A novel Simulation Environment modeling realistic interactions between patients and Decision Support Systems

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SIMULATOR

Decision support systems (DSS), such as Bolus Calculators, become increasingly complex due to the variety of integrated devices (Smart Pens) and different patient behaviors. Simulators have been successfully used for AID algorithm development but the models are mostly limited to patient physiology[1]. Our simulator allows a holistic description of therapy management by adding behavioral and device-specific models (Figure 1). This allows realistic end-to-end tests without imposing patient risk.

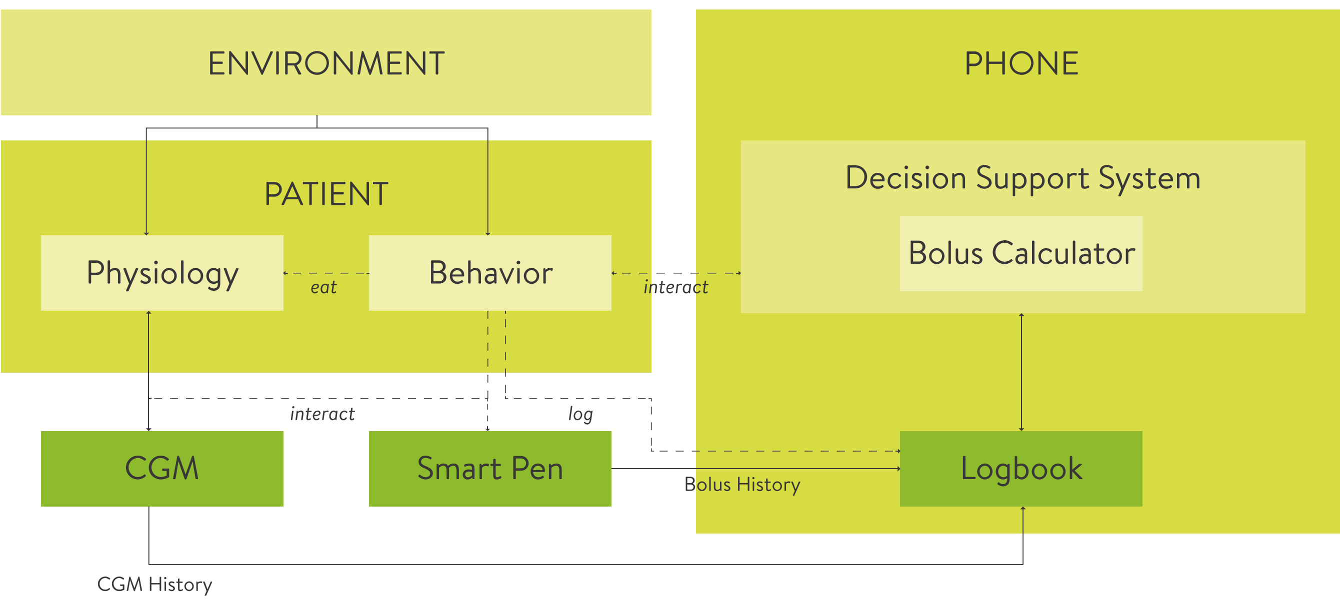

Figure 1: *Simulation Environment Components*

COMPONENTS

The simulator's modular design allows arbitrary configurations of varying complexity. At the core, Patient Physiology describes glucose dynamics with a second order differential equation[2]. The Environment provides a daily rhythm of situations (i.e. sleep, work), meals and special events (device failure). The technical setup (tools) in the example above consists of a CGM and connected Smart Pen including device specific characteristics such as uncertainties, connectivity loss and delays. Finally, the Behavior models the virtual patient's therapy decisions. The patient can interact with the devices and DSS (tools) but does not have to. Decisions are based on patient characteristics, physiological state, environmental context, available DSS and previous actions. Connecting the various components allows simulation of holistic diabetes self management (Figure 2). Instead of modeling probabilistic disturbances such as unannounced meals explicitly, it is the patient decisions and actions that challenge the system and result in a broad range of alternative outcomes.

Figure 2: *Simulation of 48 hours results in alternative decisions and outcomes. The figure also illustrates the interaction between Environment (top), diabetes-related jobs of the behavioral model (mid) and Patient Physiology (bottom).*

BEHAVIORAL MODEL

User research identified recurring daily jobs and associated actions in diabetes therapy[3]. Jobs arise as a result of physiological state, environmental contexts and events. The action taken by the user depends on the situation, available tools, personal traits and previous actions. We integrate this domain knowledge into a probabilistic model using Markov Chains with variable transition probabilities (Figure 3). A node represents a patient action u_j. Transitions to the next action u_i are modeled as situation dependent probability functions $f_{ij}(\bullet) \rightarrow [0,1] : \sum_{j=1}^{n} f_{ij}(\bullet) = 1$. Each action triggers a sequence of events in the simulator.

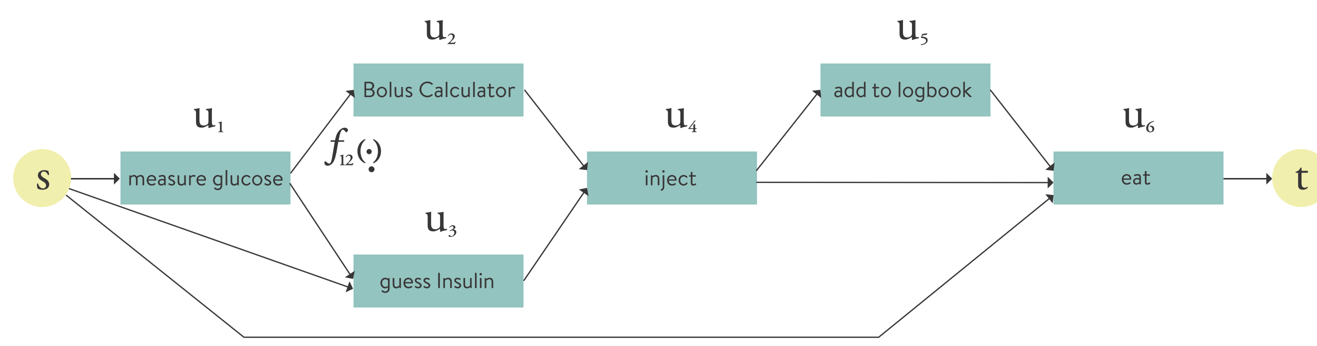

Figure 3: *A simplified example to showcase how a Markov Chain can be used to model a meal-related job. In the full implementation, this model was extended to account for airshots, bolus splitting and monitoring BGL after the meal.*

RESULTS

Decisions taken by the virtual patients are probabilistic but the sequence of action paths follow realistic decision patterns. As a result, simulations cover a wide range of alternative scenarios and outcomes as illustrated in Figure 4. Each simulation results in different therapy decisions and physiological states. The changing level of device utilization results in different levels of available information (i.e. meal announcements, insulin data, airshots, ...) for the DSS under development.

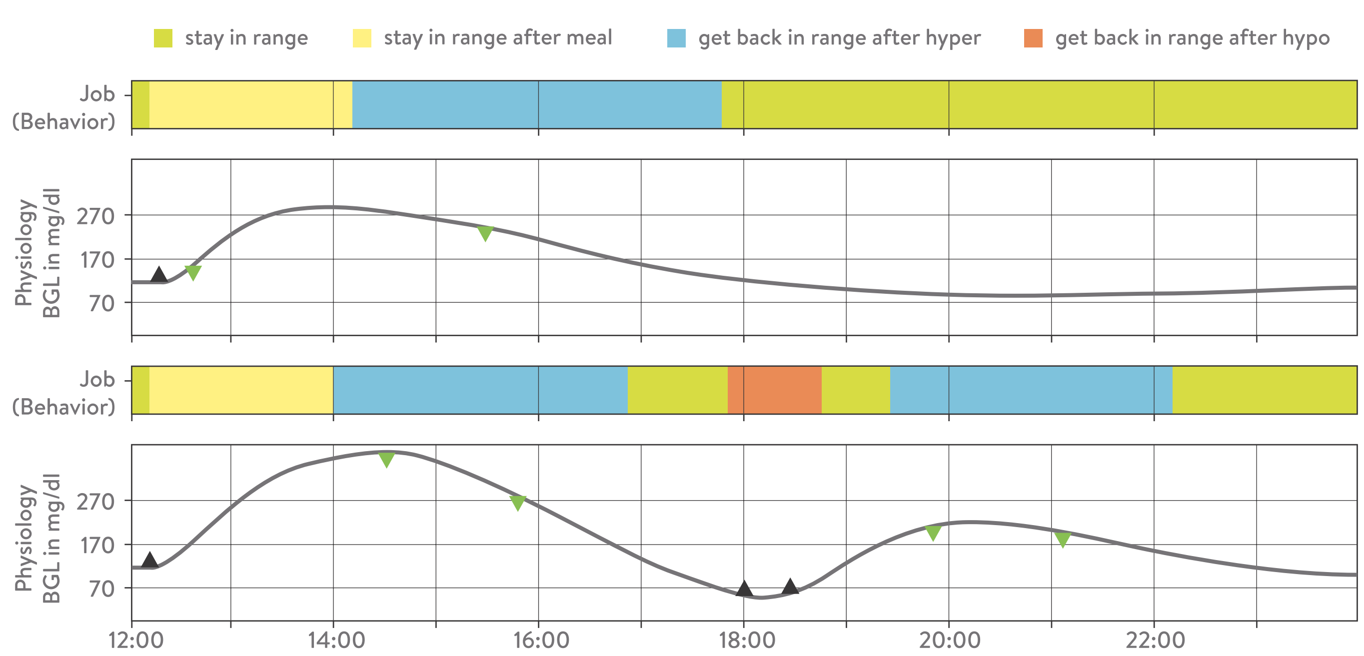

Figure 4: *The same situation results in different outcomes due to different user decisions. In the upper simulation, path s-u_1-u_2-u_4-u_6-t (Figure 3) was chosen for the "Stay in range after meal" job (yellow). The lower simulation followed the path s-u_6-t, which led to the generation of other jobs and actions later in time.*

CONCLUSION

A holistic diabetes therapy management simulator has been developed. The probabilistic and modular design combined with a underlying behavioral model allows the simulation of realistic device interactions making it a useful tool for in-silico development. In ongoing efforts, the simulator is utilized to generate artificial data sets and is planned for use in pre-clinical end-to-end tests.

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1 Kovatchev BP, Breton M, Dalla Man C, Cobelli C: In silico preclinical trials: a proof of concept in closed-loop control of type 1 diabetes. J Diabetes Sci Technol 2009;3:44–55.
2 H. Kirchsteiger and L. del Re, "A model based bolus calculator for blood glucose control in type 1 diabetes", in Proceedings of the 2014 american control conference (acc), Jun. 2014, pp. 5465–5470.
3 mySugr, Unpublished Data 2018