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TOWARDS AN ADAPTIVE DECISION-SUPPORT SYSTEM FOR TYPE I DIABETES TREATMENT BASED ON SIMULATION AND MACHINE LEARNING

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ABSTRACT
Diabetes is one of the most prevalent chronic diseases in the world, especially in middle- and low-income countries. Inter- and intra-patient variability greatly hinders the establishment of effective treatments by clinicians, even among those most experienced. This variability also prevents health administrations to establish adequate controls that guarantee the application of the most cost-effective interventions. In this work, we propose a decision support system that uses simulation and machine learning as tools to provide the clinician with information adapted to the patient on the best intervention for a patient in terms of effectiveness and cost-effectiveness.

Keywords: clinical decision-support system, cost-effectiveness, diabetes, machine learning, simulation

1. INTRODUCTION

Diabetes mellitus is a chronic disease that can be caused by a malfunction of the pancreas, which does not produce enough insulin (the hormone that regulates blood glucose), or the body, which is not able to use the insulin produced. In the long term, hyperglycemia affects the organs of the body, which leads to develop all kinds of chronic complications (cardiovascular and eye diseases, nephropathy, neuropathy...) with extremely negative effects on the patient's health and with an enormous economic impact in health systems.

Approximately 425 million adults have diabetes worldwide, and this figure is expected to increase to 629 million by 2045, with a special incidence in low- and middle-income countries (International Diabetes Federation, 2017). The precise diagnosis of diabetes is quite complex, although three main types are currently accepted: type 1 (T1DM), type 2 (T2DM) and gestational.

More specifically, T1DM is an autoimmune disease, which results in the body producing little or no insulin. Although its cause is not fully understood, it is known to be associated with genetic factors and certain environmental triggers. Typically, T1DM develops in childhood or adolescence. In high-income countries, T1DM is estimated to be between 7% and 12% of all cases of diabetes.

The adequate management of the disease relies on a constant and frequent monitoring of the blood glucose level, as well as other risk factors; accompanied by a treatment with adequate doses of insulin, and diet and healthy habits. In this way, it is possible to delay or avoid most of the worst consequences of the T1DM.

Despite the existence of clinical practice guidelines and the increasing training of health professionals, great uncertainty surrounds the potential effectiveness of a treatment in a particular patient. Hence, it is still necessary to have systems that improve the decision making of the clinicians. Furthermore, in this decision-making process, not only the effectiveness of the interventions should prevail. In the current context in which we live, the sustainability of public health systems is in question, so the cost of interventions should also be considered when recommending a treatment. Cost-effectiveness analysis is a type of economic evaluation that allows assessing both the cost and the effectiveness of a new health intervention. This type of evaluations is increasingly used in contexts where the availability of resources is limited, and respond to the need to have tools that objectively value the benefits for the population of a health technology against its cost (Briggs, Claxton, and Sculpher 2006). Specifically, in Spain, Royal Decree-law 16/2012, of 20 April, determines that the economic evaluation of health interventions is a necessary instrument to decide whether the National Health System should finance a new drug, therapy or health technology.

The rest of this paper is organized as follows. Section 2 presents a review of the state-of-the-art in terms of decision support systems for the treatment of diabetes. Section 3 highlight the main modelling frameworks

available for the economic assessment of new interventions for diabetes. Section 4 proposes a new approach that intends to incorporate economic factors into decision-making, and advance in the adaptation to the patient of the simulations by means of machine learning techniques. Within this section, special emphasis is made on the simulation model. Finally, Section 5 draws some conclusions and further research.

2. CLINICAL DECISION SUPPORT SYSTEMS FOR DIABETES TREATMENT

The creation of computerized clinical decision support systems (CDSS) in diabetes is not recent. Salzsieder et al. (1988) proposed a CDSS to predict the effect of different treatment regimens in patients with T1DM. The system was based on a simulation model that predicted the patient's metabolic evolution based on the glucose-insulin ratio.

In the 90s, a number of CDSSs based on rule-driven expert knowledge systems appeared. For example, DIABETEX was a CDSS for patients with T1DM focused on helping non-expert clinicians. The system was manually fed with follow-up data from patients. With this information, DIABETEX calculated the best insulin dose for the patient (Zahlmann et al. 1990). Carson et al. (1990) and Deutsch et al. (1990) present similar proposals.

Much more recently, Salzsieder et al. (2011) developed KADIS, a patient-centered and model-based CDSS to provide clinicians with evidence-based recommendations. KADIS uses a model of the physiological system of glucoregulation, which can be adapted to individualized patient profiles. This model provides a reference to analyze the impact of different therapies on the individual and recommends insulin guidelines. Currently, KADIS is part of an European project, called Power2DM.

METABO is another project that monitors the pharmacological and lifestyle factors that may affect the blood glucose levels of a patient. This monitoring leads to structured information that helps patients and caregivers to make decisions. The core of METABO is a compartmental model that provides immediate information to patients about how their lifestyle or treatment affects their glucose level. Clinicians benefit from the information gathered by METABO thanks to 1) the identification of rules that relate lifestyles, treatments and metabolic data; 2) the creation of groups ("clustering") of patients based on criteria hidden in the data, using machine learning tools; and 3) the classification of new patients in the identified groups based on their characteristics (Fico et al. 2015).

METABO is a clear example of the current trend, where the use of machine learning techniques stands out among other strategies. Contreras and Vehi (2018) and Kavakiotis et al. (2017) present revisions on these last approaches, of which we highlight some in the following paragraphs.

OntoDiabetic is a CDSS based on a series of ontologies, extended by rules to model clinical practice guidelines. These ontologies allow evaluating the patient's risk factors and providing treatment suggestions. This approach does not include any type of patient simulation (Sherimon et al. 2016).

The approach of Chen et al. (2017) is a CDSS for clinicians that uses multicriteria decision-making techniques for prioritizing among treatments for T2DM. Their approach also applies a fuzzy logic model to take into account patient's disposition in the decision-making process.

Caballero-Ruiz et al. (2017) present a web platform that has a CDSS for patients in relation to their diet and insulin dose. A clinician should always review the insulin dose before approval. A rule-based knowledge system, which combines the output of two finite automata to determine the patient's metabolic status, generates the recommendations.

Kang (2018) proposes a system for predicting the effectiveness of treatments for patients with T2DM based on recurrent neural networks. Neural networks incorporate information about the sequence of treatments prior to the inference process, which, according to the author, improves the accuracy of the prediction.

3. ECONOMIC MODELS FOR HEALTH INTERVENTIONS ON DIABETES

None of the aforementioned proposals incorporates elements to assess not only the effectiveness, but the cost of health interventions. In diabetes, the economic evaluation of new treatments is usually carried out with the support of models that reflect the evolution of the disease throughout the patient's life, so that the impact on both the long-term health of the patient, and the use of health resources can be quantified. Many of these models are created *ad hoc* to evaluate a specific intervention in a specific context but the complexity of this disease has led to the creation of some large commercially available generic models.

The Core Diabetes Model (CDM) of IQVIA is probably the most widely used of these models (Palmer et al. 2004a). The CDM is able to simulate the progression of T1DM and T2DM from the levels of glycosylated hemoglobin (HbA1c), blood pressure, lipids, weight and hypoglycemia. With these characteristics, it can predict life expectancy, quality-adjusted life expectancy, time to presentation of complications, and costs. CDM has been widely validated and is in continuous development (Palmer et al. 2004b).

The Prime Diabetes Model (PDM) is a similar alternative to CDM, and it is also widely validated (Valentine et al. 2017).

Both the CDM and the PDM are commercial models. Other models developed from the academic environment are the Michigan model for diabetes (Zhou et al. 2005), and the model for T1DM at the University of Sheffield (Thokala et al.2013).

All these models focus on the evaluation of new technologies, but its use as a framework for the decision making of the clinician with the existing treatments has not been considered until now.

4. A NEW APPROACH FOR SUPPORTING THE DECISIONS OF CLINICIANS ON DIABETES TREATMENT

Figure 1 shows a schematic diagram of a new CDSS based on simulation and machine learning techniques, which has three main components:

- The simulation model core
- The parameter adaptation system
- The CDSS interface

4.1. Simulation model core

Currently, the simulation model core is a highly modular discrete event simulation (DES) model that characterizes the progression of T1DM for a patient for a lifetime horizon. We selected this kind of model above other alternatives (Markov models, decision trees…) to allow the inclusion of individual characteristics to model the progression of the disease, to faithfully represent non-linearity of hazard ratios with patient characteristics, to easily include acute complications, and to avoid the explosion of states due to the multiple comorbidities that patients concurrently suffer. The model is implemented by using a Java-based DES library that incorporated all the tools for managing events and obtaining results (Castilla, García, and Aguilar 2009).

The developed model comprises, as well as other previously published studies, four groups of chronic complications of T1DM: cardiovascular disease, nephropathy, neuropathy and retinopathy (Health Quality Ontario 2018; Thokala et al. 2013). In addition, it incorporates episodes of severe hypoglycemia. The risk of progression of these complications depends, fundamentally, on the HbA1c level of each individual, though age or duration of diabetes may serve as predictors too. As shown in Figure 2, the model starts by assigning some characteristics to the individuals, such as age, HbA1c level and intervention group. HbA1c, together with the other initial characteristics, serve as a predictor of the time it will take the individual to develop each of the complications.

The onset of a chronic complication is handled as an event that modifies the patient's condition. These modifications can lead to increasing the risk of other complications, which, in turn, may shorten the time of the complication onset. Similarly, the risk of patient mortality increases with many of these complications, which may reduce their life expectancy. The manifestation of each chronic complication can be accompanied by a cost for the acute treatment of the problem, and then contribute to the annual burden of the disease with a fixed treatment and follow-up cost per year.

The model contemplates only the first event for cardiovascular disease, be it an angina, a stroke, a heart failure or a myocardial infarction.

Nephropathy involves three phases: an initial phase of microalbuminuria, i.e., with very mild or nonexistent clinical manifestations; a phase of macroalbuminuria, where the manifestations are moderate; and a final phase that is expressed as end-stage renal disease.

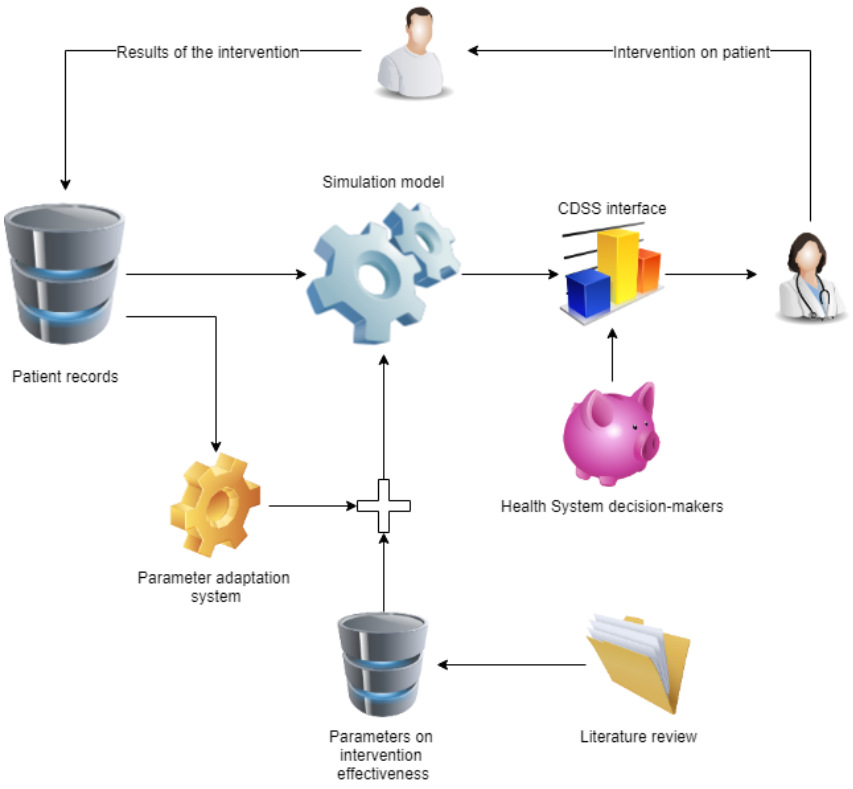

Figure 1: Simplified schema of the solution

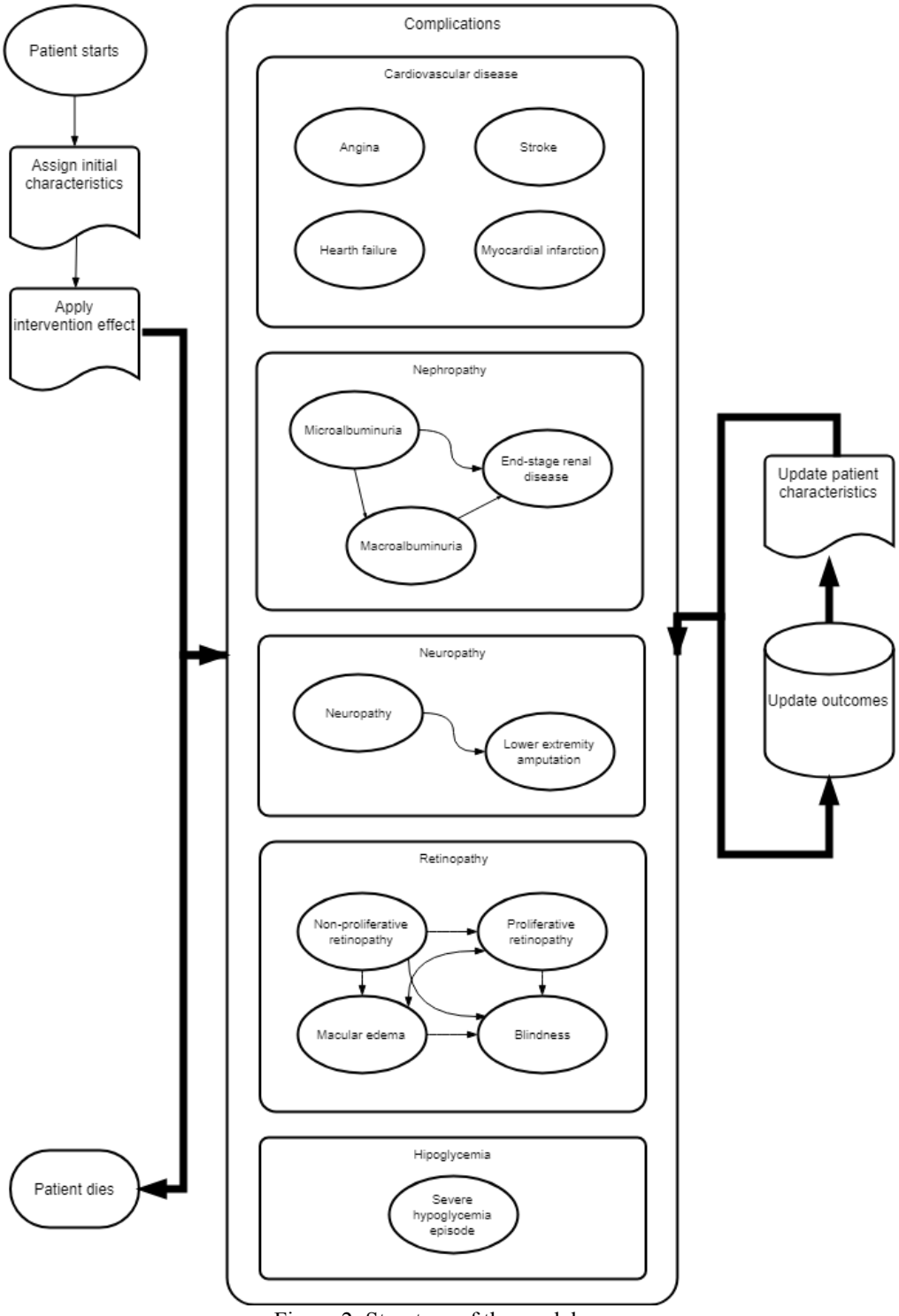

Figure 2: Structure of the model

Neuropathy considers two possibilities of evolution: a mild or moderate neuropathy, and the amputation of a lower limb as the most severe consequence, which, in turn, would lead to a marked decrease in quality of life.

For retinopathy, the model recognizes two stages of progression (non-proliferative and proliferative). At the same time, the patient can develop a diabetic macular edema. From any of these states the patient could lose sight completely.

The model handles episodes of severe hypoglycemia slightly differently. When suffering from severe hypoglycemia, patients suffers a decrease in their quality of life and have an associated probability of dying from the episode.

The parameters of the model are based on different sources. The time to develop complications is adapted from annual transition probabilities published in a

number of former economic evaluations (Health Quality Ontario 2018; Thokala et al. 2013).

We performed several validation tasks to increase the confidence in the results of the model. These tasks included the comparison with the accumulated incidence of background retinopathy, microalbuminuria and neuropathy at 9 years described in the Diabetes Control and Complications Trial (DCCT), as posed by The Mount Hood Challenge 4 Modeling Group (2007); and the parameterization of the model to reproduce the model from Health Quality Ontario (2018).

With respect to the validation with the DCCT results, we must consider the results on microalbuminuria and neuropathy as an internal validation of the model, since the probabilities used in the model were adapted from this study. Conversely, the comparison with the results for retinopathy is an external validation.

Table 1 shows the results of the validation against DCCT. The internal validity of the model is satisfactory, especially for the progression of the population in intensive treatment, which presents very low errors. For conventional treatment and the same complications, the relative error is higher, although always lower than 3 percentage points.

As regards background retinopathy, the absolute error in the intensive intervention is less than 5 percentage points. However, the discrepancy with the results of the conventional intervention is remarkable. This discrepancy could have its origin in differences due to other clinical factors between the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) population (used as a source for our model) and the DCCT population. It could also be partly explained by the way HbA1c reduction is applied to the population with intensive intervention: the behavior of the incidence of retinopathy with respect to the level of HbA1c is not linear, so the accumulated incidences are highly influenced not only by the average value of HbA1c but because of its dispersion. From the DCCT study, it was possible to obtain that the reduction of HbA1c was 1.5% on average, with a standard deviation of 1.1. However, there was not enough information to characterize this reduction in detail. In any case, although we calibrated the model to mimic the progression of DCCT in sensitivity analysis, the results remain robust.

Table 2 shows the results of the validation against the model from Health Quality Ontario (Health Quality Ontario 2018). Our model faithfully reproduced the life expectancy of the population, with relative errors lower than 2.5%. Results in quality-adjusted life expectancy also obtained low relative errors (<5%). The greatest discrepancy occurred with the costs, and could stem from the structural differences between the models: the model from Health Quality Ontario had absorbing states for amputation, end-stage renal disease or blindness, while the discrete event simulation used in this report allows an individual to suffer all those complications at the same time. Therefore, the former model may be underestimating the costs associated with treating multiple complications as the disease progresses.

The simulation model handles the effectiveness of the interventions in several ways. An intervention may reduce the HbA1c of the patient, hence increasing the time to suffer most complications. Other interventions may directly reduce the risk of a specific complication. The application will include a set of predefined interventions, characterized according to an exhaustive review of the literature; but the user will be able to create his/her own interventions too, by posing a tentative effectiveness and observing the expected evolution of the patient.

Table 1: Validation of the model against the cumulative incidence of complications in DCCT

Intervention	Complication	DCCT	Our model	Relative error	Absolute error (pp)
Conventional	Microalbuminuria	27.30%	25.52%	6.52%	1.78
	Background retinopathy	52.20%	21.62%	58.58%	30.58
	Neuropathy	21.30%	18.74%	12.02%	2.56
Intensive	Microalbuminuria	16%	16.16%	1.00%	0.16
	Background retinopathy	14.30%	9.94%	30.49%	4.36
	Neuropathy	10%	10.26%	2.60%	0.26

pp: percentage points

Table 2. Validation of the model against the model from Health Quality Ontario

Intervention	Item	Canada model	Our model	Relative error
SMBG plus multiple daily injections	Cost	$125,586.00	$180,090.03	43.40%
	QALY	18.812	17.962	4.52%
	LY	26.411	26.688	1.05%
SAP	Cost	$258,306.00	$332,805.05	28.84%
	QALY	18.944	18.417	2.78%
	LY	26.564	27.170	2.28%

LY: Life years; QALY: Quality-adjusted life years; SAP: sensor-augmented pump; SMBG: self-monitoring of blood glucose

4.2. Parameter adaptation system

As the volume of available data increases, we want to add new input variables to the system. It is possible that, by increasing the complexity of the model, the simulation will no longer properly represent the underlying relationships in the new data. At this point, we want to continue using the simulation to predict the estimated times to develop each of the pathologies depending on the current input variables under study (such as HbA1c and age), since that model has been obtained from large volumes of data and represents the relationship that exists between the input and output variables at a population level. However, these generalist predictions may not fit properly at the individual level, especially when new information is available. Therefore, we want to complement this model, with a system based on Machine Learning that predicts the estimated times to develop T1DM-related complications by using new input variables. These new input variables may include information on the presence of comorbidities, current treatment, and physiological or biochemical characteristics of the patient, both punctual estimates and time series. As the volume of available data increases, this system will learn new patterns in the data that serve to particularize predictions at the individual level. We will try different machine learning techniques such as neural networks, decision trees, probabilistic methods such as Naive Bayes or logistic regression, or kernel-based methods such as Support Vector Machines.

4.3. CDSS interface

The CDSS interface actually represents two different interfaces for two different audiences.

The clinician requires a clear interface that presents the simulation results. The interface allows a clinician to select a patient, preselect among different treatment strategies or interventions, and ask the system for prioritizing such interventions.

The second audience are health system decision maker. In this case, the interface becomes a dashboard to monitor the use of interventions and to track their actual effectiveness. The dashboard also shows a set of indexes on the use of cost-effective interventions by clinicians. Therefore, health system decision makers could economically incentivize clinicians to adhere to cost-effective interventions, and then track the achievement of the objectives.

5. CONCLUSIONS AND FURTHER WORK

Health care for diabetes requires the best support tools to improve not only the health of the patient, but also the sustainability of the public health systems. We have presented the first step towards an ambitious project on a decision-support system for clinicians that will help choosing the best treatment for T1DM patients. “Best” here refers to effectiveness of treatment, but also to cost-effectiveness. This second dimension will allow the managers of the public health systems to incorporate incentives for the use of the most cost-effectiveness treatments.

Up to now, a first version of the core simulation model is ready, which has been validated against well-known studies. We have already prepared a prototype of a standard intervention with insulin pump.

With the validated simulation model, we have a robust basis for parsimoniously incorporating Machine Learning techniques that will improve the model fitting to individual patients, and thus will move towards predictions that are more precise.

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