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"Predictive model-based decision support for diabetes patient empowerment"

D6.1: Provisional Description Decision Model

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Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

POWER2DM Consortium Partners

abbrev	Participant organization name	Country
LUMC	Leiden University Medical Center	Netherlands
IDK	Institute of Diabetes “Gerhardt Katsch” Karlsburg	Germany
SAS	SAS Servicio Andaluz de Salud	Spain

Abbreviations

This section contains the abbreviations used in this deliverable.

Abbreviation	*Definition*
CDM	**IMS CORE Diabetes Model**
DCCT	**Diabetes Control and Complications Trial**
EC	**Evaluation Campaign**
HbA1c	**Glycated hemoglobin**
LE	**Life expectancy**
LY	**Life expectancy**
NICE	**National Institute for Health and Clinical Excellence**
QALE	**Quality-adjusted life expectancy**
QALY	**Quality-adjusted life year**
T1DM	**Type 1 Diabetes Mellitus**
T2DM	**Type 2 Diabetes Mellitus**
UKPDS	**UK Prospective Diabetes Study**

Change procedure and history

This section contains the procedures for modifying the deliverable and maintaining a history of the changes.

Version	Date	Changes	From	Review
V1.0	July 7, 2017	First description of decision model	LUMC	LUMC, SAS, IDK
V1.1	July 19, 2017	First description of decision model	LUMC	LUMC, SAS, IDK

SUMMARY

The follow-up duration of the evaluation campaign is only 9 months given the limited total duration of the POWER2DM project. Decision modelling is one way to use the available clinical data in order to estimate the potential long-term clinical and economic outcomes of therapies and facilitate decision making. Therefore, task 6.1 concerns the formulation and construction of a computer decision model for evaluation of long-term effects and costs of self-management support by the POWER2DM system. This provisional deliverable provides a first description of the IMS CORE Diabetes Model (CDM) that will form the basis for our analyses. In addition, we describe the outcomes and input data that can be used to populate the model. The CDM is a non-product-specific computer simulation model that projects the long-term clinical and cost outcomes related to interventions for both T1DM and T2DM cohorts. It has been widely applied to conduct cost-effectiveness or cost utility analyses in various country settings and health technology authorities such as the National Institute for Health and Clinical Excellence (NICE) in the UK have reviewed and accepted the economic analyses performed using this model. The modular format allows detailed customization to the specific needs of the analyses in the POWER2DM project. Relevant data concerning model input parameters and outcomes will be collected in the Evaluation Campaign (EC), which is described in full detail in deliverable 5.2.2 Evaluation Campaign Methodology.

TABLE OF CONTENTS

POWER2DM Consortium Partners 2
Abbreviations 2
Change procedure and history 2
SUMMARY 3
1. INTRODUCTION 5
2. DECISION MODEL 5
3. MODEL INPUTS 6
4. MODEL OUTPUTS 7
5. REFERENCES 8

1. INTRODUCTION

An important aspect of the cost-effectiveness in diabetes management is finding a balance between self-management and support from healthcare professionals. To evaluate the POWER2DM self-management support system, a structured two-stage evaluation campaign will be conducted to test the feasibility of POWER2DM in everyday use, and secondly proof of concept that POWER2DM improves glycaemic control and analysis of the cost-effectiveness of the approach to highlight any potential issues that may impede implementation. However, the follow-up duration of the evaluation campaign is limited given the 3.5 year total duration of the POWER2DM project. Therefore, conclusions from the evaluation campaign will concern a 9-month follow-up period. Since diabetes is a chronic disorder, this is a relatively limited follow-up duration to inform clinicians and policy makers.

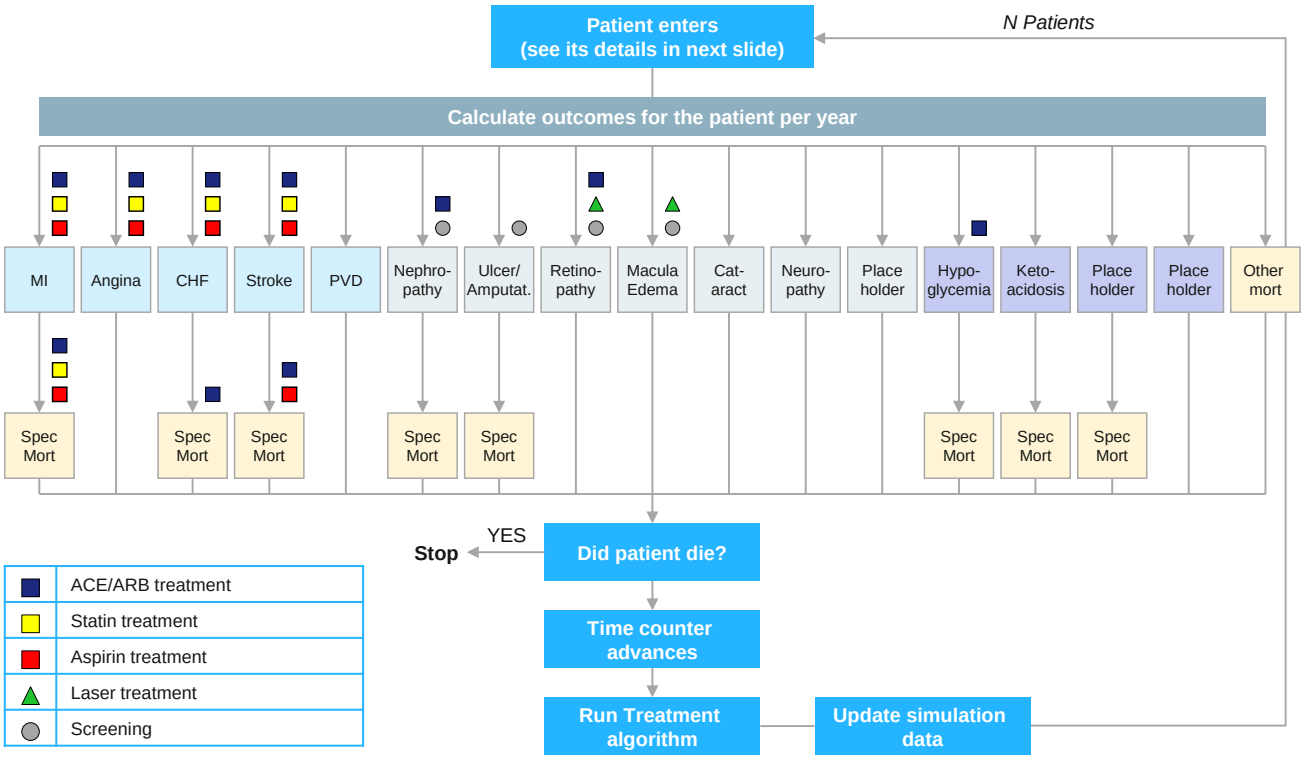
A mathematical simulation approach is one way to use the available clinical data in order to estimate the potential long-term clinical and economic outcomes of therapies and facilitate decision making. Since long-term clinical studies are difficult to conduct and very expensive decision modelling can inform the decision-making by practitioners and policy makers, such as reimbursement authorities, about optimal care and treatment strategies over a lifetime. Therefore, task 6.1 concerns the formulation and construction of a computer decision model for evaluation of long-term effects and costs. This provisional deliverable provides a first description of the model and outcomes and input data that will be used to populate the model.

2. DECISION MODEL

The decision model that we will use is the IMS CORE Diabetes Model (CDM), a non-product-specific computer simulation model that projects the long-term clinical and cost outcomes related to interventions for both T1DM and T2DM cohorts (http://www.core-diabetes.com/index.aspx) . The descriptions of the IMS CDM, including its structure and validation, have been documented previously [1]. It has been widely applied to conduct cost-effectiveness or cost utility analyses in various country settings and, most importantly, health technology authorities such as the National Institute for Health and Clinical Excellence (NICE) in the UK have reviewed and accepted the economic analyses performed using the IMS CDM [2]. Based on a review of T1DM models this study, it was identified as one of the 'best in class' methods for the different technical aspects of T1DM modelling [3].

In the IMS CDM, a series of 17 interdependent Markov sub-models simulate the clinical progression of diabetes complications over time, including major micro- and macrovascular complications such as cardiovascular, renal, diabetic foot and neuropathy, and eye disease. The model also incorporates long-term HbA1c progression, treatment algorithms (e.g., subsequent lines of therapy), and also capture treatment-specific clinical features beyond

their effects on traditional diabetes and cardiovascular risk factors. The time horizon can vary between one and fifty years. Direct and indirect costs can be incorporated, so both health system and societal perspectives can be modelled.



MI = Myocardial Infarction; CHF = Congesting Heart Failure; PVD = Peripheral Vascular Disease; Mort = Mortality; "Spec mort" = Specific Mortality (i.e. condition-related deaths)

Figure 1. Structure of the CDM

3. MODEL INPUTS

Data that inform the probabilities of events (such as hypoglycemia, amputation, a myocardial infarction, etc.), the progression of A1C, systolic blood pressure, lipids, and appropriate risk adjustments are derived from the United Kingdom Prospective Diabetes Study (UKPDS), the Diabetes Control and Complications Trial (DCCT), the Framingham Heart Study, and other sources [4,5,6]. Additionally, the IMS CDM captures the impact of disutility attributable to body mass index (BMI) values in the overweight range, based on data from the CODE-2 study [7]. Models that inform long-term glycohemoglobin (HbA1c) and systolic blood pressure (SBP) progression are derived from the UKPDS Outcomes Model, and data from the Framingham Heart Study are used to model long-term lipid and triglyceride progression [4,8]. Input parameters include:

- Patient demographics and baseline risk factors
- Treatment effects
- Treatment costs

- Mortality risk
- Costs of complications
- Costs of other medication and lab tests
- Transition probabilities or event rates for certain complications
- Relative risks for treatment effects on complications or treatment failures.

The modular format allows detailed customization to the specific needs of the analyses in the POWER2DM project. For POWER2DM, relevant data concerning model input parameters and outcomes will be collected in the Evaluation Campaign (EC). The design and measurement schedule of the EC is described in full detail in deliverable 5.2.2 Evaluation Campaign Methodology.

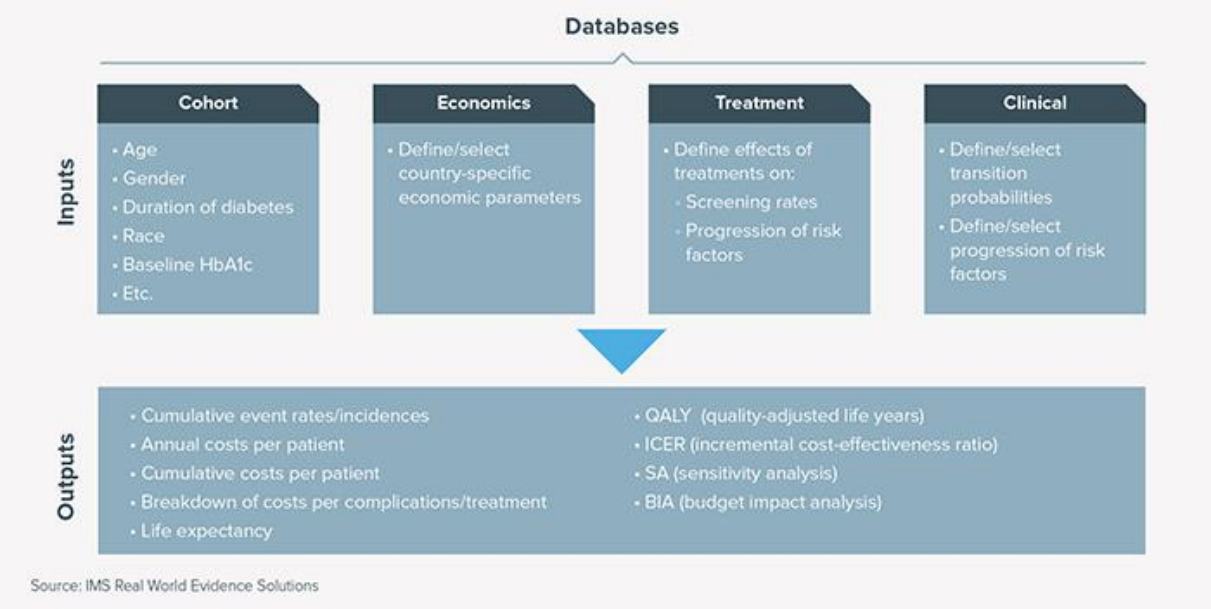


Figure 2. Model inputs and outputs

4. MODEL OUTPUTS

The CDM simulates disease progression in both T1DM and T2DM, and is widely used to estimate the impact of interventions on clinical and cost outcomes, as well as a range of economic analyses (cost-effectiveness, cost-utility, cost-benefit or cost of disease). It can also be used to identify potential high-risk patient profiles. The outputs of the model include life expectancy (LE), quality-adjusted life expectancy (QALE), direct and indirect costs, cumulative incidence and time to onset of complications, and incremental cost-effectiveness ratios per additional life year (LY) or quality-adjusted life year (QALY) gained.

5. REFERENCES

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