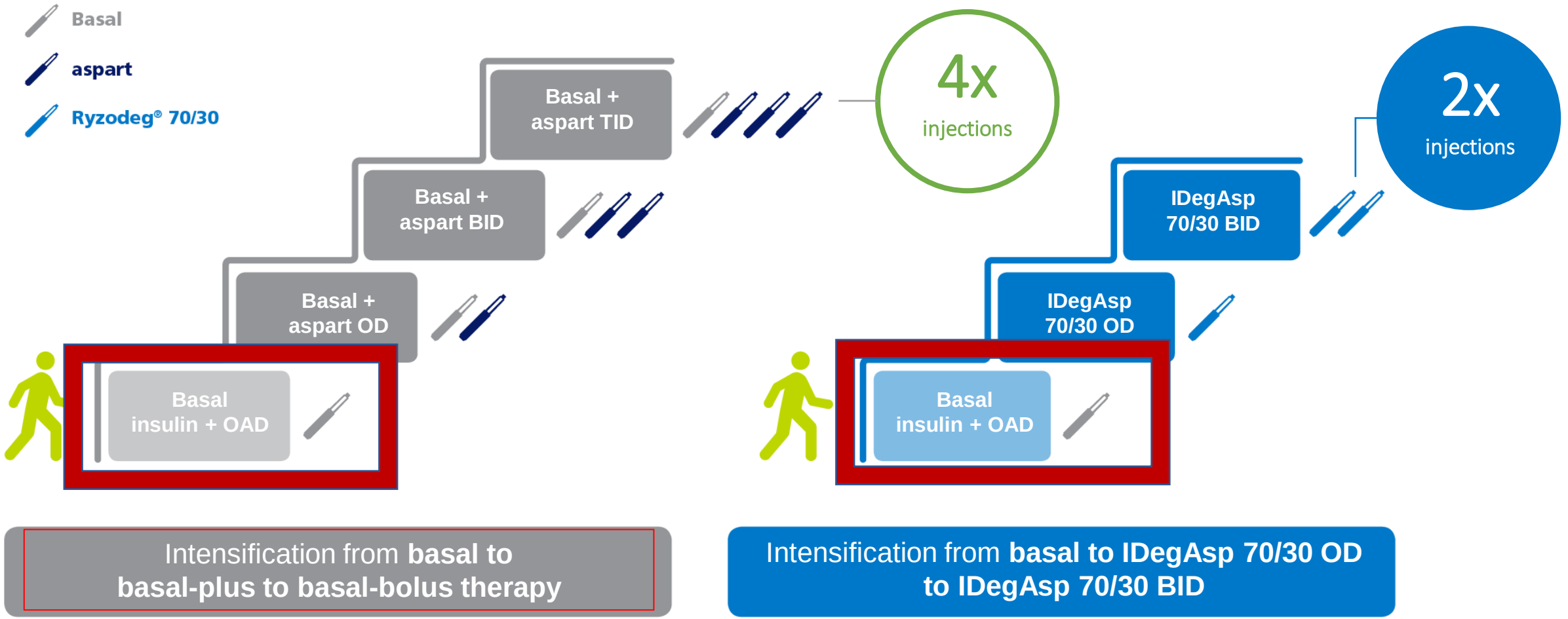
Incomplete 24-hour basal coverage

Need for re-suspension

IAsp, insulin aspart.

1. Atkin Ther Adv Chronic Dis 2015;6:375–88; 2. Kruszynska *et al. Diabetologia* 1987;30:16–21.

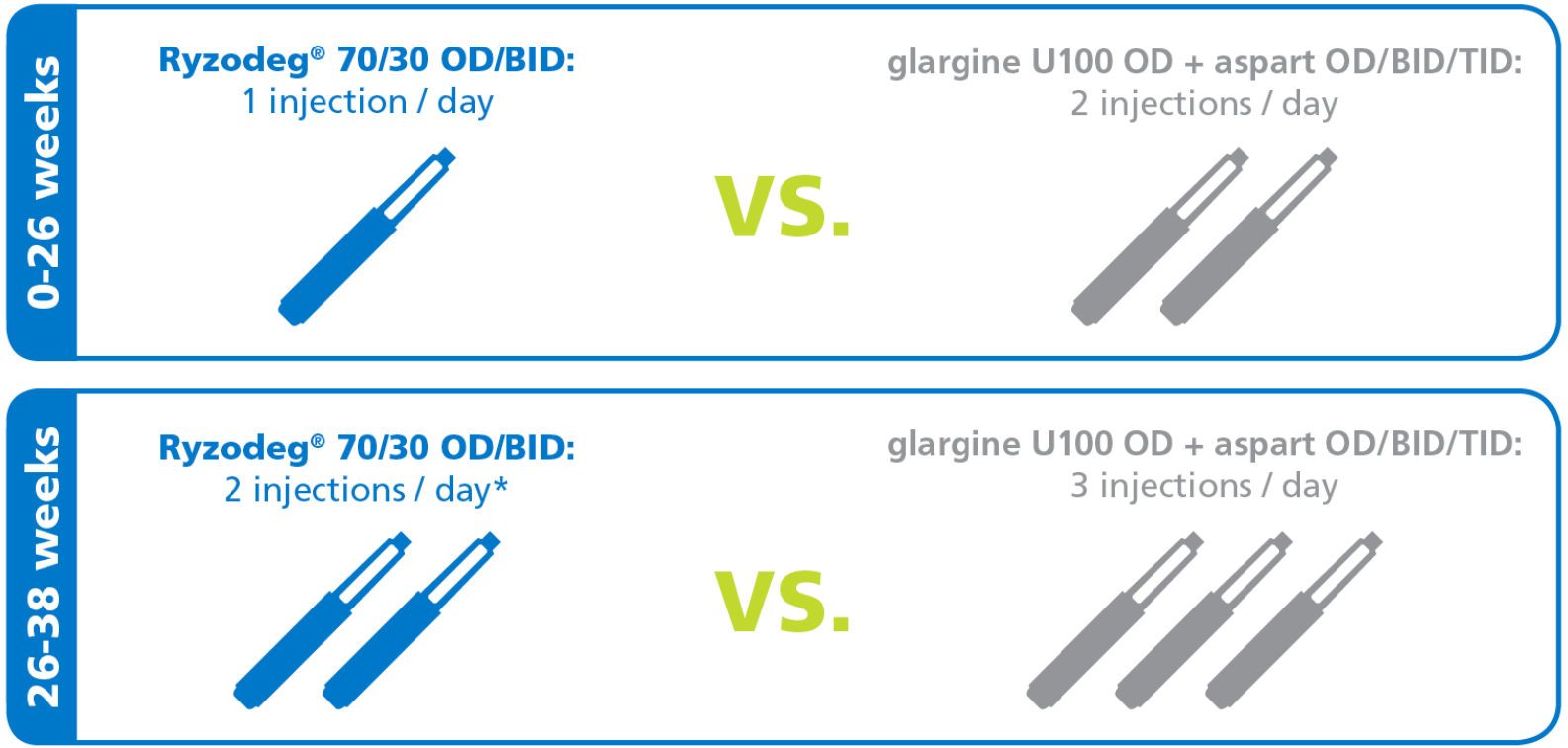
Basal insulin intensification approach[1]



BID, twice daily; **OAD**, oral antidiabetic drug; **OD**, once daily; **TID**, thrice daily.

1. American Diabetes Association. Diabetes Care 2017; 40(Suppl.1): S64–S74.

Insulin-experienced T2D OD/BID: mean total daily injections[1,2]



Fewer injections with Ryzodeg® 70/30 vs. glargine U100 + aspart

*Rounded to the nearest integer: 1.62 and 2.85 mean injections per day at 38 weeks with Ryzodeg® 70/30 OD/BID and glargine U100 OD + aspart OD/BID/TID, respectively. P-value not calculated.

BID, twice daily; **OD**, once daily; **T2D**, type 2 diabetes; **TID**, three times daily.

1. Philis-Tsimikas A, *et al. Diabetes Res Clin Pract*. 2019; 147: 157–65. **2.** Gupta Y, *et al.* Poster presented at the European Association for the Study of Diabetes 54th Annual Meeting; 1-5 October, 2018; Berlin, Germany.

Making the choice

Phenotypic choices

- ***CVD at high risk, existing CVD or kidney disease*** *–> SGLT2i*
- ***Weight focus*** *–> SGLT2i*
- ***Lower hypoglycaemia risks*** *–> SGLT2i*, and/or *DPP4 inhibitors*

- ***High glycaemic efficacy*** *–> Insulin* but increased glucose monitoring, educational support, hypoglycaemia and weight gain risks

- ***Continuing a GLP-1RA*** *–> Liraglutide,* has proven CVD benefit but cost issues

Obesity Choices

TGA approved and available

1. Phentermine oral
2. Orlistat oral
3. Buproprion/Naltrexone oral
4. Liraglutide Injectable

Australian Obesity Management Algorithm

https://diabetessociety.com.au/downloads/20220902%20Australian%20Obesity%20Management%20Algorithm%20-%20August%202022.pdf

Q&A