

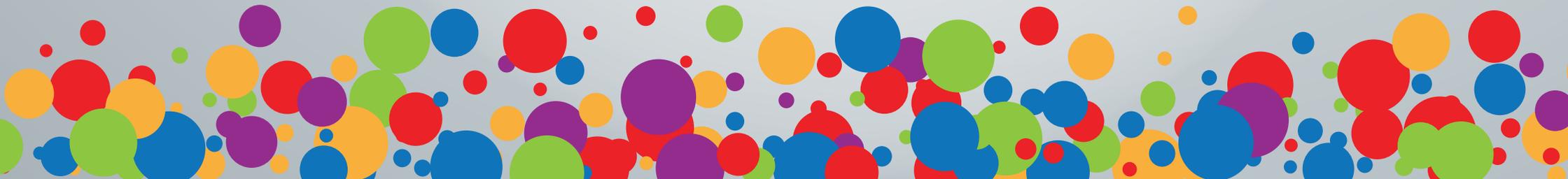
For Healthcare Professionals:

PERSON CENTRED CARE IN TYPE 2 DIABETES

YOUR GUIDE TO ADA/EASD CONSENSUS REPORT



Novo Nordisk has commissioned and funded Trend Diabetes to develop this booklet as an educational resource for healthcare professionals. Trend Diabetes have independently developed the content of this booklet and Novo Nordisk have reviewed it for factual accuracy only. Printing and distribution was funded by Novo Nordisk.



CONTENTS

Introduction	Page 3
How to use tool	Page 4
Decision cycle for person-centred glycaemic management in type 2 diabetes	Page 5
Glucose-lowering medication in type 2 diabetes: Overall approach	Page 7
Intensifying to Injectable therapies	Page 9
Medications to continue, reduce or stop when intensifying to injectables	Page 10
Summary	Page 11
Glucose-lowering medication in type 2 diabetes: A key	Page 12
References	Page 12
Glossary	Page 12



INTRODUCTION

Type 2 diabetes in adults: management NICE guideline (NG28) 3rd iteration was published in December 2015 after much discussion amongst clinicians working in diabetes care. The guideline covered the care and management of type 2 diabetes in adults (aged 18 and over). It focused on education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications. Although there have been updates in 2017 and 2019 to the guideline it focused on glucose management which we now know to be only one of the triad of considerations for the management of type 2 diabetes.

In December 2018 the '**Management of hyperglycaemia in type 2 diabetes: A consensus report by American Diabetes Association (ADA) & the European Association for the Study of Diabetes (EASD)**' was published. A consensus report is defined as a comprehensive analysis by a panel of experts of a scientific or medical issue. Guidelines are often used by prescribing committees, whereas a consensus report/position statement represents an expert panel's collective analysis, evaluation, and opinion at that point in time, and represents expert opinion only. The writing group for the 2018 consensus report consisted of 10 experts (five from EU and five from the US) selected by ADA and EASD, with limited disclosures. The updated 2018 consensus report was presented at the EASD congress on 5 October 2018 in Berlin, with simultaneous publication in *Diabetes Care*¹ and *Diabetologia*².

This educational tool will guide you through the sections of the Consensus document where there is greater focus on person-related issues and self-management which have a major impact on success of any pharmacological interventions. The Consensus document also gives choices of glucose-lowering medications supported by the new evidence from Cardiovascular Outcomes Trials and consideration of major clinical need. The Consensus document has a greater focus on lifestyle interventions, with increased emphasis on weight loss and obesity management.

The sections include:

- **Decision cycle for person-centred glycaemic management in type 2 diabetes**
- **Glucose-lowering medication in type 2 diabetes**
- **Intensifying to injectable medication**
- **Continued use of oral medication when intensifying to injectable medication**

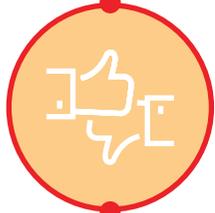


HOW TO USE TOOL

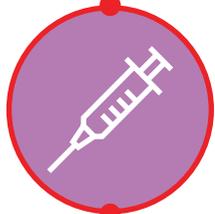
Imagine you have someone with type 2 diabetes sat in front of you, all your decisions around the treatment pathway for this individual has them at the centre with the main care goals being preventing complications and optimising their quality of life. The joint agreement between you and the person with diabetes about what the treatment pathway may look like now and in the future is crucial to its success.



The **first section** guides you through the comprehensive assessment of the person with type 2 diabetes to ascertain their needs and goals. The assessment process is ongoing and will be revisited throughout their diabetes career.



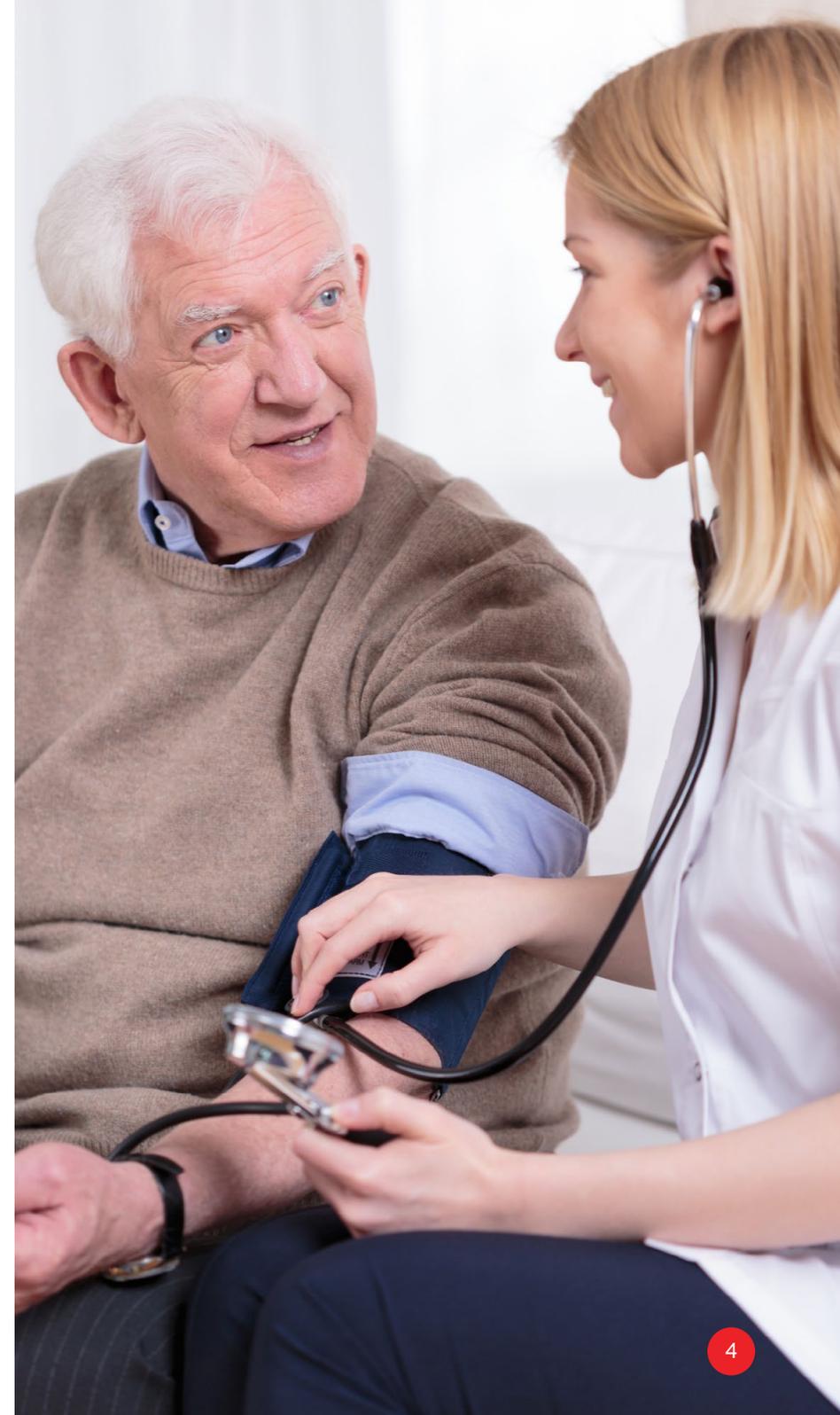
The **second section** allows you to assess the main area/areas of concern relating to the individual and choose the most appropriate medication to reduce or prevent the problem worsening. There are five treatment pathways to choose from.



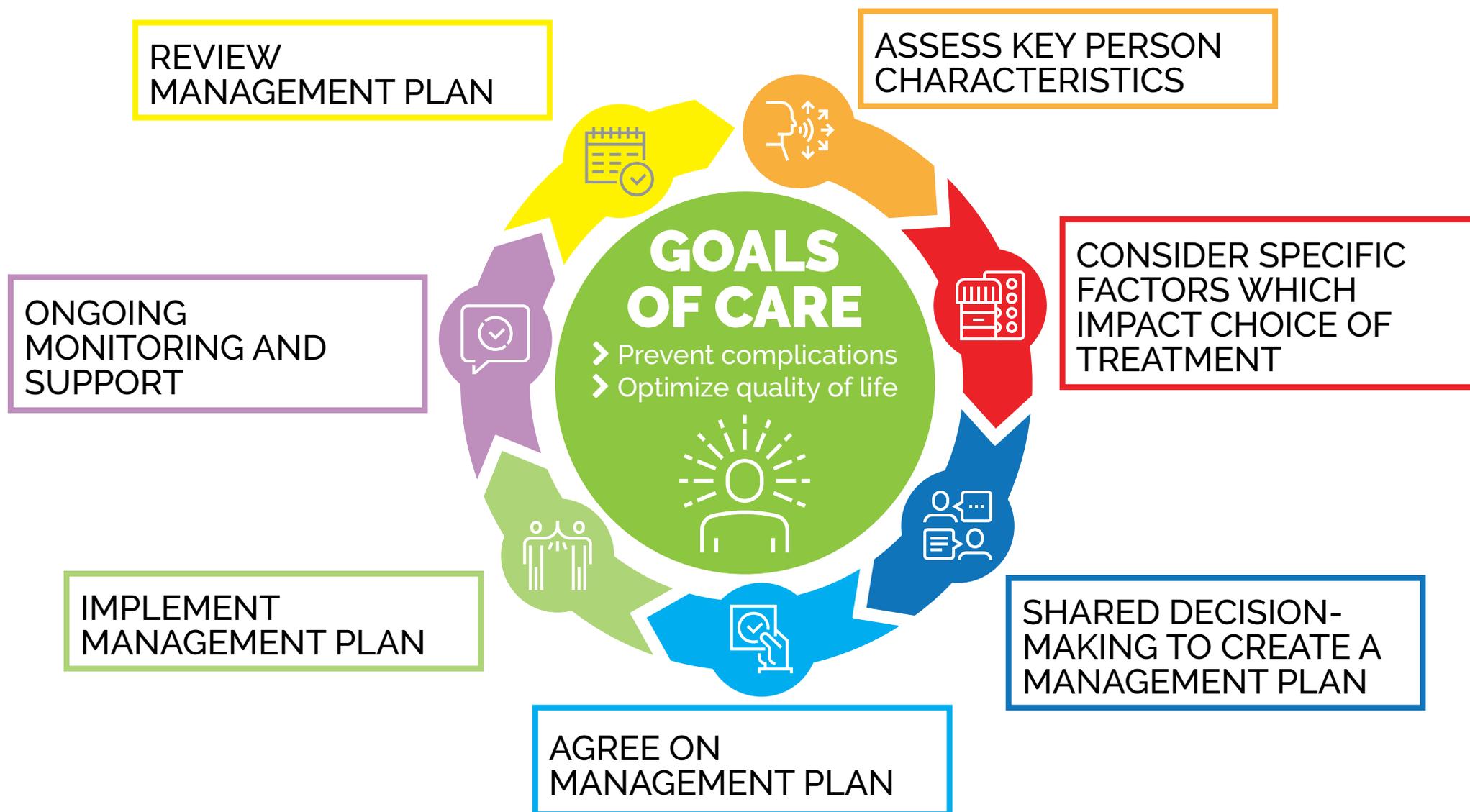
The **third section** looks at introducing an injectable medication into the treatment pathway. Correct Injection technique is crucial to ensure that the injected medication is absorbed as the manufacturers intended and the person who is injecting the medication receives optimum benefit from the medication. The **Injection Technique Matters – Best Practice in Diabetes Care** guideline provides the up to date information for correct injection technique plus there is a Toolkit for every person commencing injectable medication. Both of these resources are available at www.trend-uk.org



The **fourth section** looks at the combination of oral and injectable medication to achieve the target HbA1c.



DECISION CYCLE FOR PERSON-CENTRED GLYCAEMIC MANAGEMENT IN TYPE 2 DIABETES





ASSESS KEY PERSON CHARACTERISTICS

- Current lifestyle
- Comorbidities i.e. ASCVD, CKD, HF
- Clinical characteristics i.e. age, HbA1c, weight
- Issues such as motivation and depression
- Cultural and socio-economic context



CONSIDER SPECIFIC FACTORS WHICH IMPACT CHOICE OF TREATMENT

- Individualised HbA1c target
- Impact on weight and hypoglycaemia
- Side effect profile of medication
- Complexity of regimen i.e. frequency, mode of administration
- Choose regimen to optimise adherence and persistence
- Access, cost and availability of medication



SHARED DECISION-MAKING TO CREATE A MANAGEMENT PLAN

- Involves an educated and informed person with type 2 (and their family/ caregiver)
- Seeks the preferences of the individual
- Effective consultation includes motivational interviewing, goal setting and shared decision-making
- Empowers the person
- Ensures access to DSMES



AGREE ON MANAGEMENT PLAN

Specify SMART goals:

- **S**pecific
- **M**easurable
- **A**chievable
- **R**ealistic
- **T**ime limited



IMPLEMENT MANAGEMENT PLAN

- An individual not meeting goals generally should be seen at least every 3 months as long as progress is being made; more frequent contact initially is often desirable for DSMES



ONGOING MONITORING AND SUPPORT

Including:

- Emotional well-being
- Check tolerability of medication
- Monitor glycaemic status
- Biofeedback including SMBG, weight, step count, HbA1c, BP, lipids



REVIEW AND AGREE ON MANAGEMENT PLAN

- Review management plan
- Mutual agreement on changes
- Ensure agreed modification of therapy is implemented in a timely fashion to avoid clinical inertia
- Decision cycle undertaken regularly (at least once/twice a year)

GLUCOSE-LOWERING MEDICATION IN TYPE 2 DIABETES: OVERALL APPROACH

TO AVOID CLINICAL INERTIA REASSESS AND MODIFY TREATMENT REGULARLY (3-6 MONTHS)

FIRST-LINE THERAPY IS METFORMIN AND COMPREHENSIVE LIFESTYLE (INCLUDING WEIGHT MANAGEMENT AND PHYSICAL ACTIVITY)

NO

INDICATORS OF HIGH-RISK OR ESTABLISHED ASCVD, CKD OR HF^A

Consider independently of baseline HbA1c or individualised HbA1c target

ASCVD PREDOMINATES

- Established ASCVD
- Indicators of high ASCVD risk (age ≥ 55 years + LVH or coronary, carotid, lower extremity artery stenosis $>50\%$)

PREFERABLY

- GLP-1 RA with proven CVD benefit^B
- OR
- SGLT2i with proven CVD benefit^C if eGFR adequate^D

If HbA1c above target

If further intensification is required or individual is now unable to tolerate GLP-1 RA and/or SGLT2i, choose agents demonstrating CV safety:

- For individuals on a GLP-1 RA, consider adding SGLT2i with proven CVD benefit^B
- DPP-4i if not on GLP-1 RA
- Basal insulin^E
- TZD^F
- SU^G

HF OR CKD PREDOMINATES

- Particularly HFrEF (LVEF $<45\%$)
- CKD: Specifically eGFR 30-60 ml min⁻¹ [1.73m]⁻² or UACR >30 mg/g, particularly UACR >300 mg/g

PREFERABLY

- SGLT2i with evidence of reducing HF and/or CKD progression in CVOTs if eGFR adequate^D
- OR
- If SGLT2i not tolerated or contraindicated or if eGFR less than adequate^C add GLP-1 RA with proven CVD benefit^B

If HbA1c above target

- Avoid TZD in the setting of HF

- Choose agents demonstrating CV safety:
- For individuals on a SGLT2i, consider adding GLP-1 RA with proven CVD benefit^B
 - DPP-4i (not saxagliptin) in the setting of HF (if not on GLP-1 RA)
 - Basal insulin^E
 - SU^G

If HbA1c above individualised target proceed as below

COMPELLING NEED TO MINIMISE HYPOGLYCAEMIA

DPP-4i

GLP-1 RA

SGLT2i^C

TZD

If HbA1c above target

If HbA1c above target

If HbA1c above target

If HbA1c above target

SGLT2i^C

SGLT2i^C

GLP-1 RA

SGLT2i^C

OR

Continue with addition of other agents as outlined above

If HbA1c above target

Consider the addition of SU^G or basal insulin:

- Choose later generation SU with lower risk of hypoglycaemia
- Consider basal insulin with lower risk of hypoglycaemia^H

COMPELLING NEED TO MINIMISE WEIGHT GAIN OR PROMOTE WEIGHT LOSS

GLP-1 RA with good efficacy for weight loss^I EITHER/OR SGLT2i^C

If HbA1c above target

SGLT2i^C

GLP-1 RA with good efficacy for weight loss^I

If HbA1c above target

If quadruple therapy required, or SGLT2i and/or GLP-1 RA not tolerated or contraindicated, use regimen with lowest risk of weight gain

PREFERABLY

DPP-4i (if not on GLP-1 RA) based on weight neutrality

If DPP-4i not tolerated or contraindicated or person already on GLP-1 RA, cautious addition of:

- SU^G • TZD^F • Basal insulin

COST IS A MAJOR ISSUE^{G-H}

SU^G

TZD^H

If HbA1c above target

TZD^K

SU^G

If HbA1c above target

Insulin therapy basal insulin with lowest acquisition cost

OR

Consider DPP-4i or SGLT2i with lowest acquisition cost^K

ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASVCD):

The Consensus recommends that in appropriate high-risk individuals with established type 2 diabetes, the decision to treat with a GLP-1 receptor agonist or SGLT2 inhibitor to reduce MACE, hHF, cardiovascular death, or CKD progression should be considered independently of baseline HbA1c or individualized HbA1c target.

It also suggests that to reduce risk of MACE, GLP-1 receptor agonists can also be considered in people with type 2 diabetes without established CVD with indicators of high risk, specifically, people with type 2 diabetes aged 55 years or older with coronary, carotid, or lower extremity artery stenosis >50%, left ventricular hypertrophy, an estimated glomerular filtration rate (eGFR) <60 mL min⁻¹ [1.73 m]⁻², or albuminuria.

The authors believe that for people with type 2 diabetes and established atherosclerotic CVD (such as those with prior myocardial infarction, ischemic stroke, unstable angina with ECG changes, myocardial ischemia on imaging or stress test, or revascularization of coronary, carotid, or peripheral arteries) that the level of evidence for ASCVD benefit is greatest for GLP-1 receptor agonists.

HF OR CKD PREDOMINATES

- For people with type 2 diabetes with or without established atherosclerotic CVD, but with HFrEF (EF <45%) or CKD (eGFR 30 to 60 mL min⁻¹ [1.73 m]⁻² or UACR >30 mg/g, particularly UACR >300 mg/g), SGLT2 inhibitors with evidence of reducing HF and/or CKD progression in CVOTs if eGFR adequate.
- SGLT2 inhibitors are recommended in people with type 2 diabetes and HF, particularly those with HFrEF, to reduce hHF, MACE, and CV death.
- SGLT2 inhibitors are recommended to prevent the progression of CKD, hHF, MACE, and CV death in people with type 2 diabetes with CKD.
- Individuals with foot ulcers or at high risk for amputation should only be treated with SGLT2 inhibitors after careful shared decision making around risks and benefits with comprehensive education on foot care and amputation prevention.

COMPELLING NEED TO MINIMISE HYPOGLYCAEMIA

- For people with type 2 diabetes where there is compelling need to minimise hypoglycaemia (those older frail individuals, people who drive for their occupation, work at heights, work with water, gas, electricity, or drive HGVs or passenger vehicles)
- For people with type 2 diabetes who are not able to care for themselves due to a learning disability or dementia or those who reside in a care home)

The medications suggested for these groups needs to be assessed individually for each person with Type 2 diabetes depending on their treatment goals. The algorithm suggests appropriate additional medications which may be needed in combination to reach the individual's target HbA1c.

COMPELLING NEED TO MINIMISE WEIGHT GAIN OR PROMOTE WEIGHT LOSS

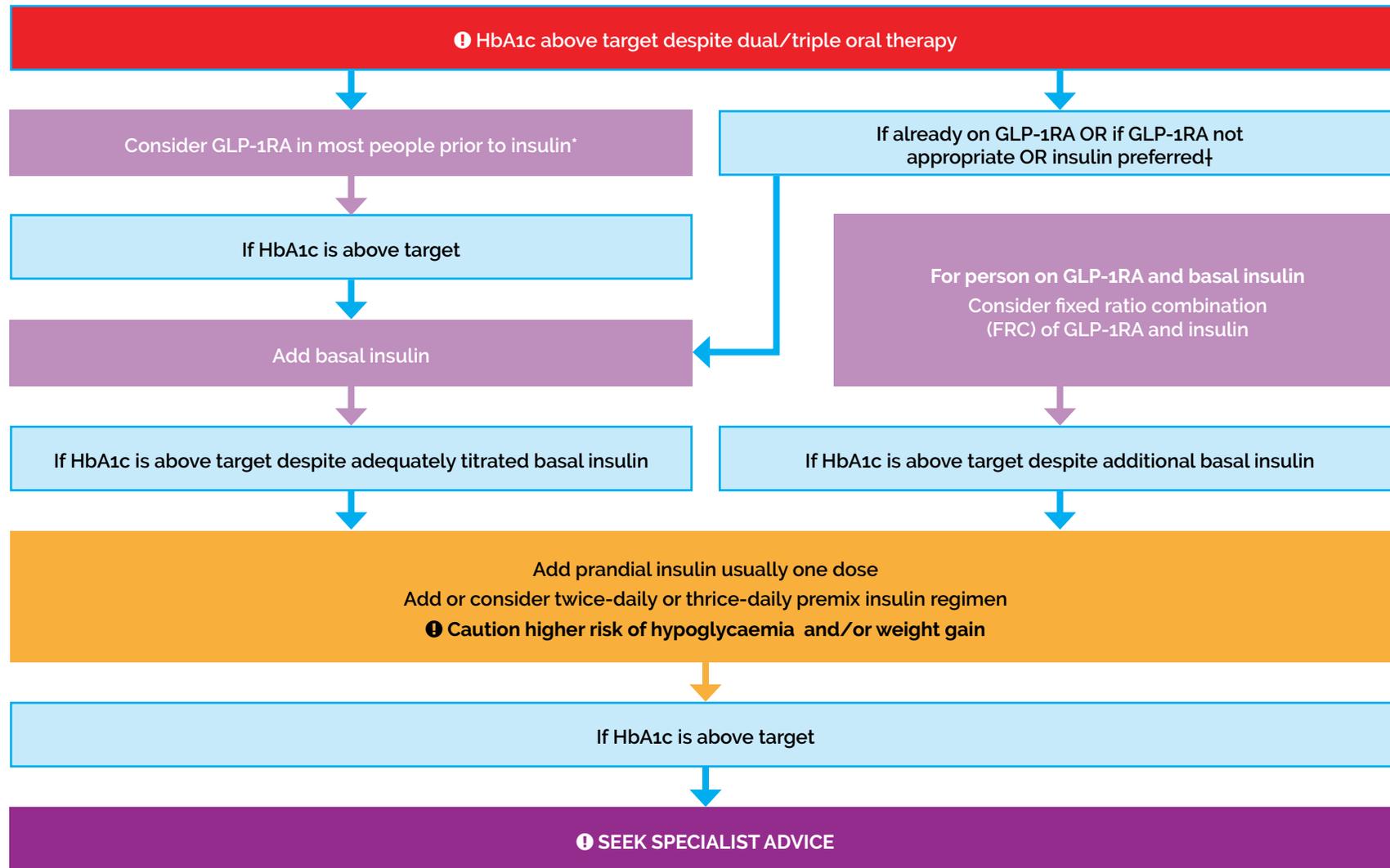
- The GLP-1 receptor agonist class and the SGLT-2 inhibitor class appear once again when we are trying to help people with type 2 diabetes manage their weight. Although not licensed specifically for weight loss both these classes have got proven evidence for weight reduction.

COST IS A MAJOR ISSUE

As this is a Consensus that is used throughout the world there are some countries who have economic difficulties in accessing newer therapies or the newer therapies have yet to be available in some countries this section was developed to ensure there is still a treatment pathway for people with type 2 diabetes who live within these countries.

- i** There are several major questions regarding the optimal application of new diabetes drugs. One obvious question arising from recent trial results is whether combined use of GLP-1 receptor agonists and SGLT2 inhibitors provides additional benefit for the prevention of MACE, CV death, hHF, and CKD progression. Three trials have demonstrated the HbA1c lowering and weight-reduction efficacy of the combination, but none addresses the impact of the combination of the two on cardiorenal end points. Recent secondary analyses of SGLT2 inhibitor studies is whether there are subsets of individuals who benefit disproportionately, or very little, from treatment with the newer diabetes drugs. The emerging evidence that SGLT2 inhibitors may be particularly useful in preventing adverse outcomes in people with diabetes and with HFrEF has now raised the strong possibility of more targeted use of these agents.

INTENSIFYING TO INJECTABLE THERAPIES



* Consider choice of GLP-1RA considering persons preference, HbA1c lowering, weight-lowering effect or frequency of injection. If CVD, consider GLP-1RA with proven CVD benefit;

† Consider insulin as preferred to GLP-1RA if symptoms of hyperglycaemia are present, or evidence of ongoing catabolism (polyuria, polydipsia or weight loss)

MEDICATIONS TO CONTINUE, REDUCE OR STOP WHEN INTENSIFYING TO INJECTABLES

METFORMIN (MF)



- Continue treatment with metformin

SULFONYLUREA (SU)



- If on SU, reduce dose by 50% when basal insulin initiated
- Consider stopping SU if prandial insulin initiated or on a premix regimen

THIAZOLIDINEDIONE (TZD)



- Stop TZD when commencing insulin
- **OR** reduce dose

DPP-4 INHIBITORS (DPP-4i)



- Stop DPP-4i if GLP-1 RA initiated

SGLT2 INHIBITORS (SGLT2i)



- If on SGLT2i, continue treatment
 - Consider adding SGLT2i if:
 - Established CVD
 - If HbA1c above target or as weight reduction aid
- Beware:**
- DKA (euglycaemic)
 - Instruct on sick-day rules
 - Do not down-titrate insulin over-aggressively

SUMMARY

Trend Diabetes hope you have found this evidence-based treatment pathway for people with type 2 diabetes, in your care, useful and informative. We are all much more aware now that the treatment of type 2 diabetes is much more than just managing glucose levels. We have emerging research relating to the new medications, namely the SGLT2 inhibitors and the GLP-1 RAs, showing us that these classes not only lower glucose levels but help with weight loss. They are instrumental in protecting people with type 2 diabetes from cardiovascular disease including heart failure but also protecting people from renal damage.

The ADA/EASD Consensus document (2019) is used throughout the world to help improve the care of people with type 2 diabetes and support in preventing complications associated with type 2 diabetes such as myocardial infarction, stroke, renal failure, blindness and amputations. By utilising this treatment pathway, as early as possible, we can encourage engagement from the person with type 2 diabetes to understand what part they have to play in reducing the risk of complications in the future by understanding when and what medications are used to maintain the blood glucose level to near normal levels.

The person with type 2 diabetes should have access to regular structured education by whatever means they prefer either via groups, social media or face to face. Only by having informed people with type 2 diabetes on the benefits of healthy eating, physical activity and appropriate treatment can we hope to reduce the burden of type 2 diabetes on the person with this condition as well as on the National Health Service.

We would like to thank Novo Nordisk for supporting this important project.

Thank you.



GLUCOSE-LOWERING MEDICATION IN TYPE 2 DIABETES: A KEY

- A. Actioned whenever these become new clinical considerations regardless of background glucose-lowering medications.
- B. Proven CVD benefit means it has label indication of reducing CVD events.
- C. Be aware that SGLT2i labelling varies by region and individual agent with regard to indicated level of eGFR for initiation and continued use
- D. Empagliflozin, canagliflozin and dapagliflozin have shown reduction in HF and to reduce CKD progression in CVOTs. Canagliflozin has primary renal outcome data from CREDENCE. Dapagliflozin has primary heart failure outcome data from DAPA-HF
- E. Degludec and U100 glargine have demonstrated CVD safety
- F. Low dose may be better tolerated though less well studied for CVD effects
- G. Choose later generation SU to lower risk of hypoglycaemia, Glimepiride has shown similar CV safety to DPP-4i
- H. Degludec / glargine U300 < glargine U100 / detemir < NPH insulin
- I. Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide
- J. If no specific comorbidities (i.e. no established CVD, low risk of hypoglycaemia and lower priority to avoid weight gain or no weight-related comorbidities)
- K. Consider country- and region-specific cost of drugs. In some countries TZDs relatively more expensive and DPP-4i relatively cheaper

REFERENCES

1. Davies MJ et al. Diabetes Care 2018. dci180033;
2. Davies MJ et al. Diabetologia 2018. DOI: <https://doi.org/10.1007/s00125-018-4729-5>
3. Buse JB, Wexler DJ, Apostolos T et al, 2019 Update to: Management of Hyprglycaemia in Type 2 Diabetes 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) <https://doi.org/10.2337/dci19-066>
4. Vilsboll T, Gumprecht J, Silver RJ et al Diabetes 2018 Semaglutide Treatment and Renal Function in the SUSTAIN 6 Trial Jul; 67(Supplement1): Jul; 67(Supplement1): - <https://doi.org/10.2337/db18-1084-P>

GLOSSARY

ASVCD = Atherosclerotic Cardiovascular Disease
CKD = Chronic Kidney Disease
DSMES = Diabetes Self-Management Education and Support
LVEF = Left Ventricular Ejection Fraction
LVH = Left Ventricular Hypertrophy
HFrEF = Heart Failure reduced Ejection Fraction
hHF = Hospitalisation for Heart Failure
MACE = Major Adverse Cardiovascular Events
UACR = Urine Albumin-to-Creatinine Ratio



™ Trend Diabetes Limited. Content to be reviewed August 2022

✉ info@trend-uk.org

www.trend-uk.org

🐦 @_trenduk

August 2020