Toward Plug and Play Medical Cyber-Physical Systems (Part 2)

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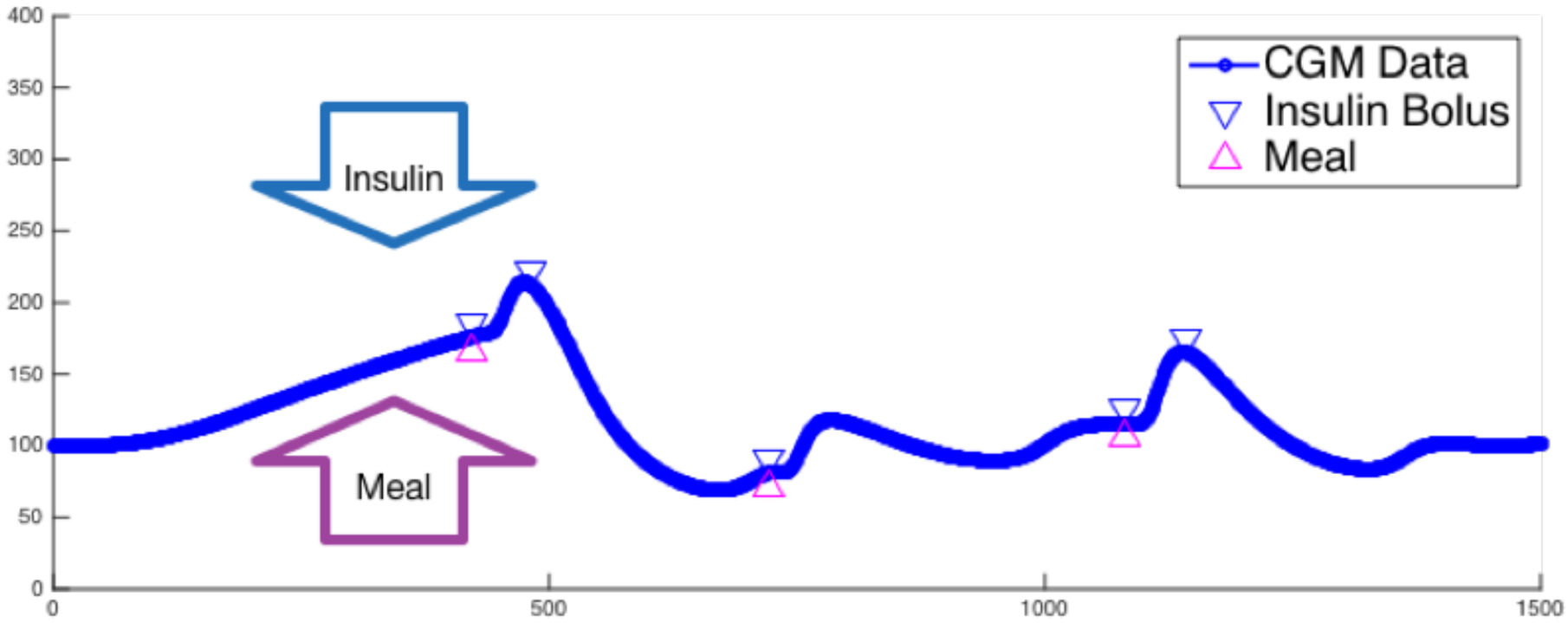
MODELING AND ANALYSIS OF BG CONTROL IN ARTIFICIAL PANCREAS

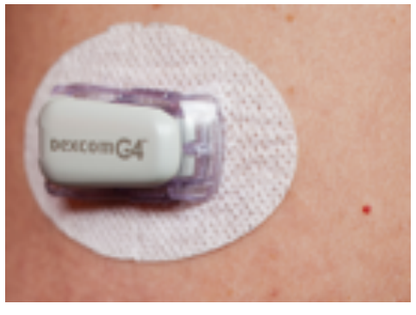
Intro BG and problems in general

- 29 million Americans have diabetes (9.3% of the U.S. population)
  - Type 1: pancreas does not produce insulin
  - Type 2: cells do not respond normally to insulin
- A challenging control problem:
  - Hypoglycemia (low blood glucose) —> seizures, coma, death
  - Hyperglycemia (high blood glucose) —> infections, nerve damage, amputation
  - Two driving forces: carbohydrates and insulin

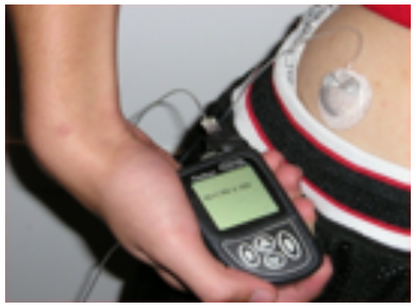


Modeling and Verification of Artificial Pancreas

- Artificial Pancreas: “continuous glucose monitoring + controller + insulin pump”
  - No fully autonomous controller has been approved by regulators yet
  - Current systems are semi-closed-loop: human and controller share control authority



- Towards verification of outpatient glucose control
  - Need to consider the full model (additional nonlinearities in the meal pathway)
  - Uncertainties of meal input
    - Meal time: Current insulin pumps rely on user self-report mealtimes
    - Carb count: user-estimated carb amount
  - Uncertainties of control actions
    - Unlike caregivers in the operating room, outpatients do not necessarily follow guidelines
    - Need to model their control “behaviors”
  - Verification of a non-linear physiological model with a controller, a human behavior model, and uncertain meal inputs



An Intraoperative Glucose Control Benchmark for Formal Verification [ADHS 2015]

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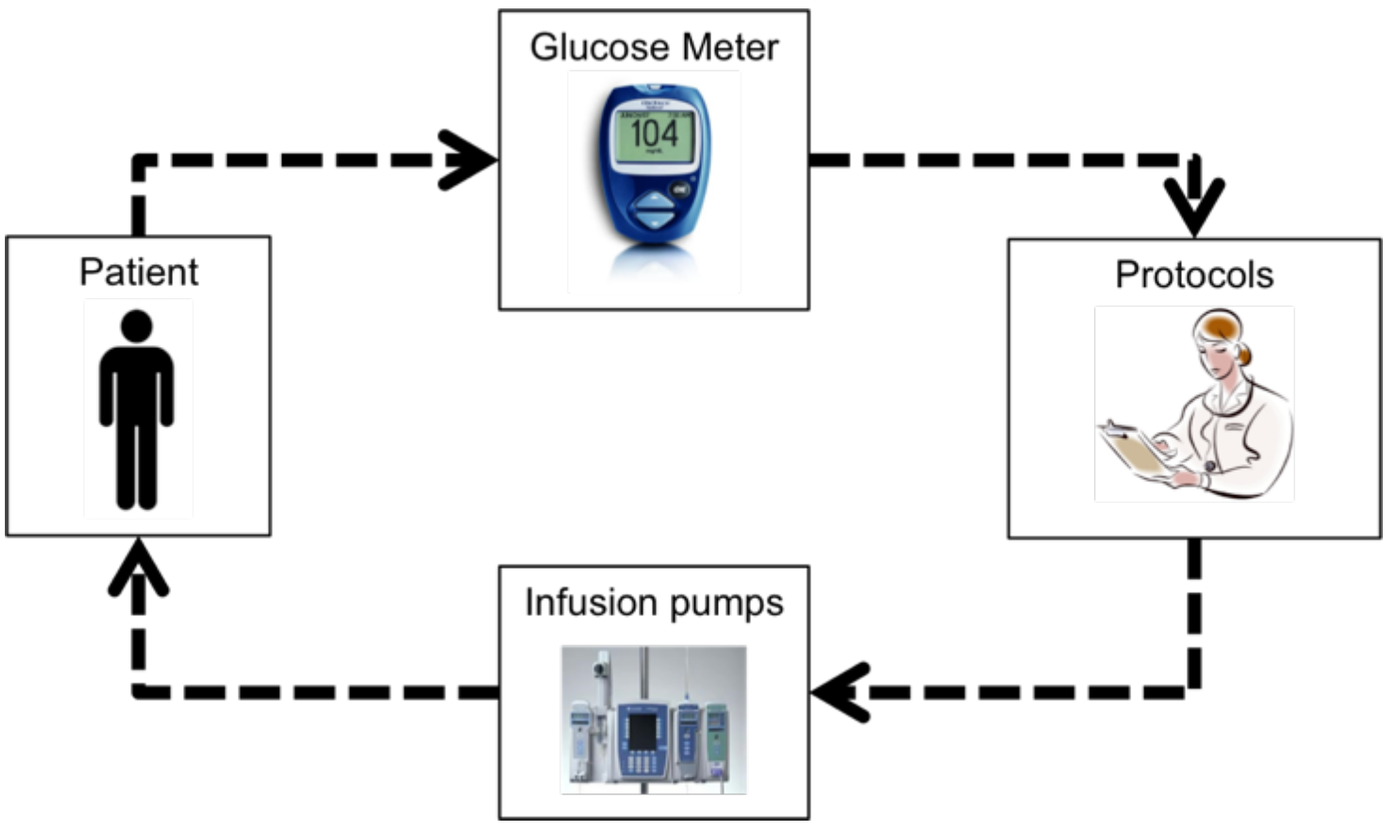
Outline

- **Background**
  - Glucose Control During Surgeries
- Modeling
  - Physiological Model
  - Mode-Switching Controller
  - Hybrid System Model
- Proof-of-Concept Implementation in dReach
- Concluding Remarks

Intraoperative Glucose Control

- Intraoperative glycemic control is important
  - Stress-induced hyperglycemia —> higher risk of infection
  - Hypoglycemia —> life threatening
- Current practice: Caregivers manually adjust insulin rate following rule-based protocols
- Existing protocols are empirically designed to an “average” patient
  - Question: how to verify that a protocol is safe for a patient population?



Outline

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- **Modeling**
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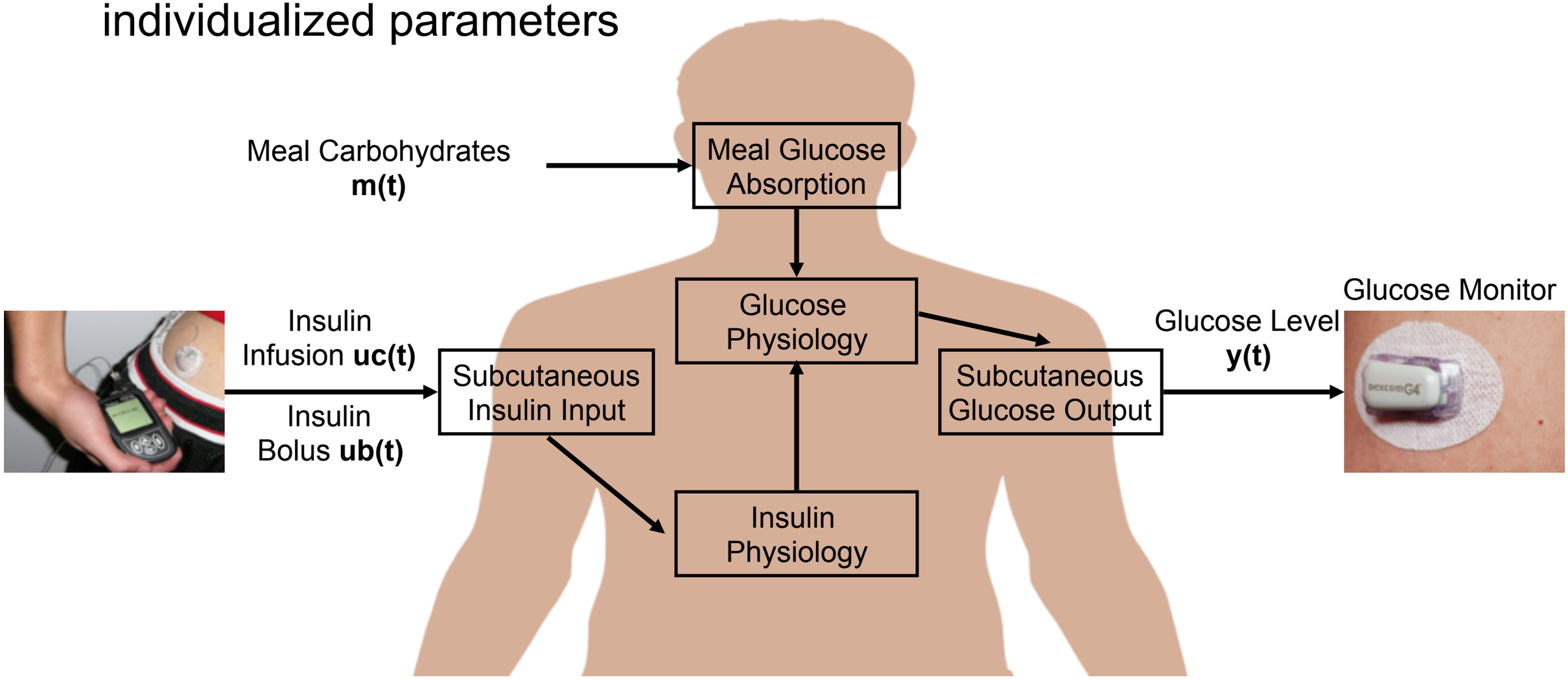
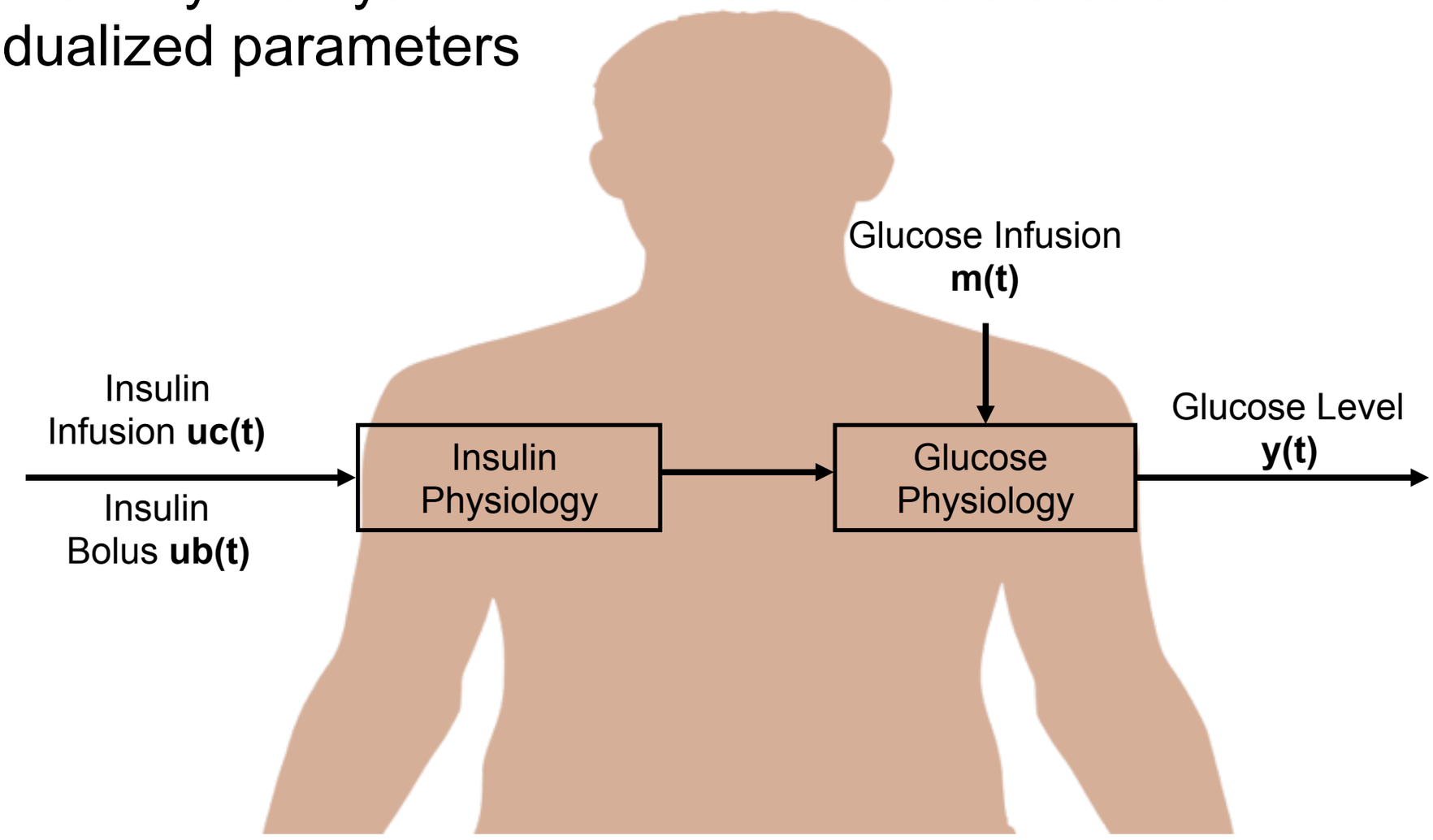
Physiological Model

- First-principle high-fidelity model
- First FDA-accepted simulator as a substitute to animal tests in pre-clinical trials
  - UVA/Padova Type 1 Diabetes Simulator
- Non-linear hybrid system with 13 continuous states and 32 individualized parameters



Intraoperative Physiological Model

- Surgical scenario:
  - Patients do not eat (no meal absorption)
  - Insulin & glucose go directly into plasma (intravenous infusion)
  - Glucose is measured directly from blood
- Non-linear hybrid system with 7 continuous states and 18 individualized parameters



Intraoperative Physiological Model

- Insulin Physiology:
  - Plasma: $\dot{I}_p(t) = -(m_2 + m_4)I_p(t) + m_1 I_l(t) + u(t) * 10^2/BW$
  - Remote tissue: $\dot{X}(t) = P_{2U}/V_i I_p(t) - P_{2U} X(t) - P_{2U} * I_b$
  - Transportation: $\dot{I}_1(t) = k_i/V_i I_p(t) - k_i I_1(t)$
  - RGC action: $\dot{I}_d(t) = k_i I_1(t) - k_i I_d(t)$
  - Liver: $\dot{I}_l(t) = m_2 * I_p(t) - (m_1 + m_3)I_l(t).$
- Glucose-System
  - Plasma:

$$\dot{G}_p(t) = -k_1 * G_p(t) + k_2 * G_t(t) - F_{snc} + m(t) * 10^3/BW + \max(0, k_{p1} - k_{p2} * G_p(t) - k_{p3} * I_d(t)) - 1 - \max(0, k_{e1} * (G_p(t) - k_{e2}))$$

Endogenous Glucose Production (EGP)

  - Remote tissue:

$$\dot{G}_t(t) = -\frac{(V_{m0} + V_{mx} * X(t)) * G_t(t)}{K_{m0} + G_t(t)} + k_1 * G_p(t) - k_2 * G_t(t)$$

Renal Glucose Clearance (RGC)

Nonlinear Insulin Action on Glucose

State and Parameter Ranges

- Ranges of 7 states

States	Ranges	Units	Example Nominal Value
I_p	$[0, 30]$	pmol/kg	5
X'	$[-500, 500]$	pmol/liter	30
I_1	$[0, 300]$	pmol/liter	120
I_d	$[0, 300]$	pmol/liter	120
I_l	$[0, 30]$	pmol/kg	3
G_p	$[0, 1000]$	mg/kg	200
G_t	$[0, 1000]$	mg/kg	150

- Ranges of 18 parameters

Parameters	Ranges	Units	Example Nominal Value
m_1	$[0.1, 1]$	min^{-1}	0.2
m_2	$[0.1, 1]$	min^{-1}	0.3
m_3	$[0.1, 1]$	min^{-1}	0.3
m_4	$[0.05, 0.5]$	min^{-1}	0.1
k_i	$[0.001, 0.02]$	min^{-1}	0.01
P_{2u}	$[0.01, 0.1]$	min^{-1}	0.03
V_i	$[0.02, 0.1]$	liter/kg	0.06
I_b	$[0, 300]$	pmol/liter	100
BW	$[0, 300]$	kg	90
k_1	$[0.02, 0.1]$	min^{-1}	0.05
k_2	$[0.05, 0.3]$	min^{-1}	0.1
k_{p1}	$[1, 10]$	mg/kg/min	5
k_{p2}	$[0.0001, 0.01]$	min^{-1}	0.004
k_{p3}	$[0.001, 0.03]$	mg/kg/min per pmol/liter	0.01
V_{m0}	$[1, 10]$	mg/kg/min	5
V_{mx}	$[0.01, 0.15]$	mg/kg/min per pmol/liter	0.05
K_{m0}	$[100, 1000]$	mg/kg	200
V_g	$[1, 5]$	dL/kg	2

Challenges of Using the T1DMS Model

- Only 1 state (glucose level) is measurable
- Most parameters (except body weight) cannot be directly measured
- Current best practice:
  - FDA holds 300 “virtual subjects” for black-box testing of a controller in pre-clinical trials
- No formal guarantee with respect to the full state and parameter space

An Intraoperative Glucose Controller

- Previous work: a mode-switching controller (30min sampling interval)

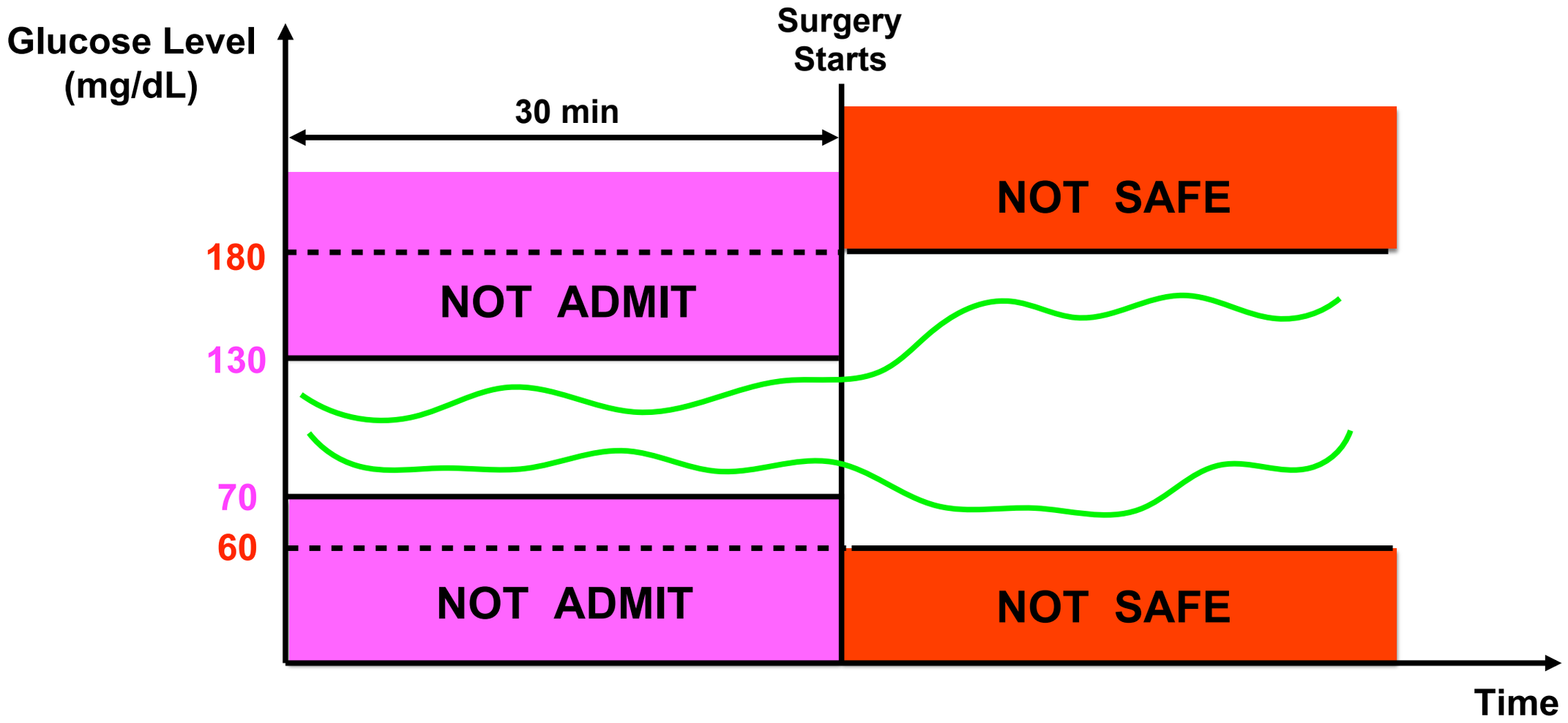
Condition	Control Input Update
$y(k) \leq 60$	$uc(k) = 0, ub(k) = 0, m(k) = 12.5$
$60 < y(k) < 100$ AND $y(k) - y(k-1) < -30$	$uc(k) = 0, ub(k) = 0, m(k) = -0.1 * (y(k) - y(k-1))$
$100 \leq y(k) < 300$ OR $y(k) - y(k-1) \geq -30$	$uc(k) = \max(0, 0.05 * (y(k) - 100) + 0.06 * (y(k) - y(k-1))) + 1), ub(k) = 0, m(k) = 0$
$y(k) \geq 300$	$u(k) = 15, ub(k) = 15, m(k) = 0$

- Comparison with the existing clinical protocol in simulation study
  - FDA-accepted simulator with 10 “virtual subjects” (realizations of parameters)
  - Reduced hypoglycemia and glucose variability
- Question: is the controller safe for all “virtual subjects”?
- Verification problem:
  - Given the physiological model and the controller, during the surgery time $[0, t_{\max}]$, given any model parameter P and initial condition X_{init}, does glucose level y stays in the safe region?

$$\forall t \in [0, t_{\max}], \ \forall \mathcal{P} \in \mathcal{R}_P, \ \forall \mathcal{X}_{init} \in \mathcal{R}_{\mathcal{X}}, \quad y \notin \mathcal{R}_{unsafe}$$

Perioperative Monitoring Period

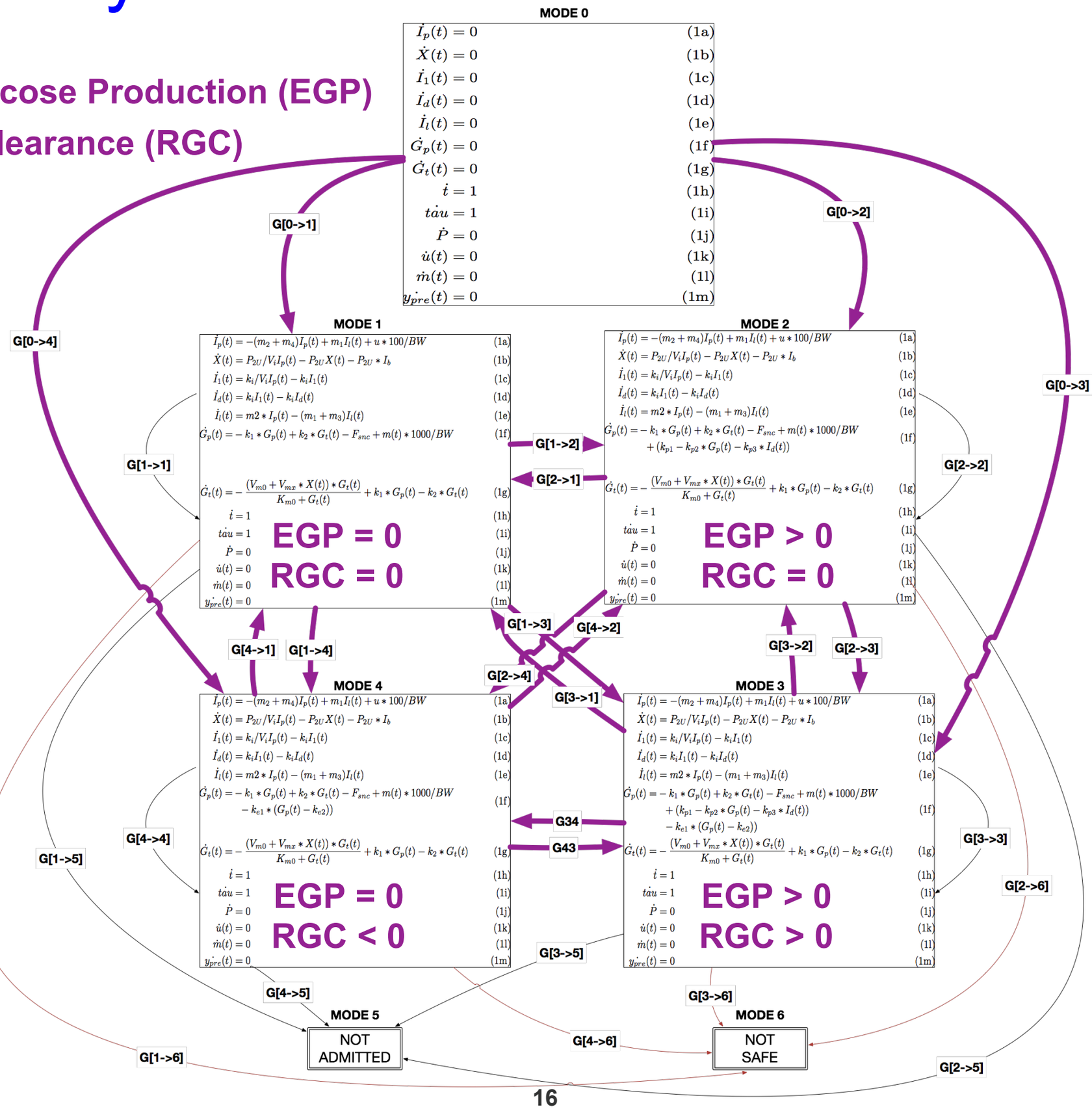
- Glucose monitoring typically starts 30 minutes before surgeries
- Extreme glucose measurements during the perioperative period will delay the start of surgery



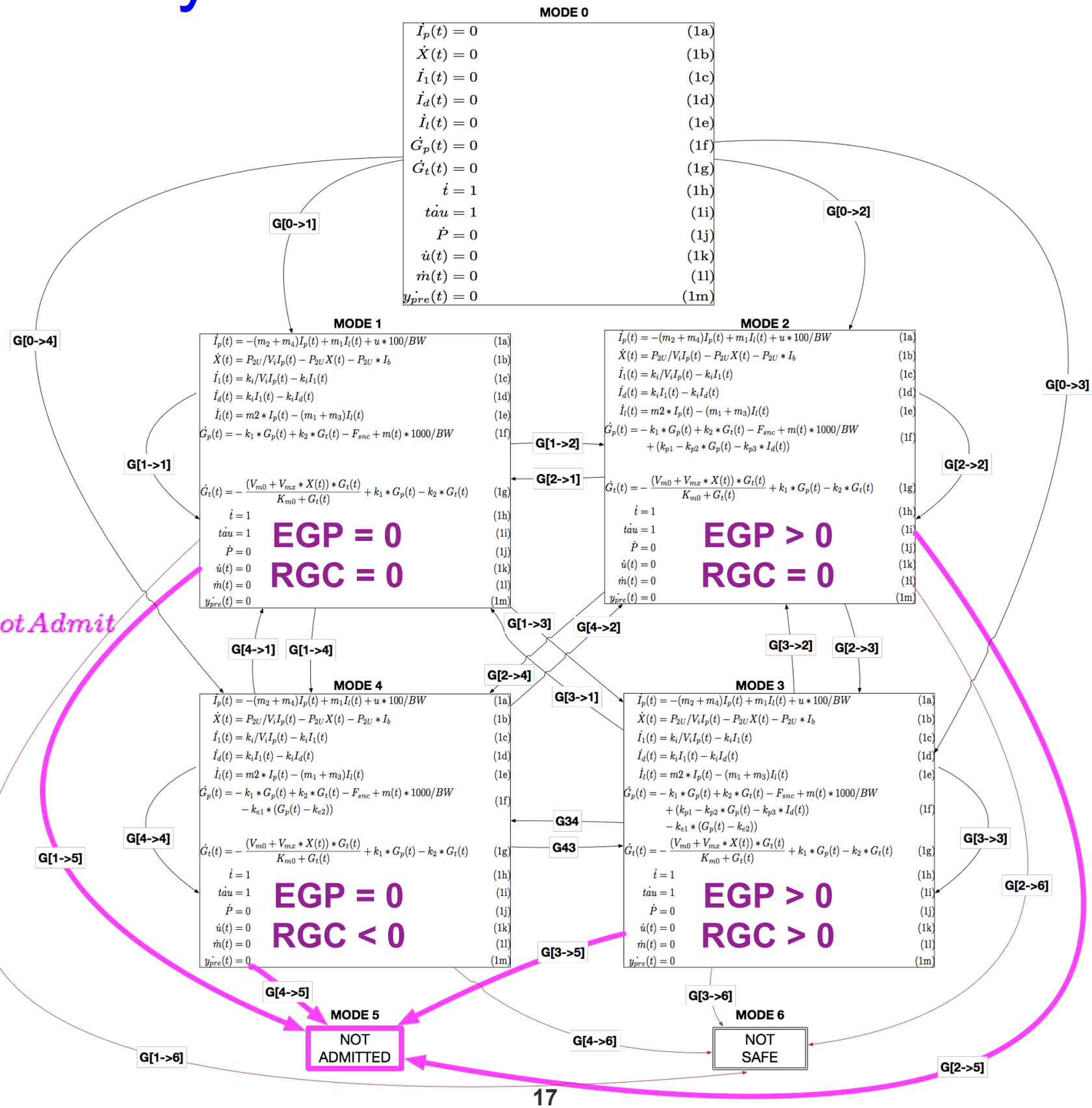
Hybrid System Model: EGP/RGC Conditions

Endogenous Glucose Production (EGP)

Renal Glucose Clearance (RGC)

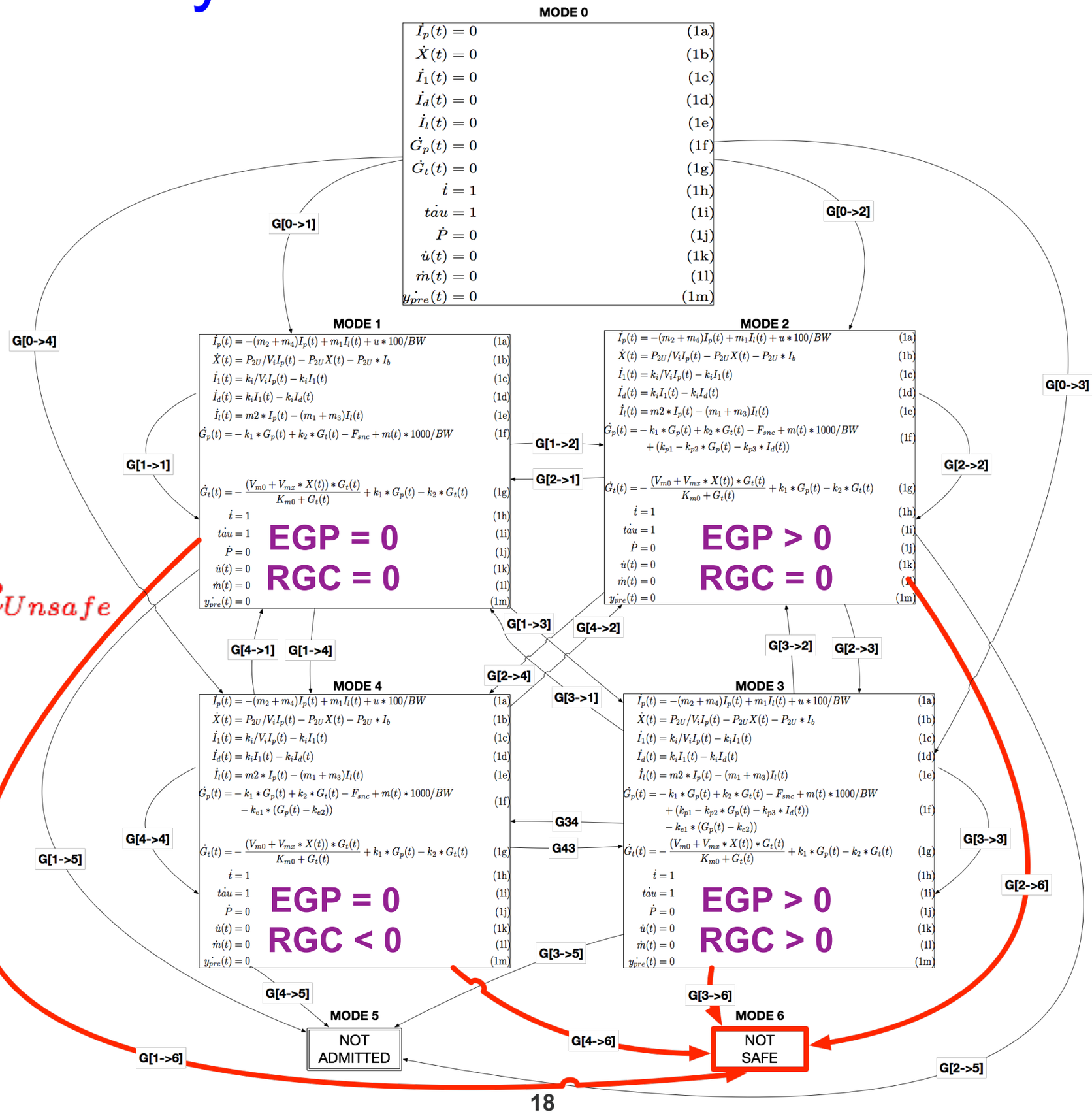


Hybrid System Model: “Not Admit” State



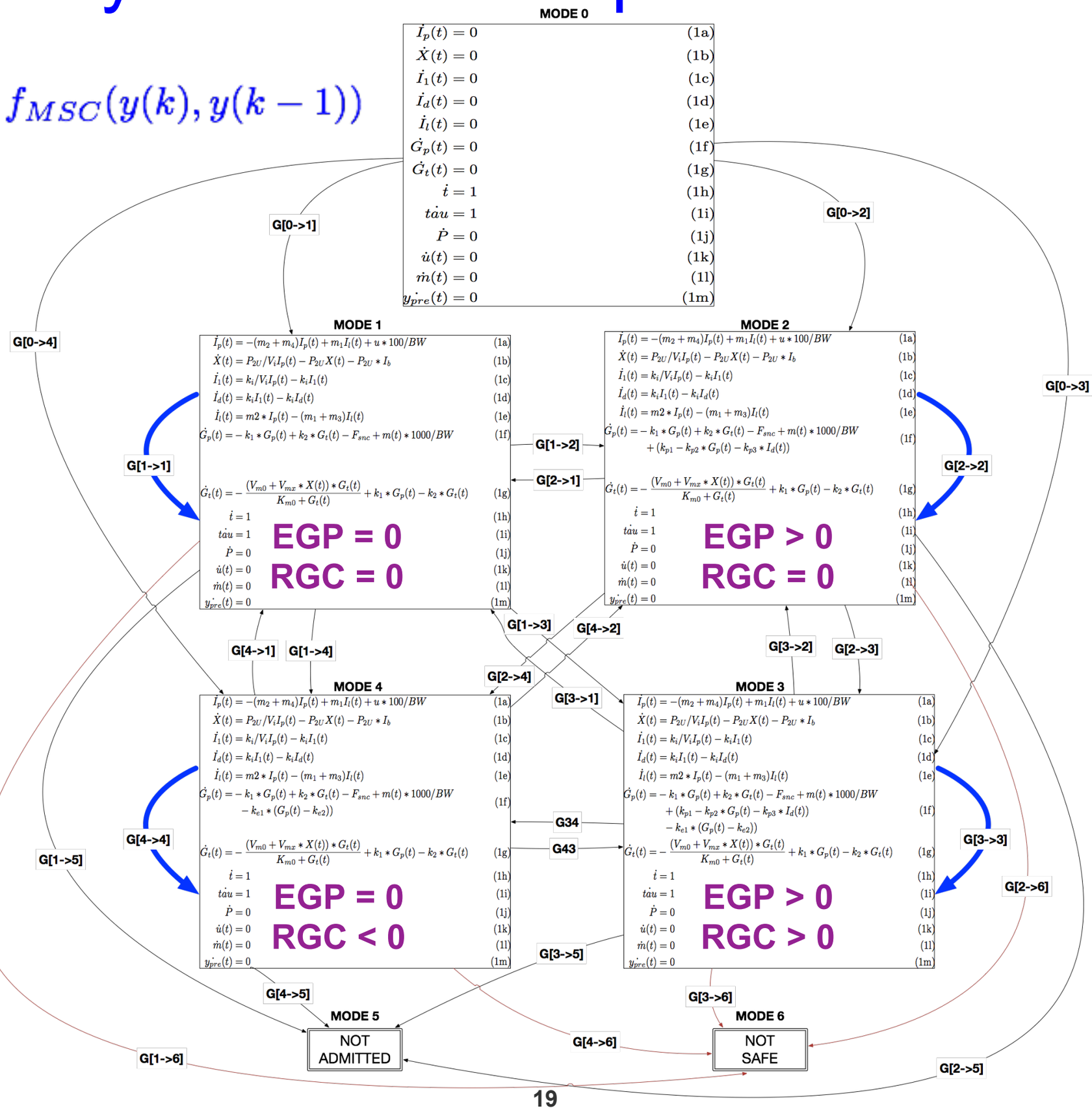
Hybrid System Model: “Not Safe” State

$$t >= 30 \wedge y \in R_{Unsafe}$$



Hybrid System Model: Update Control Inputs

$$[u(k), m(k)] = f_{MSC}(y(k), y(k-1))$$



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Implementation in dReach

- Model: Intraoperative glucose control system with non-linear dynamics
- Off-the-shelf tool that can directly encode the model
  - Possible choices include dReach, Flow*, KeYmaera
  - Other tools (e.g., HyTech, PHAVer, SpaceEx) require transforming the non-linear hybrid system into a suitable form
  - Chose dReach for a proof-of-concept implementation
- dReach model has 30 continuous states
  - 7 physiological states
  - 18 parameters (with zero derivatives)
  - 2 inputs (insulin rate u and glucose rate m), updated every 30 minutes
  - 1 state to record the last glucose reading, updated every 30 minutes
  - 1 global time state, and 1 local timer state

Preliminary Results on dReach

- Goal: “Reach the Unsafe state”
  - dReach returns UNSAT means “safe”
- Full state: Initialize 7 states to their full ranges
- Full parameter: Initialize 18 parameters to their full ranges
- x_0 and p_0 are the nominal values (single points provided by the FDA model)
- dReach version 2.15.01 on a Linux server with a Intel(R) Xeon(R) E5-2667 v2 3.30GHz CPU and 64 GB memory
- Path length of 7 corresponds to a maximum surgery duration of 2.5 hrs

Physiological Range		Path	Time	Result
State	Parameter	Length	(hours)	
Full	Full	3	30	safe
Full	Full	4	DNF	-
Full	$\boldsymbol{p}_0$	3	0.1	safe
Full	$\boldsymbol{p}_0$	4	0.6	safe
Full	$\boldsymbol{p}_0$	5	3.1	safe
Full	$\boldsymbol{p}_0$	6	8.2	safe
Full	$\boldsymbol{p}_0$	7	16.4	safe
Full	$\boldsymbol{p}_0$	8	DNF	-
$\boldsymbol{x}_0 \pm 0.5$	$\boldsymbol{p}_0 \pm 0.5$	3	0.1	safe
$\boldsymbol{x}_0 \pm 0.5$	$\boldsymbol{p}_0 \pm 0.5$	4	0.4	safe
$\boldsymbol{x}_0 \pm 0.5$	$\boldsymbol{p}_0 \pm 0.5$	5	1.1	safe
$\boldsymbol{x}_0 \pm 0.5$	$\boldsymbol{p}_0 \pm 0.5$	6	2.9	safe
$\boldsymbol{x}_0 \pm 0.5$	$\boldsymbol{p}_0 \pm 0.5$	7	8.1	safe
$\boldsymbol{x}_0 \pm 0.5$	$\boldsymbol{p}_0 \pm 0.5$	8	DNF	-

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Concluding Remarks

- An intraoperative glucose control benchmark
  - Practical relevance: Diabetes affects a large, fast growing population
  - Technical importance: No formal guarantee yet on the control performance given the space of uncertain states and parameters
  - Computationally challenging: dReach could not finish search depth of 4 after 30 hours given the full state and parameter variance ranges
- A general benchmark for medical CPS
  - Under-actuated, limited-sensing, un-identifiable parameters, hybrid systems with nonlinear dynamics
  - The purpose of formal verification in medicine is for pre-clinical trials

- [ADHS 2015] An Intraoperative Glucose Control Benchmark for Formal Verification. Sanjian Chen, Matthew O'Kelly, James Weimer, Oleg Sokolsky, Insup Lee. ADHS (IFAC Conf. on Analysis and Design of Hybrid Systems), Oct 14-16, 2015.

Thanks! Questions?

A Data-Driven Behavior Modeling and Analysis Framework for Diabetic Patients on Insulin Pumps
[ICHI 2015]

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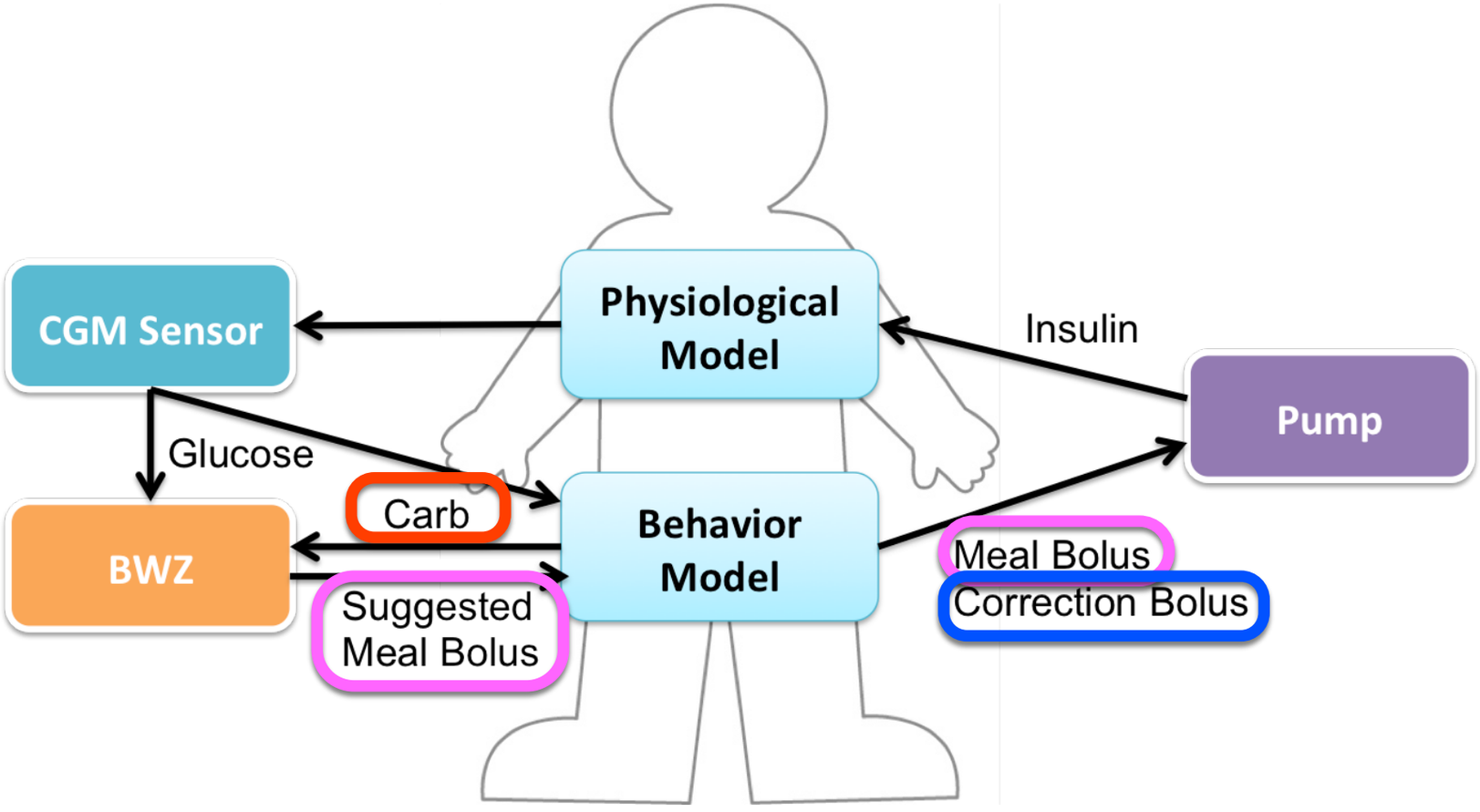
Type 1 Diabetes (T1D) on Insulin Pumps

- **Sensor-augmented subcutaneous insulin therapy**
  - 30% - 40% T1D patients in the US use insulin pumps
  - Requires user supervision
  - Critical needs for understanding the impact of insulin pumps on diabetic users, as highlighted in a American Association of Clinical Endocrinologists report



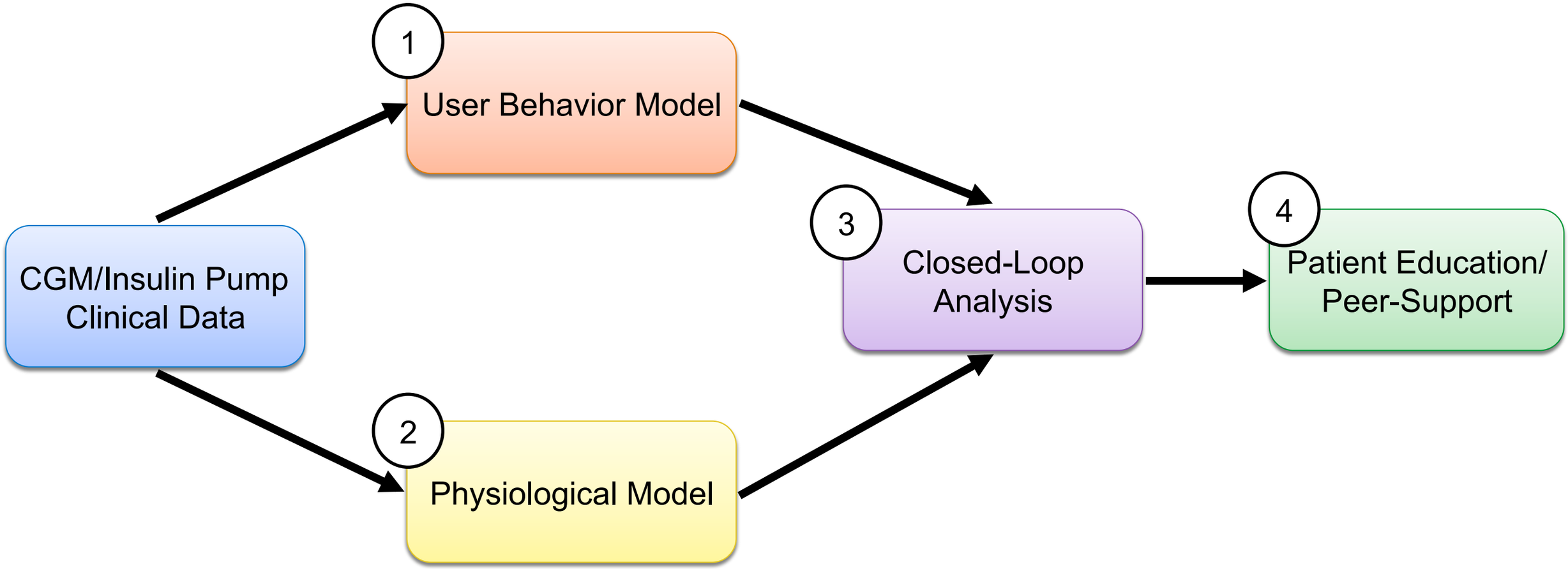
Goal and Problem Statement

- **The correctness of the closed-loop glycemic control system depends crucially on human interaction**
  - A fully automated closed-loop system that requires no user supervision is not likely to be available in the near future.

- **There is a need for understanding and modeling user behavior**
  - Analyze the effects of user behavior on glycemic control
  - User behavior models can also be used for closed-loop safety analysis

- **Problem**: **how to extract user models from the real patients' data?**
  - An important yet largely open research problem
  - Challenges:
    1. From messy data to meaningful model
    2. Individual behavior? Population clustering?
    3. Model validation

Approach Overview

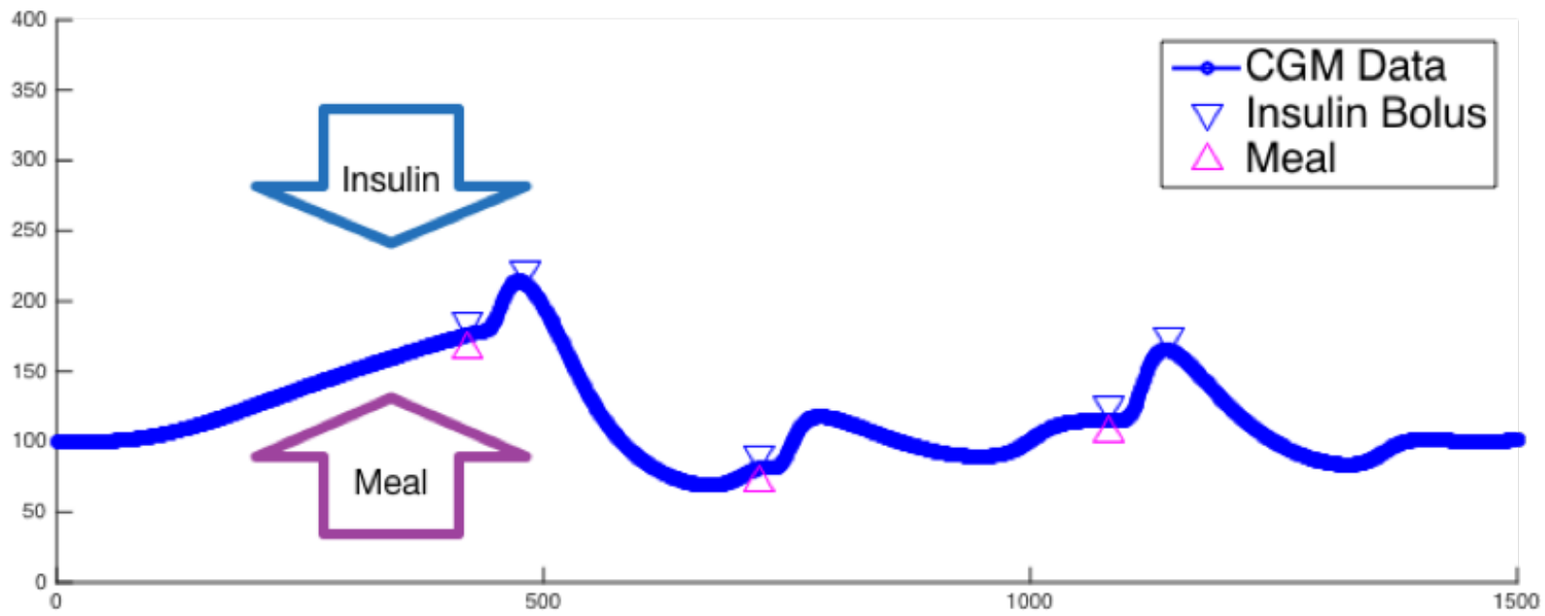


1. Extracting user behavior models from data
2. Individualize parameters of glucose/insulin physiological model
3. Closed-loop analysis: probabilistic model checking
4. Patient education/peer-support: how behaviors affect outcomes

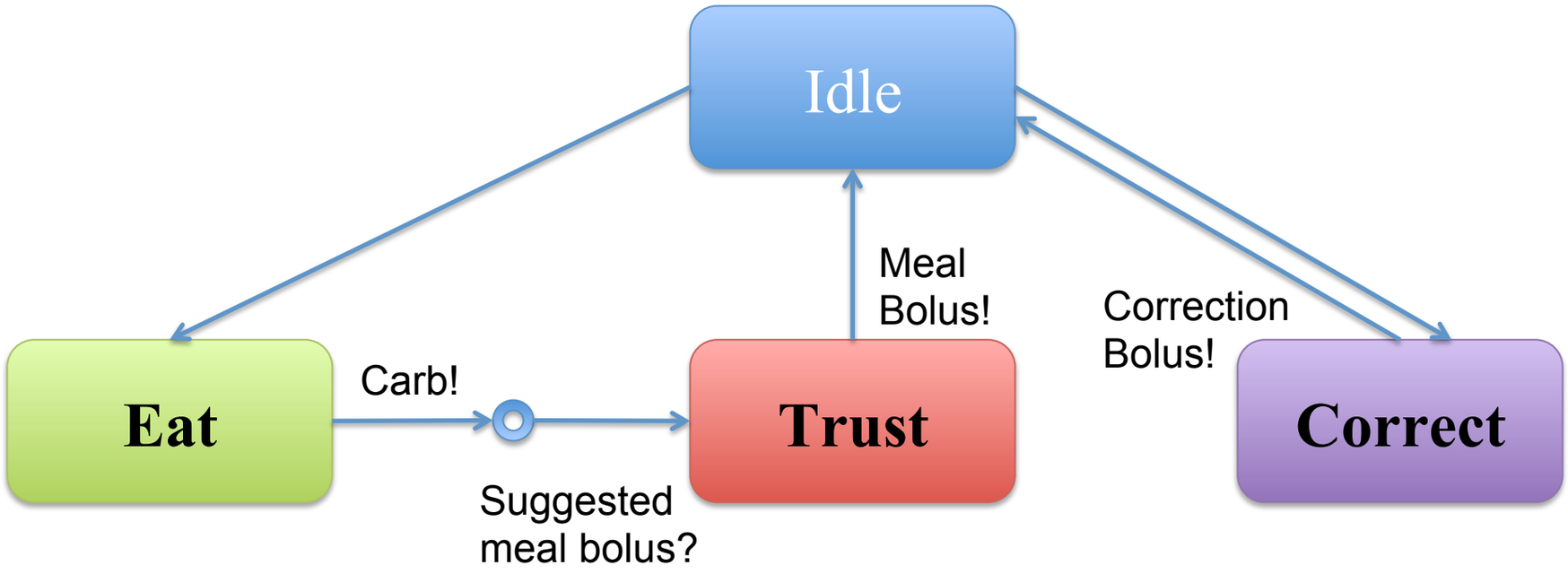
Clinical Dataset

- The dataset involves 55 T1D patients
  - Age 45.7 ± 15.3, body weight 79.2 ± 21.9 kg
  - Average time duration 31 days

- Sensor-augmented insulin pump data
  - CGM readings, mealtimes & carb counts, pump suggested boluses, user-selected boluses



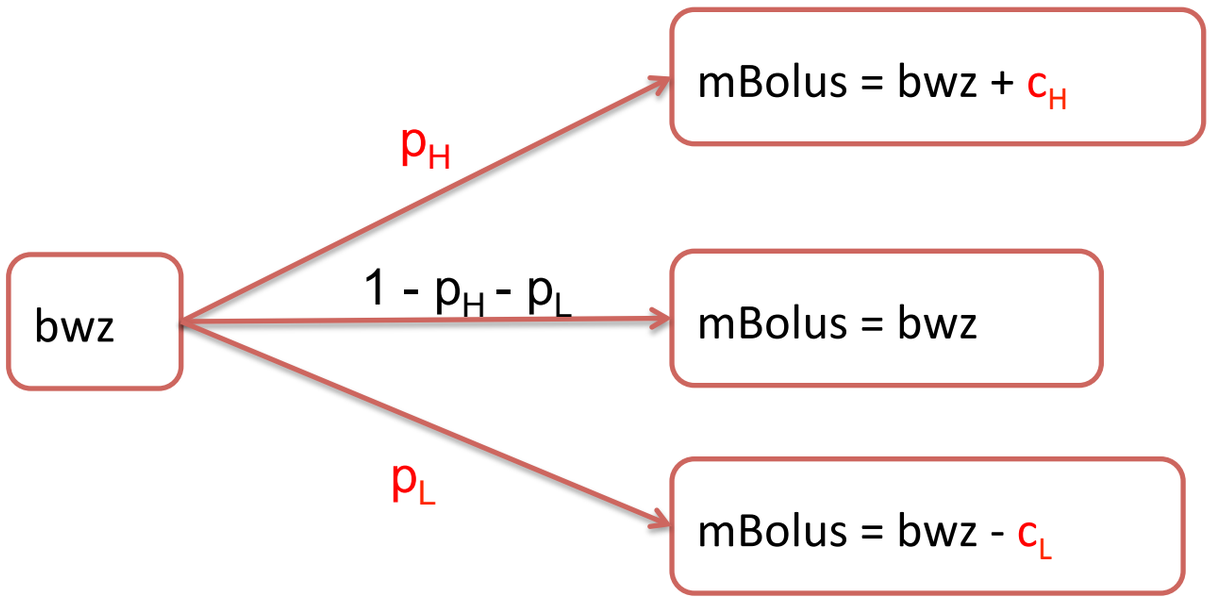
“Eat-Trust-Correct” Modeling Framework



- **Eat**: how often the patient eats throughout a day, and how much carbohydrate he/she eats
- **Trust**: whether the patient follows the BWZ recommended bolus doses, and if not, how much dosage he/she adjusts
- **Correct**: how often the patient takes correction boluses and how much dosage he/she takes

Probabilistic User Behavior Models

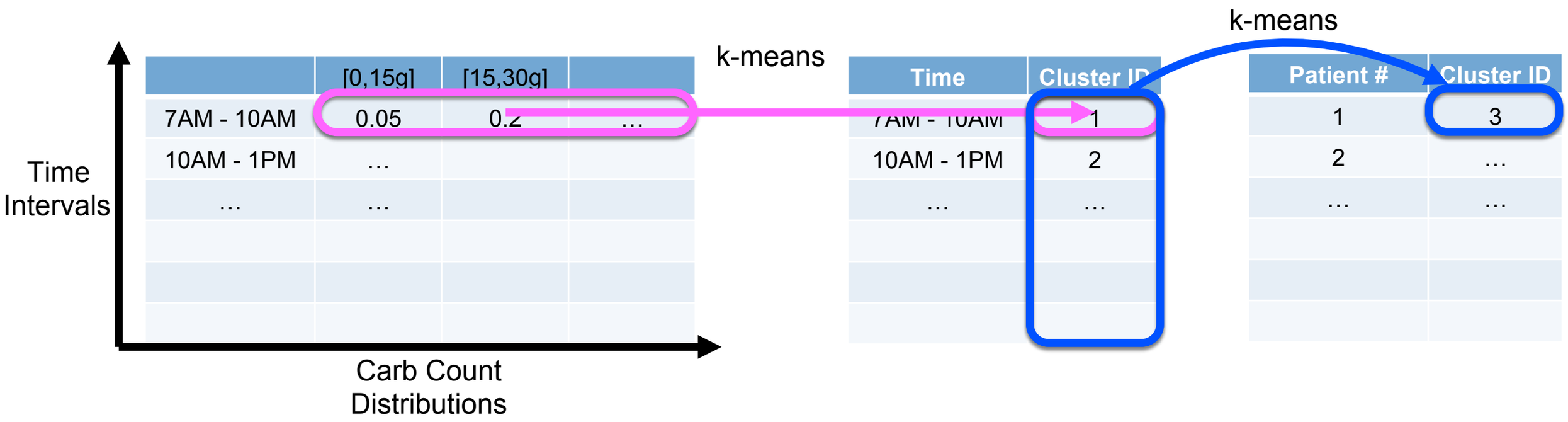
- We model the “Eat-Trust-Correct" user behavior as a discrete-time Markov chain
  - **Eat**: distributions of mealtime and carb counts
  - **Trust**: the likelihood of following pump-suggested boluses and distributions of dose adjustments
  - **Correct**: distributions of correction-bolus frequencies and doses



Clutering for User Behavior Patterns

- Challenge:
  - High-dimensional data for clustering

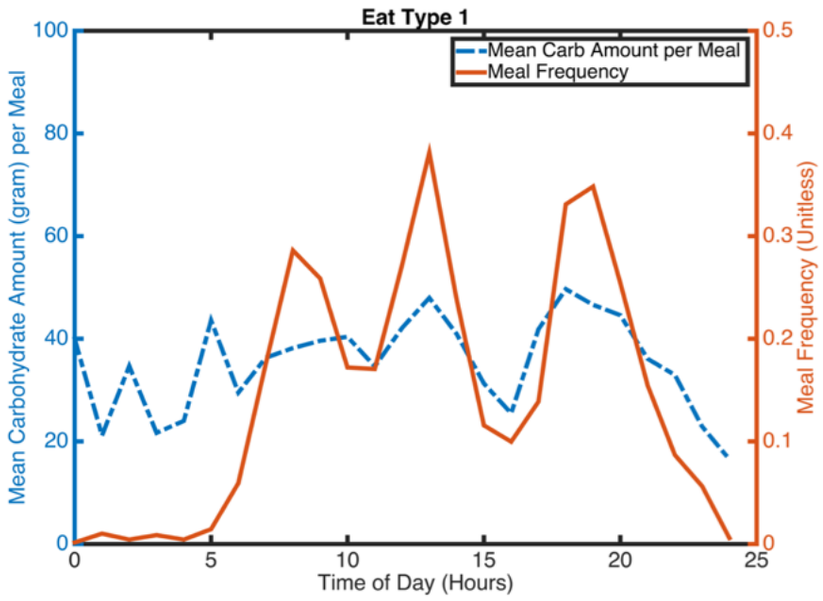
- Our approach: two-tier clustering heuristic
  - 1st stage: Probability Table —> Vector of Row Cluster ID
  - 2nd stage: Vector of Row Cluster ID —> Patient Cluster ID



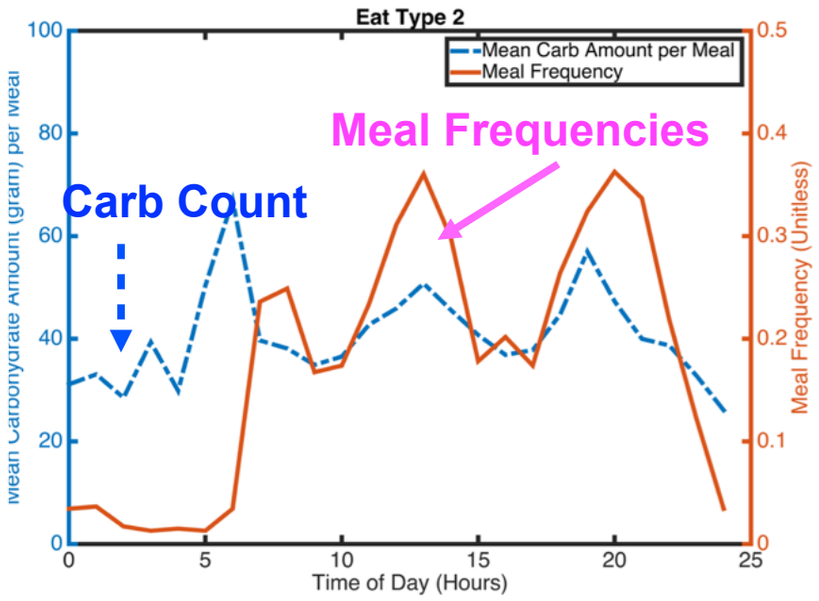
Eat Clusters

- Eat Type 1: 3 regular meals with low-carb inter-meal snacks
- Eat Type 2: 3 regular meals with moderate-carb inter-meal snacks
- Eat Type 3: no regular meal times

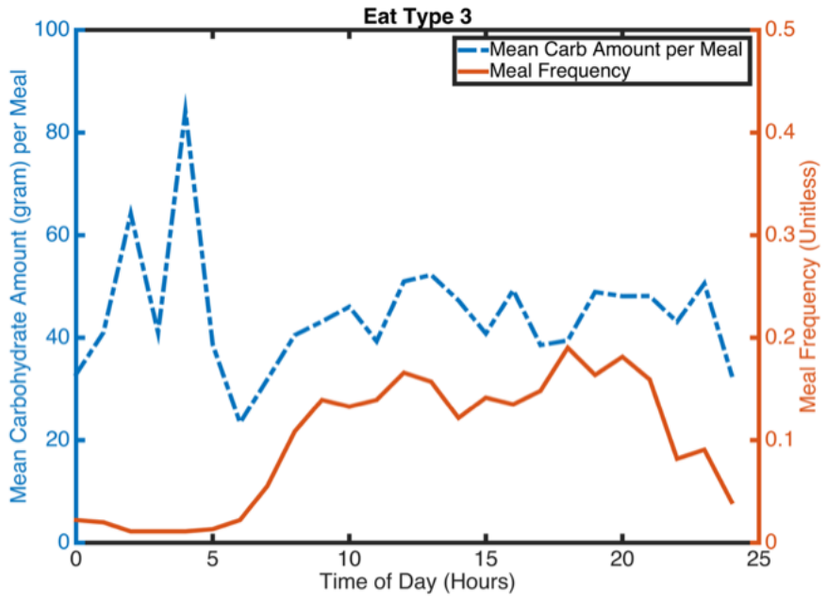
22 Patients



17 Patients



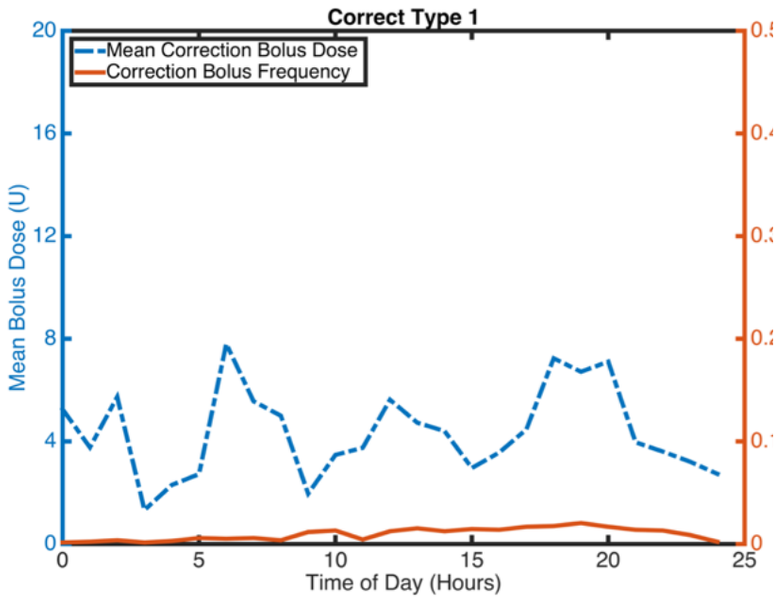
16 Patients



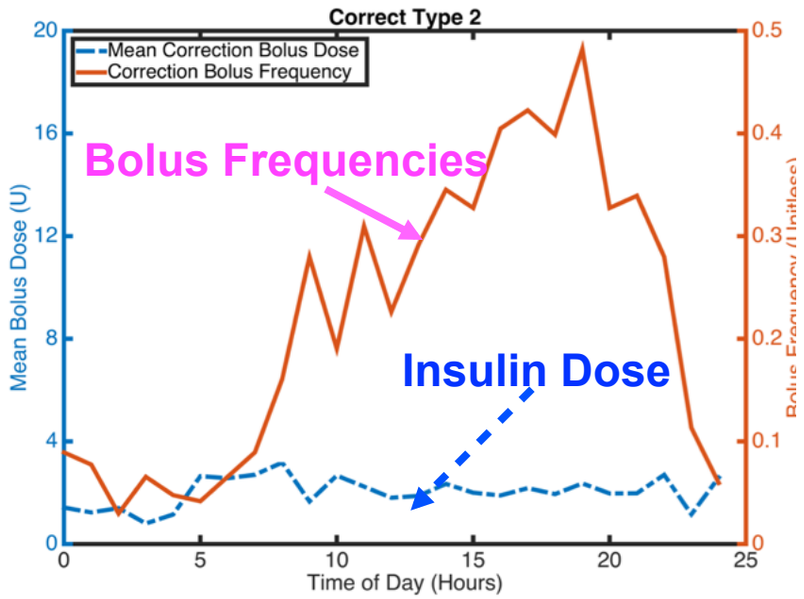
Correct Clusters

- Correct Type 1: infrequent high-dose correction boluses
- Correct Type 2: frequent correction boluses during daytime
- Correct Type 3: occasional correction boluses with peak frequencies at night and in the morning

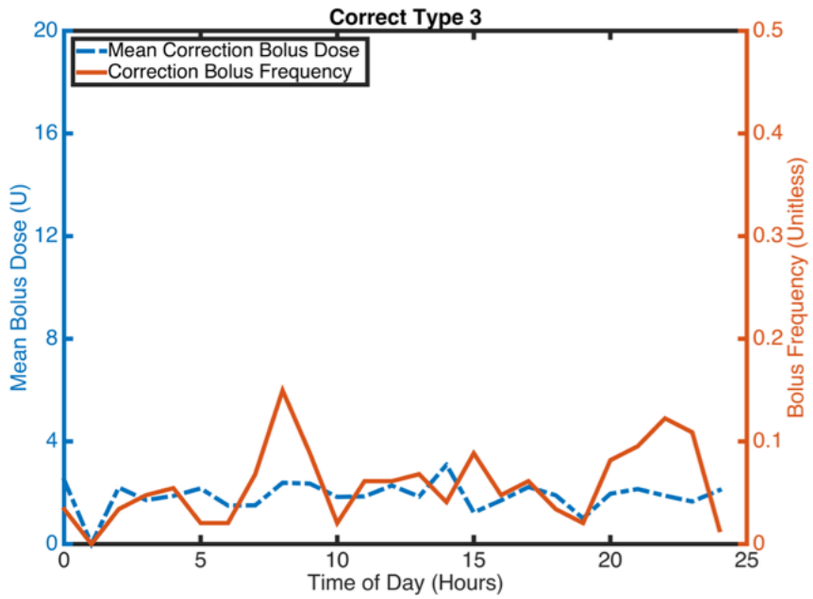
40 Patients



7 Patients

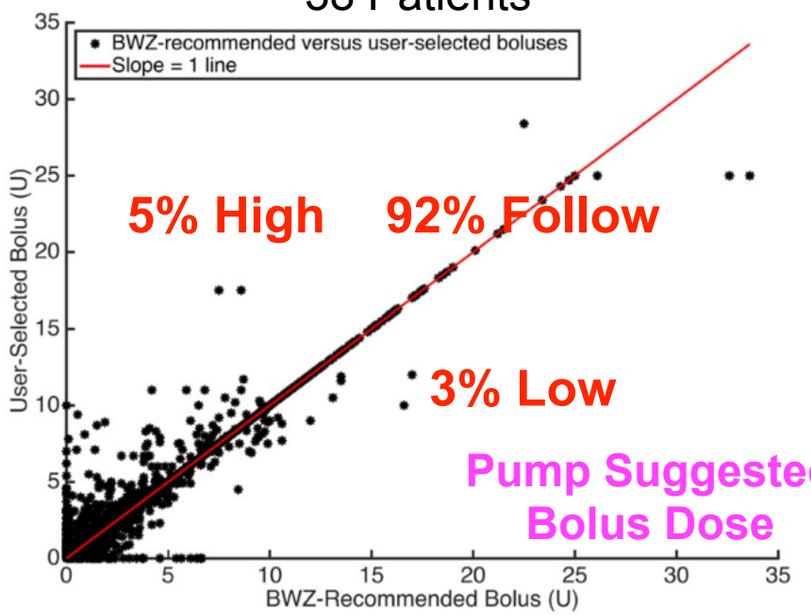


8 Patients

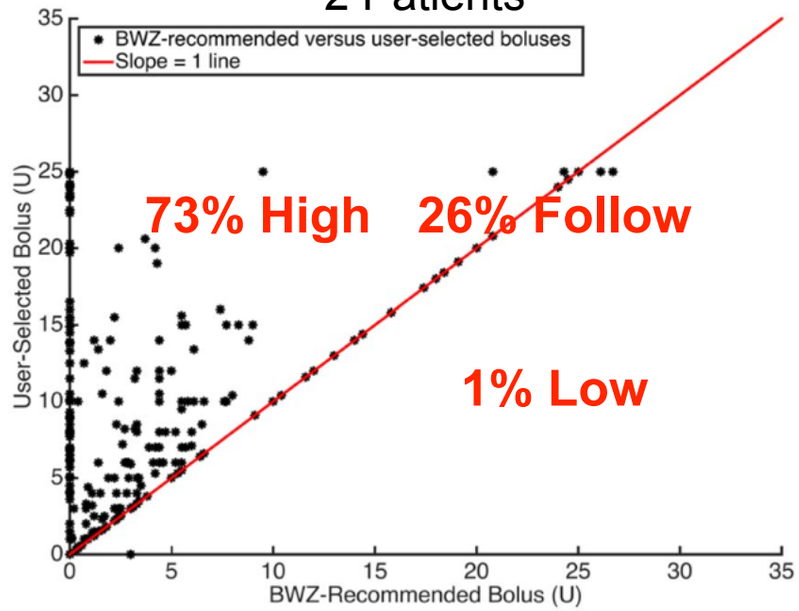


Trust Clusters

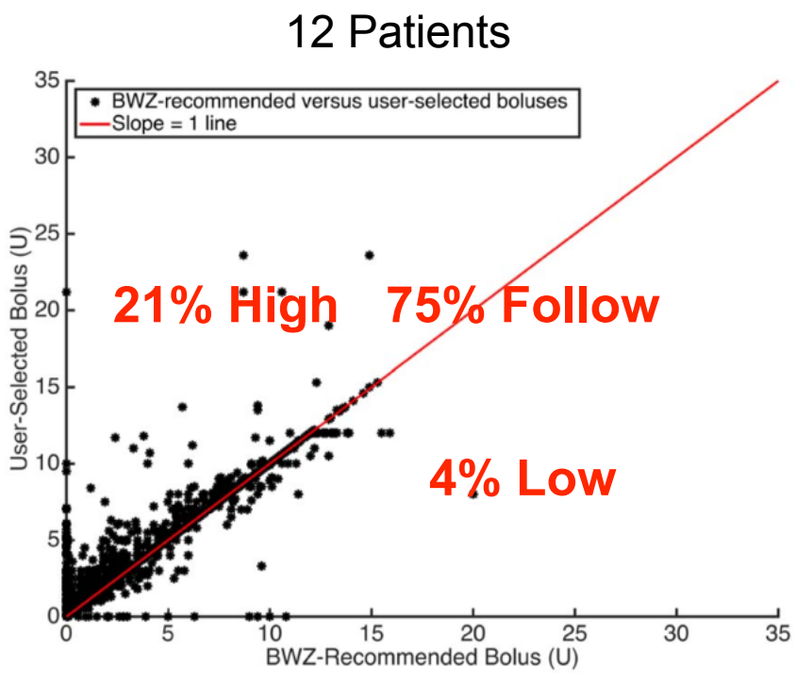
User Selected Bolus Dose



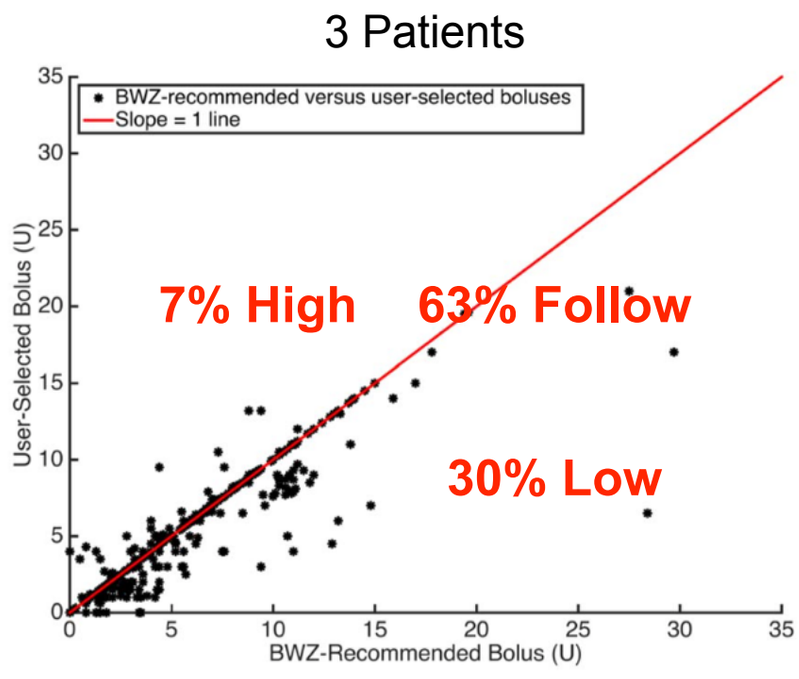
(a) Trust T1: high probability of following BWZ-recommended doses



(b) Trust T2: high probability of increasing BWZ-recommended doses



(c) Trust T3: moderate probability of increasing BWZ-recommended doses



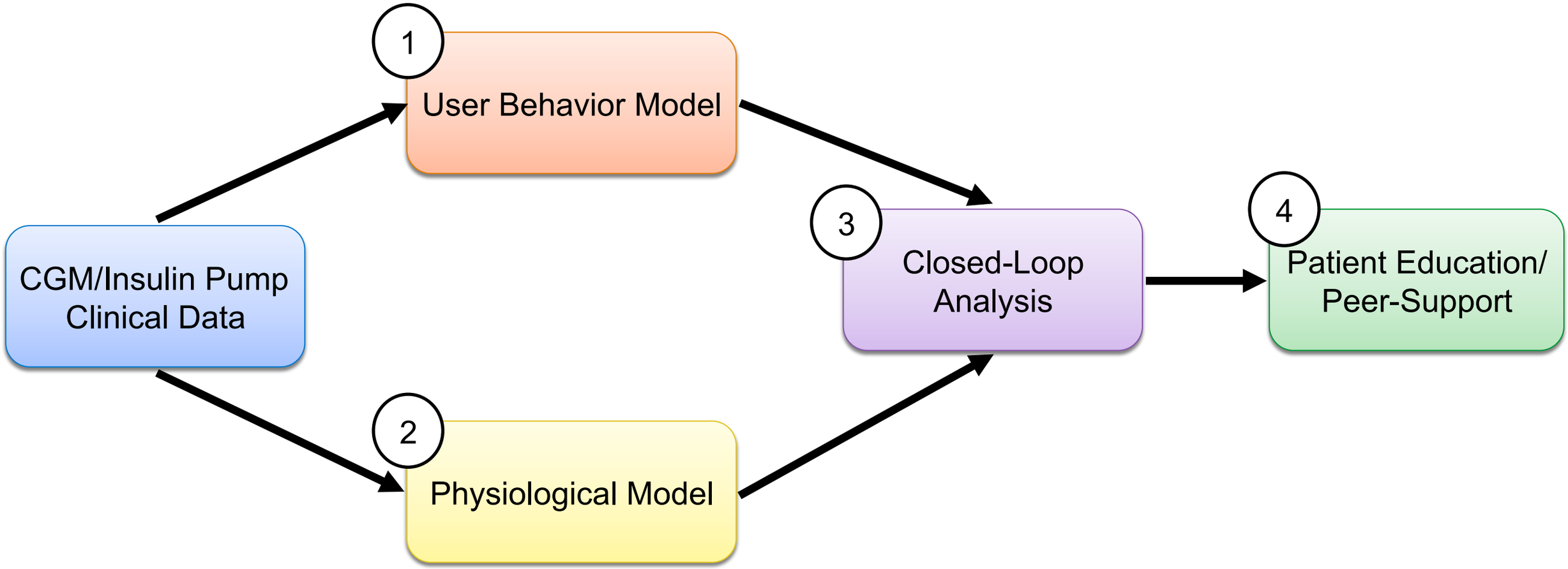
(d) Trust T4: high probability of decreasing BWZ-recommended doses

User Behavior Patterns

- Summary of “Eat-Trust-Correct” behavior patterns
  - 3 Eat types, 4 Trust types, 3 Correct types
  - Model validation: clinically relevant

ETC Type	Frequencies (in 55 patients)
E1T1C1	0.25
E3T1C1	0.16
E2T1C1	0.13
E2T3C1	0.09
E2T1C3	0.05
E1T3C1	0.05
E1T1C3	0.04
E3T1C2	0.04
E2T4C3	0.02
E1T3C3	0.02
E3T4C2	0.02
E3T3C2	0.02
E2T3C2	0.02
E1T2C2	0.02
E1T1C2	0.02
E3T4C1	0.02
E3T3C1	0.02
E3T2C1	0.02

Approach Overview



1. Extracting user behavior models from data
2. Individualize parameters of glucose/insulin physiological model
3. Closed-loop analysis: probabilistic model checking
4. Patient education/peer-support: how behaviors affect outcomes

Physiological Model

- Bergman model: compartmental physiological model

Plasma Glucose →

$$\frac{d}{dt}\begin{bmatrix} G(t) \\ g(t) \\ m(t) \\ x(t) \\ I(t) \end{bmatrix} = \begin{bmatrix} p1 & 0 & 1 & 0 & p2 \\ 0 & \frac{-1}{t_G} & 0 & 0 & 0 \\ 0 & \frac{1}{t_G} & \frac{-1}{t_G} & 0 & 0 \\ 0 & 0 & 0 & -k_a & 0 \\ 0 & 0 & 0 & \frac{k_a}{V_d} & -k_e \end{bmatrix} \begin{bmatrix} G(t) \\ g(t) \\ m(t) \\ x(t) \\ I(t) \end{bmatrix} + \begin{bmatrix} p_3 \\ \frac{A_G}{t_G} D_G(t) \\ 0 \\ u(t) \\ 0 \end{bmatrix}$$

← Meal Input

← Insulin Input

Plasma Insulin →

- Fit the parameters to reproduce the key glycemic statistics
  - Ranges of parameters are given in clinical literature

Population Statistics

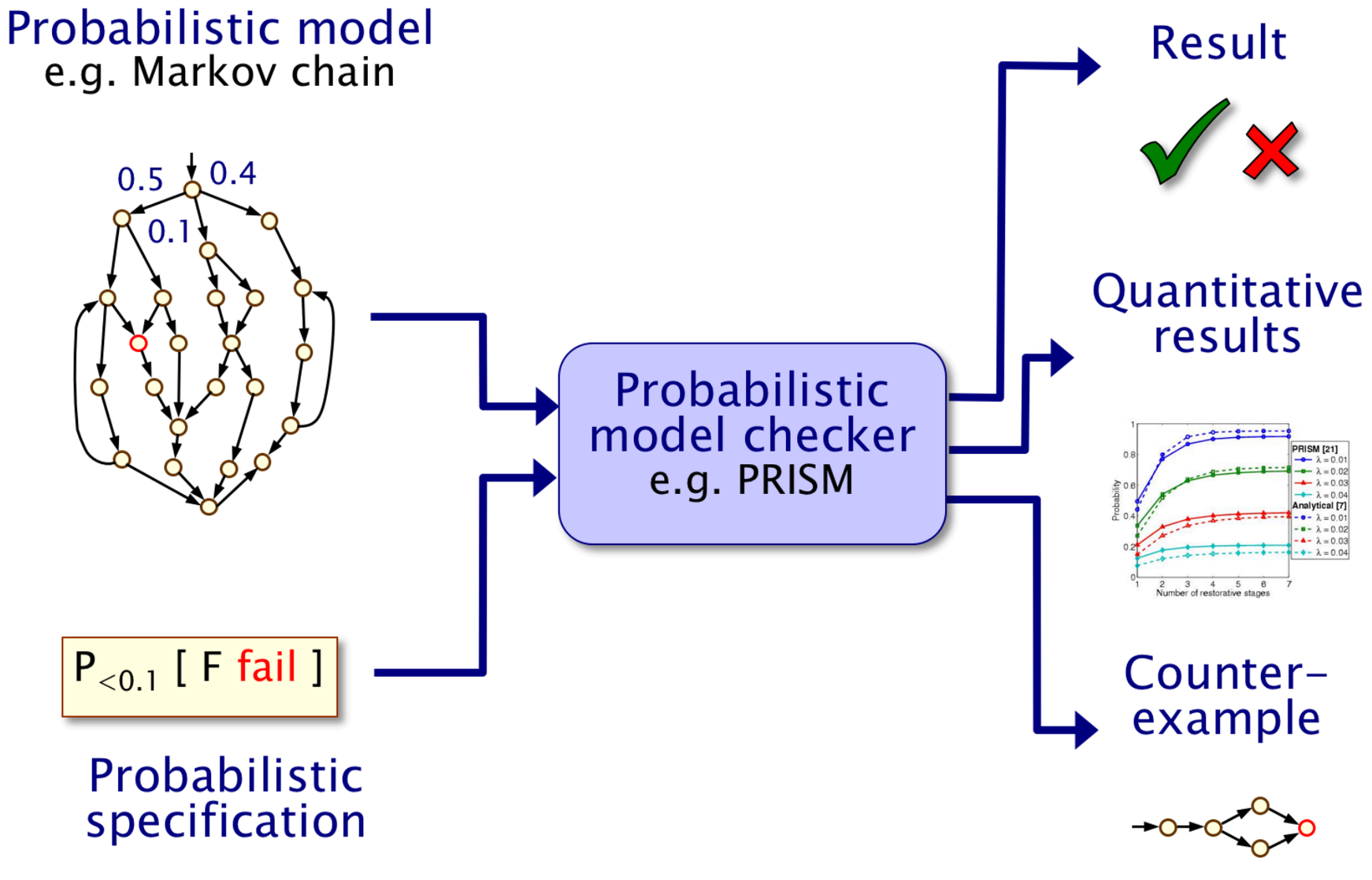
	CSII Dataset BG	Model Simulated BG
Mean BG	163	159
Max BG	365	379
Min BG	50	49
BG $>$ 180	35%	30%
BG $<$ 70	3%	3%
BG in [70,180]	62%	67%

Per-Subject Statistics

Metric	Value
Mean Difference of Per-Patient Mean BG	14 mg/dL
Mean Difference of Per-Patient BG $>$ 180 Percentage	5%
Mean Difference of Per-Patient BG $<$ 70 Percentage	1%
Mean Difference of Per-Patient BG in [70,180] Percentage	6%

Probabilistic Model Checking

- Probabilistic model checking using PRISM
  - Modeling and analysis the quantitative properties of probabilistic models
  - Exhaustively explore *all* possible model executions/paths



Closed-Loop Analysis

- Integrate individualized physiological model and behavioral models

- Clinical-relevant properties:
  - Explore how changing behavior types may impact outcomes
  - Hypoglycemia: % of CGM readings < 70 mg/dL
  - Hyperglycemia: % of CGM readings > 180 mg/dL

- Modeling in PRISM
  - User behavior model: discrete-time Markov chains
  - Physiological model: discrete form of the Bergman model
  - Pump/sensor model: finite-state machines
  - Properties:
    - assign cost functions to transitions (e.g., count adds 1 for every CGM<70)
    - compute the total expected cost (e.g., total number of CGM readings <70 mg/dL) and divide it by the total number of CGM samples over a period of time (e.g., 3 days)

Example PRISM User Behavior

```
// user behaviour model
module user

        // user states: 0-idle,1-eat,2-requestBWZ,3-trust,4-correct
        xu:[0..4] init 0;
        // meal carb amount
        mCarb: [0..7] init 0;
        // meal bolus
        mBol : [0..10] init 0;
        // correction bolus
        cBol : [0..10] init 0;

        [tick] (xu = 0) & (t != BREAKFAST) & (t != mSNACK) & (t != LUNCH) & (t != aSNACK) & (t != DINNER) & (t != eSNACK) & (t != COR1) & (t !=

        // Eat meals
        [tick] (xu = 0) & (t = BREAKFAST) -> 0.29: (xu' = 1) & (mCarb' = 0) + 0.05: (xu' = 1) & (mCarb' = 1) + 0.42: (xu' = 1) & (mCarb' = 2) +
        [tick] (xu = 0) & (t = mSNACK) -> 0.37: (xu' = 1) & (mCarb' = 0) + 0.24: (xu' = 1) & (mCarb' = 1) + 0.23: (xu' = 1) & (mCarb' = 2) + 0.
        [tick] (xu = 0) & (t = LUNCH) -> 0.20: (xu' = 1) & (mCarb' = 0) + 0.19: (xu' = 1) & (mCarb' = 1) + 0.20: (xu' = 1) & (mCarb' = 2) + 0.1
        [tick] (xu = 0) & (t = aSNACK) -> 0.64: (xu' = 1) & (mCarb' = 0) + 0.14: (xu' = 1) & (mCarb' = 1) + 0.07: (xu' = 1) & (mCarb' = 2) + 0.
        [tick] (xu = 0) & (t = DINNER) -> 0.24: (xu' = 1) & (mCarb' = 0) + 0.09: (xu' = 1) & (mCarb' = 1) + 0.12: (xu' = 1) & (mCarb' = 2) + 0.
        [tick] (xu = 0) & (t = eSNACK) -> 0.74: (xu' = 1) & (mCarb' = 0) + 0.10: (xu' = 1) & (mCarb' = 1) + 0.07: (xu' = 1) & (mCarb' = 2) + 0.

        // Trust: decide whether to follow BWZ recommended bolus
        [mBolRequest] (xu = 1) -> (xu' = 2);
        [] (xu = 2) -> 0.92: (mBol' = mBolbwz) & (xu' = 3) + 0.05: (mBol' = min(10,floor(mBolbwz + 1))) & (xu' = 3) + 0.03:(mBol' = max(0,floor
        [sync] (xu = 3) -> (xu' = 0) & (mBol' = 0) & (mCarb' = 0);

        // Correct: user decides whether to give a correction bolus based on CGM readings
        [tick] (xu = 0) & (t = COR1) & (bg < 173) -> (xu' = 4);
        [tick] (xu = 0) & (t = COR2) & (bg < 173) -> (xu' = 4);
        [tick] (xu = 0) & (t = COR3) & (bg < 173) -> (xu' = 4);
        [tick] (xu = 0) & (t = COR4) & (bg < 173) -> (xu' = 4);
        [tick] (xu = 0) & (t = COR5) & (bg < 173) -> (xu' = 4);
        [tick] (xu = 0) & (t = COR6) & (bg < 173) -> (xu' = 4);

        [tick] (xu = 0) & (t = COR1) & (bg >= 173) -> 1.00:(cBol' = 0) & (xu' = 4) + 0.00:(cBol' = 1) & (xu' = 4) + 0.00:(cBol' = 2) & (xu' = 4
```

Results

- Switching behavior types may improve the glycemic control outcomes

	ETC Type	Hypoglycemia Rate (%)	Hyperglycemia Rate (%)
Actual type	E3T2C1	**6.93**	8.43
Change E subtype	E1T2C1	6.20	12.78
	E2T2C1	5.99	13.72
Change T subtype	E3T1C1	0.02	10.33
	E3T3C1	0.04	10.09
	E3T4C1	0.02	11.05
Change C subtype	E3T2C2	7.04	6.30
	E3T2C3	6.95	7.93
Change multi-subtypes	E2T1C1	0.04	16.46
	E2T2C1	5.99	13.72
	E3T1C3	0.10	9.76
	E2T1C3	0.08	15.42

	ETC Type	Hypoglycemia Rate (%)	Hyperglycemia Rate (%)
Actual type	E1T1C1	0	**43.92**
Change E subtype	E2T1C1	0	44.38
	E3T1C1	0	41.62
Change T subtype	E1T2C1	0	39.13
	E1T3C1	0	43.46
	E1T4C1	0	45.31
Change C subtype	E1T1C2	0	41.59
	E1T1C3	0	43.47
Change multi-subtypes	E1T2C2	0	37.22
	E3T2C1	0	35.45
	E3T1C2	0	38.01
	E3T2C2	0	32.56

Conclusion

- Methods for extracting user behavior models from a clinical dataset containing 55 T1D patients
  - “Eat-Trust-Correct” probabilistic models based on data statistics and clustering

- Closed-loop analysis using probabilstic model checking suggests switching behavioral types may improve glycemic control outcomes
  - More effective patient education and peer-support

- Future work
  - Testing on larger clinical datasets
  - Further development and validation of learning techniques
  - Plug in other physiological models

- [ICHI 2015] A Data-Driven Behavior Modeling and Analysis Framework for Diabetic Patients. Sanjian Chen, Lu Feng, Michael Rickels, Amy Peleckis, Oleg Sokolsky and Insup Lee. IEEE Int. Conf. on Healthcare Informatics (ICHI), Oct 21-23, 2015.

Thanks! Questions?