

### Medicines Management in Type 1 Diabetes

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#### **Presenter Disclosure**

Speaker's Bureau-Ascensia, Abbott, Novo Nordisk

Educational grant - Boehringer Ingelheim, Ascensia, Abbott

Equipment - AMSL (loan)

Associate Editor - Diabetes Care

NB - None related to this presentation



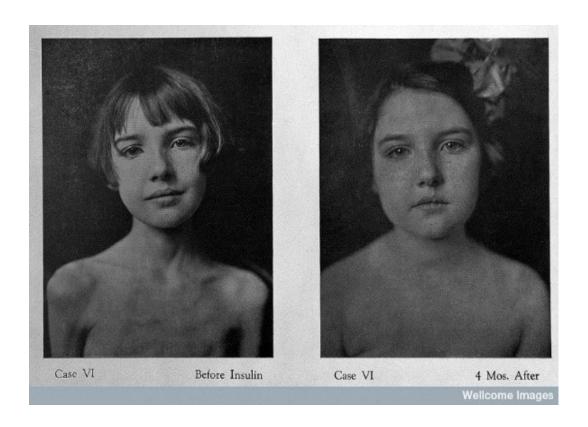


### Medicines Management in Type 1 Diabetes

- Principles of Insulin management
- Hypoglycaemia
- Avoiding Hypoglycaemia and Hyperglycaemia
- Emerging issues



#### **Discovery of insulin - 1921**



#### **Management of insulin**

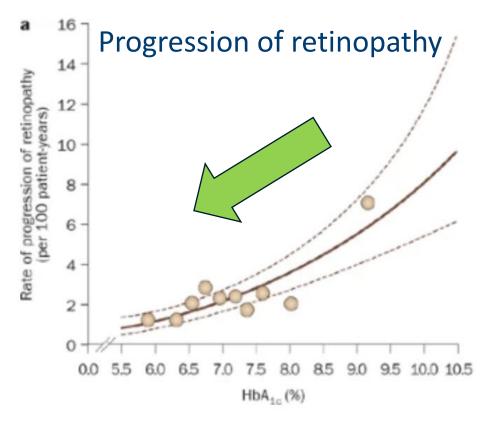
- Longer acting insulins allowed twice and then once/day insulin regimens
- More concern over hypoglycaemia than long term complications
- Did not think it was necessary to change insulin doses
- -> Fixed insulin, fixed carbohydrate regimen
- -> "Diabetic Diet"
- Make it easy for people with diabetes
- -> Once/day long acting
- -> Twice per day mixed quick and medium acting





### 1983 – 1993: The Diabetes Control and Complications Trial



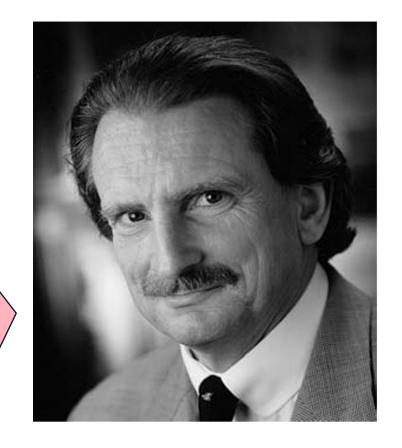


 1441 people with T1D randomised to intensified insulin therapy or usual care





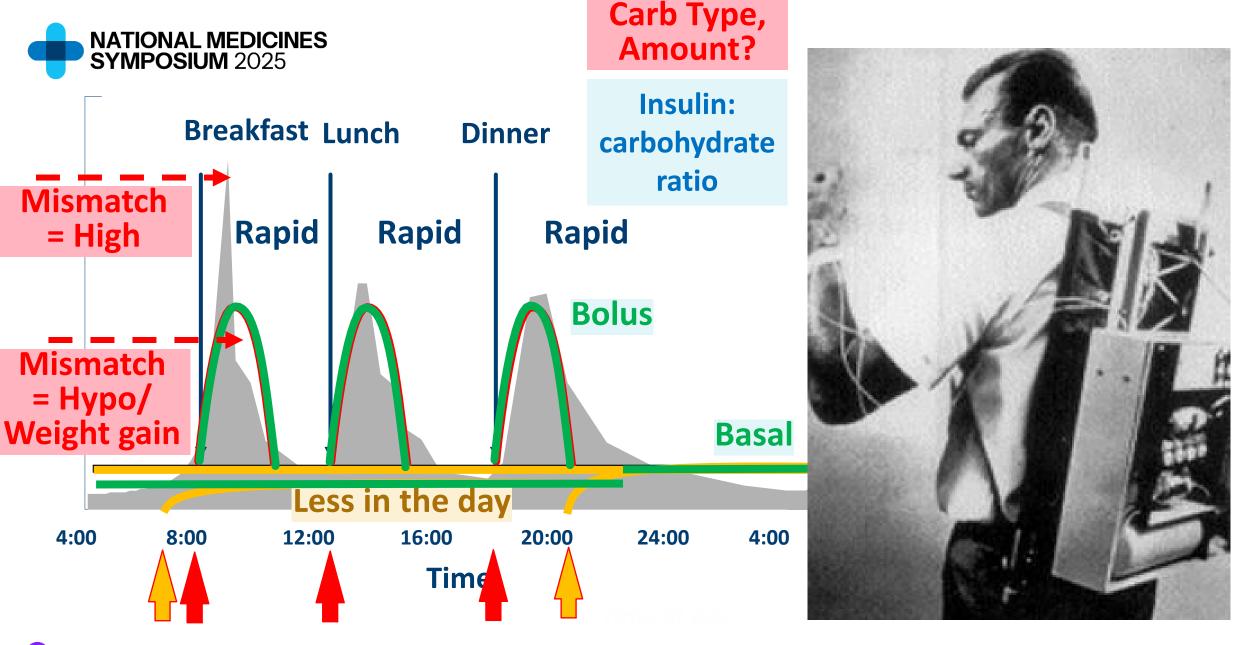
- Type 1 diabetes is a disease of insulin deficiency
- The treatment of type 1 diabetes is insulin replacement not diet



Prof Michael Berger

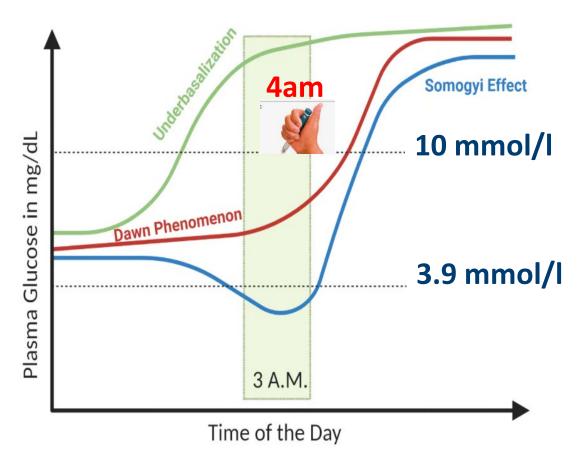
02.06.1944 – 18.08.2002

researcher, physician, educator, visionary





### Everyone is different!







### **Hypoglycaemia - Implications**

- Hypos disrupt everyday activities, provokes unpleasant symptoms
- Severe hypoglycaemia can cause coma, seizures, strokes, arrhythmias and even death
- Negative effects on mood and emotions
- Impairs cognitive function; can affect performance of many activities; falls
- Long term effects, weight gain







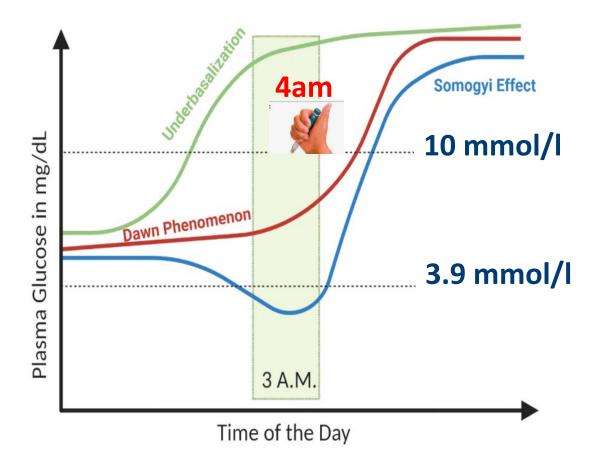
## Hypoglycaemia Assessment, Prevention, and Treatment (continued)

- **6.16** Glucagon should be prescribed for all individuals taking insulin. A Family, caregivers, school personnel, and others providing support to these individuals should know its location and be educated on how to administer it. Glucagon preparations that do not have to be reconstituted are preferred. **B**
- **6.17** All individuals taking insulin A should receive structured education for hypoglycemia prevention and treatment, with ongoing education for those who experience hypoglycemic events.
- **6.18** One or more episodes of level 2 or 3 hypoglycemia should prompt reevaluation of the treatment plan, including deintensifying or switching diabetes medications if appropriate. **E**



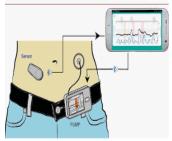


### Everyone is different!









Automated Insulin Delivery \$\$

POSITION STATEMENT SUMMARY

# EQUITABLE ACCESS TO DIABETES TECHNOLOGY







### **Avoiding Hypoglycaemia and Hyperglycaemia in Type 1 Diabetes**

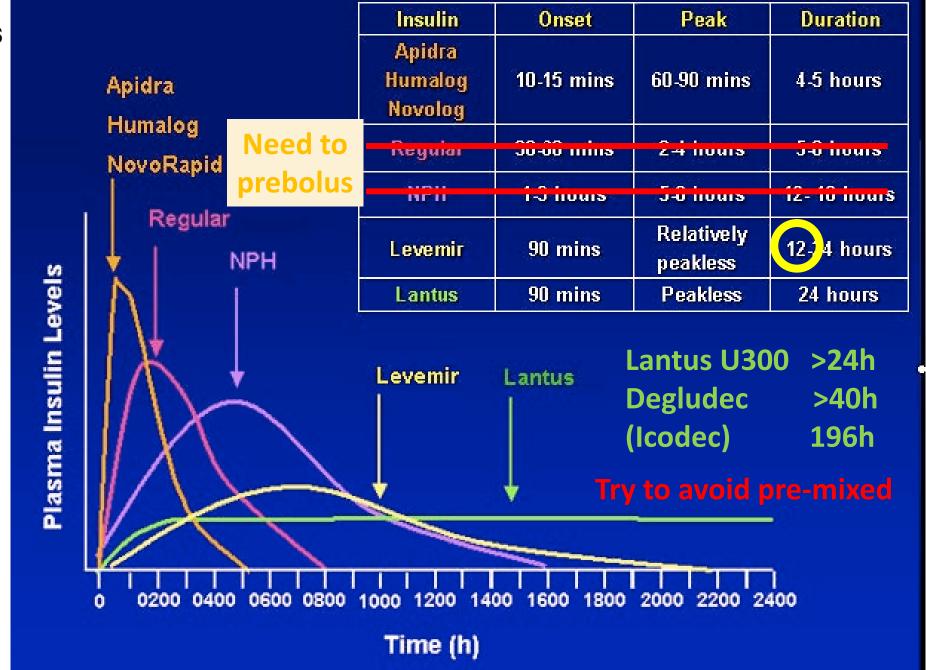
If it weren't for hypoglycaemia, we could give as much insulin as we want!

### 1. Better Insulin Regimen





## Insulin regimens



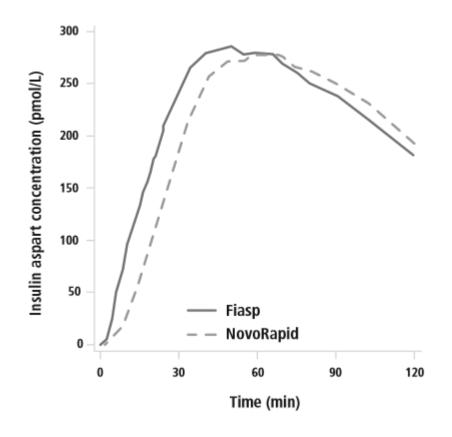




### **Everyone is different: Ultra rapid Insulins**

Fiasp = Ultra fast aspart (5m)

Lyumjev = Ultra fast lispro (11m)





### Make it easy-use a pen!

#### Devices Non-disposable - 0.5 - 1 unit increments





Australian Commission on Safety and Quality in Health Care



#### **Know your insulins**

#### Duration of action

Ultra short

acting

#### Insulin brand name (active ingredient name)

100 units/mL unless otherwise stated



When to administer

(immediately before meals)

Short acting





Insuman® Infusat (insutin neutral): available via SAS

(up to 30 minutes before meals)

Intermediate acting



ONCE or TWICE daily (with/without food)

ONCE or TWICE

daily

(up to 30 minutes

Mixed long and short acting





Mixtard® 30/70 Innolet® (insulin neutral 30% + insulin isophane 70%)

Other less commonly used product: Mixtard 50/50® (insulin neutral 50% + insulin isophane 50%) cartridge

Mixed long acting with ultra short acting



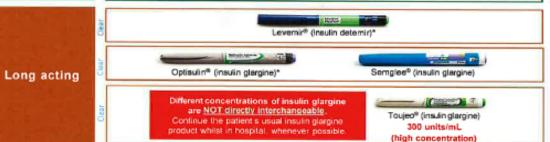
before meals)

ONCE or TWICE daily (immediately before meals)

Mixed ultra long acting with ultra short acting



ONCE or TWICE daily (immediately before meals)

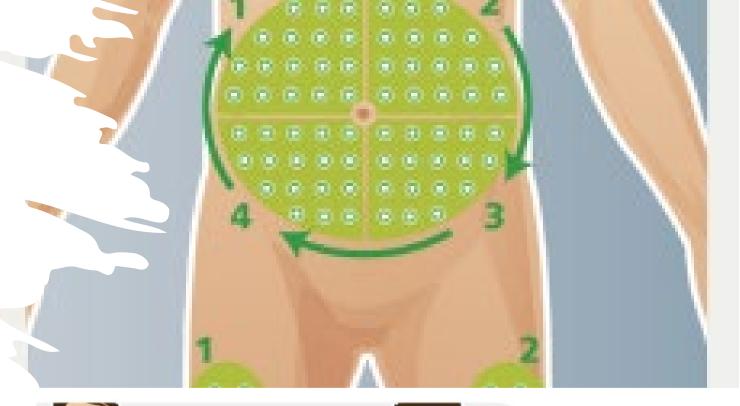


Usually ONCE dailvI sometimes large doses prescribed TWICE daily) 2(with/without food)



### Injection sites

- Children
- Adults
- Absorption can be affected by:
- Needle length
- Technique
- Injecting rapid insulin into areas of muscle











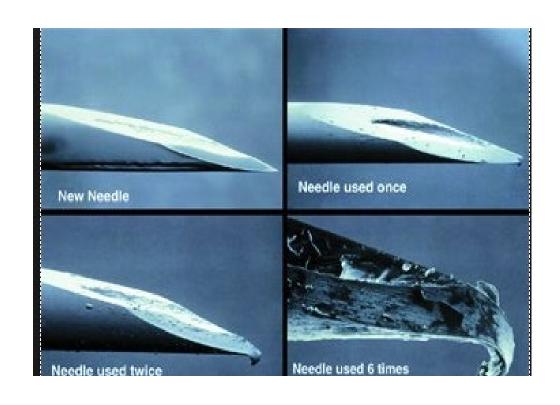






### How many times should a pen needle be used?

- All pen needles are SINGLE use only
- FREE under the National Diabetes Services Scheme (NDSS)





### Lipohypertrophy





### **Avoiding Hypoglycaemia and Hyperglycaemia in Type 1 Diabetes**

If it weren't for hypoglycaemia, we could give as much insulin as we want!

### 2. Technology can help!





### **Current technology in type 1 diabetes**

#### **Insulin delivery**

- Insulin pen
- Insulin pump
- Conventional pump
- Patch pump

#### Glucose sensing

- Capillary blood glucose
- Continuous glucose monitoring
- Flash glucose monitoring
- Conventional
- Implantable

If High->
correction/Insulin
Sensitivity FactorNeeds a target

## Insulin: carbohydrate ratio

#### **Data management**

- Health-care professional-centred
- Data and/or web portals
- Patient-centred
- Data and/or web portals
- Remote monitoring
- Mobile apps

### Glucose-responsive insulin delivery

- Threshold-based suspension
- Predictive low-glucose suspension
- Hybrid single-hormone closed-loop



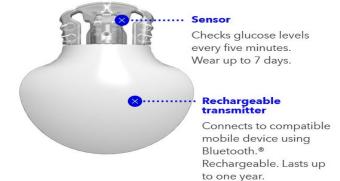


### Continuous Glucose Sensors





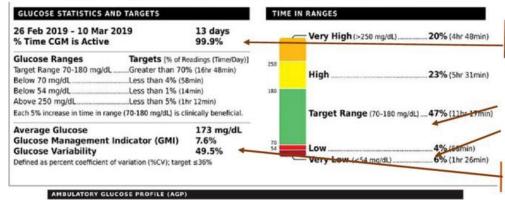
#### Guardian 4 smart CGM

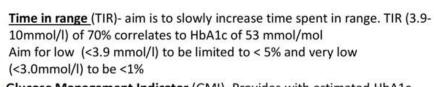




#### **Example of an AGP (ambulatory glucose profile)**

days) for reliable data



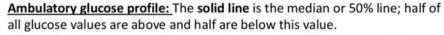


wear. It correlates well to 3 months of \*CGM data

Ambulatory Glucose profile (AGP) report is displayed for 14 days of sensor

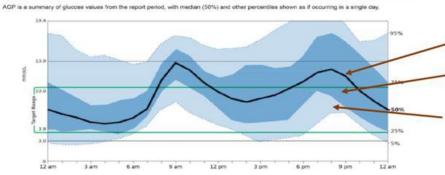
CGM is active 99.9%% of time. Recommendation is for min 70% usage (10

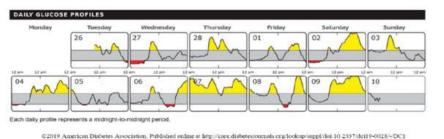
<u>Glucose Management Indicator</u> (GMI)- Provides with estimated HbA1c <u>Glucose variability</u> (GV)- refers to how much the glucose readings varies from mean or median glucose. Low GV indicates stable glucose profile



The 25th and 75th percentile curves shaded in **dark blue** represent the interquartile range or 50% of all values and are a good visual indicator of the degree of GV.

The dashed outer lines (the 10th to 90th percentile curves) in **light blue** indicate that only 10% of glucose readings were above or below these value





Graph showing daily data. Each daily profile represents midnight to midnight data



2022;107:188-193







### **Smart glucose meters (Bolus Calculators)**

- Majority of patients either do not correct for high glucose at all or get the calculations wrong
- Meter programmed with insulin:carb ratio and correction factor. Each bolus consists of insulin for carbs and insulin for correcting high glucose
- Studies have shown improved HbA1c, reduced hypos and improved QOL



Glucose Meters with Built-In Automated Bolus Calculator: Gadget or Real Value for Insulin-Treated Diabetic Patients?

Ides M. Colin · Isabelle Paris





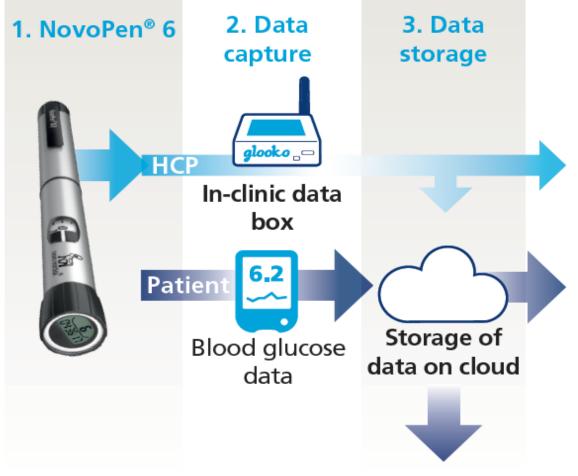




### **Smart Insulin Pens**

NovoPen 6 and NovoPen Echo





Anonymised data transfer to Novo Nordisk for research and product development purposes 4. HCP review of data



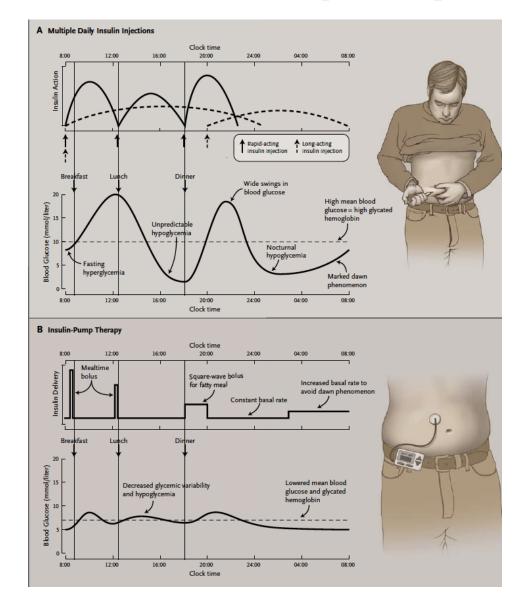
Visualisation of patient data (insulin dosing and glucose data) on same interface using HCP platform





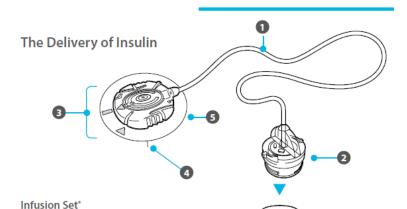
### Benefits of insulin pumps

- CSII allows more physiological replacement of basal insulin requirements
- Lower variability of absorption of basal insulin
- On demand modulation of basal insulin to match individual needs; e.g. exercise or stress
- With CGM Predictive low glucose suspend technology





### **Tube vs patch pumps**



#### No Fiasp

- 1 Tubing: carries insulin from the pump to you
- Reservoir Connector: end of the tubing that attaches the reservoir which holds the insulin
- 3 Insertion Site Section: other end of the tubing that attaches to you
- Cannula: tiny flexible tube placed into your body\*\* by the insertion needle included in the insertion site section
- **3** Adhesive: holds the infusion set in place
- 6 Reservoir Compartment: part of the pump where the reservoir fits

You should replace both the infusion set and the reservoir every 2 to 3 days.



Reservoir









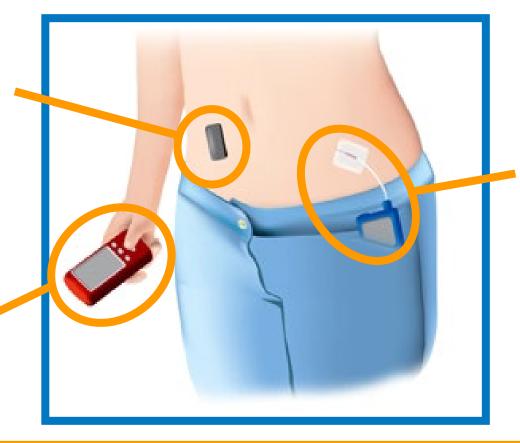
<sup>\*</sup>Quick-set\* infusion set shown in illustration.



### Closed-loop system components









个TIR 12+% **↓** HbA1c 0.5+%



smart CGM

Checks glucose levels Wear up to 7 days.

Connects to compatible mobile device using to one year.

Australian Commission on Safety and Quality in Health Care

Autonomous, graduated modulation of insulin delivery to achieve target glucose

Hybrid = Meal bolus still required



### **Closed Loop-Automated Insulin Delivery "AID"**













### **Avoiding Hypoglycaemia and Hyperglycaemia in Type 1 Diabetes**

If it weren't for hypoglycaemia, we could give as much insulin as we want!

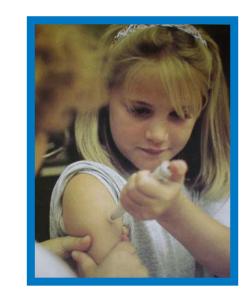
### 3. Self Management Barriers





### Type 1 diabetes (T1DM)

- No condition that demands more of the individual than T1DM, Requires life-long insulin therapy, impose a heavy burden on the individual, family and healthcare systems
- Current treatment multiple daily injections or insulin pump therapy.
   Requires multiple finger-prick measurements/CGMS, carbohydrate counting and dynamic dose adjustments



- Many have "poor control", glycaemic variability frustrates many;
   Depression, anxiety and reduced quality of life very common
- Impaired awareness of hypoglycaemia (IAH) affects 20-40% of T1DM,
   Severe hypoglycaemia (SH) affects up to 30% of individuals with T1D





Being described as 'non-compliant' is awful and does not reflect the fact that everyone is doing their best, maybe not the same best as someone else, or even their best 'best' but just the best they can at that moment. Life is way more than Type 1 Diabetes and it isn't always given top priority. Life gets in the way.

Person with Type 1 Diabetes

### Language and Diabetes-stigma

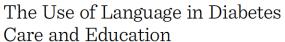
Poor control => U R Not controlling it!

Bringing an end to diabetes stigma and discrimination: an international consensus statement on evidence and recommendations

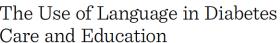
Jane Speight\*, Elizabeth Holmes-Truscott\*, Matthew Garza, Renza Scibilia, Sabina Wagner, Asuka Kato, Victor Pedrero, Sanya Deschênes, Susan J Guzman, Kevin L Joiner, Shengxin Liu, Ingrid Willaing, Katie M Babbott, Bryan Cleal, Jane K Dickinson, Jennifer A Halliday, Eimear C Morrissey, Giesje Nefs, Shane O'Dannell, Anna Serlachius, Per Winterdijk, Hamzah Alzubaidi, Bustanul Arifin, Liz Cambron-Kopca, Carinna Santa Ana, Emma Davidsen, Mary de Groot, Moortje de Wit, Phyllisa Deroze, Stephanie Haack, Richard I G Halt, Walther Jensen, Kamlesh Khunti, Karoline Kragelund Nielsen, Tejal Lathia, Christopher J Lee, Bridget McNulty, Diana Naranjo, Rebecca L Pearl, Surnan Prinjha, Rebecca M Puhl, Anita Sabidi, Chitra Selvan, Jazz Sethi, Mohammed Seyam, Jackie Sturt, Mythily Subramaniam, Helle Terkildsen Maindal, Virginia Valentine, Michael Vallis, Timothy C Skinner

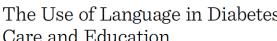
 The language used by healthcare professionals can have a profound impact on people living with diabetes





https://doi.org/10.2337/dci17-0041





Jane K. Dickinson, 1 Susan J. Guzman, 2 Melinda D. Maryniuk, Catherine A. O'Brian, Jane K. Kadohiro, 5 Richard A. Jackson. 6 Nancy D'Hondt.7 Brenda Montgomery,8 Kelly L. Close,9 and Martha M. Funnell<sup>10</sup>





### Factors contributing to high HbA1c sub-optimal glycaemia (T1DM)

- Physiology! Imperfect Technology
- Variable insulin absorption & problems with insulin injection sites
- Fear of hypoglycaemia; Needle Phobia; Diabulimia
- Relentless Burden; Depression, anxiety and lack of motivation
- Not monitoring glucose
- Clinical inertia
- Lack of access to technology / HCP
- Lack of access / non-engagement with high quality structured education (self-management skills)



#### **42 Factors** that affect **Blood Glucose**

# FOOD ↑↑ 1 Carbohydrate quantity ↑↑ 2 Carbohydrate type ↑↑ 3 Fat ↑↑ 4 Protein ↑↑ 5 Caffeine ↑↑ 6 Alcohol ↑↑ 7 Meal timing ↑ 8 Dehydration ? 9 Personal microbiome

## MEDICATION → 10 Medication dose → ↑ 11 Medication timing → ↑ 12 Medication interactions ↑ ↑ 13 Steroid administration ↑ 14 Niacin (Vitamin B3)





### BIOLOGICAL ↑ 20 Too little sleep

- 100 little sleep
- 21 Stress and illness
- ↑ 24 Dawn phenomenon
- ↑ 25 Infusion set issues
- ↑ 26 Scar tissue / lipodystrophy
- 🖖 🖖 27 Intramuscular insulin delivery
- ↑ 28 Allergies
- 29 A higher BG level (glucotoxicity)
- 🖖 🛧 30 Periods (menstruation)
- ↑↑ 31 Puberty
- 🖖 🛧 32 Celiac disease
- 33 Smoking

#### **ENVIRONMENTAL**

- ↑ 34 Expired insulin
- \$\ldot\ \frace\$ \quad \text{35} \quad \text{Inaccurate BG reading}
- \$\ldot\ \frac{\ldot\}{\ldot\} \quad 36 Outside temperature
  - 🕂 37 Sunburn
  - ? 38 Altitude

#### **BEHAVIOR & DECISIONS**

- 39 More frequent BG checks
- 40 Default options and choices
- ◆ ↑ 41 Decision-making biases
- 42 Family and social pressures



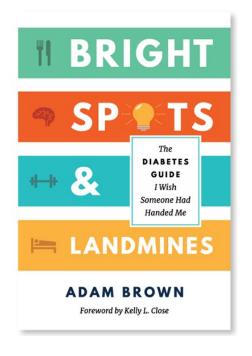
#### Factors that affect Blood Glucose

As a person with diabetes, I always fall into the trap of thinking I'm at fault for out-of-range blood sugars.

....

But after 18 years living with diabetes and 70,000 hours wearing continuous glucose monitoring (CGM), I've learned that there are all kinds of factors that affect blood glucose (BG), many of which are impossible to control, remember, or even measure.









### **Avoiding Hypoglycaemia and Hyperglycaemia in Type 1 Diabetes**

If it weren't for hypoglycaemia, we could give as much insulin as we want!

### 4. Self Management Skills





## OzDAFNE? Dose Adjustment for Normal Eating



- 5 day group program for 6-8 adults with type 1 diabetes using insulin pens (also OzDAFNE Pump)
- Structured, comprehensive self-management education
  - Insulin assessment and adjustment
  - Counting carbohydrates
  - Managing challenging situations such as illness, hypoglycaemia, physical activity, alcohol and eating out
  - Sick day rules
- Run by OzDAFNE CDE (RN) and dietitian (APD)
- Follow up 6 weeks, 6 months and 12 months





Type 1 Diabetes: Less guesswork. More freedom. Better health.

**DAFNE Study Group, Oct 2002, BMJ** 

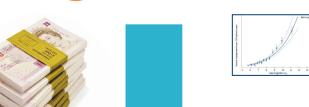
### **Outcomes of DAFNE**

Papers

Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial

DAFNE Study Group





64

HbA1c lowered 0.4%

ther a course teaching atment combining distant ment can improve both it y of life in type I disbett i with participants either tely (immediate DAFNE) trols and attending is months later.

English health districts.

Participants 169 adults with type 1 diabetes and moderate or poor glycaemic control.

> Glycated haemoglobin mia, impact of diabetes on

is, was significantly better in a (mean 8.4%) than in 8.4%) (a=0.1, P < 0.0001). dietary freedom was mmediate DAFNE patients (E=5.4, each of diabetes on overall

glycaemic control. However, the intensive approx used in the trial involved frequent outpatient visits we close supervision of insulin dose adjustment and I not been incorporated into general diabetes practi-The increased risk of severe hypoglycaemia in t diabetes control and complications trial may unacceptable, and the staffing ratio of around the patients to each healthcare professional in beyond to some of most healthcare professional in beyond to

Other reasons why intensified treatment has not been widely adopted may exist. Clinicians usually propose treatment good committed from the medical perspective, for whereas patient of the medical outcomes, whereas patient whereas patient daily certain the same of the committee of the committee

iment Northern Ger at an Hospita, Her ent is Road Sheffer so 7AU prove shellerill d may thefferd.ac.uk

hejine 2002,529.748

QoL

Treatment satisfaction

d ma

insulin doses Need for

**CSII** 



Risk of DKA reduced by 61%



Risk of severe hypoglycaemia reduced by 72%



Anxiety & depression reduced to background



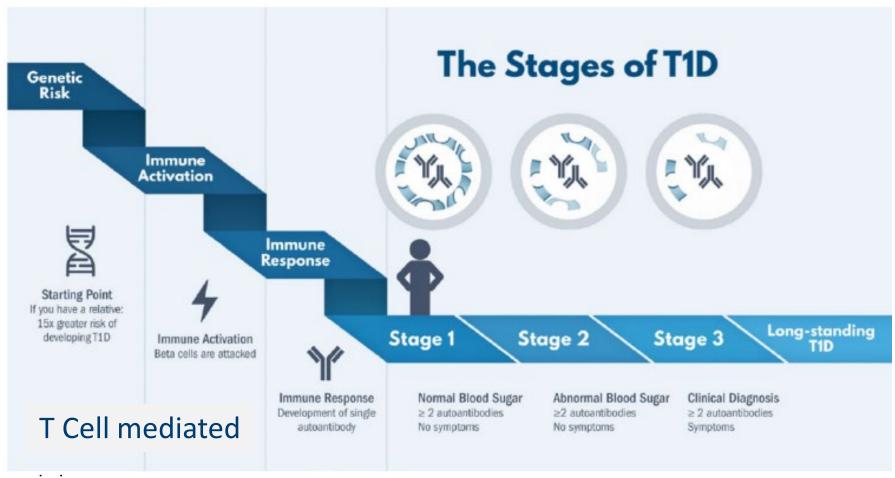
Hopkins et al, Diabetes Care, 2012 Elliott et al., Diab Med 2014



# **Emerging issues in Type 1 Diabetes**

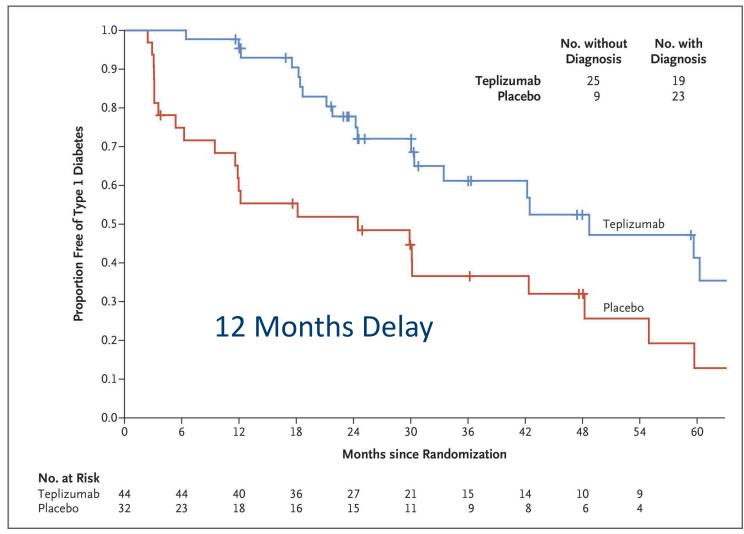


### Stages of Type 1a diabetes in children and adolescents





### **Disease Modifying Agents in Type 1 Diabetes**



# Teplizumab approval for type 1 diabetes in the USA

On Nov 17, 2022, the US Food and Drug Administration (FDA) approved teplizumab as the first disease-modifying therapy in type 1 diabetes. The approval of teplizumab to delay the onset of stage 3 type 1 diabetes in adults and children aged 8 years and older is the culmination of nearly 20 years of investigation and clinical trials of anti-CD3-based therapies. The

Effects of Teplizumab on Development of Stage 3 Type 1 Diabetes







## The loss of Levemir-when no CSII

Important information from Novo Nordisk



Important Advance Notice: Upcoming Changes to Novo Nordisk® Insulin Portfolio

ACTIVE SUBSTANCE	BRAND NAME	PRESENTATIONS TO BE DISCONTINUED	NOVO NORDISK® PRESENTATIONS REMAINING AVAILABLE	
Insulin detemir	Levemir®	FlexPen® & Penfill® (PBS listed)	December 2026	No other product presentation of Levemir® will be available.

**DIABETIC**Medicine

DOI: 10.1111/dme.12806

#### **Research: Educational and Psychological Issues**

Twice- rather than once-daily basal insulin is associated with better glycaemic control in Type 1 diabetes mellitus 12 months after skills-based structured education in insulin self-management

H. E. Hopkinson<sup>1</sup>, R. M. Jacques<sup>2</sup>, K. J. Gardner<sup>3</sup>, S. A. Amiel<sup>4</sup> and P. Mansell<sup>5</sup>

New Victoria Hospital, Glasgow, <sup>2</sup>University of Sheffield, <sup>3</sup>University of Dundee, <sup>4</sup>King's College London and <sup>5</sup>Nottingham University Hospitals NHS Trust, UK

- Some individuals:
- Moving to once/day from bd Levemir, different day and night doses either:
- More insulin in the day->hypos
- Less insulin at night->hyperglycaemia





# Double Diabetes

Obesity in Adults with T1D

3.3% 1985-1990

22.2% 2015-2020

Combined insulin deficiency (type 1) and insulin resistance (type 2).

Features of adult-onset T1DM can overlap with T2DM, given their slow metabolic progression and risk of metabolic syndrome (which occurs in about 40%), so that the distinction between the types of diabetes may be blurred.

Previous clinical criteria e.g. lower age and lower BMI can be poor discriminators as rates of obesity in the overall population increases.

In the previous decade: Obesity rates seem to have stabilised among younger people but have increased over time in adults with T1DM.

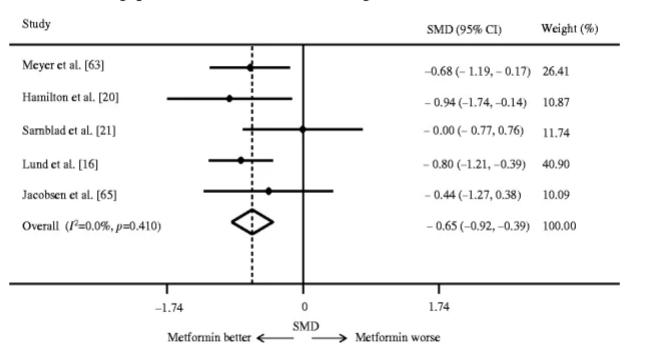




# The use of metformin in type 1 diabetes: a systematic review of efficacy

S. Vella • L. Buetow • P. Royle • S. Livingstone • H. M. Colhoun • J. R. Petrie

### From: The use of metformin in type 1 diabetes: a systematic review of efficacy



2020 review 19 RCTs N = 1540 -2.24 kg

Standardised mean difference of insulin dose between metformin-treated and metformin-free type 1 diabetes patients from five randomised controlled studies, including the largest study to date [16] (see text for equivalent insulin dose units)



# RCT SGLT2i and Type 1 diabetes

	Pooled analysis of DEPICT-1 and DEPICT-2 studies <sup>78</sup>			Phase 3 trial <sup>79</sup> (n=175)	Pooled analysis of Tandem1 <sup>80</sup> and Tandem2 <sup>81</sup> (n=1575)		
	Dapagliflozin 5 mg/day (n=548)*	Dapagliflozin 10 mg/day (n=566)	Placebo	Ipragliflozin 50 mg/day	Sotagliflozin 200 mg/day	Sotagliflozin 400 mg/day	Placebo
Effect on bodyweight	-3·11% (-3·61 to -2·62)	-3·71% (-4·20 to -3·22)	NA	-2·87 kg (-3·58 to -2·16)	-2·17% (-2·54 to -1·80)	-3·02% (-3·39 to -2·65)	NA
Effect on HbA <sub>1c</sub>	-0·41% (-0·48 to -0·31)	-0·43% (-0·52 to 0·34)	NA	-0·36% (-0·57 to -0·14)	-0·36% (-0·44 to -0·29)	-0·38% (-0·45 to -0·31)	NA
Effect on insulin dosage	-9·57% (-12·01 to -7·07)	-11·75% (-14·13 to -9·30)	NA	-7·35 IU (-9·09 to -5·61)	7·10 % (SE 1·30); p<0·001 vs placebo at 52 weeks	–10·33 % (SE 1·30); p<0·001 vs placebo at 52 weeks	NA
Adverse events: diabetic ketoacidosis†	2-00%	1.90%	0-60%	No diabetic ketoacidosis reported in either group	2-90 %	3.80 %	0-20 %

Data are mean (95% CI) for comparison with placebo at 24 weeks, unless otherwise stated. Dapagliflozin is an SGLT2 inhibitor approved for use in Europe and Japan. Ipragliflozin is an SGLT2 inhibitor approved for use in Japan. Sotagliflozin is a dual SGLT1/2 inhibitor approved by the European Medicines Agency. NA-not applicable. IU-international units. \*p<0.0001. †Other adverse events were not reported consistently between studies.

#### Table 2: Approved SGLT inhibitors as adjunct therapy in people living with type 1 diabetes

- 78 Phillip M, Mathieu C, Lind M, et al. Long-term efficacy and safety of dapagliflozin in patients with inadequately controlled type 1 diabetes: pooled 52-week outcomes from the DEPICT-1 and -2 studies. Diabetes Obes Metab 2021; 23: 549–60.
- 79 Kaku K, Isaka H, Sakatani T, Toyoshima J. Efficacy and safety of ipragliflozin add-on therapy to insulin in Japanese patients with type 1 diabetes mellitus: a randomized, double-blind, phase 3 trial. Diabetes Obes Metab 2019; 21: 2284–93.
- 80 Rodbard HW, Giaccari A, Lajara R, et al. Sotagliflozin added to optimized insulin therapy leads to HbA1c reduction without weight gain in adults with type 1 diabetes: a pooled analysis of inTandem1 and inTandem2. Diabetes Obes Metab 2020; 22: 2089–96.
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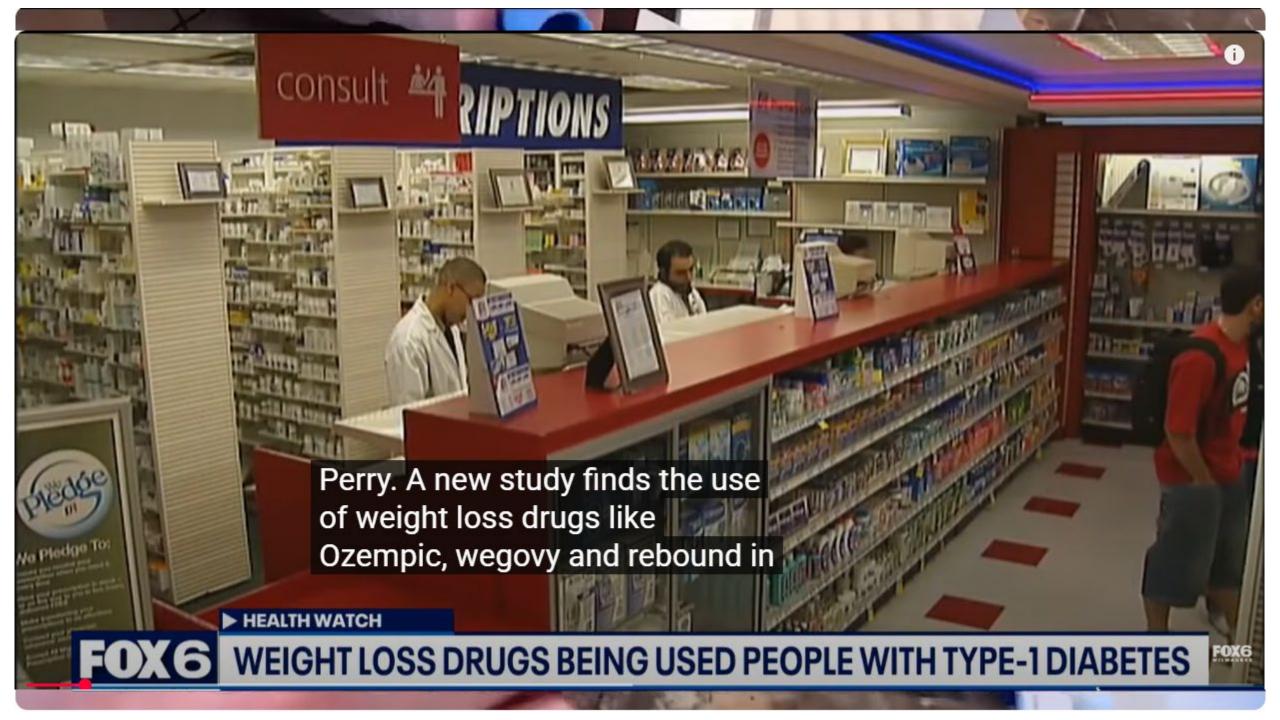
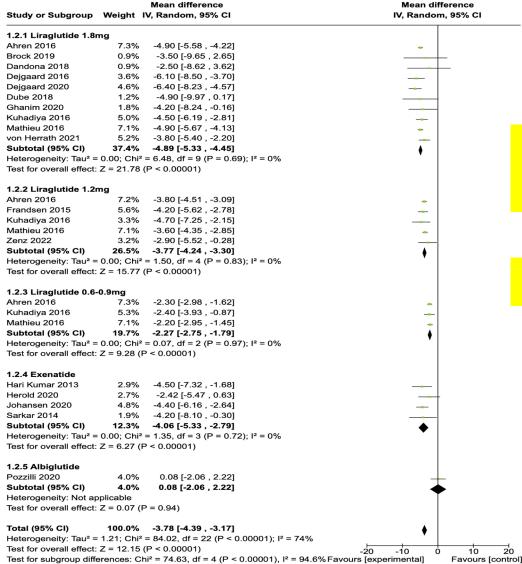




Figure 4. Forest plot for changes in body weight after use of glucagon-like peptide 1 (GLP-1) analogues in patients with T1D





Total daily Insulin -5.84 (-7.51 to -4.16) units

-3.78 (-4.39 to -3.17) kg







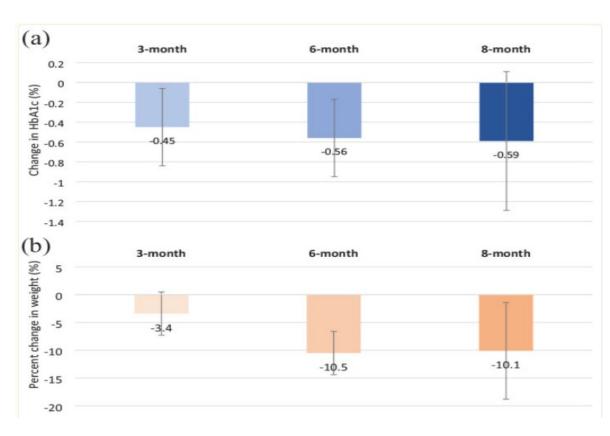
## **GLP1/GIP Agonist (Tirzepatide) and T1DM**

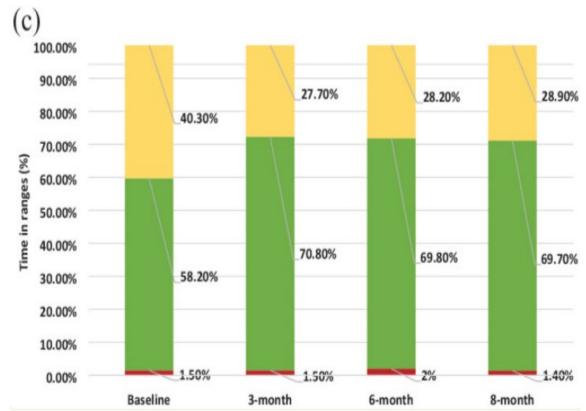
USA-N=26 BMI 36.7 kg/m<sup>2</sup>

42y

HbA1c 7.3% TDD 83.9 IU 73% CSII

96% CGM



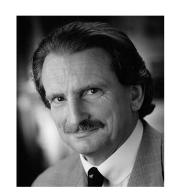




# Conclusions

- Type 1 diabetes requires insulin treatment has 3 jobs
  - Background, cover food, bring glucose down if high
- Unpredictability of glucose makes life hard
- Hypoglycaemia remains a key barrier for achieving near normal glucose levels
- Self management skills crucial Empowered with hope OzDAFNE has RCT evidence of benefit
- Much development in insulins, devices to help management
- Ability to monitor glucose continuously with no or limited finger-sticks is life changing. Everybody
  with type 1 DM has access to CGM technology through the NDSS
- Automated / Closed-loop insulin delivery is now a reality
  - Pump cost is the main barrier vs other HIC
- Emerging issues: T1D prevention, Obesity, Loss of Levemir







# Thank you!

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