

In Silico Monte Carlo Virtual Trials of a Model-Based Adaptive T1DM Control Protocol

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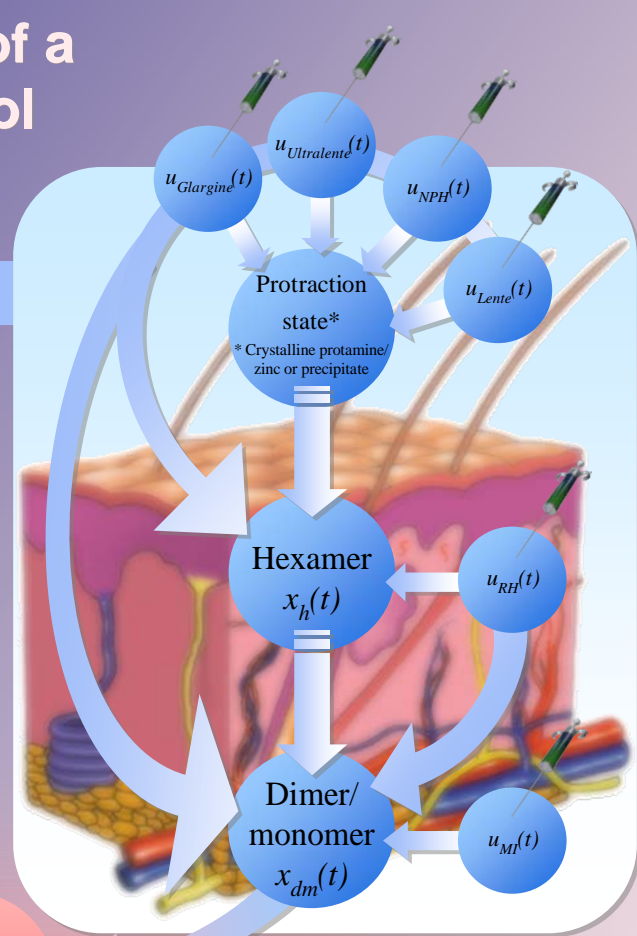
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1 The Background...

- The hormone *insulin* controls blood glucose levels. **Diabetes** results from defective *insulin secretion and/or action*, causing wildly fluctuating glucose levels
- Low levels (**hypoglycaemia**) and high levels (**hyperglycaemia**) increase the risk of complications and death
- Diabetes** is an **epidemic** in developed countries. In 2002, the disease cost **US\$132 billion**, was the **6th leading cause of death**, and affected **7% of the population** (US figures)¹. In NZ, that cost is **NZ\$400 million**, set to rise to **NZ\$1 billion by 2020**²
- Complications and associated healthcare costs can be **reduced by up to 76%**³ with good control. **But, ~45% of people with diabetes** are deemed **'poorly controlled'**⁴
- This Research:** Examines an adaptive protocol using Monte Carlo analysis for robustness, performance and safety

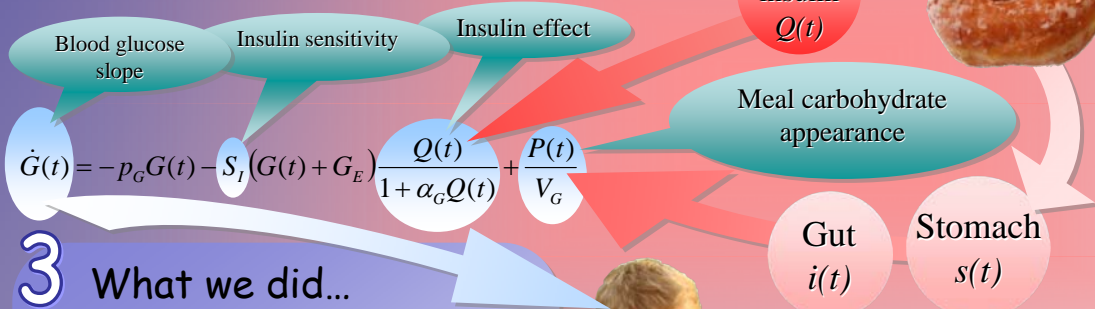
2 The Protocol

- Basal:** Titration based on published methods (Fritsch & Riddel et al).
- Prandial:** 2 measurements / meal at t=0 and t=90 mins for correction
- Correction Bolus:** Only on those meals requiring it uses the model to determine it (fit S_t + carb count).
- Use up to 3 meals and 2 snacks (**Measure: 10 total, goal is 4 or less**)
- Goal:** The system must rely on **minimal glucose measurements** and **minimal technology** for the 85% or more who don't use pumps.



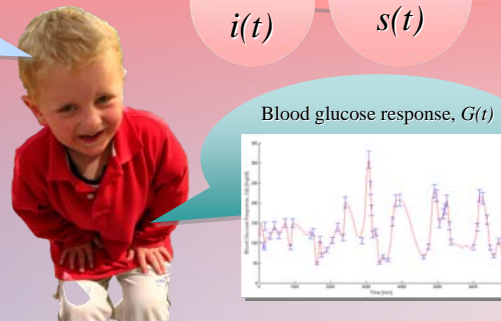
Insulin Absorption Model

Glucose-Insulin Model



3 What we did...

- Monte Carlo virtual patient (simulation) study using 40 AIDA cohort patients as a basis
 - Average HbA1c = 8% matching US
- Account for **variability** and **error** in model parameters (physiology, dosing, carb counting, etc) with published data or larger
- Each patient simulated 1 week x 8300 variations** → **1.4M different patient hours**
- HbA1c estimated with published formula



4 The Results...

- Our findings...**
 - 6 measmt/day** satisfy ADA guidelines⁵ for **100%** of patients.
 - Using conventional control (CC), just **~49-52%** meet guidelines⁴
 - Hypoglycaemia reduced by ~8x**
 - Time below 54mg/dL **~0**
 - Barely different for 4/day**
- Conclusions:** This control approach **doubled** the number of patients **safely** meeting clinical guidelines. It uses common low cost treatment methods.

References

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