



**King's Diabetes
Research Group**

KING'S
College
LONDON

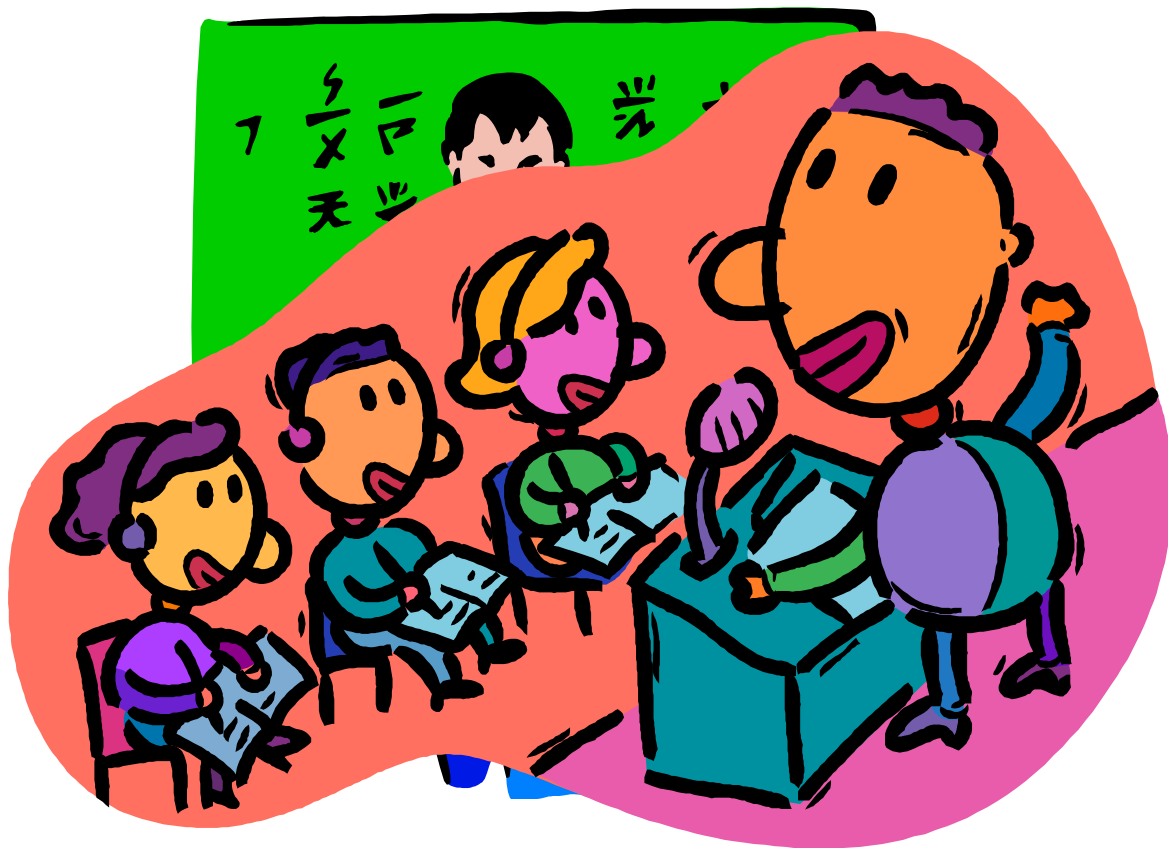
ABCD Spring meeting, 2011

Insulin pump therapy in diabetes:

Stephanie A Amiel

RD Lawrence Professor of Diabetic Medicine

King's College London





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ABCD Spring meeting, 2011

Insulin pump therapy in diabetes: Whys, wherefores, whence and whither?

Stephanie A Amiel

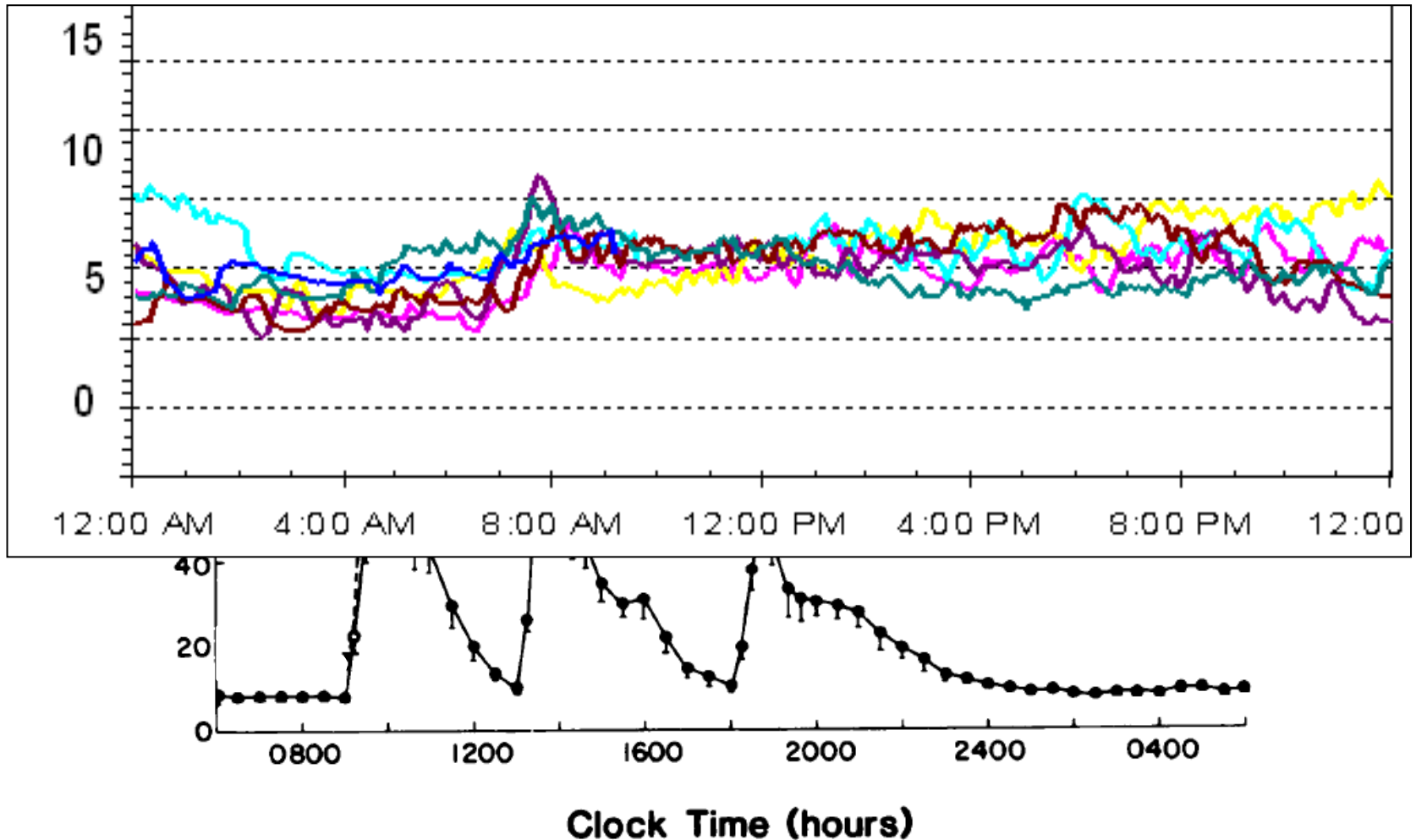
Bob Ryder

Chris Walton

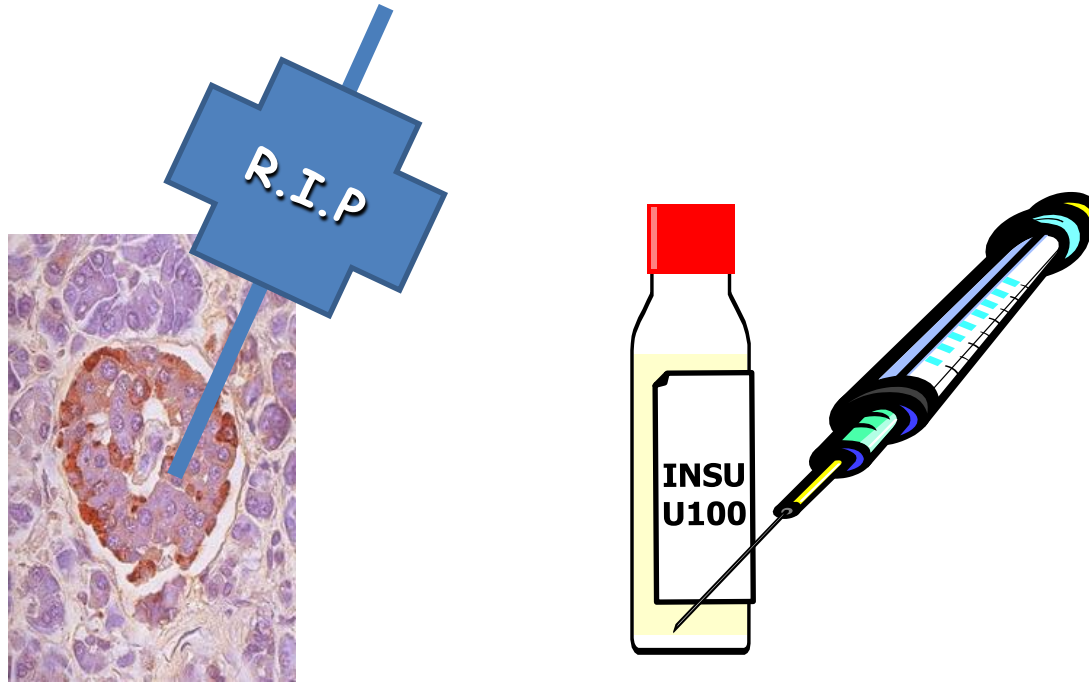
Dinesh Nagi

And other members of ABCD

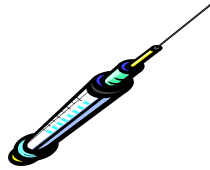
The challenges of insulin Rx



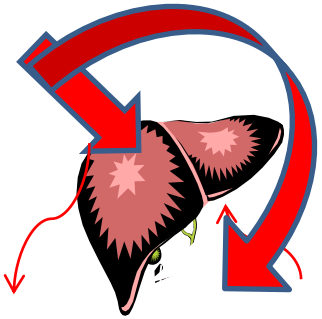
The challenges of insulin Rx



The challenges of insulin Rx



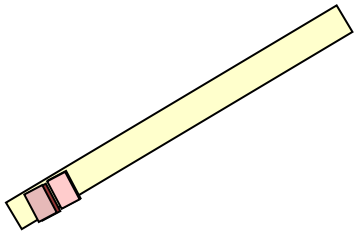
Injectable



Loss of portal:peripheral gradient



Weight gain



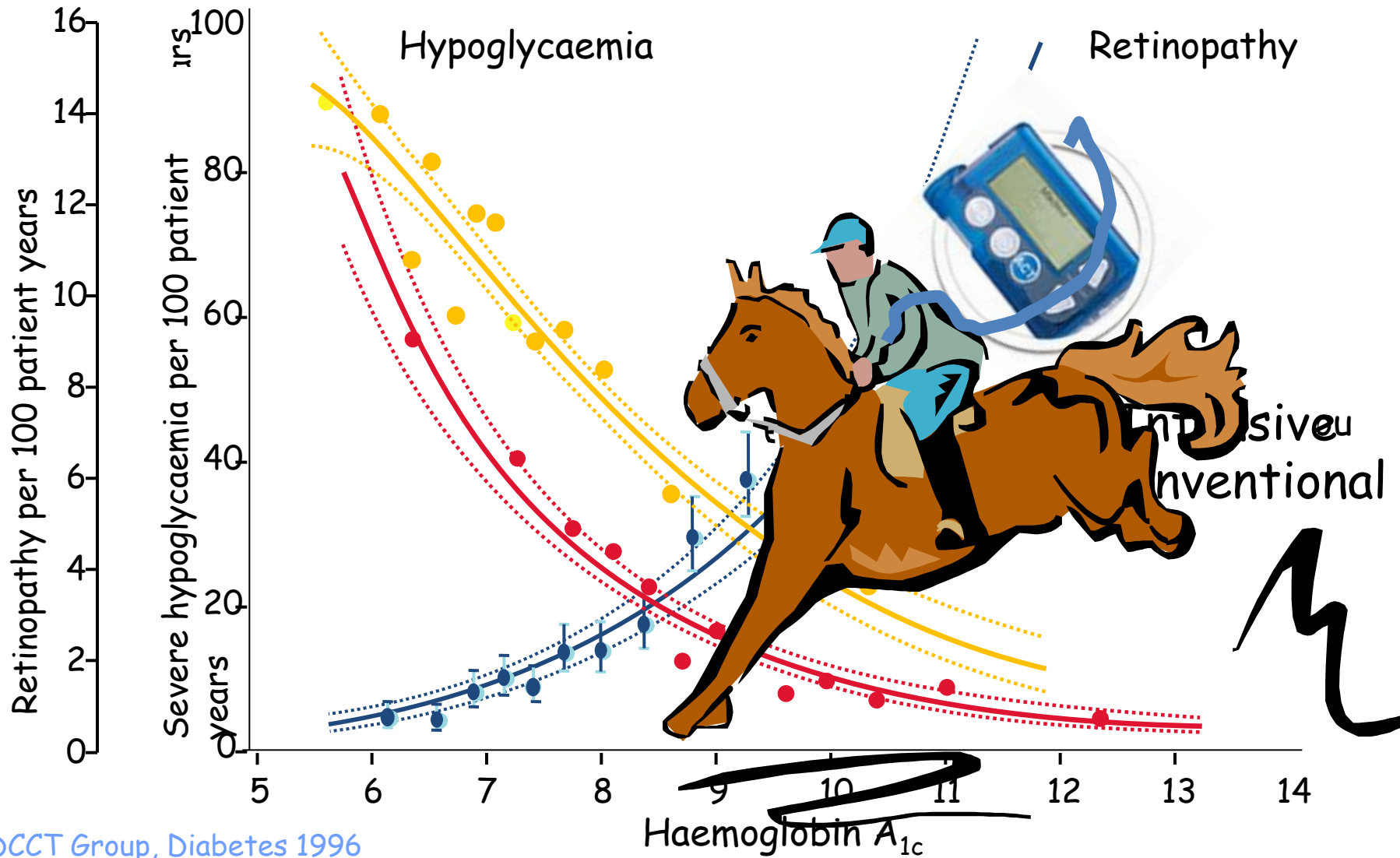
Hypoglycaemia



GLUCOSE RESPONSIVE INSULIN DELIVERY

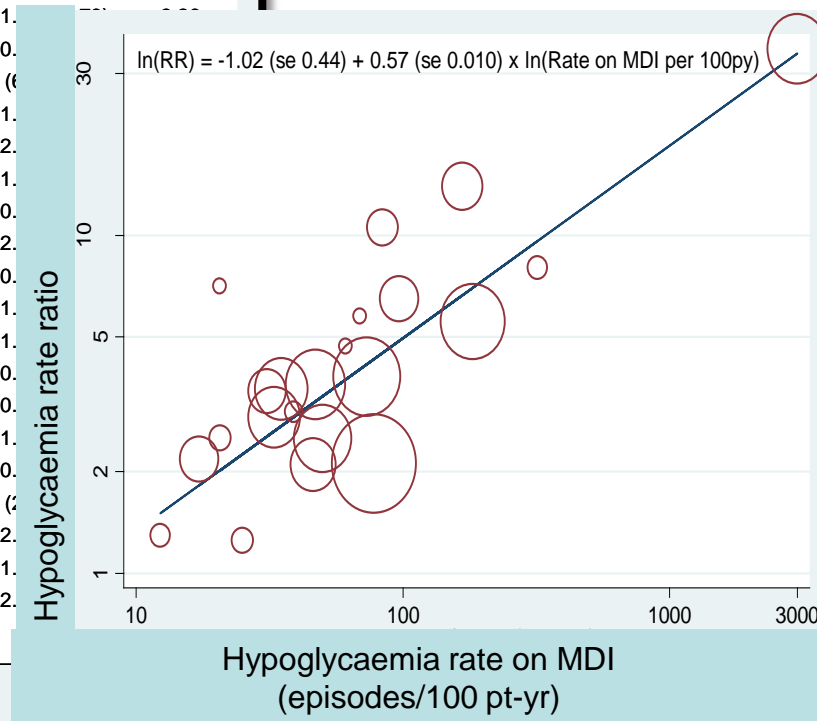
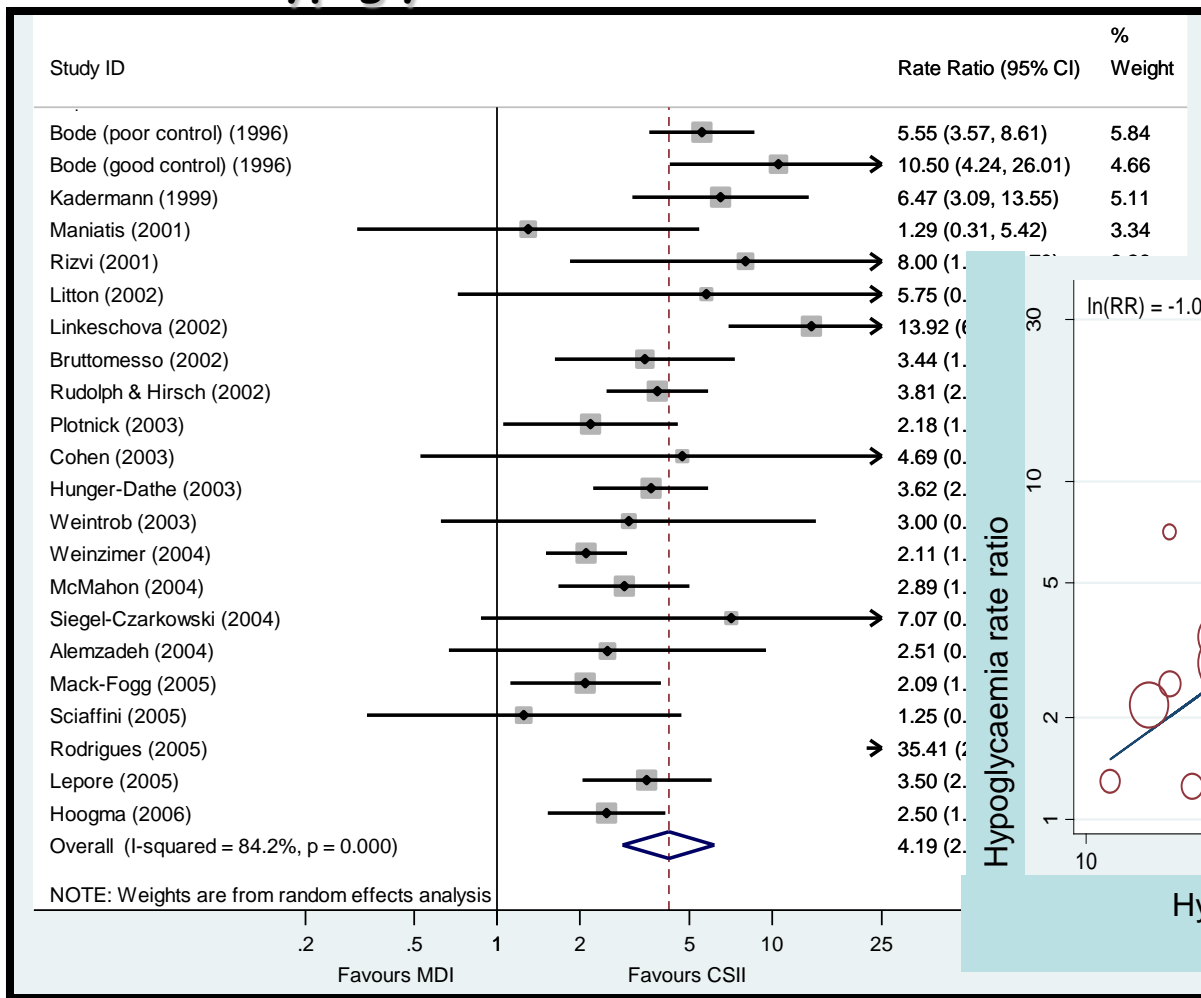


In the beginning....



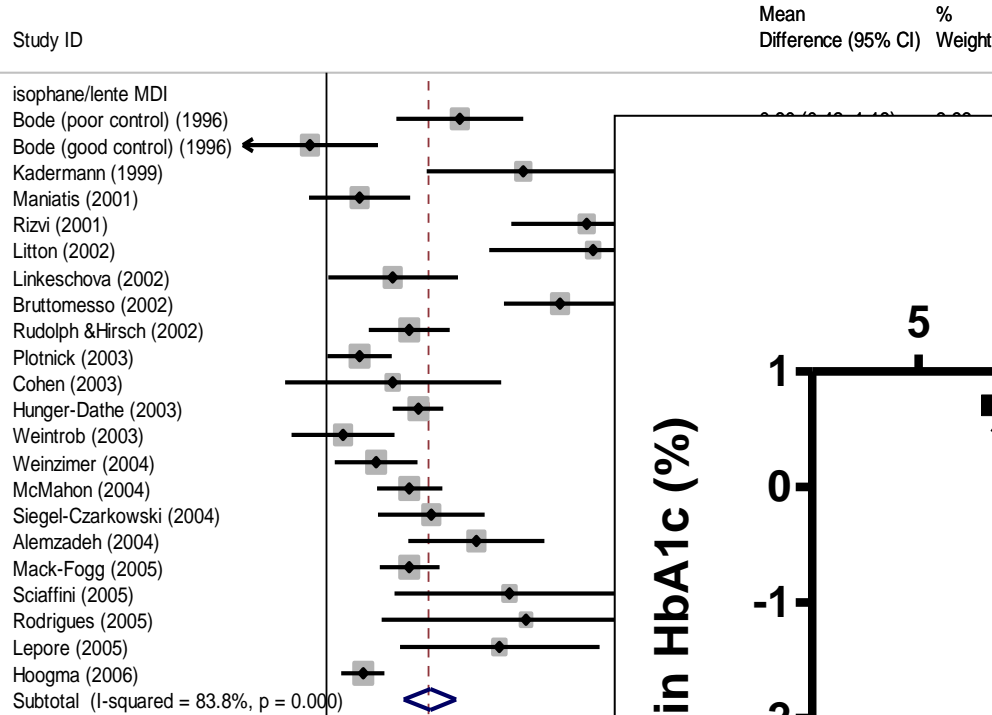
Meta-analysis of MDI vs CSII:

Hypoglycaemia rate ratio

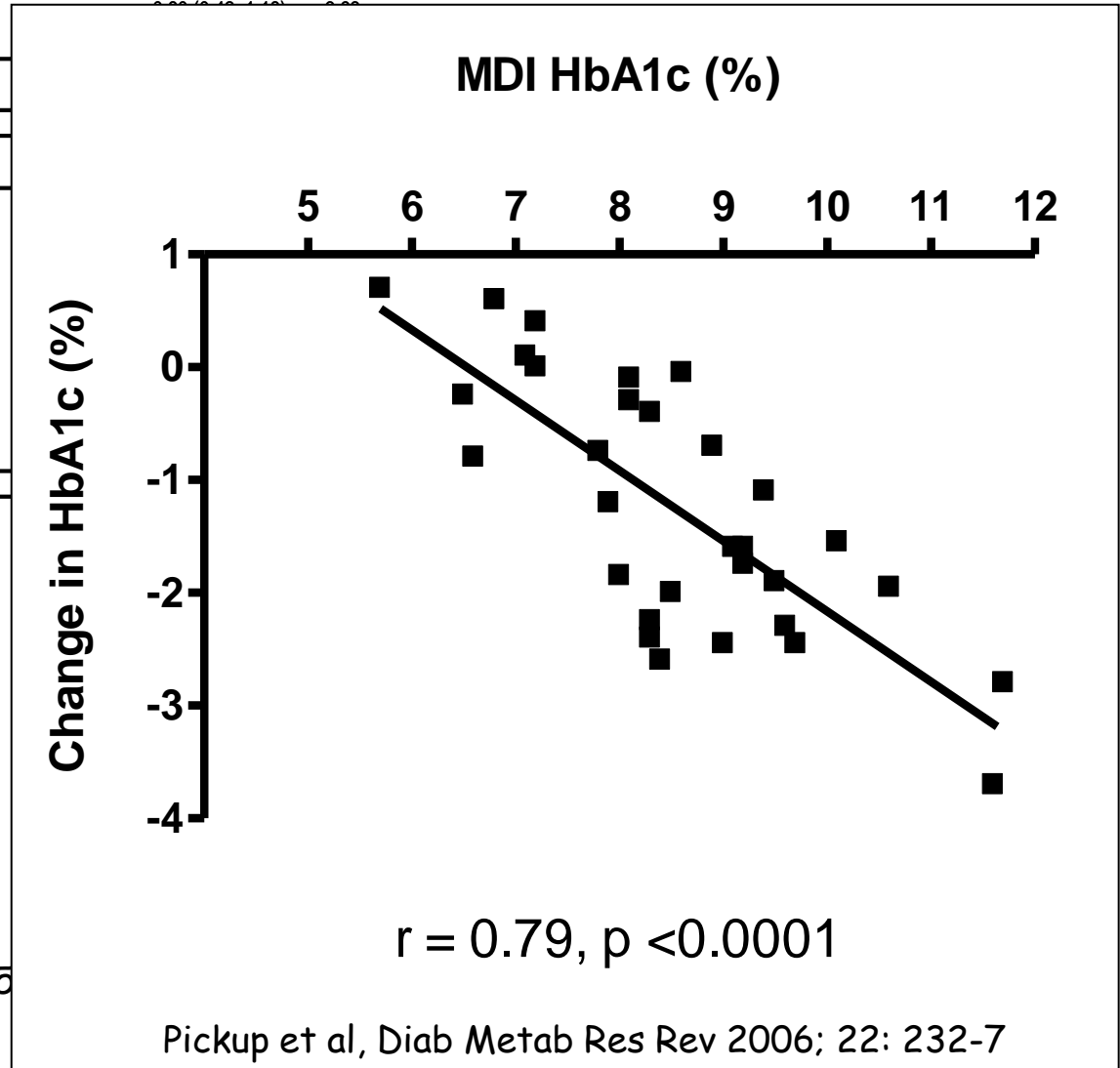


Rate ratio 4.19 [95% CI 2.86 to 6.13]

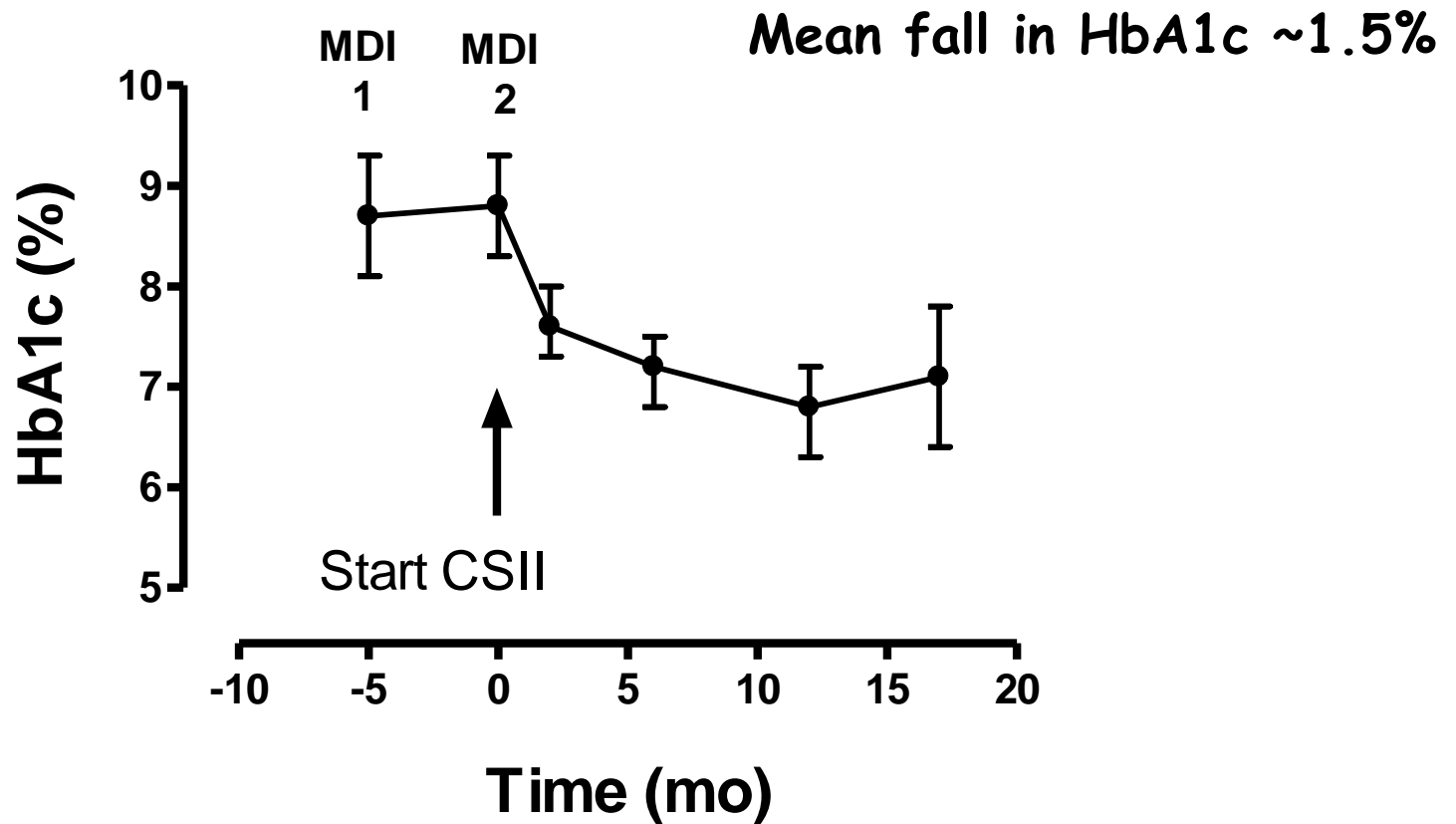
Control of hyperglycaemia



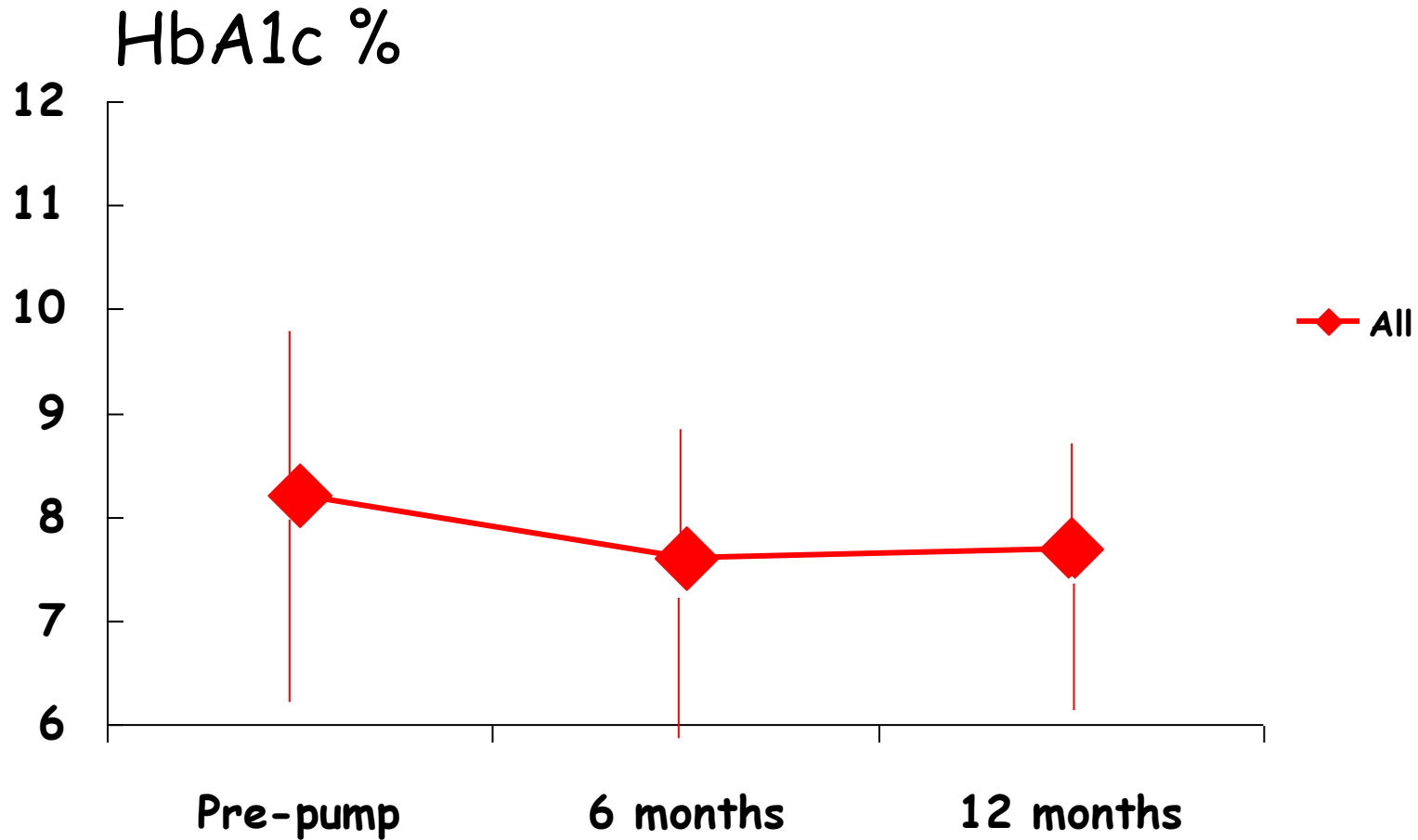
Fall in HbA1c ~ 0.5%



CSII in hypoglycaemia-prone

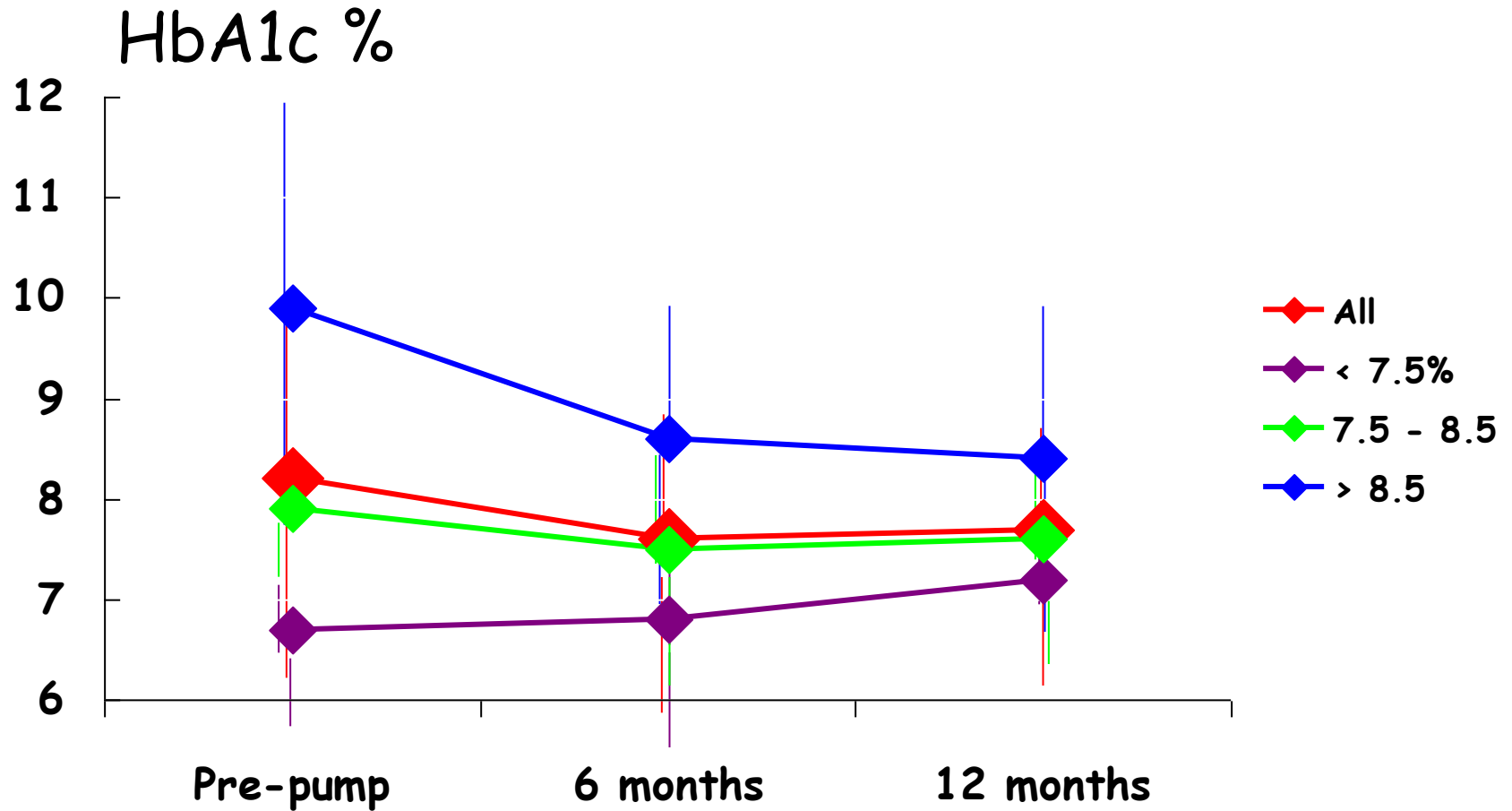


KCH pump clinic audit



Green, Rogers and Amiel, clinical audit data

KCH pump clinic audit

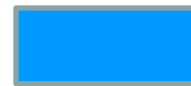


Use of CSII in diabetic Pregnancy



Unpublished data showing similar diabetes control in patients converted to pump in pregnancy to patients Using pumps prior to pregnancy, or patients in good control on MDI

No adverse effect of starting CSII in pregnancy



HbA1c < 7.5% (all)



CSII started in pregnancy

Unpublished data showing no significant differences in neonatal outcomes in patients started on CSII in pregnancy compared to those in good control pre- and through pregnancy on CSII and MDI

Neonatal hypoglycaemia

- Unpublished data from Dr Hammond's ^{p < 0.05}
- Diabetic pregnancy service showing ^{p < 0.05} reduced neonatal hypoglycaemia and better maternal glycaemia in patients using pump in pregnancy

NICE on CSII 2008

Consider CSII if

- attempts to achieve target HbA1c with MDI → “disabling hypoglycaemia”
- HbA1c \geq 8.5% on MDI, despite “high level of care”
- Children < 12 yrs
- Not for Type 2

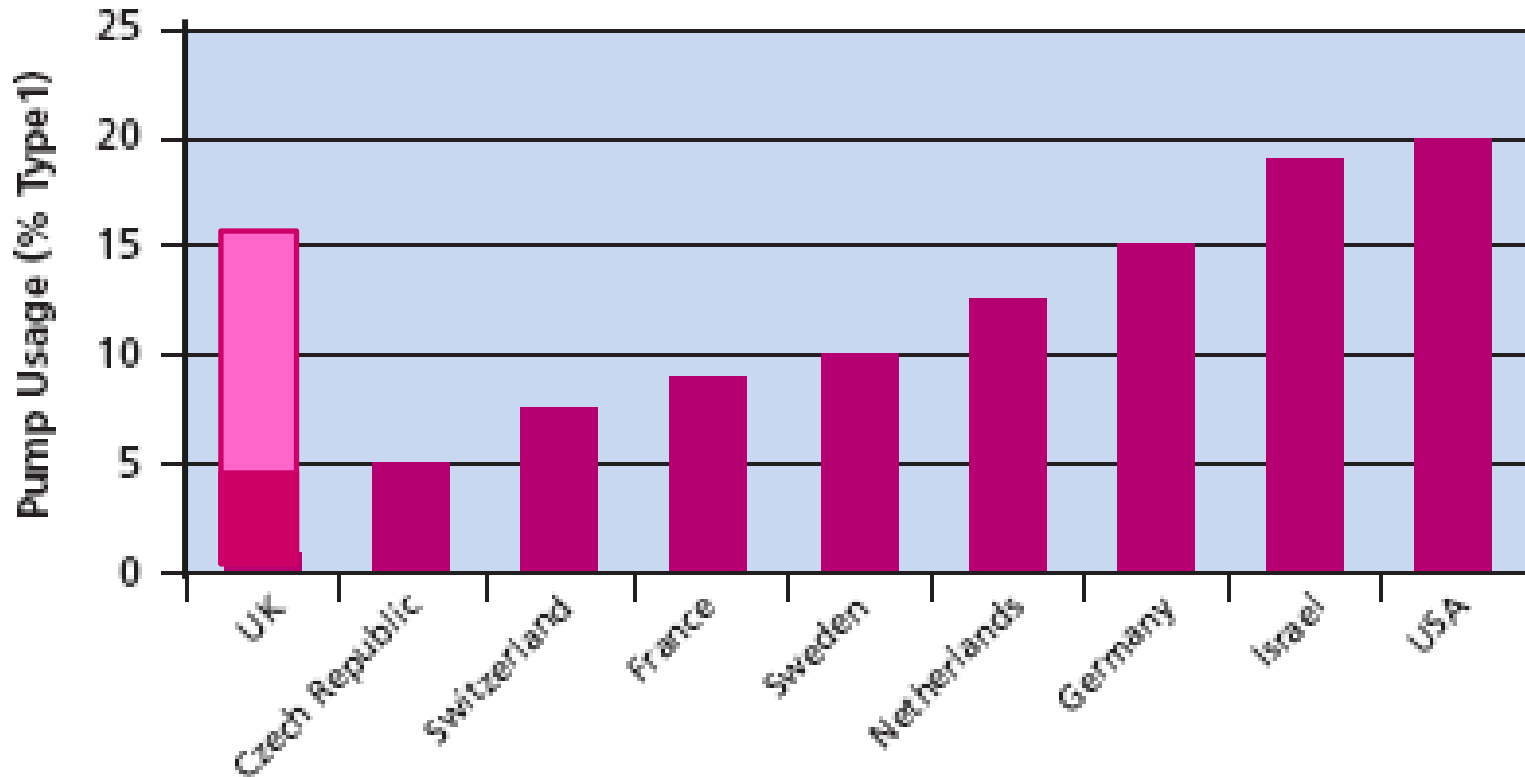
Vs 2003

- If HbA1c < 7.5% (6.5% with complications) cannot be achieved without disabling hypoglycaemia
- OK for adolescents
- Caution in pregnancy
- Not for Type 2

What patients say about pumps (Waugh et al., HTA 2007)

- 'The pump has freed me to be the person I always could have been'
- 'The best tool and educator for living with and understanding diabetes'
- 'The most amazing thing for me was the return of hypo awareness'

How to, why to?



National Technology Adoption Centre

<http://www.technologyadoptioncentre.nhs.uk/Continuous-Subcutaneous-Insulin-Infusion/>

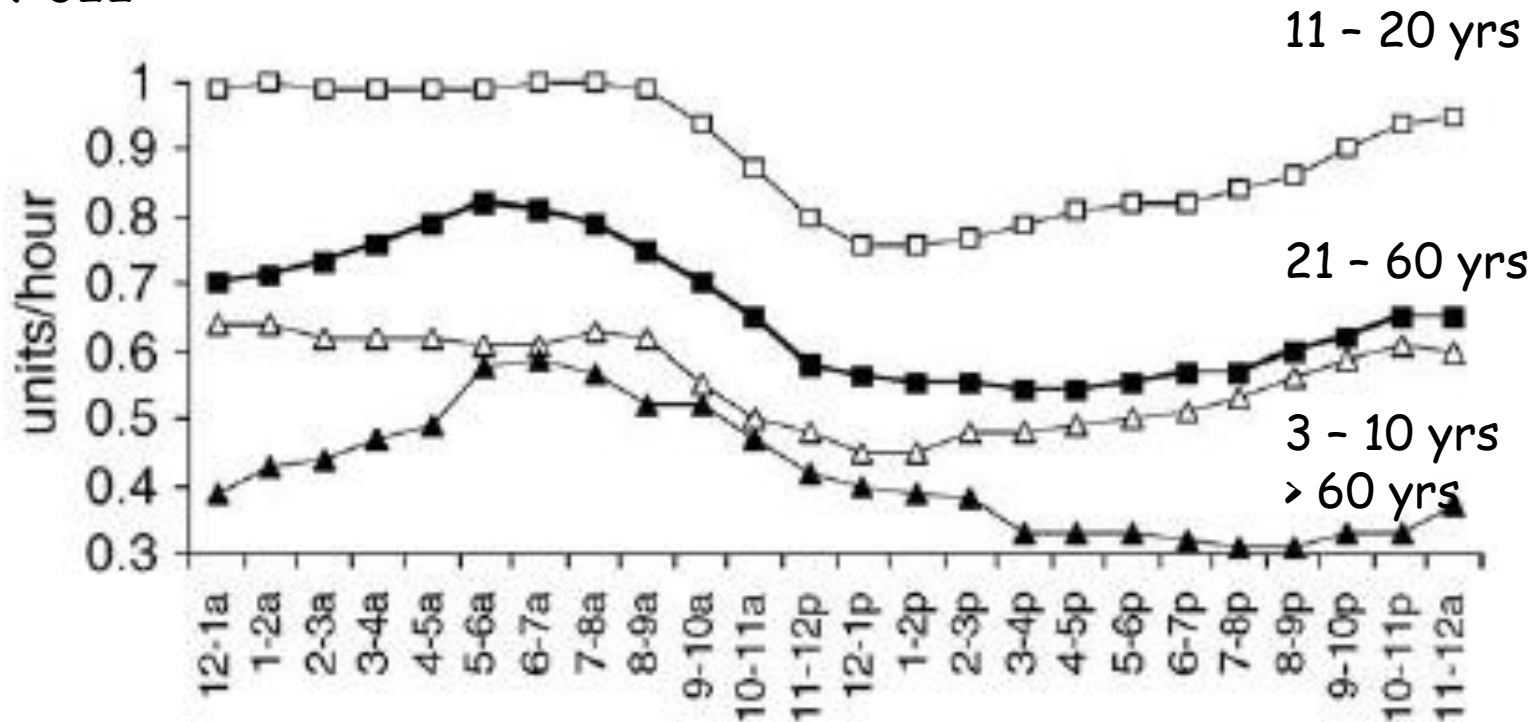
Whom and how?

What does CSII do differently?

1. The basal rate

Diurnal variation in insulin infusion rate

N=322



Range 0 - 3.5 units/hr

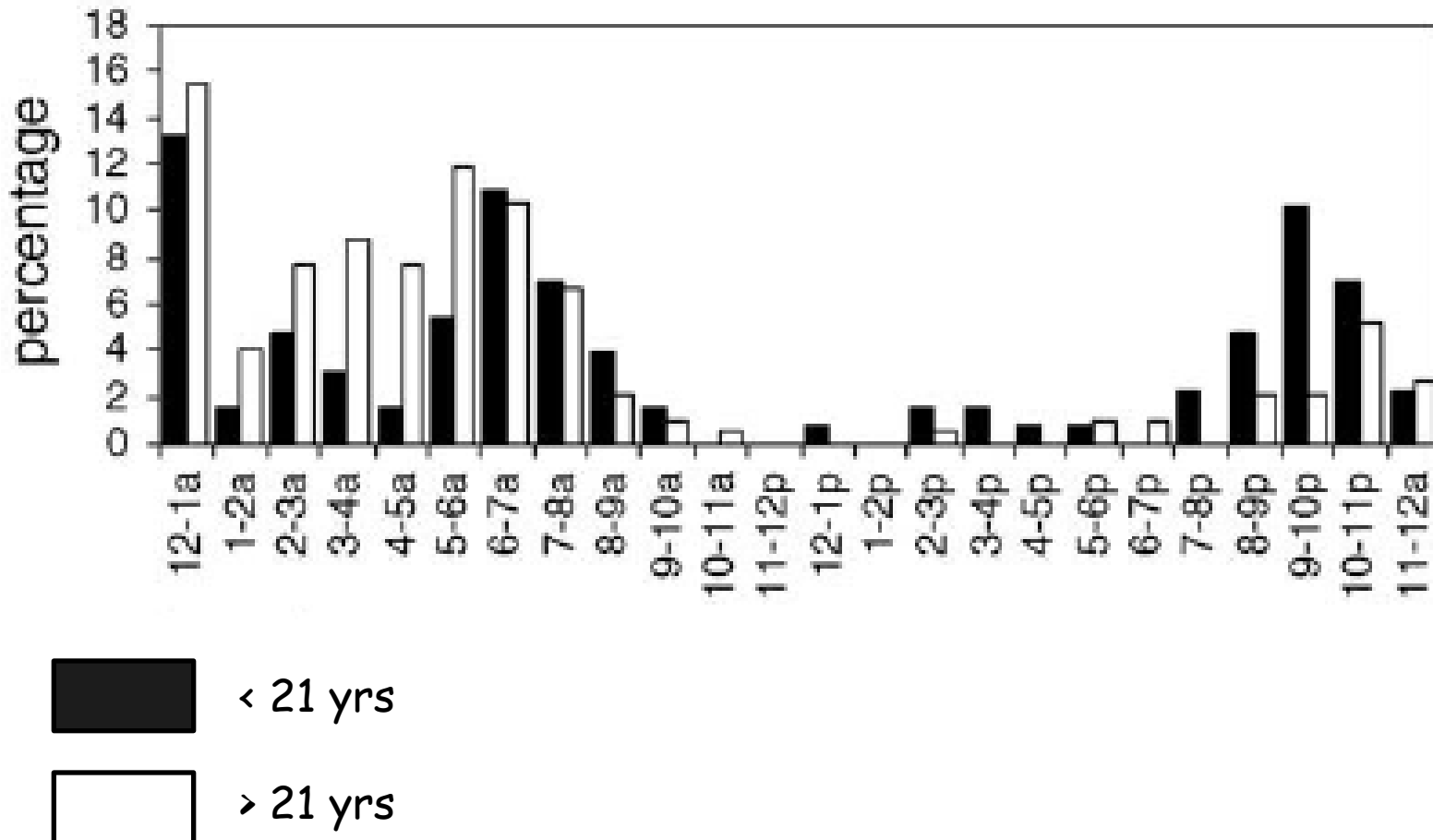
14.3 % 0 peak

82.3 % 1 peak

3.4 % 2 peaks

Max 4 - 8 am; min 11am - 8pm

Time of start of rise in insulin infusion rate

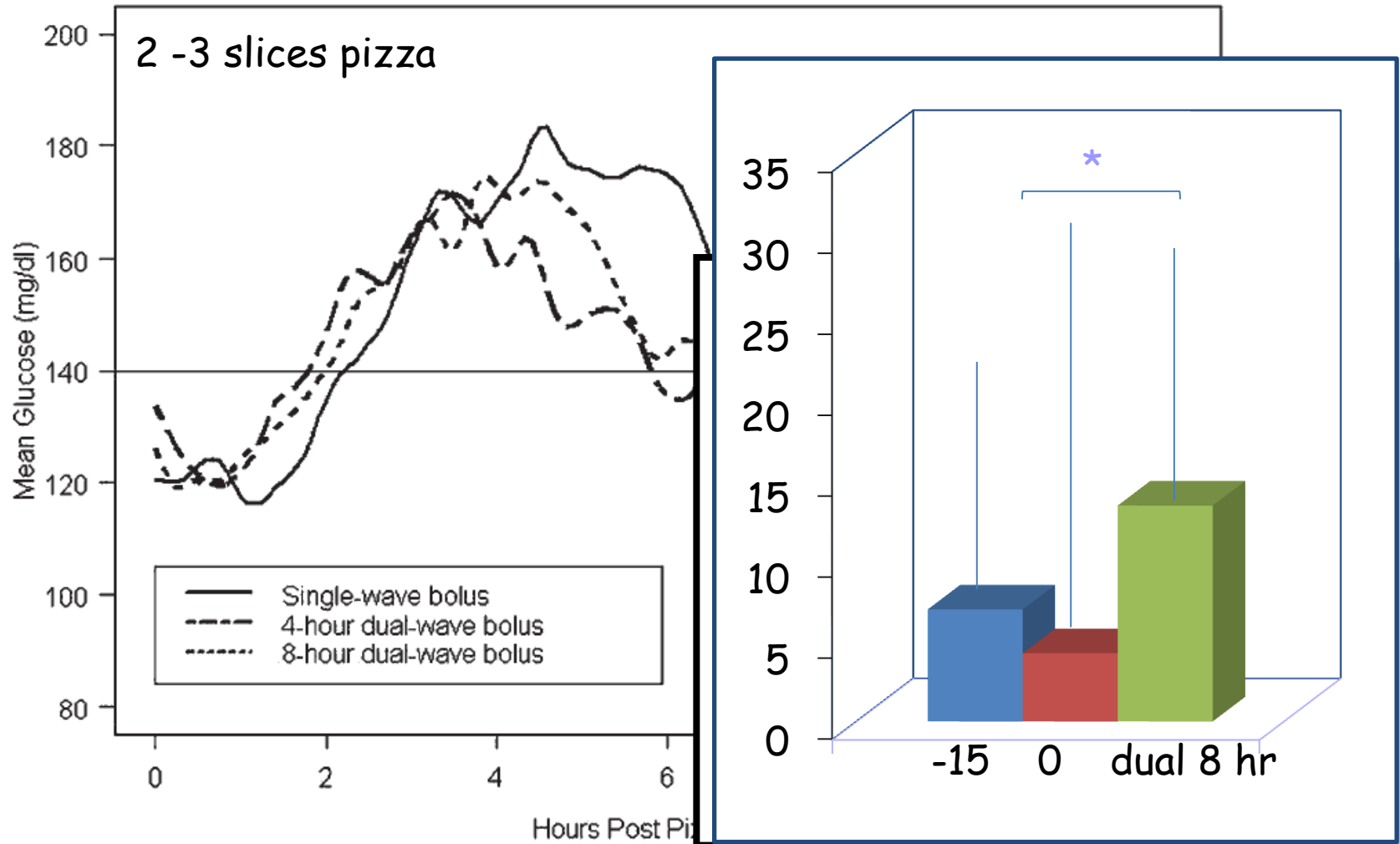


Whom and how?

What does CSII do differently?

2. The bolus

The dual wave data



The bolus calculator



Plasma glucose, n - 36 children

14
13

*

*

Does mathematics

Includes estimation of "active insulin"

Reduces impact of post prandial corrections

Reduces risk of stacking corrective doses

6

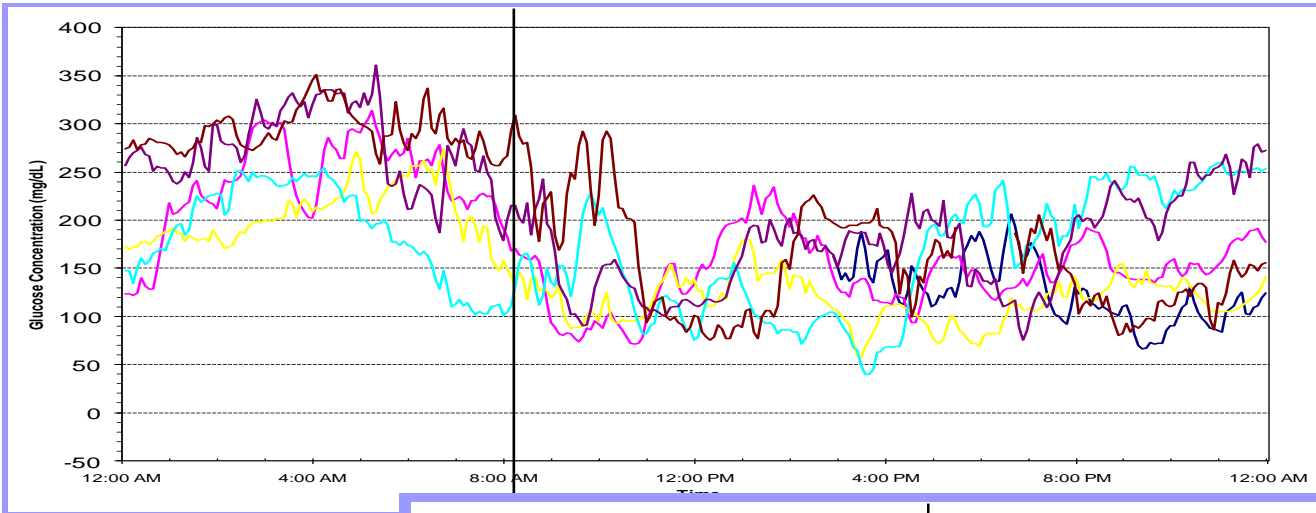
Pre meal

2 hr post

What to do if it doesn't deliver?

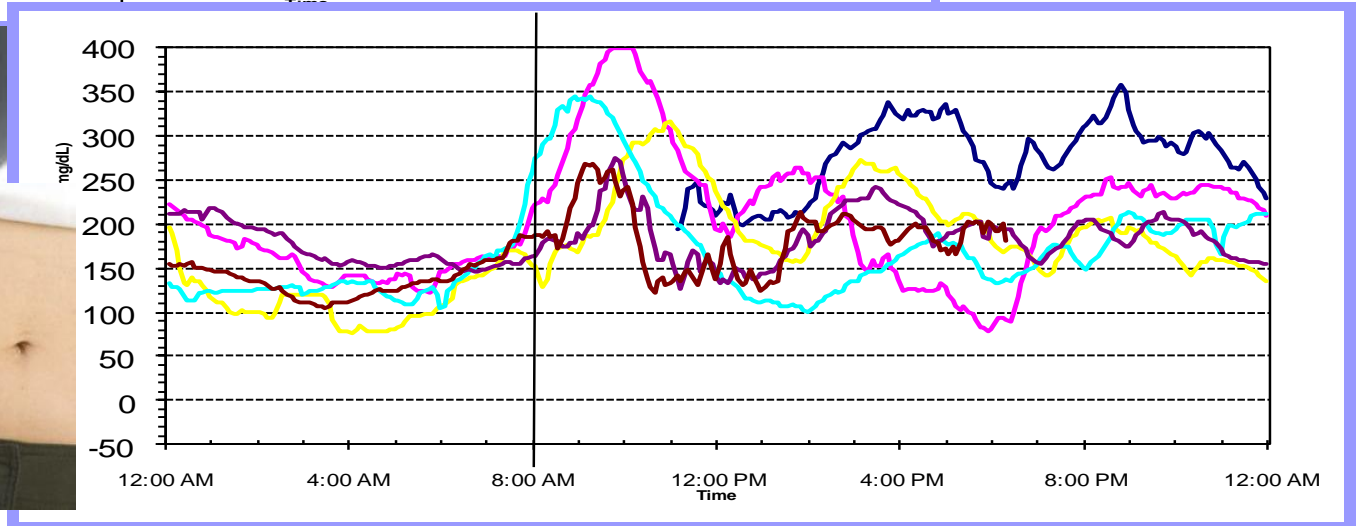
- Review diagnosis
- Frequency of site change
- Problems with CHO counting
- Timing of meal doses
- Lack of adjustment
- Close the loop???

Continuous glucose monitoring

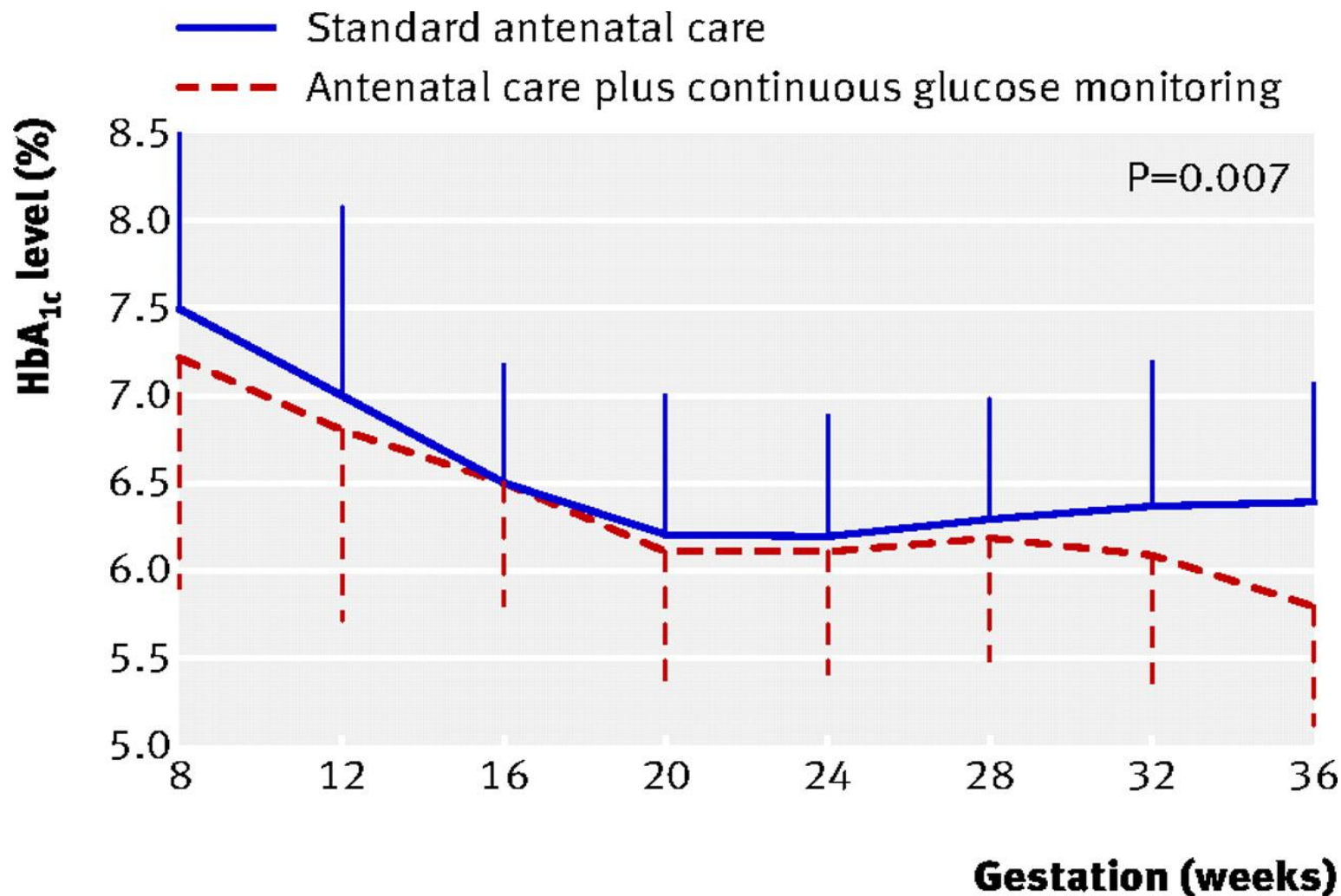


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Closed loop monitoring in pregnancy



Reduced risk of LGA: Odds ratio 0.36 (95% CI 0.13 - 0.98; p = 0.05)

Murphy H et al., BMJ

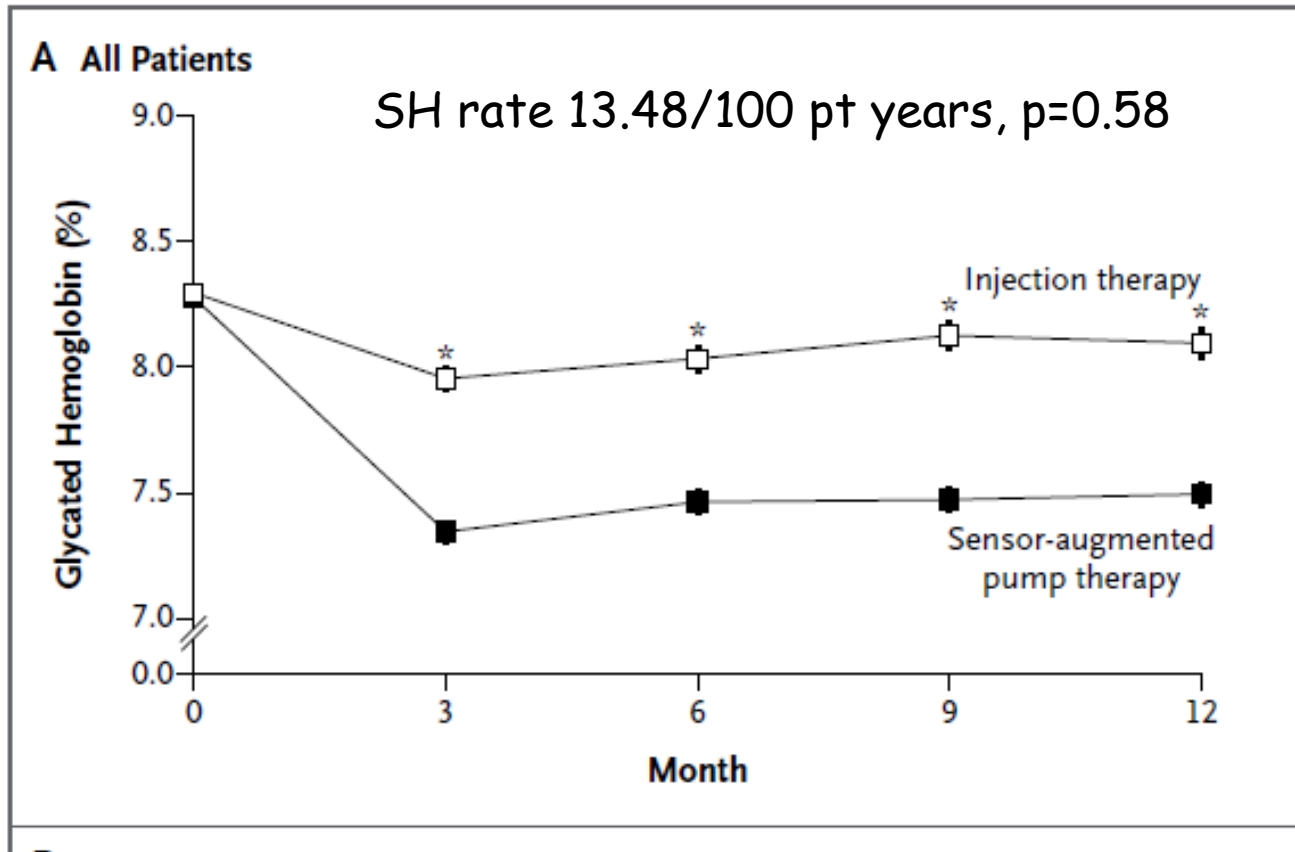
Real time glucose monitoring

- Time lag
 - Interstitial vs blood glucose
 - Data collection vs data analysis



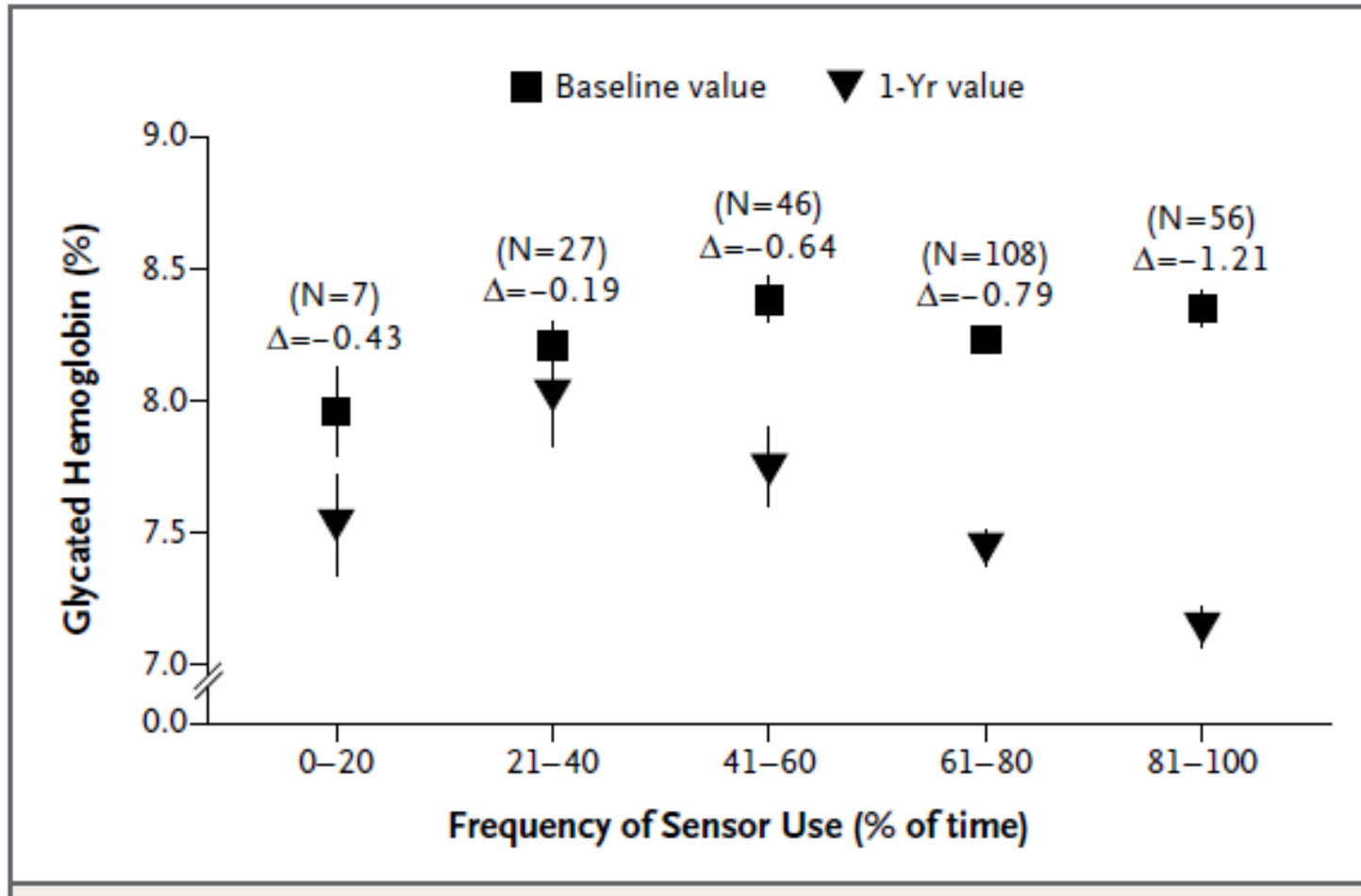
Real time monitoring

STAR 3 trial - "sensor augmented pump therapy"



Bergenstal et al, 2010, NEJM; 363: 311-20

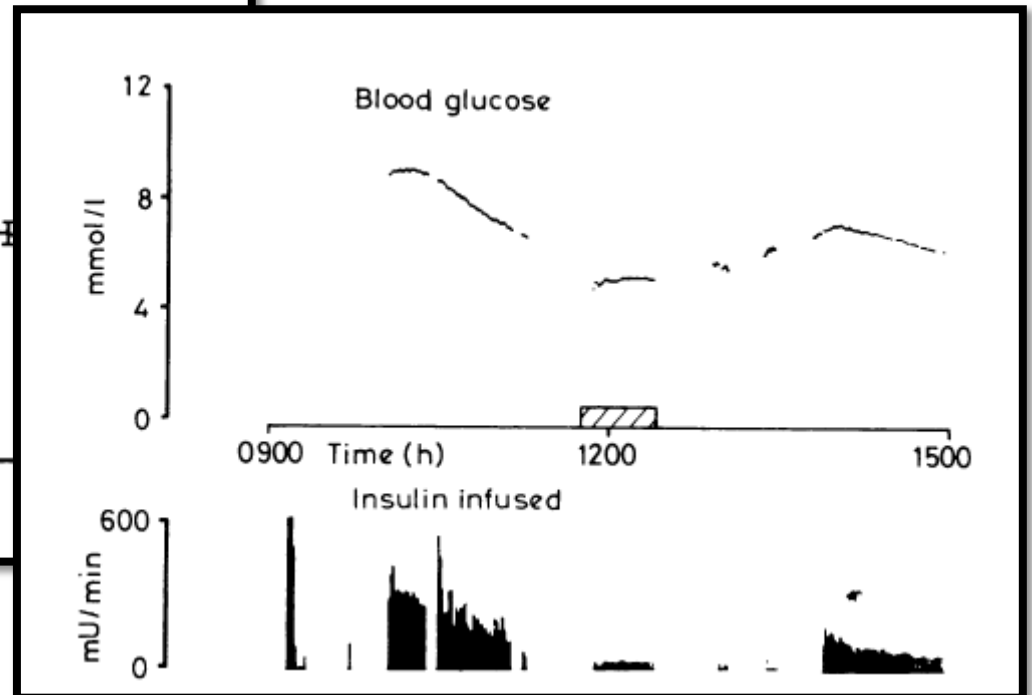
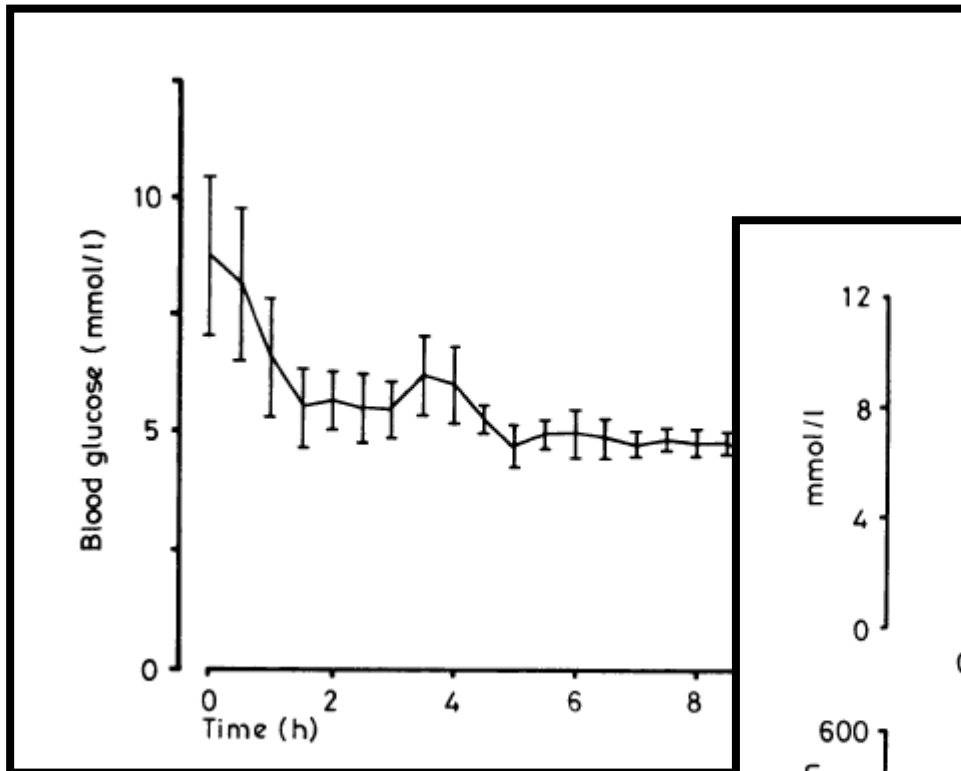
The patient factor!





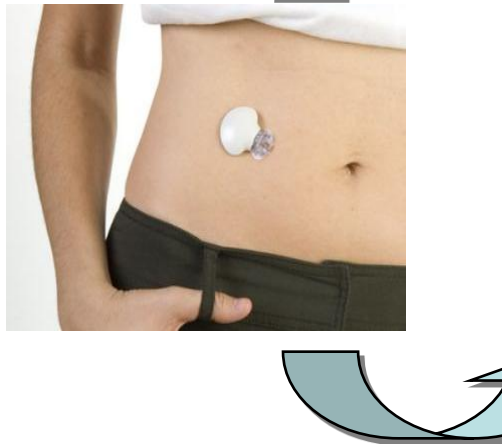
Closing the loop 1

- Clinical use of the biostator in 5 labours



Closing the loop 2

- "Low glucose suspend" with the Veo

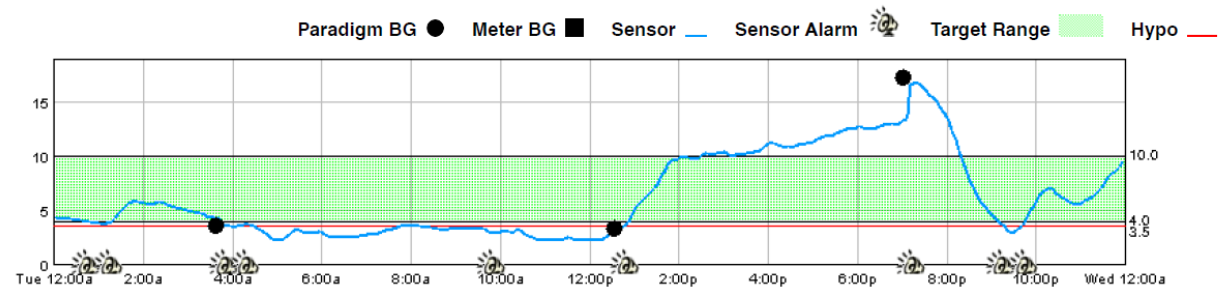


HbA1c: No Data

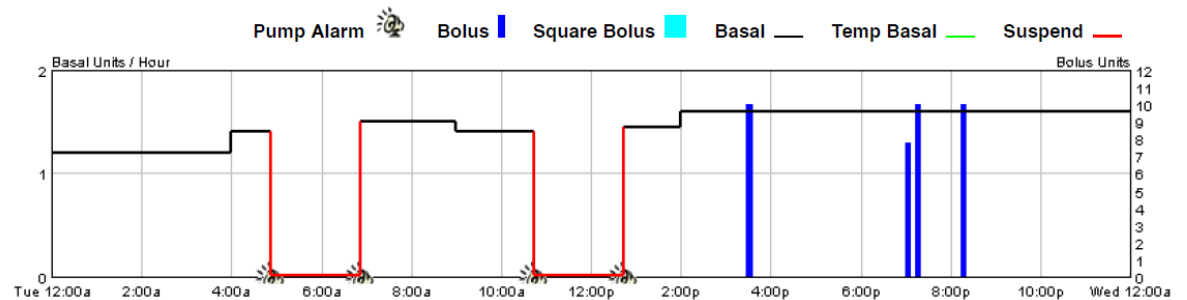
Meter: Paradigm System
Pump: Paradigm 754
Sensor: In use

#88873
#311109

Glucose (mmol/L)



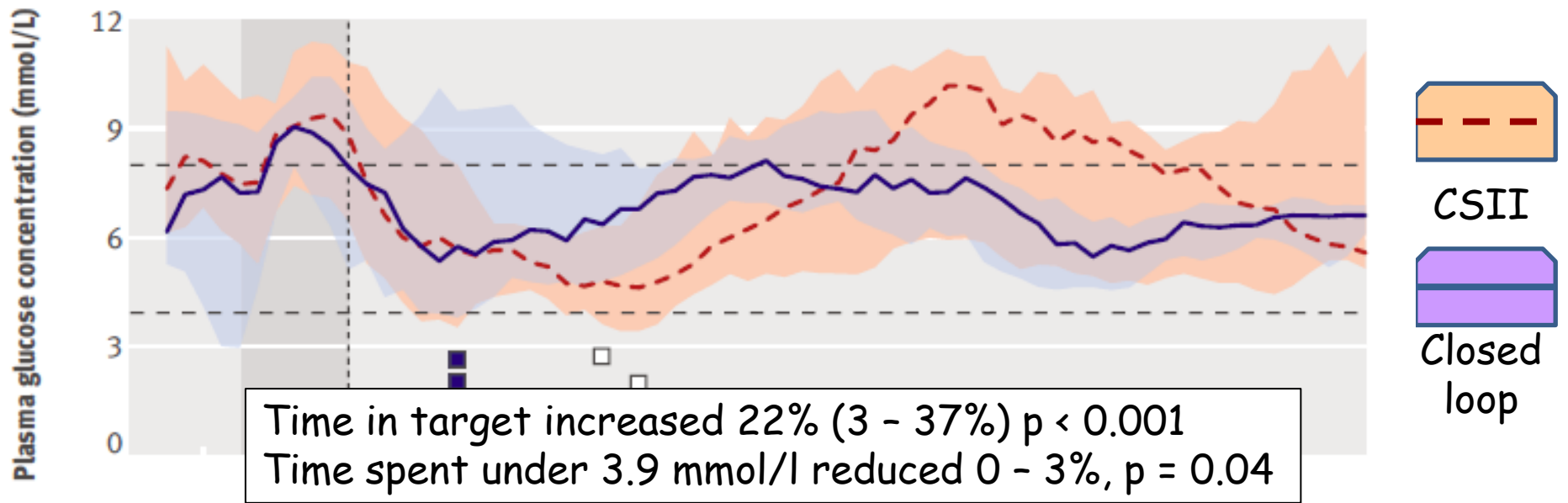
Insulin Delivery



Reducing hypoglycaemia with LGS

Unpublished data showing reduced time in hypoglycaemia for patients with most frequent hypoglycaemia prior to a user evaluation study of the "low glucose suspend" feature during study

Overnight control with closed loop: eating out



What the pump is not

1. An artificial pancreas
2. A cure for diabetes
3. An automatic diabetes care device

What the pump can do

1. Reduce hypoglycaemia problems
2. Improve overnight control esp dawn phenomena
3. Improve diabetes control in selected individuals

And a final thought....



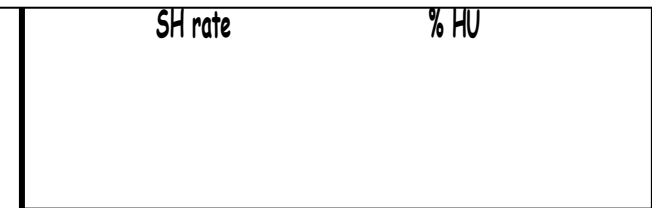
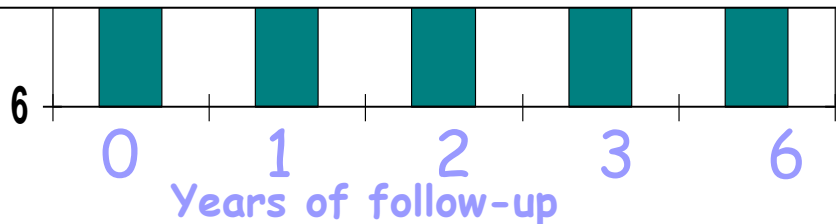
Severe Hypoglycaemia pre course
& at one year, clinical audit data
10

'For the first time in 25 years I was able to holiday abroad with a sense of freedom.'

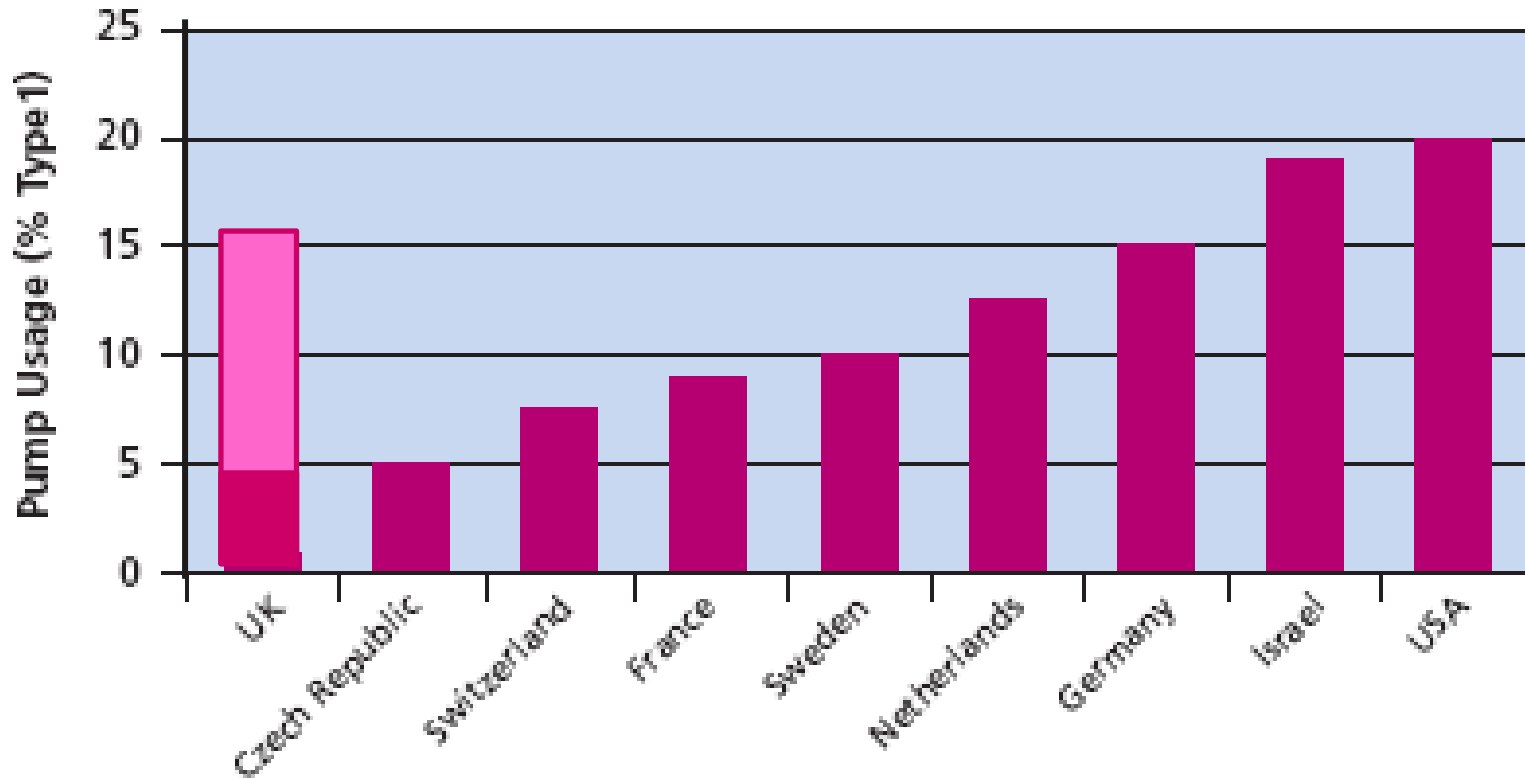
'At last! After 23 years I finally feel in control''

'It's taken away the guilt...'

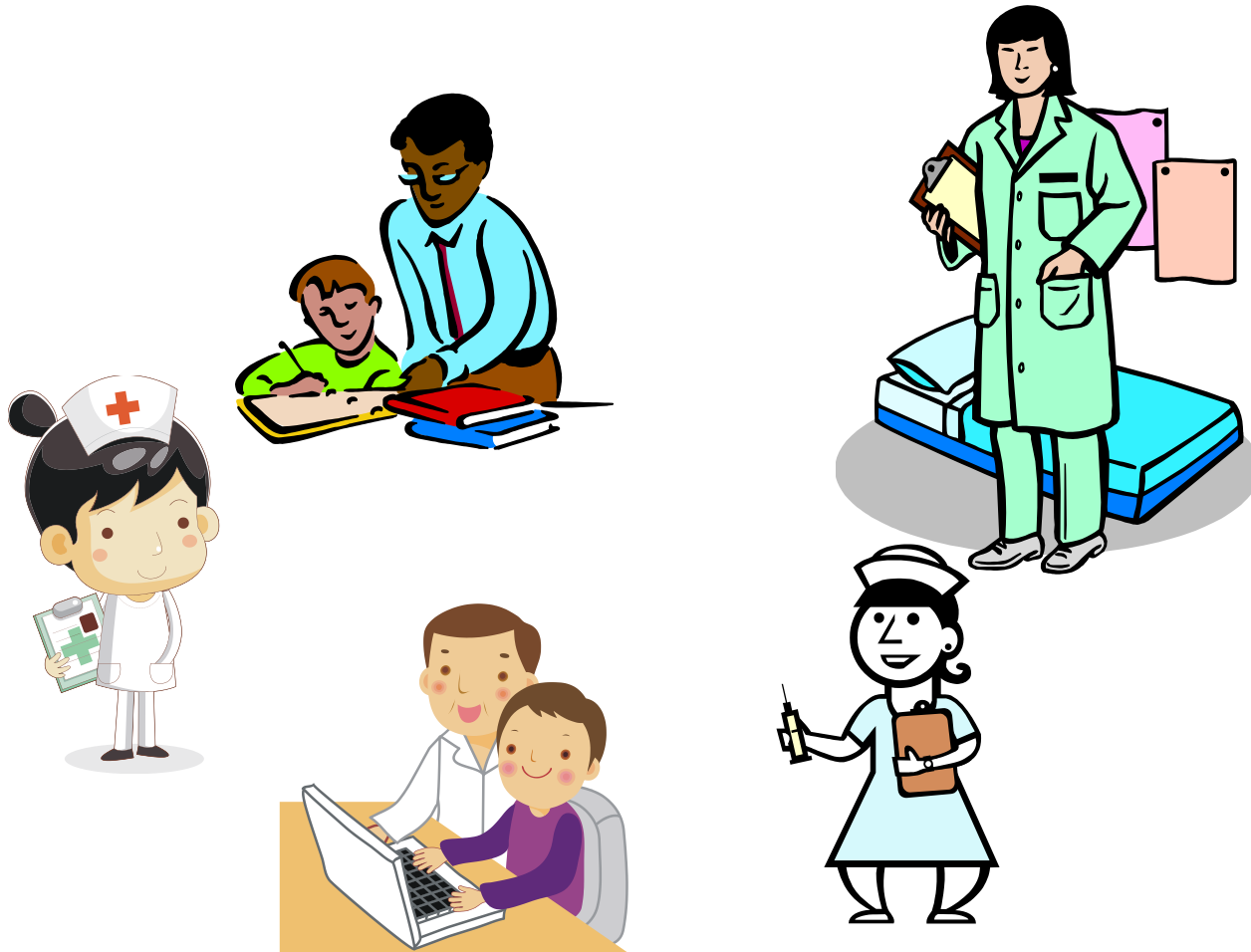
'It's given me a real reason for doing blood tests.'



Why not 100%?



An integrated specialist T1 service



PUMP INITIATION PROTOCOL

PATIENT SELF REFERRED

Structured education in flexible insulin (DAFNE)

PATIENT REFERRED BY MEDICAL TEAM

PATIENT SELECTION CRITERIA & ASSESSMENT BY A PUMP TEAM MEMBER-

Must:

- Have type 1 diabetes.
- Demonstrate that they have tried to improve diabetes control using an intensified insulin programme with support and education from the Diabetes Care Team (DCT).
- Be unable to achieve and maintain a glycosylated Hb level <7.5% (or 6.5% in the presence of microralbuminuria or adverse features of the metabolic syndrome) without disabling hypoglycaemia occurring.
- Disabling hypoglycaemia means the repeated and unpredictable occurrence of hypoglycaemia requiring third-party assistance that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.
- Be doing or willing to do 4+ blood glucose tests per day.
- Be on a multiple insulin regimen, which includes a trial with BD Levemir or Glargine/Lantus
- Demonstrate the technical ability to use a pump and calculate carbohydrate values and insulin needs (or carer).
- Be willing to undergo an assessment by a clinical psychologist, if deemed necessary by the DCT.
- Demonstrate a willingness to engage in appropriate follow-up in clinic.
- Have sites for pump attachment.

Optional:

- Other indications for pump use include: pregnancy, paediatrics, dawn phenomenon and gastroparesis.

NO

YES

REFER FOR 2ND OPINION, if appropriate

YES

FUNDING APPROVAL

YES

WAITING LIST

PRE-PUMP SENSOR PLACEMENT

NO

PUMP START - by designated Pump DSN and Dietitian