

FreeStyle Libre (Flash Glucose Monitoring)

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<http://www.londonscn.nhs.uk/publications/>

The FreeStyle Libre Flash Glucose Monitoring System

Healthcare Professional and
Patient Training - London



What is the FreeStyle Libre?

- A flash-glucose monitoring system, another form of glucose self-monitoring.
- Complements capillary BGL monitoring (aka finger-prick BGL monitoring).
- NOT a replacement for capillary BGL testing.



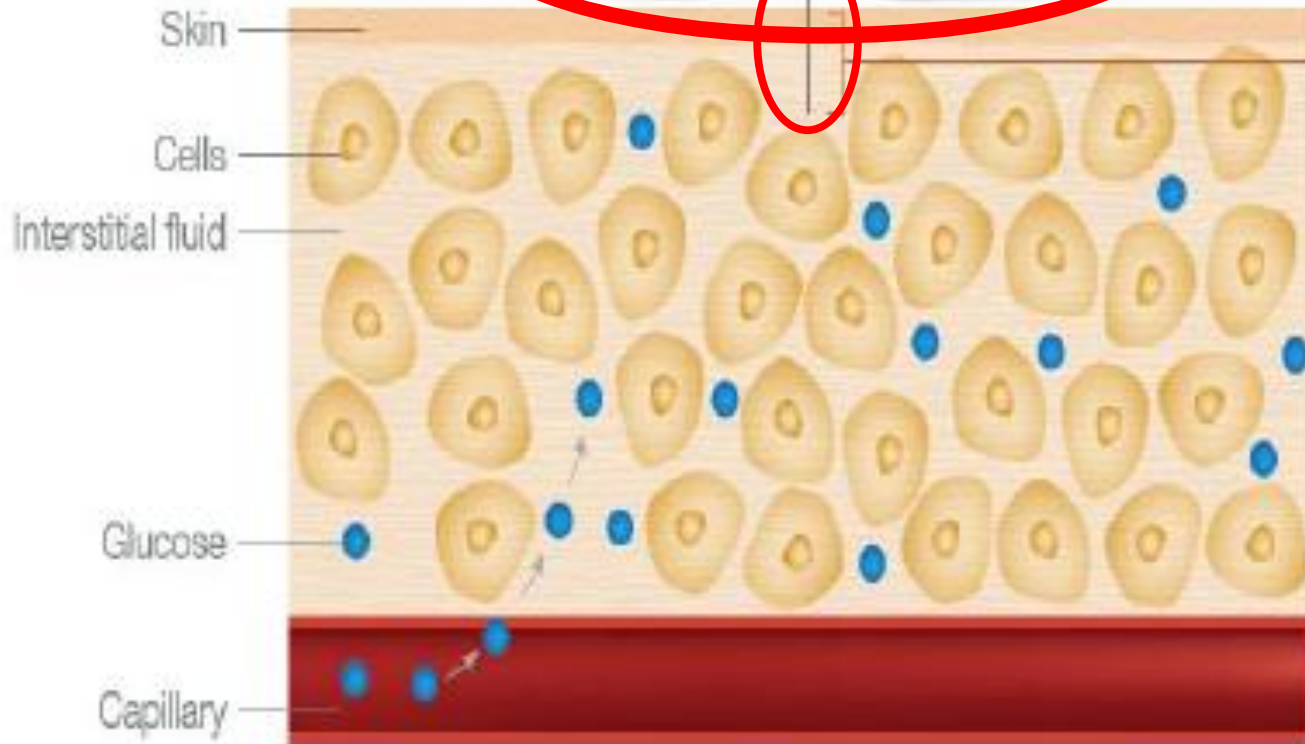
The FreeStyle Libre reader



The FreeStyle Libre sensor



LibreView software*



The sensor filament is less than 0.4 millimetres thick and is inserted 5 millimetres under the skin surface

For illustrative purposes only. Image not drawn to scale.



Glucose Reading Screen

Current
Glucose
reading

Food note

Glucose Trend
Arrow

Direction and
rate of change

Glucose
history







Upload a meter

- 1 Connect meter to your computer
- 2 Choose upload option below



Create 1-Time Report

or



Create Report Linked to Patient

Upload a meter to view and print a report now.
No information will be saved.

- Viewable for 24 hours
- No information saved permanently
- Data cannot be added to a patient profile

Upload a meter and link to a patient to save the
data for viewing at any time.

- Adds data from meter to patient profile
- Saves data for future viewing

Find out more

FreeStyle Libre for glucose monitoring

Medtech innovation briefing

Published: 3 July 2017

nice.org.uk/guidance/mib110

Diabetes UK Consensus Guideline for Flash Glucose Monitoring

“We are lucky to be able to afford the Libre, it has made a huge difference to my daughter’s lifestyle and her diabetes care. It’s a travesty that those who can’t afford it don’t have access to such a **life changing** technology.”

Emma, mother of a child with
Type 1 diabetes

Flash gives an interactive way of managing my diabetes. I can watch things unfolding and react accordingly. I am now trying to avoid the events rather than avoiding recording the events. It takes away the stress and guesswork around testing and management of the condition.”

Mike, who's living with Type 1 diabetes

From: XXXXXXXXXXXX

Sent: 22 November 2017 13:37

To: MORRIS, Luke (HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST)

Subject: Re: Libre Freestyle pick-up

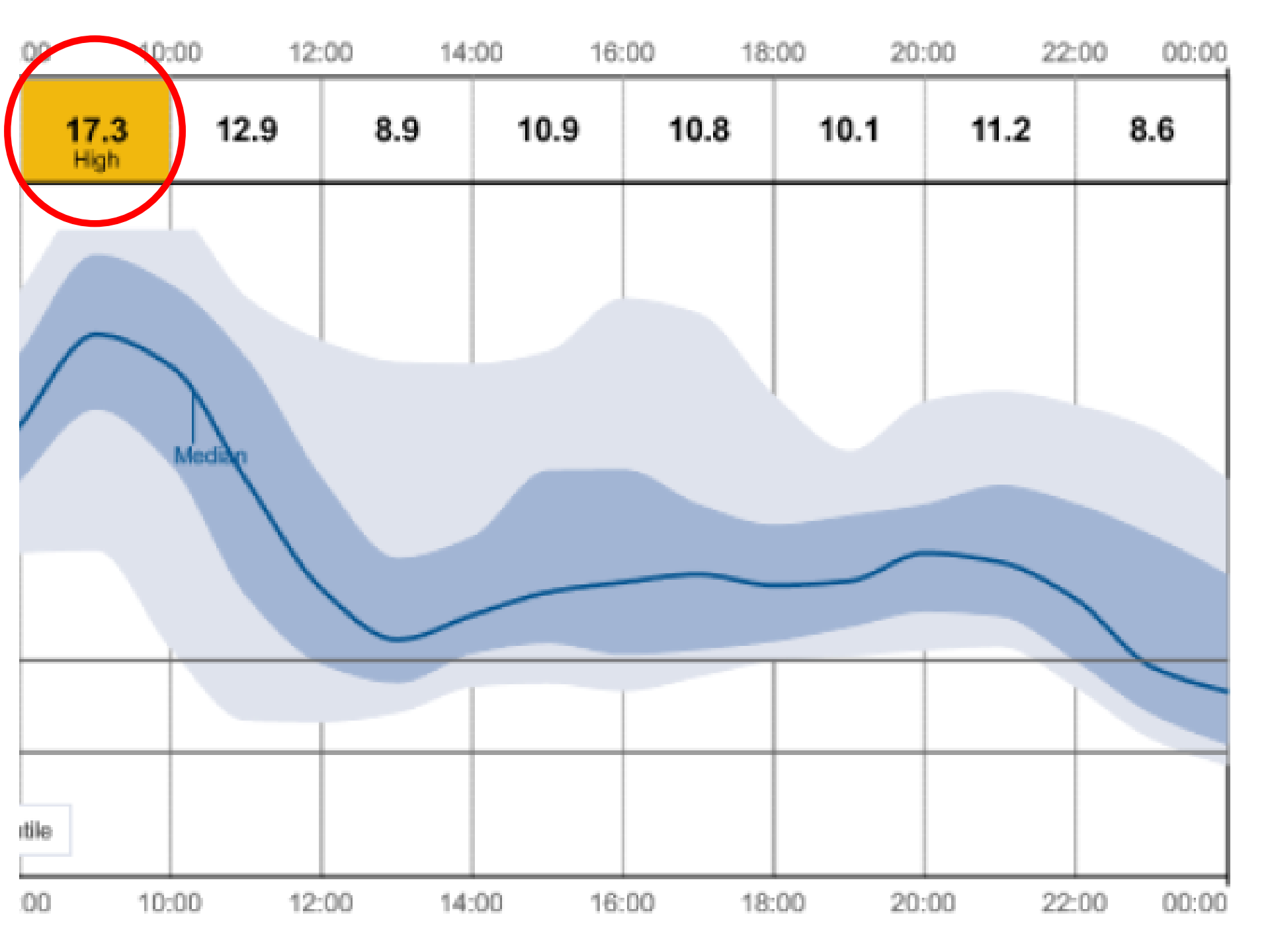
Afternoon Luke,

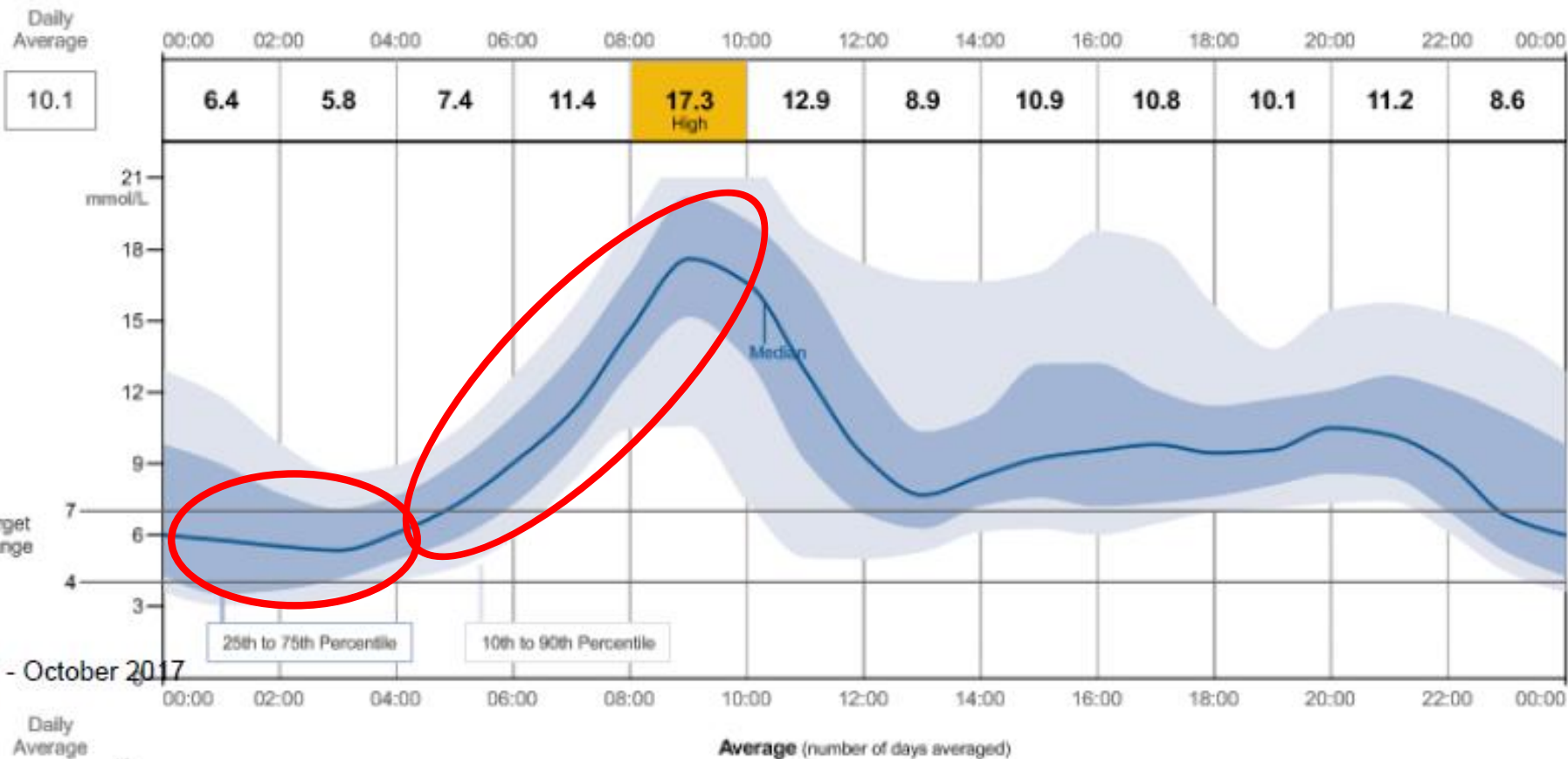
OMG I am in awe of the FreeStyle, its so brilliant, its made me feel in control, more confident and for the first I really feel like I can live with this as opposed to what felt like a life long sentence of drudgery where I was just being swept along.

Its actually made me feel like I can happily bob along.

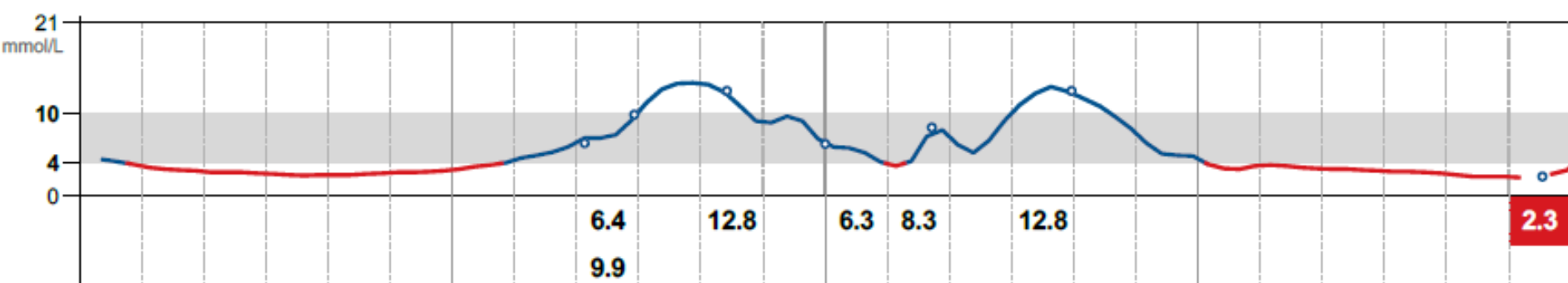
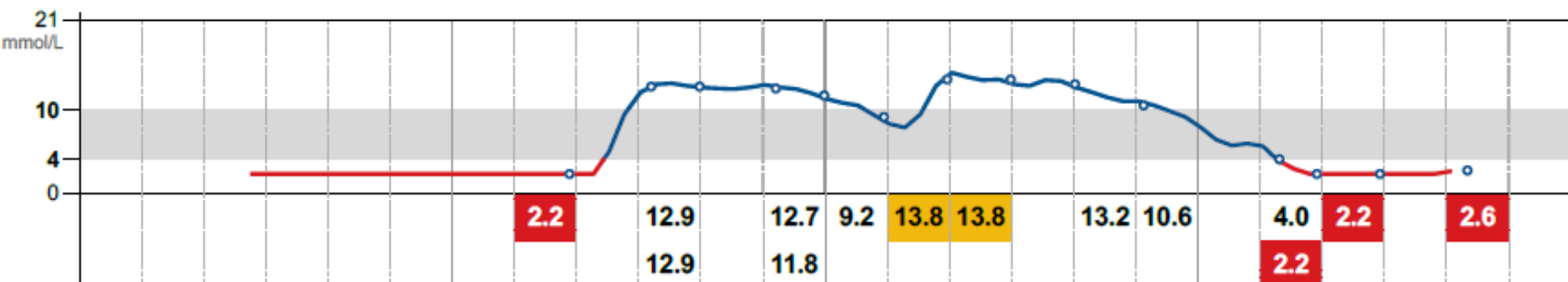
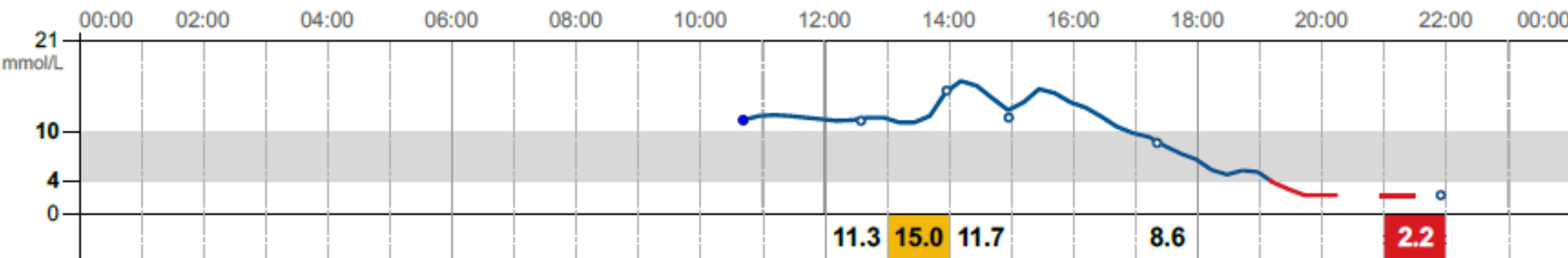
Benefits of FreeStyle Libre

- Greater convenience
- Facilitates monitoring
- Reduces capillary testing
- For assessment & management of:
 - Mealtime insulin dosages
 - Mealtime insulin timing
 - Insulin adjustments for high blood glucose
 - Background insulin dosages
 - Physical Activity
 - Alcohol
 - High fat, high protein, high carb meals.




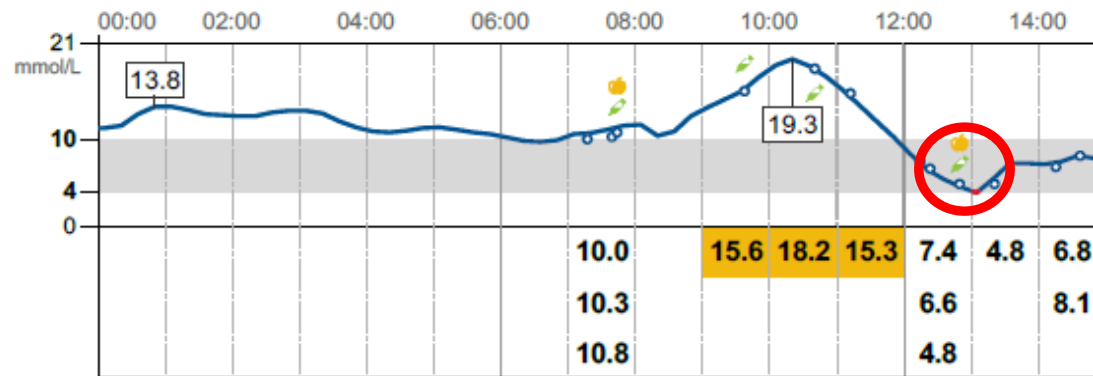


n 1 - October 2017




Tue 1 May

 **Glucose**
mmol/L



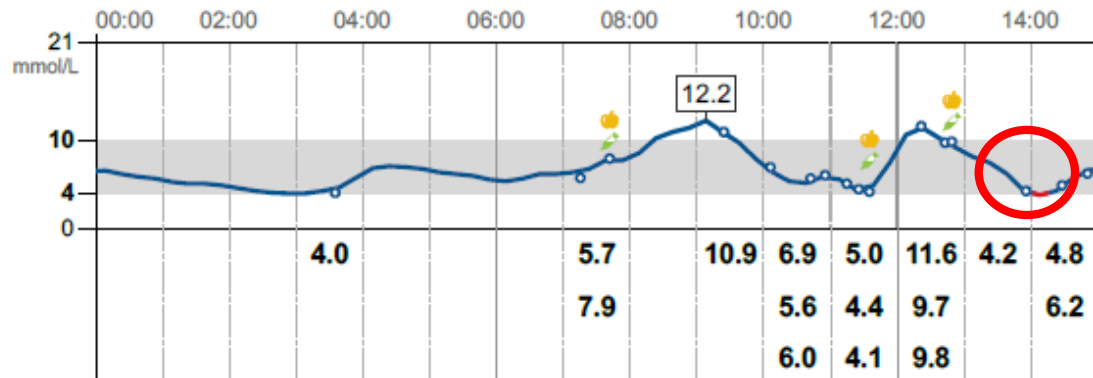
 **Carbs**
grams


 **Rapid-Acting Insulin**
units

 **Long-Acting Insulin**
units


Wed 2 May

 **Glucose**
mmol/L



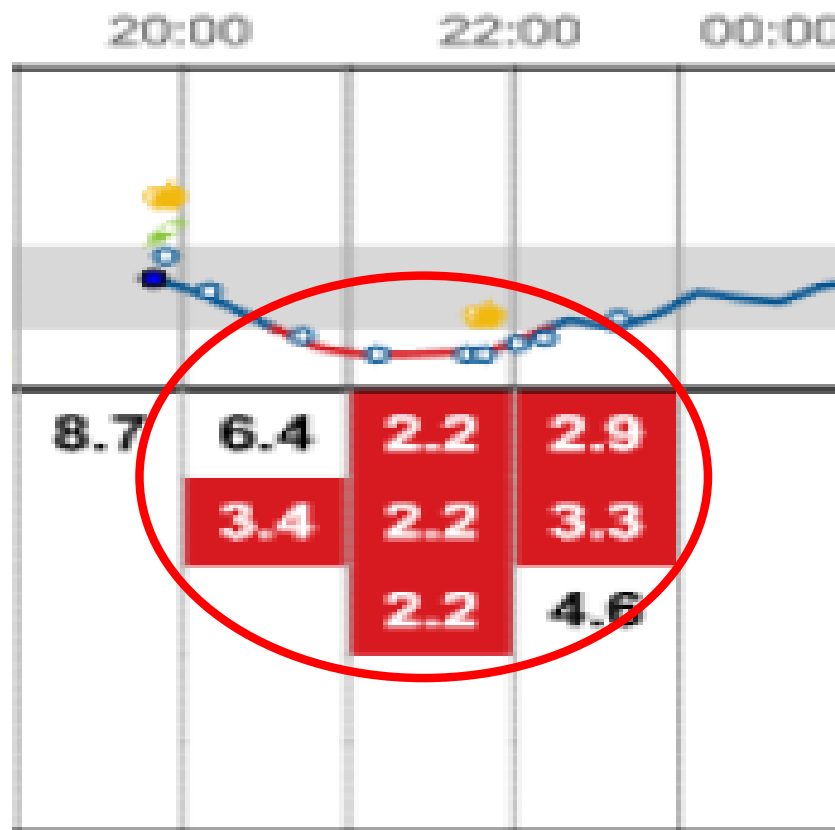
 **Carbs**
grams

 **Rapid-Acting Insulin**
units

 **Long-Acting Insulin**
units

Wed 2 May


 **Glucose**
mmol/L




 **Carbs**
grams

160

30






 **Rapid-Acting Insulin**
units

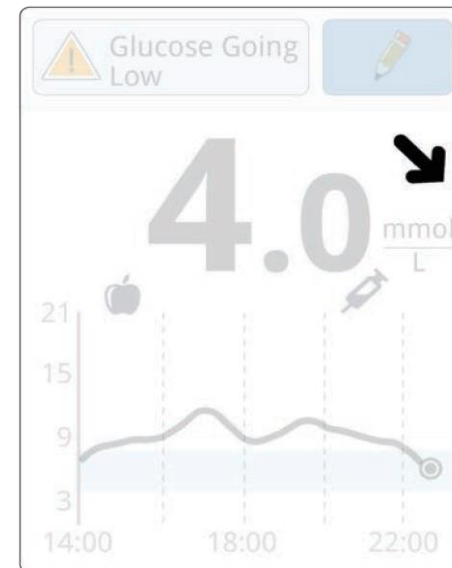
16.0

 **Long-Acting Insulin**
units

20.0

Glucose Trend Arrows

-  Glucose has **risen quickly**,
by $>6\text{mmol/L}$ per hour
-  Glucose has **risen**,
 $3.6 - 6\text{mmol/L}$ per hour
-  Glucose has **changed slowly**,
 $0 - 3.6\text{mmol/L}$ per hour
-  Glucose has **fallen quickly**,
 $3.6 - 6\text{mmol/L}$ per hour
-  Glucose has **fallen quickly**,
by $>6\text{mmol/L}$ per hour



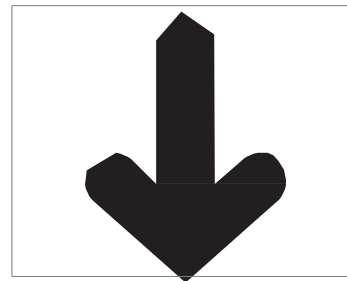
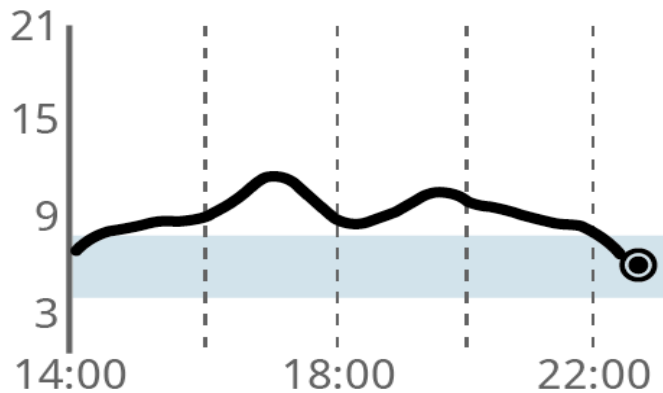
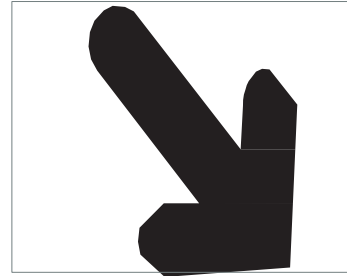
Glucose
Trend
Arrow

Indicates
the recent
direction

Glucose Reading
Screen

Using glucose trend arrows to anticipate hypos

6.2 $\frac{\text{mmol}}{\text{L}}$

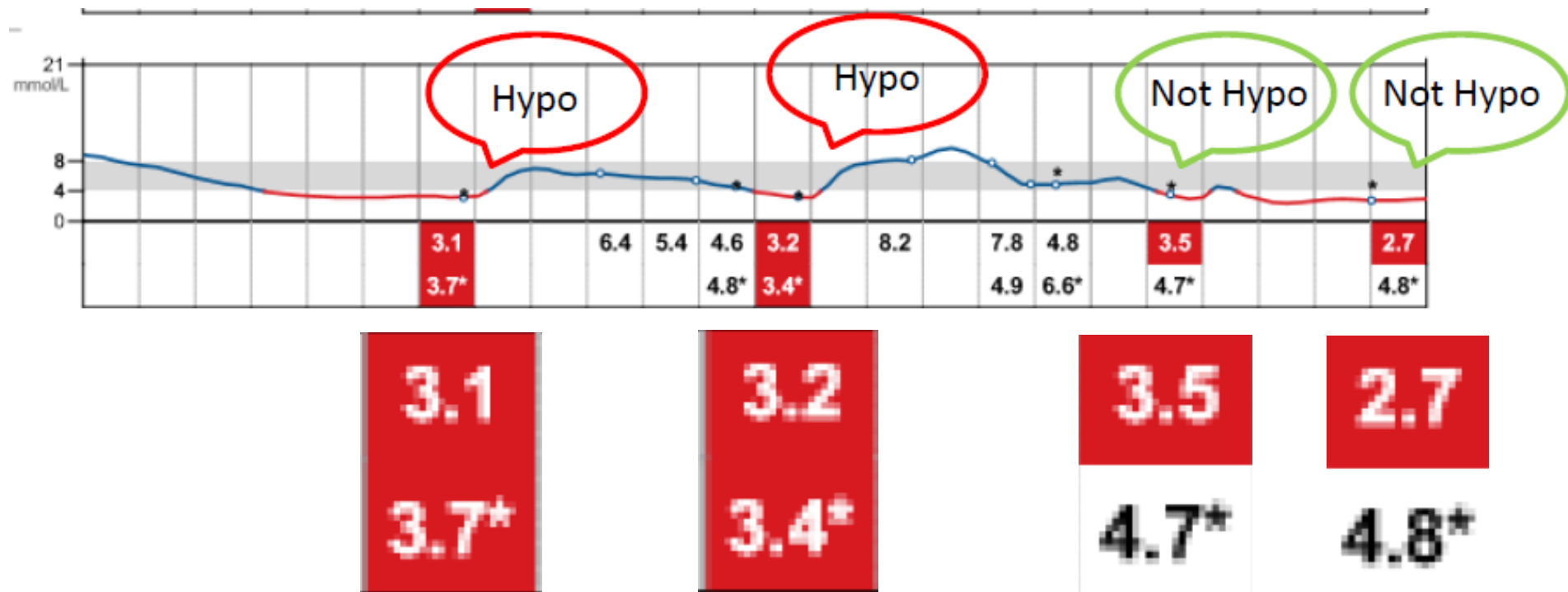


Savi



.. ?

Limitations: Reduced accuracy & delay



Limitations: No low glucose alarm

London Procurement Partnership (2018),
NICE DG21, (2016):

Choose CGM with an alarm for:

- Impaired awareness of hypos
- A history of Severe Hypoglycaemia
- Frequent asymptomatic episodes.

When is capillary BGL testing still required?

- 1) With rapidly changing glucose levels $\uparrow\downarrow$
- 2) If flash glucose readings show hypoglycaemia or impending hypoglycaemia.
- 3) When symptoms do not match the flash glucose readings.
- 4) To meet the DVLA requirements.
- 5) Insulin bolus advisor calculators (eg Pumps)

Are capillary BGL tests still required?

Secure | <https://www.freestylelibre.co.uk/libre/>

WHY PRICK WHEN YOU CAN SCAN?¹

The FreeStyle Libre flash glucose monitoring system is designed to liberate patients from the hassles of glucose monitoring.



Sensor applicator



Sensor pack



Sensor



Clinical waste disposal



Clinical waste disposal



Non-clinical waste disposal



**household
waste**

Libre on prescription



London

Clinical Networks



London Procurement Partnership

**Implementation of FreeStyle Libre® prescribing guidance
across the NHS in London**

Core eligibility criteria

- A) Type 1 Diabetes
- B) Under specialist care
- C) MDI or Insulin Pump therapy

PLUS

Meeting one of the three following sub-criteria...

Further eligibility criteria

- 1) Frequent capillary BGL testing
- OR
- 2) Meet eligibility criteria for starting insulin pump therapy
- OR
- 3) Are unable to perform capillary BGL tests

1) High Frequency Testing (HFT)

Can user SAFELY reduce strips by $\geq 8x/d$?



< 3/12 of HFT. E.g.:
Pre conception / Pregnancy
Elective surgery
Ca treatment

> 6/12 of HFT



Consider why HFT, & would Libre SAFELY ↓ by 8x/d?



If likely to reduce, trial the Libre

2) Eligible for an Insulin Pump start

Disabling hypoglycaemia or high HbA1c with MDI, despite high level care?



≥4x/d SMBG?

Self-management?

Engaged with specialist Diabetes team?

Diabetes education? (Dose adjustments; hypo treatment; hyper treatment etc.)



Consider a FreeStyle Libre trial.

3) Conventional SMBG not possible

Factors* outside the patient's / carer's control



*'True' needle phobia

Relevant physical impairment / ↓ dexterity / disability
e.g. missing limbs, clubbed fingers

Resistant to 3rd party testing, resulting in ↓ monitoring
e.g. LD, Dementia, severe mental illnesses



Consider a FreeStyle Libre trial

1) High Frequency Testing (HFT)

Can user SAFELY reduce strips by $\geq 8x/d$?



< 3/12 of HFT. E.g.:
Pre conception / Pregnancy
Elective surgery
Ca treatment

> 6/12 of HFT



Consider why HFT, & would Libre SAFELY \downarrow by $8x/d$?



If likely to reduce, trial the Libre

Pathway for “HFT” patients

Libre group education (if required)
Patient self fund sensors for first 2/12
Gradual ↓ strips over first 6/52



Specialist team review @ 2/12.
Primary care review @ 6-8/52.
Safe reduction in strips?



YES: Sensors px
(Primary Care). Review annually



NO:
Sensors not px

2) Eligible for an Insulin Pump start

Disabling hypoglycaemia or high HbA1c with MDI, despite high level care?



≥4x/d SMBG?

Self-management?

Engaged with specialist Diabetes team?

Diabetes education? (Dose adjustments; hypo treatment; hyper treatment etc.)



Consider a FreeStyle Libre trial.

Pathway, “Pump Criteria” pts

Libre group education (if required)
Patient self funds sensors for first 2/12



Acute primary care sensor prescription, months 2-6



Secondary care team review outcomes ~3-6/12:
↓ HbA1c by 0.6% / 6.6mmol/mol, AND / OR
↓ severe hypo episodes by 75%



YES: Px Sensors
(Primary Care). Review annually



NO:
Sensors not px

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Consider a FreeStyle Libre trial

Pathway for “Criteria 3” pts

“Appropriate Monitoring” defined & agreed
Libre group education (if required)
Patient self fund sensors for first 2/12



Specialist team OR Primary Care review @ 6-8/52.



Appropriate Monitoring?
Sensors px
(Primary Care). Review annually



No Appropriate
Monitoring?
Sensors not px

FreeStyle Libre

Patient criteria / documentation

Ching Yee Ngan

Medication Review Pharmacist

City and Hackney CCG



City and Hackney
Clinical Commissioning Group

CCG / HUH position

- Prescribing guidance across NHS in London – NHSE London diabetes clinical networks and NHS London Procurement Partnership
- For T1 DM , under specialist care, using multiple daily inj (MDI – 4 or more doses of insulin a day) or insulin pump
- Initiation carried out by local specialist diabetes team
- Prescribing to be transferred to primary care at 2 mths
- Transfer of care documents to be used



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Patient criteria

1. T1DM on MDI or insulin pump who test frequently

- ❖ To safely reduce test strips by at least 8 strips a day (7 in children aged 0-19yrs).
- ❖ Reduction in use of SMBG test strips should be gradual and takes place over the initial 6 wks
- ❖ Self-funders – primary care prescribing data for test strips prior to initiation and 6 mths post initiation to be reviewed



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Patient criteria

2. T1DM with HbA1c >8.5% (69.4mmol/mol) or disabling hypo who would be eligible for insulin pump as per NICE

- ❖ To reduce HbA1c by 0.6% (6.6mmol/mol) and/or reduce severe hypo episodes by 75%
- ❖ Review of outcomes with specialist around 3-6 mths
- ❖ Libre is not a like-for-like alternative to CGM devices or insulin pump
- ❖ Self-funders – sustained improvements to be demonstrated post initiation over a period of 6 mths or more



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Patient criteria

3. T1DM on MDI or insulin pump where conventional monitoring not possible with SMBG testing

- ❖ To ensure appropriate monitoring of glucose levels
- ❖ Primary care or specialist to review and determine continuation of prescribing at 6-8 wks
- ❖ Not appropriate if adequate monitoring in place even if via a third party; not appropriate if compliance issues are the sole barrier
- ❖ Self-funders – Prescribing data for test strips to be reviewed for the previous year (also recent meter download info) with consideration of monitoring prior and post initiation of Libre



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Supply info

- FreeStyle Libre readers (with one sensor) will be supplied to clinics free of charge by Abbott
- The disposable sensor must be replaced every 2 wks
- £35 for one sensor (DT price), ie. £70 per month
- It is recommended that specialist will supply a further 3 sensors (ie. 2 months in total) and then continuation in primary care



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Documentation

- Patient-prescriber agreement / notification form – completed form to be sent to GP once FreeStyle Libre initiated in specialist clinic
- Follow-up or short-term prescribing request form – to be sent to GP by specialist to confirm if GP agrees to prescribe until next clinic appt
- Long-term prescribing request form – to be sent to GP by specialist to confirm if GP agrees to prescribe long-term



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Questions??

- Any Questions??
- Questions after this meeting - please contact your practice support pharmacists or Medicines Management Team



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Diabetes Education Event

Clare Highton
Prevention Clinical Lead



NHS
City and Hackney
Clinical Commissioning Group



Finding a practical
management solution for
T2DM, in primary care

Primary Outcome Results of **DiRECT**

the **D**iabetes **R**emission **C**linical **T**rial

Mike Lean, Roy Taylor, and the DiRECT Team

IDF Abu Dhabi, December 5th 2017, 16.30-16.55



Disclosures

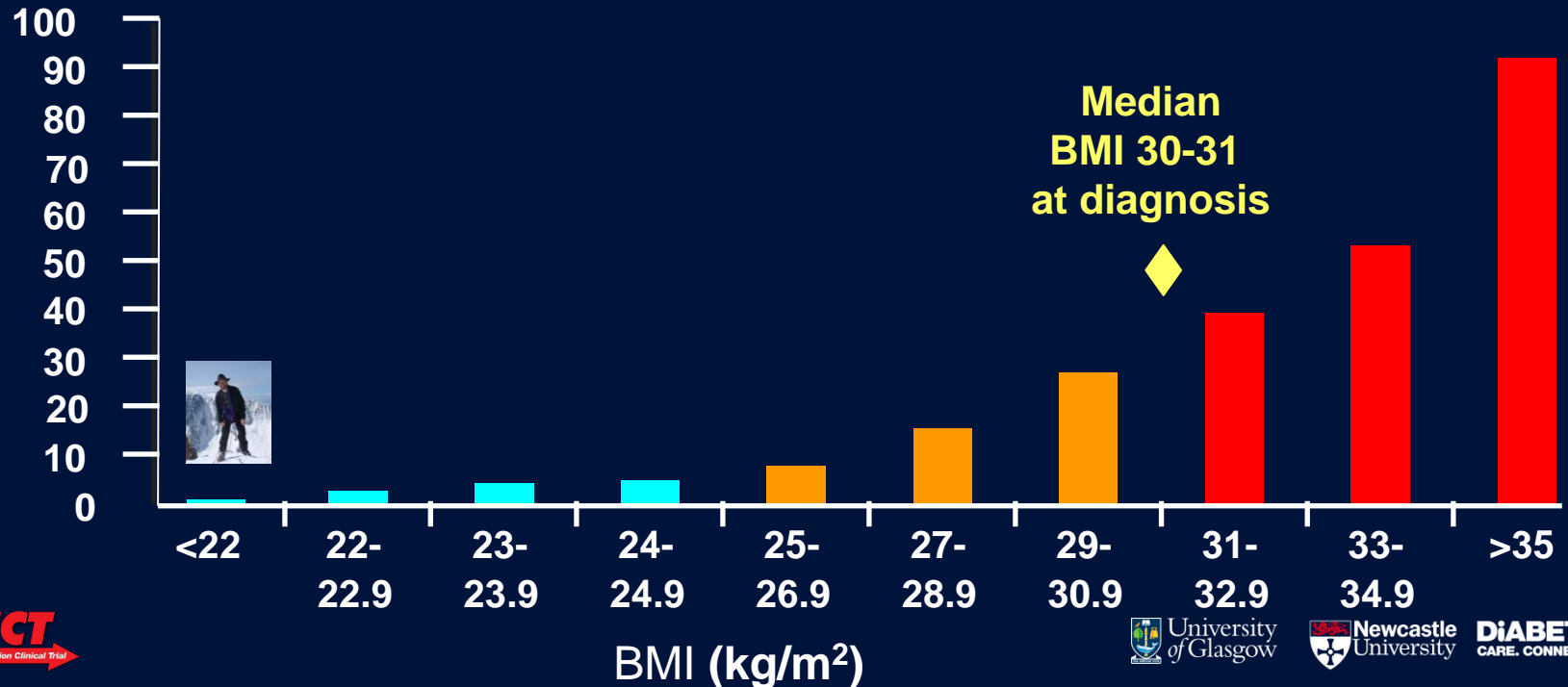
- Departmental research funds, support for conference attendance and fees for Advisory Boards from Novo Nordisk, Orexigen, Janssen, and Cambridge Weight Plan. Medical consultancy fees from Counterweight Ltd.

Weight gain/ obesity is the main driver of T2DM

Colditz GA et al. Ann Int Med, 1995

Adjusted RR

(BMI <22 = referent)



DiRECT: Aim and Design

Aim: To assess whether intensive weight management, within routine primary care, would achieve remission of T2DM

Design: Open-label, cluster-randomised, clinical trial

Randomised by GP practices: stratified for sex and practice size

- **Intervention:**
 - Weight management programme: Target $\geq 15\text{kg}$ weight loss
 - Withdraw all anti-diabetes and antihypertensive medications
 - Plus best practice care, by guidelines
- **Control:** best practice care, by guidelines

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DiRECT Intervention: Counterweight-Plus Protocol

Total Diet Replacement - Counterweight Pro800

- Nutritionally complete (vitamins & minerals)
- 830 kcal: 61%E carbohydrate, 13% fat, 26% protein
- >2.25 litres fluid per day
- Fibre supplement
- **Maintain PA** ~30mins/ day
- **STOP** all anti-diabetes medications
- **STOP** all antihypertensive medications

Screening



Total Diet Replacement



Lean et al, Br J General Practice (2013),

Leslie et al, BMC Family Practice (2016)

DiRECT Intervention: Counterweight-Plus Protocol

Stepped Food Reintroduction

- Add a ~400kcal meal every 2-3 weeks
Step-counters: gradually increase PA

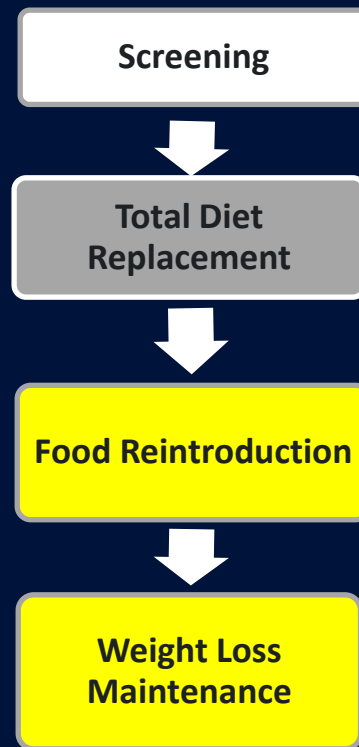
Weight Loss Maintenance

- Food-based diet
- 50%E carbohydrate, 35% fat, 15% protein
- Encourage up to 15,000 steps/day

Relapse Management

(regain >2kg, relapse of diabetes)

- Tool-kit approach: offer orlistat , meal replacement, brief TDR and FR



Lean et al, Br J General Practice (2013),

Leslie et al, BMC Family Practice (2016)

DiRECT: inclusion & exclusion criteria

Inclusion

- Men and women
- Age 20–65 years
- BMI 27–45kg/m²
- T2DM diagnosed within 6 years
- HbA1c ≥ 48 mmol/mol
(≥ 43 mmol/mol on anti-diabetes drugs)
- Signed informed consent

Exclusion

- Insulin treatment, anti-obesity drugs
- Learning difficulties
- Pregnancy or considering pregnancy,
- Weight loss >5kg within 6m, eGFR <30 mls/min, severe or unstable heart failure, known cancer, myocardial infarction within 6m
- Eating disorder/ purging , severe depression, antipsychotic drugs, substance abuse

ITT Primary Outcome Results

1st Co-Primary Outcome: ≥ 15 kg weight loss

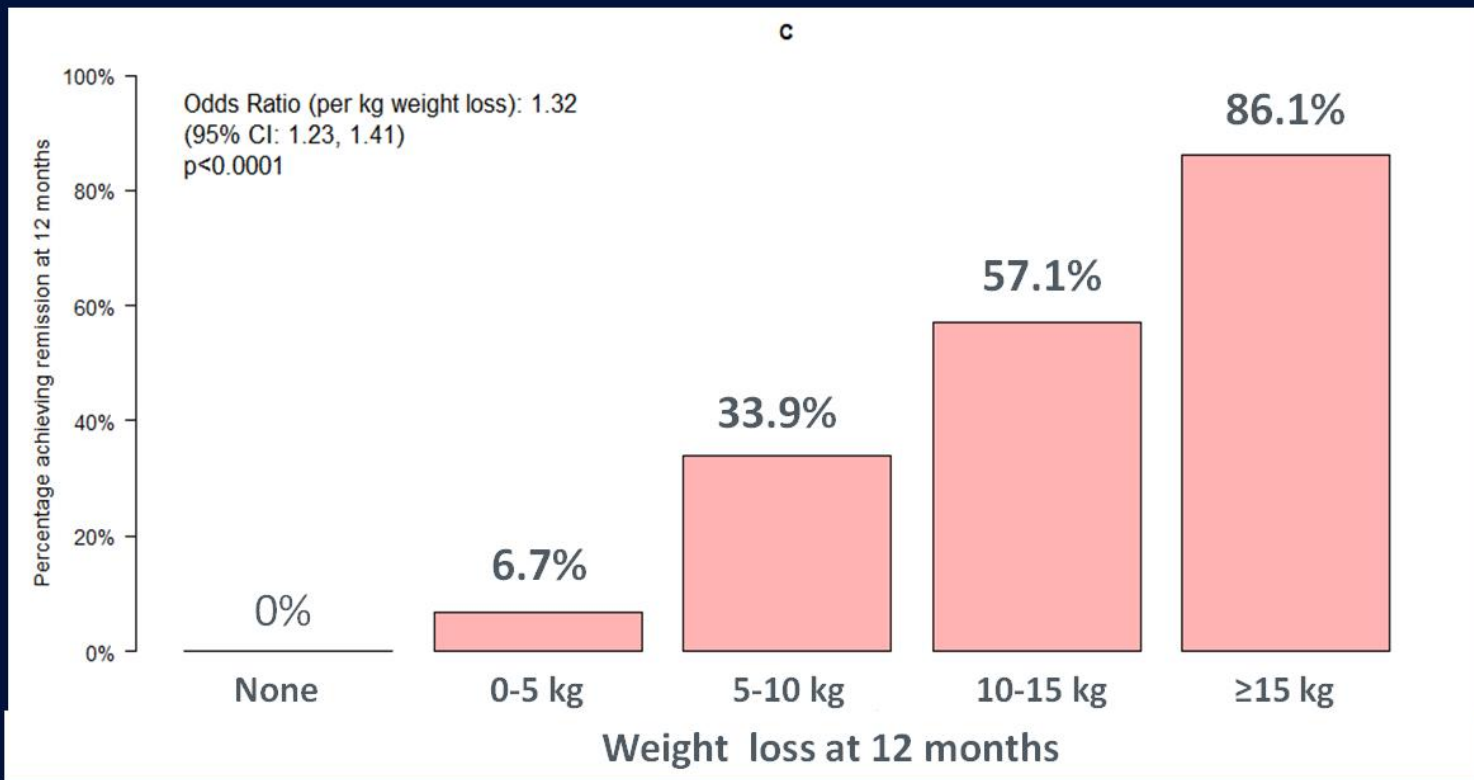
Intervention	36/149 (24%)	$p < 0.0001$
Control	0/149	

2nd Co-Primary Outcome: Remission of diabetes*

Intervention	68/149 (46%)	$p < 0.0001$
Control	6/149 (4%)	

* HbA1c < 48 mmol/mol,
off all anti-diabetes medication for at least 2 months

Remissions by 12m weight loss: entire study population



ITT secondary outcomes: mean changes at 12m

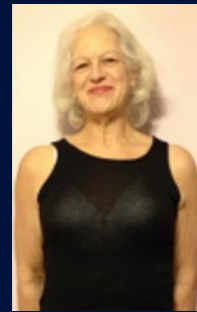
	Intervention	Control	P
Weight (kg)	-10	-1	<0.0001
HbA1c (mmol/mol)	-10	+1	<0.0001
HbA1c (%)	-0.9	+0.1	<0.0001
% on anti-diabetes meds	22%	82%	0.0032
Systolic BP (mm Hg)	-1.3	-1.7	ns
% on antihypertensive meds	32%	61%	<0.0001
Serum Triglycerides (mmol/l)	-0.3	+0.1	<0.0001
Quality of Life (EQ5)	+7.2	-2.9	0.0012

N(%) reporting symptoms (AEs) pre-specified as of interest, **and sought**, during Total Diet Replacement

	TDR phase (12-20 weeks)				Total (n=124)
	Total (n=139)	Mild	Moderate	Severe	
Constipation	65 (46.8)	30 (21.6)	24 (17.3)	11 (7.9)	18 (14.5)
Sensitivity to cold	57 (41.0)	37 (26.6)	12 (8.6)	8 (5.8)	30 (24.2)
Headache	53 (38.1)	31 (22.3)	13 (9.4)	9 (6.5)	15 (12.1)
Dizziness	49 (35.3)	40 (28.8)	7 (5.0)	2 (1.4)	11 (8.9)
Fatigue	45 (32.4)	24 (17.3)	11 (7.9)	10 (7.2)	18 (14.5)
Mood change	35 (25.2)	16 (11.5)	12 (8.6)	7 (5.0)	10 (8.1)
Nausea	25 (18.0)	15 (10.8)	4 (2.9)	6 (4.3)	3 (2.4)
Diarrhoea	23 (16.5)	11 (7.9)	10 (7.2)	2 (1.4)	5 (4.0)
Indigestion	20 (14.4)	15 (10.8)	3 (2.2)	2 (1.4)	4 (3.2)
Hair Loss	19 (13.7)	10 (7.2)	7 (5.0)	2 (1.4)	13 (10.5)
Data reported as N(%)					

DiRECT: Conclusions

- T2DM is a complication of weight gain and excess body fat, and it is not necessarily a permanent condition
- Almost half with early T2DM can achieve remission (73% if $\geq 10\text{kg}$ loss)
- Structured 1^o care weight management welcomed by patients, & staff



BMJ 14/7/18 for an overview of dietary guidelines for Type 2 diabetes

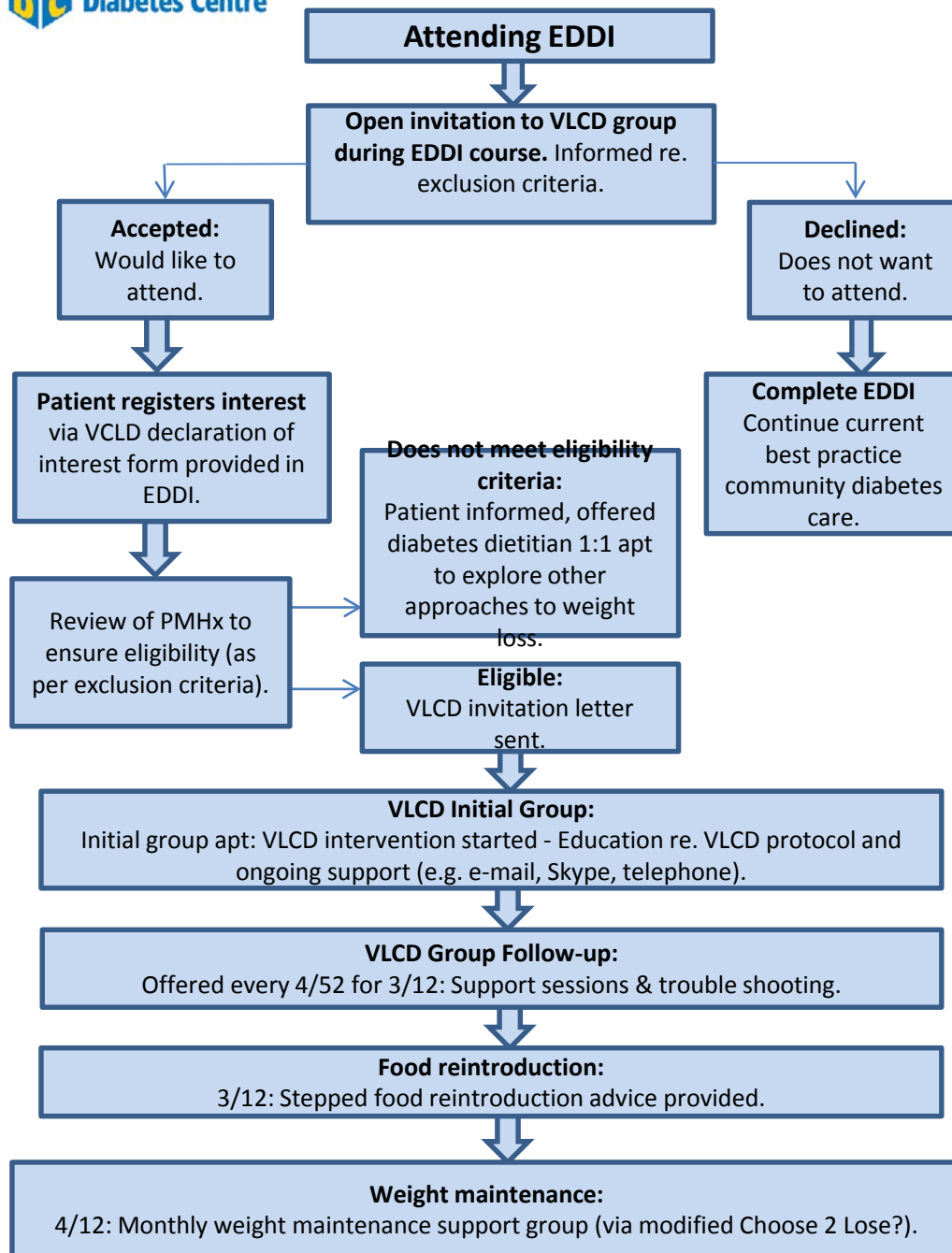
Low calorie energy deficient diets:

- Use stores in liver and pancreas first, get 30% decrease in hepatic fat in 7 days
- Switch back on insulin secretion as B cells in pancreas recover
- Fasting glucose can normalise in 7 days
- Low CHO diet probably not detrimental to lipids
- Low fat or low CHO can be an individual choice, tailored.

Local Pilot

- Patients are asking, publicity for Direct from Diabetes UK, 'The fast fix' on ITV
- Option vs Bariatric Surgery
- ?Different demographic from Tyneside and Borders

- 2 groups - 30 in total
- Highly motivated
- Pay for sachets, £50 per week
- 1 year programme



Implications for Primary Care

- Exclusion criteria
- Support to keep going and maintain afterwards
- Managing meds and frequent testing
- Future if it succeeds?