
trend UK
TRAINING, RESEARCH AND EDUCATION
FOR NURSES IN DIABETES

Insulin master class- Insulin regimens: One Size Doesn't Fit All

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Learning objectives

- At the end of this session you will:
- Have gained an understanding of current National and International insulin guidelines
- Be able to discuss factors that can assist the healthcare professional and the person living with diabetes in the various insulin treatment options and regimens available.
- Be aware of newer insulin preparations including biosimilar and high concentration insulin
- Be able to describe the risks and safety precautions required when using insulin.

Insulin1922

Insulin

- Until the 1980s insulin was available in different “strengths” 40 or 80 strength
- Then came 100 units of insulin in 1ml (U100)
- Now new “different strengths” are back
- U200, U 300 and U500 insulin is available

How many people use insulin in the UK?

- 3.7 million) have diabetes, 8% -type 1 diabetes, 90% - type 2 diabetes
- 2% - other type of diabetes
- 20-30% are insulin treated
- Between 1991 and 2010, UK insulin users trebled in line with increasing numbers diagnosed with type 2 diabetes

Diabetes UK State of the Nation (England): challenges for 2015 and beyond. http://www.diabetes.org.uk/About_us/What-we-say/Statistics/State-of-the-nation-challenges-for-2015-and-beyond/

Holden SE et al. How many people inject insulin? UK estimates from 1991 to 2010. *Diabetes Obes Metab* 2014, 16(6): 553-9

National guidance on insulin use

SIGN 116, NICE Guidance for Type1 and type 2 and pregnancy are available – All are due to be updated Individual preference EASD/ADA recommendations are current

- Glycaemic targets
- Lifestyle issues
- Dexterity
- Cost
- Family support
- Preconception and health beliefs

Lilly

Humulin® I
Humulin® M3
Humulin® S
Humalog® 100 units/mL
Humalog® 200 units/mL
Humalog® Mix25
Humalog® Mix50
Abasaglar

novo nordisk®

Actrapid®
Insulatard®
Fiasp

Levemir®
NovoMix® 30
NovoRapid®
Tresiba® 100 units/mL
Tresiba® 200 units/mL
Xultophy®

SANOFI

Insuman® Basal
Insuman® Comb 15
Insuman® Comb 25
Insuman® Comb 50
Insuman® Rapid
Lantus®
Toujeo®
Apidra®

Insulin Lispro Sanofi

WOCKHARDT

trend UK

Hypurin® Porcine 30/70
Hypurin® Porcine Isophane
Hypurin® Porcine Neutral

Mylan
Better Health for a Better World

Semglee

National guidance

NICE Guidance Type1 (NG 15)and Type 2 diabetes (NG 28), ADA 2019

- Insulin treatment of choice
- Glycaemic targets
- Lifestyle issues
- Dexterity
- Family support
- Preconception and health beliefs

Insulin types

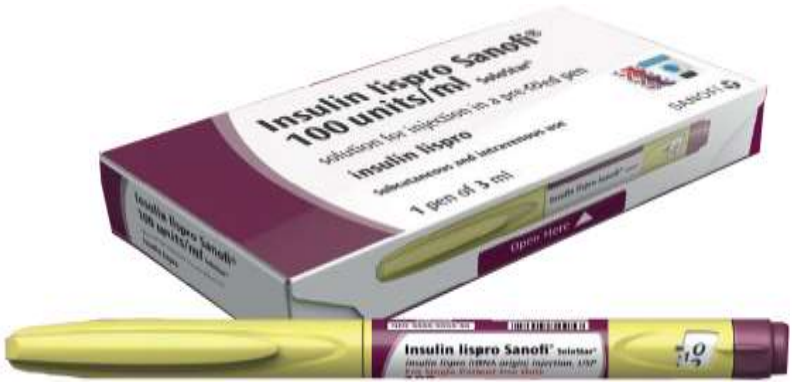
- Short acting
- Ultra rapid acting
- Rapid acting
- Intermediate acting
- Long acting
- Pre-mixed insulin

Higher concentration insulin

- 200 units/mL
- 300 units /mL - Toujeo (Intermediate acting analogue)
- 500 unit/mL insulin (short acting)is used in some countries – each mark on the syringe is 5 units)

Biosimilar Insulin

- A “biosimilar” is a biological copy that is not identical, but demonstrates similarity to the original product, in terms of quality, efficacy, and safety
- Biosimilar insulin is cheaper to develo than other analogue insulin



We know what insulin is available but what regimens should be used in individualised care?

- Aged 22 years
- Height 6 ft. 7 (200cm)
- Slim waist
- Exercises ++
- Develops type 1 diabetes
- What insulin regimen should be use?
- Which type of insulin is needed?
- What HbA1c targets are needed?

SIGN 116- Type 1 Diabetes

Recommends :

Intensive insulin therapy (part of a comprehensive support package).

Basal insulin analogues in those experiencing severe or nocturnal

CSII therapy should be considered in patients that experience recurring episodes of severe hypoglycaemia

NICE NG15- Type I diabetes and insulin in Adults

- MDI regimens are recommended
- Twice-daily mixed [biphasic], basal-only, or bolus-only regimens) **are not** recommended for adults with newly diagnosed type 1 diabetes.
- Twice-daily **insulin detemir** should be offered, unless the person is achieving their agreed target on an existing regimen, in which case that can be continued.
- Twice-daily basal insulin injection is not acceptable to the person, in which case once-daily **insulin glargine** or **insulin detemir** can be considered.
- If **Insulin detemir** is not tolerated, in which case once-daily **insulin glargine** can be considered.
- Other basal insulin regimens should be considered only if targets are not achieved

NICE NG 15 (2015) Type 1 diabetes and insulin

- A rapid-acting insulin analogue injected before meals is recommended, rather than rapid-acting soluble human or animal insulin.
- The routine use of rapid-acting insulin analogues after meals should be discouraged.
- If the person has a strong preference for an alternative mealtime insulin, they should be offered their preferred insulin

If a multiple daily injection basal–bolus insulin regimen is not possible and a twice-daily mixed insulin regimen is preferred:

- A twice-daily human mixed insulin regimen should be considered for most people. If persistant hypoglycaemia consider using an analogue insulin

HbA1c and blood glucose targets (Type 1 diabetes)

- Fasting plasma glucose level of 5–7 mmol/L on waking.
- Plasma glucose level of 4–7 mmol/L before meals at other times of the day.
- Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimize the risk of long-term vascular complications
- Ensure that aiming for the HbA1c target is not accompanied by problematic hypoglycaemia.

Continuous subcutaneous insulin infusion or ‘insulin pump’ therapy

NICE Guidance

Recommended therapy for adults and children>12 years when;

- All attempts to achieve HbA1C on MDI result in disabling hypoglycaemia (this may be unpredictable, cause anxiety or reduced quality of life)
- HbA1C remained high >69mmol/mol (8.5%) despite high level of care

Or <12 years when;

- MDI impractical or inappropriate
- It is also recommended all individuals with diabetes have a trial with MDI between the ages of 12-18 years

CSII is not recommended by NICE for the treatment of type 2 diabetes

NICE Recommendation
(Specialist Teams)

- CSII therapy should be initiated only by a trained specialist team comprising:
  - A physician with a specialist interest in insulin pump therapy
  - A diabetes specialist nurse
  - A dietitian
- People wanting to use an insulin pump must be using a basal bolus regimen and have attended a carbohydrate counting course
- They must be willing to do multiple blood glucose testing each day it use CGMS/ Flash glucose monitoring devices

Superhero with type 2 diabetes

- Aged 40 years
- Given up his super hero work
- Depressed
- Weight now 162 KG
- Little exercise
- Central obesity
- Type 2 diabetes
- On maximum Metformin
- Osmotic symptoms and needs insulin
- Which regimen should he use?

longer-term risk-reduction benefits. Where appropriate, support the person to aim for the HbA1c levels in the algorithm. Measure HbA1c levels at 3/6 monthly intervals, as appropriate. If the person achieves an HbA1c target lower than target with no hypoglycaemia, encourage them to maintain it. Be aware that there are other possible reasons for a low HbA1c level.

- Base choice of drug treatment on: effectiveness, safety (see MHRA guidance), tolerability, the person's individual clinical circumstances, preferences and needs, available licensed indications or combinations, and cost (if 2 drugs in the same class are appropriate, choose the option with the lowest acquisition cost).
- Do not routinely offer self-monitoring of blood glucose levels unless the person is on insulin, on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery, is pregnant or planning to become pregnant or if there is evidence of hypoglycaemic episodes.

If the person is symptomatically hyperglycaemic, consider insulin or an SU. Review treatment when blood glucose control has been achieved.

ADULT WITH TYPE 2 DIABETES WHO CAN TAKE METFORMIN

If HbA1c rises to 48 mmol/mol (6.5%) on lifestyle interventions:

- Offer standard-release metformin
- Support the person to aim for an HbA1c level of 48 mmol/mol (6.5%)

If standard-release metformin is not tolerated, consider a trial of modified-release metformin

FIRST INTENSIFICATION
If HbA1c rises to 58 mmol/mol (7.5%):

- Consider dual therapy with:
  - metformin and a DPP-4i
  - metformin and pioglitazone[a]
  - metformin and an SU
  - *metformin and an SGLT-2i*[b]
- Support the person to aim for an HbA1c level of 53 mmol/mol (7.0%)

SECOND INTENSIFICATION
If HbA1c rises to 58 mmol/mol (7.5%):

- Consider:
  - triple therapy with:
    - metformin, a DPP-4i and an SU
    - metformin, pioglitazone[a] and an SU
    - *metformin, pioglitazone[a] or an SU, and an SGLT-2i*[b]
  - insulin-based treatment
- Support the person to aim for an HbA1c level of 53 mmol/mol (7.0%)

If triple therapy is not effective, not tolerated or contraindicated, consider combination therapy with metformin, an SU and a GLP-1 mimetic[c] for adults with type 2 diabetes who:
- have a BMI of 35 kg/m^2 or higher (adjust accordingly for people from black, Asian and other minority ethnic groups) **and** specific psychological or other medical problems associated with obesity **or**
- have a BMI lower than 35 kg/m^2, **and** for whom insulin therapy would have significant occupational implications, **or** weight loss would benefit other significant obesity-related comorbidities

METFORMIN CONTRAINDICATED OR NOT TOLERATED

If HbA1c rises to 48 mmol/mol (6.5%) on lifestyle interventions:

- Consider one of the following[d]:
  - a DPP-4i, pioglitazone[a] or an SU
- Support the person to aim for an HbA1c level of 48 mmol/mol (6.5%) for people on a DPP-4i or pioglitazone **or** 53 mmol/mol (7.0%) for people on an SU

FIRST INTENSIFICATION
If HbA1c rises to 58 mmol/mol (7.5%):

- Consider dual therapy[e] with:
  - a DPP-4i and pioglitazone[a]
  - a DPP-4i and an SU
  - pioglitazone[a] and an SU
- Support the person to aim for an HbA1c level of 53 mmol/mol (7.0%)

SECOND INTENSIFICATION
If HbA1c rises to 58 mmol/mol (7.5%):

- Consider insulin-based treatment
- Support the person to aim for an HbA1c level of 53 mmol/mol (7.0%)

Insulin-based treatment

- When starting insulin, use a structured programme and continue metformin for people without contraindications or intolerance. Review the continued need for other blood glucose lowering therapies[f].
- Offer NPH insulin once or twice daily according to need.
- Consider starting both NPH and short-acting insulin either separately or as pre-mixed (biphasic) human insulin (particularly if HbA1c is 75 mmol/mol (9.0%) or higher).
- Consider, as an alternative to NPH insulin, using insulin detemir or glargine[e] if the person: needs assistance to inject insulin, lifestyle is restricted by recurrent symptomatic hypoglycaemic episodes **or** would otherwise need twice-daily NPH insulin in combination with oral blood glucose lowering drugs.
- Consider pre-mixed (biphasic) preparations that include short-acting insulin analogues, rather than pre-mixed (biphasic) preparations that include short-acting human insulin preparations, if: the person prefers injecting insulin immediately before a meal, hypoglycaemia is a problem **or** blood glucose levels rise markedly after meals.
- Only offer a GLP-1 mimetic[c] in combination with insulin with specialist care advice and ongoing support from a consultant-led multidisciplinary team[c].
- Monitor people on insulin for the need to change the regimen.
- *An SGLT-2i in combination with insulin with or without other antidiabetic drugs is an option*[b].

Abbreviations: [DPP-4]Dipeptidyl peptidase-4 inhibitor, [GLP-1]Glucagon-like peptide-1, [SGLT-2]Sodium–glucose cotransporter 2 inhibitors, [SU]Sulfonylurea. Recommendations that cover DPP-4 inhibitors, GLP 1 mimetics and sulfonylureas refer to these groups of drugs at a class level.

a. When prescribing pioglitazone, exercise particular caution if the person is at high risk of the adverse effects of the drug. Pioglitazone is associated with an increased risk of heart failure, bladder cancer and bone fracture. Known risk factors for these conditions, including increased age, should be carefully evaluated before treatment: see the manufacturers' summaries of product characteristics for details. Medicines and Healthcare products Regulatory Agency (MHRA) guidance (2011) advises that 'prescribers should review the safety and efficacy of pioglitazone in individuals after 3–6 months of treatment to ensure that only patients who are deriving benefit continue to be treated'.

b. Treatment with combinations of drugs including sodium–glucose cotransporter 2 inhibitors may be appropriate for some people at first and second intensification; see NICE technology appraisal guidance 288, 315 and 336 on dapagliflozin, canagliflozin and empagliflozin respectively. All three SGLT-2 inhibitors are recommended as options in dual therapy regimens with metformin under certain conditions. All three are also recommended as options in combination with insulin. At the time of publication, only canagliflozin and empagliflozin are recommended as options in triple therapy regimens. The role of dapagliflozin in triple therapy will be reassessed by NICE in a partial update of TA288. Serious and life-threatening cases of diabetic ketoacidosis have been reported in people taking SGLT-2 inhibitors (canagliflozin, dapagliflozin or empagliflozin) or shortly after stopping the SGLT-2 inhibitor. MHRA guidance (2015) advises testing for raised ketones in people with symptoms of diabetic ketoacidosis, even if plasma glucose levels are near normal.

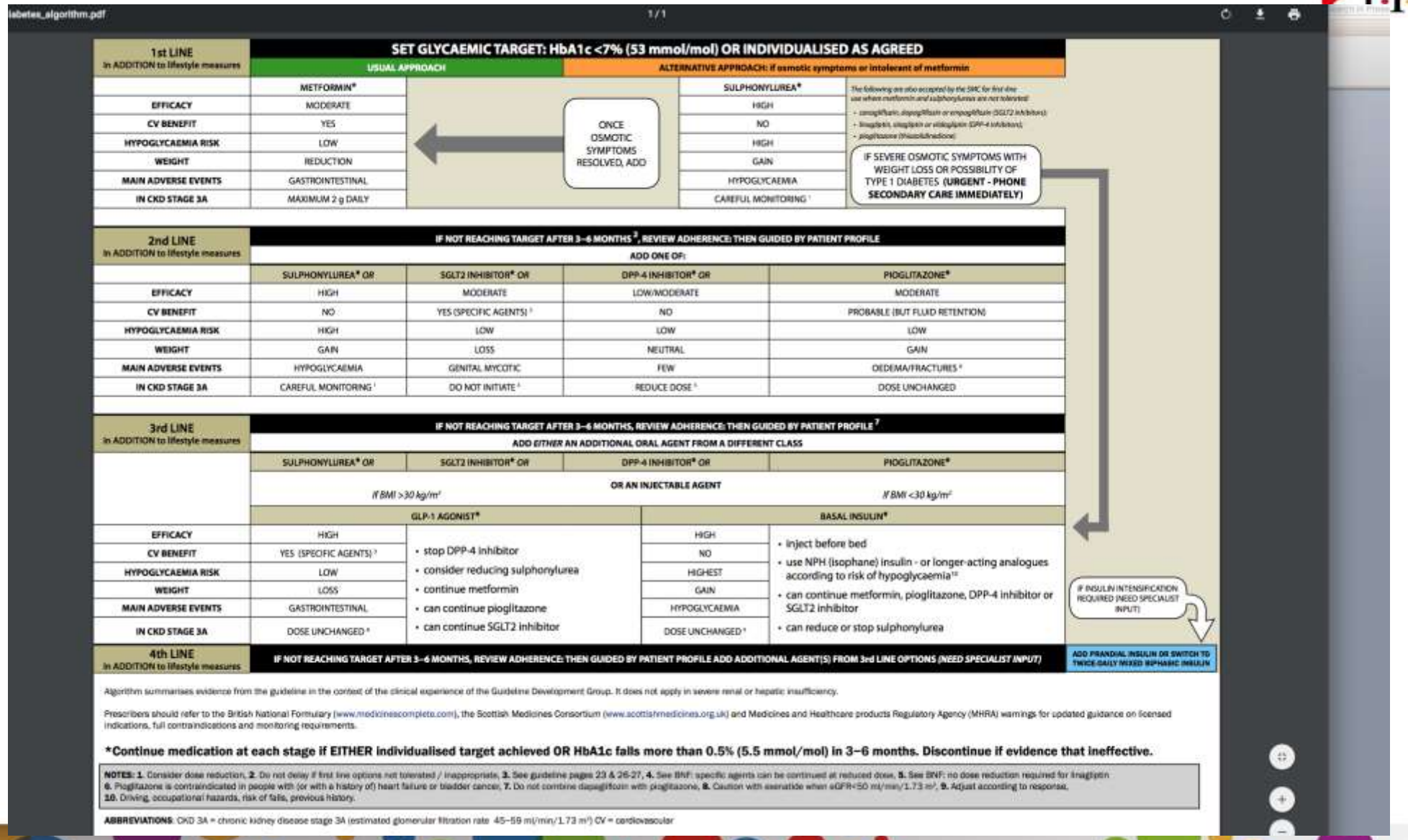
c. Only continue GLP-1 mimetic therapy if the person has a beneficial metabolic response (a reduction of HbA1c by at least 11 mmol/mol [1.0%] **and** a weight loss of at least 3% of initial body weight in 6 months).

d. Be aware that, if metformin is contraindicated or not tolerated, repaglinide is both clinically effective and cost effective in adults with type 2 diabetes. However, discuss with any person for whom repaglinide is being considered, that there is no licensed non-metformin-based combination containing repaglinide that can be offered at first intensification.

e. Be aware that the drugs in dual therapy should be introduced in a stepwise manner, checking for tolerability and effectiveness of each drug.

f. MHRA guidance (2011) notes that cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for the development of cardiac failure. It advises that if the combination is used, people should be observed for signs and symptoms of heart failure, weight gain, and oedema. Pioglitazone should be discontinued if any deterioration in cardiac status occurs.

SIGN 116/164



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1st LINE In ADDITION to lifestyle measures

SET GLYCAEMIC TARGET: HbA1c <7% (53 mmol/mol) OR INDIVIDUALISED AS AGREED

	USUAL APPROACH: METFORMIN*	ALTERNATIVE APPROACH: if osmotic symptoms or intolerant of metformin: SULPHONYLUREA*
EFFICACY	MODERATE	HIGH
CV BENEFIT	YES	NO
HYPOGLYCAEMIA RISK	LOW	HIGH
WEIGHT	REDUCTION	GAIN
MAIN ADVERSE EVENTS	GASTROINTESTINAL	HYPOGLYCAEMIA
IN CKD STAGE 3A	MAXIMUM 2 g DAILY	CAREFUL MONITORING [1]

ONCE OSMOTIC SYMPTOMS RESOLVED, ADD

The following are also accepted by the SMC for first-line use where metformin and sulphonylureas are not tolerated:
- *canagliflozin, dapagliflozin or empagliflozin (SGLT2 inhibitors);*
- *linagliptin, sitagliptin or vildagliptin (DPP-4 inhibitors);*
- *pioglitazone (thiazolidinedione).*

IF SEVERE OSMOTIC SYMPTOMS WITH WEIGHT LOSS OR POSSIBILITY OF TYPE 1 DIABETES **(URGENT - PHONE SECONDARY CARE IMMEDIATELY)**

2nd LINE In ADDITION to lifestyle measures

IF NOT REACHING TARGET AFTER 3–6 MONTHS [2], REVIEW ADHERENCE: THEN GUIDED BY PATIENT PROFILE

ADD ONE OF:

	SULPHONYLUREA* OR	SGLT2 INHIBITOR* OR	DPP-4 INHIBITOR* OR	PIOGLITAZONE*
EFFICACY	HIGH	MODERATE	LOW/MODERATE	MODERATE
CV BENEFIT	NO	YES (SPECIFIC AGENTS) [3]	NO	PROBABLE (BUT FLUID RETENTION)
HYPOGLYCAEMIA RISK	HIGH	LOW	LOW	LOW
WEIGHT	GAIN	LOSS	NEUTRAL	GAIN
MAIN ADVERSE EVENTS	HYPOGLYCAEMIA	GENITAL MYCOTIC	FEW	OEDEMA/FRACTURES [6]
IN CKD STAGE 3A	CAREFUL MONITORING [1]	DO NOT INITIATE [4]	REDUCE DOSE [5]	DOSE UNCHANGED

3rd LINE In ADDITION to lifestyle measures

IF NOT REACHING TARGET AFTER 3–6 MONTHS, REVIEW ADHERENCE: THEN GUIDED BY PATIENT PROFILE [7]

ADD *EITHER* AN ADDITIONAL ORAL AGENT FROM A DIFFERENT CLASS

	SULPHONYLUREA* OR	SGLT2 INHIBITOR* OR	DPP-4 INHIBITOR* OR	PIOGLITAZONE*
				If BMI <30 kg/m²

OR AN INJECTABLE AGENT

If BMI >30 kg/m²

	GLP-1 AGONIST*	BASAL INSULIN*
EFFICACY	HIGH	HIGH
CV BENEFIT	YES (SPECIFIC AGENTS) [3]	NO
HYPOGLYCAEMIA RISK	LOW	HIGHEST
WEIGHT	LOSS	GAIN
MAIN ADVERSE EVENTS	GASTROINTESTINAL	HYPOGLYCAEMIA
IN CKD STAGE 3A	DOSE UNCHANGED [8]	DOSE UNCHANGED [9]

- stop DPP-4 inhibitor
- consider reducing sulphonylurea
- continue metformin
- can continue pioglitazone
- can continue SGLT2 inhibitor

- inject before bed
- use NPH (isophane) insulin - or longer-acting analogues according to risk of hypoglycaemia [10]
- can continue metformin, pioglitazone, DPP-4 inhibitor or SGLT2 inhibitor
- can reduce or stop sulphonylurea

IF INSULIN INTENSIFICATION REQUIRED (NEED SPECIALIST INPUT)

4th LINE In ADDITION to lifestyle measures

IF NOT REACHING TARGET AFTER 3–6 MONTHS, REVIEW ADHERENCE: THEN GUIDED BY PATIENT PROFILE ADD ADDITIONAL AGENT(S) FROM 3rd LINE OPTIONS *(NEED SPECIALIST INPUT)*

ADD PRANDIAL INSULIN OR SWITCH TO TWICE-DAILY MIXED BIPHASIC INSULIN

Algorithm summarises evidence from the guideline in the context of the clinical experience of the Guideline Development Group. It does not apply in severe renal or hepatic insufficiency.

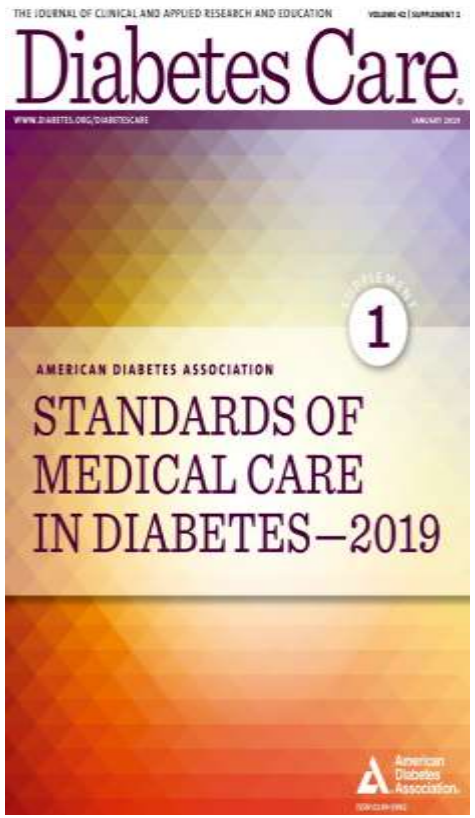
Prescribers should refer to the British National Formulary (www.medicinescomplete.com), the Scottish Medicines Consortium (www.scottishmedicines.org.uk) and Medicines and Healthcare products Regulatory Agency (MHRA) warnings for updated guidance on licensed indications, full contraindications and monitoring requirements.

***Continue medication at each stage if EITHER individualised target achieved OR HbA1c falls more than 0.5% (5.5 mmol/mol) in 3–6 months. Discontinue if evidence that ineffective.**

NOTES: 1. Consider dose reduction, **2.** Do not delay if first line options not tolerated / inappropriate, **3.** See guideline pages 23 & 26-27, **4.** See BNF: specific agents can be continued at reduced dose, **5.** See BNF: no dose reduction required for linagliptin **6.** Pioglitazone is contraindicated in people with (or with a history of) heart failure or bladder cancer, **7.** Do not combine dapagliflozin with pioglitazone, **8.** Caution with exenatide when eGFR<50 ml/min/1.73 m², **9.** Adjust according to response, **10.** Driving, occupational hazards, risk of falls, previous history.

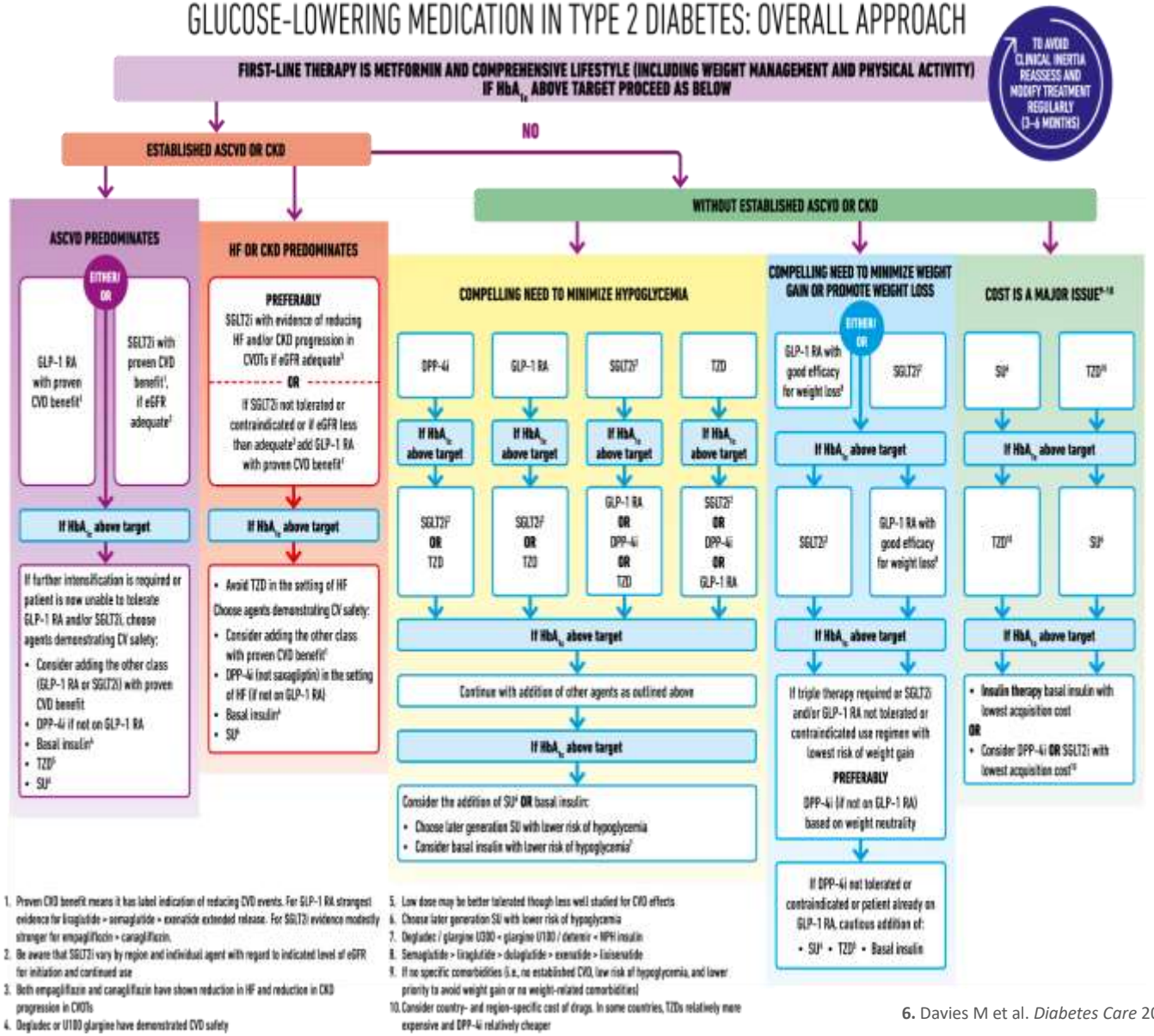
ABBREVIATIONS: CKD 3A = chronic kidney disease stage 3A (estimated glomerular filtration rate 45–59 ml/min/1.73 m²) CV = cardiovascular

ADA/EASD Consensus Guidelines 2018[6]



6. Davies M et al. *Diabetes Care* 2018; 41: 2669-2701.

GLUCOSE-LOWERING MEDICATION IN TYPE 2 DIABETES: OVERALL APPROACH



1. Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1 RA strongest evidence for liraglutide > semaglutide > exenatide extended release. For SGLT2i evidence modestly stronger for empagliflozin > canagliflozin.
2. Be aware that SGLT2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use
3. Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs
4. Degludec or U100 glargine have demonstrated CVD safety
5. Low dose may be better tolerated though less well studied for CVD effects
6. Choose later generation SU with lower risk of hypoglycemia
7. Degludec / glargine U300 > glargine U100 / detemir > NPH insulin
8. Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide
9. If no specific comorbidities (i.e., no established CVD, low risk of hypoglycemia, and lower priority to avoid weight gain or no weight-related comorbidities)
10. Consider country- and region-specific cost of drugs. In some countries, TZDs relatively more expensive and DPP-4i relatively cheaper

6. Davies M et al. *Diabetes Care* 2018; 41: 2669-2701.

Type 2 diabetes and blood glucose targets

HbA1c:

- 53 mmol/mol at diagnosis
- 58 mmol/mol for on going care once on Metformin plus
- Clinical targets should be individualised

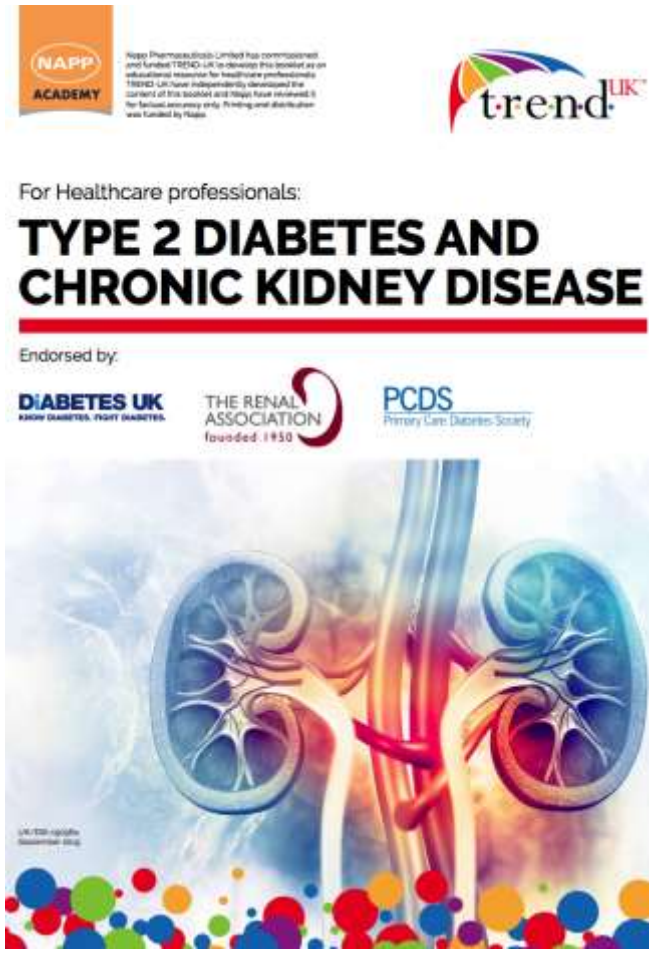
Helen Parr (Elastigirl)

- 38 years old
- Mum to 3 children
- What if she had type 1 diabetes?
- Consider what insulin regimen would she need?
- What HbA1c targets and BG readings are needed in pregnancy

NICE NG3 (2015)

- HbA1c target of < 48 mmol/mol
- A fasting plasma glucose level of 5–7 mmol/litre on waking **and**
- A plasma glucose level of 4–7 mmol/litre before meals at other times of the day.
- Risk of hypoglycaemia is high and particularly in 1st trimester

Diabetes and CKD
NICE NG182 (2014)



Insulin and CKD

- Insulin requirements in individuals with type 2 diabetes and diabetic nephropathy may increase in the early stages of CKD as a result of insulin resistance.
- However as renal function deteriorates and because the kidney excretes insulin, the doses of insulin may need to be reduced to minimise the risk of hypoglycaemia; because insulin has a longer profile when CKD slows down excretion.
- In people using insulin therapy with CKD 3b or below and where the HbA1c is 58 mmol/mol or below, consider dose reduction (Winocour et al 2018).

Frailty

Frailty Guidance

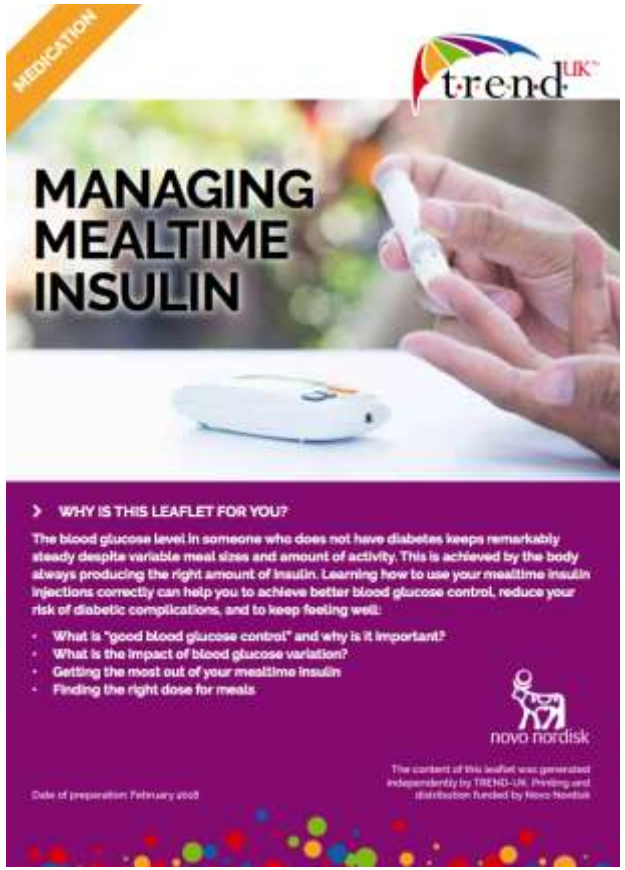
- The fit older adult with diabetes – 53 -58 mmol/mol
- Moderate – severe frailty- 58-64 mmol/mol
- Severe frailty - cautious use of insulin and metformin mindful of renal function.
- Very severe frailty- 64 mmol/mol -70mmol/mol and withdraw sulfonylureas and short-acting insulin because of risk of hypoglycaemia **and**
- Review timings and suitability of NPH insulin with regard to risk of hypoglycaemia.

Strain et al(2018) https://doi.org/10.1111/dme.13644

End of life care and insulin

- Do NOT stop insulin in people with type 1 diabetes
- In type 2 diabetes insulin can often be significantly reduced or stopped
- Aim for blood glucose readings 6-15 mmol/L and no symptoms

Useful resources



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