Economics Modelling and Diabetes: The Mount Hood Six Challenge

Johns Hopkins Mount Washington Conference Center

Baltimore, Maryland, USA.

7th & 8th June 2012

Contents

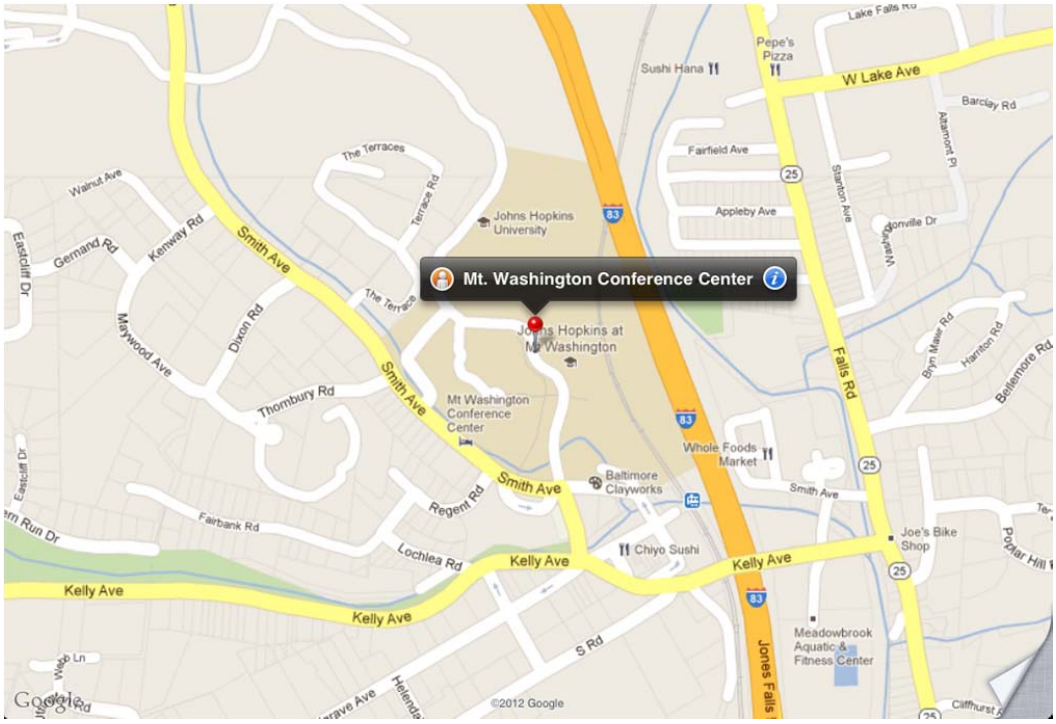
NOTE: The challenge results have been removed from this program. Please contact individual authors if you would like to access them.

Abstracts re work in progress and should not be quoted without permission.

Economics, Modelling and Diabetes:

The Mt Hood Six Challenge, Baltimore 2012

Location: the symposium will be held at the Mt. Washington Conference Center 5801 Smith Avenue Baltimore, MD 21209; Phone: 410.735-7964



Registration will be from 8:30am onward on Thursday 7th June. The conference will conclude at 3:15 Friday 8th June 2012.

Pre-conference Reception at Mount Washington:
Wednesday 6th June 6.00-7.00 pm. Transport into Baltimore will be available after the reception for those wanting to have dinner in the city. Dinner on 6 June is not included in the conference.

Accommodation:
If you have not already reserved accommodation, you can still call the reservations desk at Mount Washington (800) 488-8734. If they have no

more rooms available they will be able to advise on booking a room at the Radisson nearby. Quote 'Mount Hood' to be given the conference rate.

Mount Hood Six Organising Committee

Philip Clarke, The University of Melbourne (Chair of Health Economics)

Alastair Gray, The University of Oxford

David Grant, IMS Health

Louis W. Niessen, John Hopkins University

Andrew Palmer, The University of Hobart

Alison Hayes, The University of Sydney

Elbert Huang, The University of Chicago

Michael Willis, The Swedish Institute for Health Economics

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Thanks and due to:

The conference has received help and support from David Grant & IMS in locating a venue; Louis Niessen and John Bridges from John Hopkins University for hosting this conference; Jose Leal, Christian Asseburg and Mike Willis on developing the Challenges; Ping Zhang for arranging the abstracts; Tom Lung and Ed Fitzgerald for the program; Especially to Alison Gater for her help with organising the conference.

List of participants

Maria	Alva	Health Economics Research Centre, University of Oxford
Rinat	Ariely	GSK
Christian	Asseburg	ESiOR Oy
Jay	Bae	Eli Lilly
Jacob	Barhak	Freelancer
Jonas	Bech Møller	Novo Nordisk A/S
Hayley	Bennett	Swansea Centre for Health Economics, Swansea University
Nicole	Brazier	Janssen Inc.
John	Bridges	Johns Hopkins
Morgan	Bron	Takeda Pharmaceuticals
Michael	Calloway	GlaxoSmithKline
Anthony	Carpenter	University of Queensland
Barrie	Chubb	Novo Nordisk
Philip	Clarke	University of Melbourne
Mirella	Daja	Novo Nordisk
Steven	Dehmer	HealthPartners Research Foundation
Ravinder	Dhawan	Janssen Global Services
Tuan	Dinh	Archimedes- Inc.
Ruth	Etzioni	Fred Hutchinson Cancer Research Center
Talitha	Feenstra	RIVM and UMCG
Volker	Foos	IMS
Nicolas	Furiak	Medical Decision Modelling Inc.
Paddy	Gillespie	School of Business and Economics, National University of Ireland
Lindsay	Govan	University of Glasgow
David	Grant	IMS Health
Alastair	Gray	Health Economics Research Centre, University of Oxford
Danielle	Groleau	Novo Nordisk Canada Inc
Jens	Gundgaard	Novo Nordisk A/S
Helge	Gydesen	Novo Nordisk A/S
Alison	Hayes	University of Sydney
Jimmy	He	Janssen Global Services
Elbert	Huang	University of Chicago
Priya	John	The University of Chicago
Susan	Joy	Johns Hopkins
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Marion	Kerr	NHS Diabetes and Kidney Care
Robert	Klein	Medical Decision Modelling Inc.
Jen	Kruger	University of Sheffield
Neda	Laiteerapong	University of Chicago
Mark	Lamotte	IMS Health Consulting
Jakob	Langer	Novo Nordisk Inc.
Iris	Lansdorp-Vogelaar	Erasmus Medical Center
Adrien	Lawrence	HERON Evidence Development
Jose	Leal	Health Economics Research Centre, University of Oxford

List of participants(continued)

Tom	Lung	The University of Sydney
Elliot	Marseille	Health Strategies International
Silas	Martin	Janssen Scientific Affairs- LLC
Nisa	Maruthur	Johns Hopkins University
Ryan	McCabe	Cancer Treatment Centers of America
Phil	McEwan	Swansea University
Cheryl	Neslusan	Janssen Global Services
Kirsi	Norrbacka	Eli Lilly and Company
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Roberto	Palencia	Boehringer Ingelheim GmbH
Andrew	Palmer	University of Tasmania
James	Palmer	IMS Health
Jaime	Peters	Peninsula College of Medicine and Dentistry
Uffe Jon	Ploug	Novo Nordisk A/S
Jorge	Puelles	Takeda Pharmaceuticals Europe Ltd
Andrea	Puig	Janssen
Gabriel	Rogers	NICE
Lizheng	Shi	Tulane University School of Public Health
Sonal	Singh	Johns Hopkins
Sonja	Sorensen	United Biosource Corporation
Camilla	Sortsoe	COHERE - University of Southern Denmark
Erika	Szabo	Eli Lilly and Company
Anna	Teschemaker	Janssen Pharmaceutical Companies of J & J
Carl	Tilling	Sanofi
Shana	Traina	Janssen
Amber	van der Heijden	VU University Medical Centre
Michael	Willis	IHE
Matthew	Wintle	Amylin Pharmaceuticals
Sorrel	Wolowacz	RTI Health Solutions
S. Melany	Worbes Cerezo	Janssen
Alison	Wright	Janssen Cilag Australia
Wen Ye	Ye	University of Michigan, Department of Biostatistics
Burcu	Yetkin	Novo Nordisk
Ping	Zhang	CDC Atlanta
Xiaohui	Zhuo	Centers for Disease Control

Economics, Modelling and Diabetes: Mount Hood Six Challenge 2012

Conference Program

Day 1	**Thursday 7th June 2012**		
8:30-9:00am	**REGISTRATION**		
9:00-9:10am	**Welcome – Prof Philip Clarke** **Location:** ***Pullen Plaza***		
9:10-11:00am	***Mt Hood Six: Validation Challenges*** **Chair: A/Prof Elbert Huang, University of Chicago** Overview: Philip Clarke Outline of the challenge & results Groups presenting a (very brief) overview of their model & interpretation of major validation results (10 minutes per model) 1. IMS CORE Model 2. IHE / ECHO–T2DM Model 3. UKPDS Outcomes Model 4. Cardiff Model 5. Reference Model 6. CDC-RTI Diabetes Cost-Effectiveness Model 7. Diabetes Modelling and Analysis Framework 8. MICADO: Modelling Integrated Care for Diabetes based on Observational Data **Location:** ***Pullen Plaza***		
11:00-11:30am	***Tea and Coffee***		
11:30am-12:30pm	***General discussion of Validation Results*** Chair: Dr Alison Hayes Location: *Pullen Plaza*		
12:30-1:30 pm	***Lunch***		
1:30-3:00pm	**Conference session 1** Chair: Prof A. Palmer **Pullen Plaza**	**Conference session 2** Chair: Dr Ping Zhang **Room 202**	**Conference session 3** Chair: A/Prof J Bridges (20 Minutes each) **Room 18**
3:00-3:30pm	***Tea and Coffee***		
3:30-5:00pm	**Conference session 4** Chair: Dr Neda Laiteerapong **Pullen Plaza**	**Conference session 5** Dr David Grant **Room 202**	**Conference session 6** Ms Priya John **Room 18**
5:00- 6:00pm	**Business meeting: Where to next with Mt Hood?** Chair: Prof Philip Clarke **Location:** ***Pullen Plaza***		
7:00pm onwards	**CONFERENCE DINNER** At the Mt Washington Conference Centre		

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Conference Program

Day 2	**Friday 8th June 2012**
9:00-11:00am	***How should we deal with uncertainty in diabetes models?*** **Chair: Prof Andrew Palmer** Overview of Mt Hood Six Uncertainty Challenge results & discussion by participating modelling groups **Speakers: Dr Jose Leal, University of Oxford (15 Minutes);** **Dr Christian Asseburg, IHE (15 Minutes)** General discussion **Location: *Pullen Plaza***
11:00-11:30am	***Tea and Coffee Break***
11:30am-12:15noon	***What have the Mt Hood Six Challenges revealed*** **Chair: A/Prof Louis. Niessen** Further discussion of challenges. **Location: *Pullen Plaza***
12:15-1:15pm	***Lunch***
1:15-2:15	***What can we learn from cancer simulation modelling?*** ***Chair: Prof Alastair Gray*** ***Speakers:*** Dr Roman Gulati,, Fred Hutchinson Cancer Research Center, Seattle, USA. Dr. Iris Lansdorp-Vogelaar, Department of Public Health, Erasmus University Medical Center, The Netherlands. **Location: *Pullen Plaza***
2:15-3pm	***General discussion*** **Location: *Pullen Plaza***
3:00-3:15	***Wrap up***
CLOSE (Afternoon Coffee to finish)	

Economics, Modelling and Diabetes: Mount Hood Six Challenge 2012

Speakers for the Cancer Simulation Modelling Session

Roman Gulati, MS. is a statistician and cancer modeler in the Division of Public Health Sciences at Fred Hutchinson Cancer Research Center. In recent years, he has worked as the primary developer of the FHCRC prostate cancer models, which cover onset, progression, detection, and, treatment. He is lead or co-author of several high-profile publications of the CISNET prostate cancer working group, including studies to estimate lead time and overdiagnosis associated with screening, the role of screening in the decline in advanced stage incidence, the impact of contamination on mortality results of the prostate section of the Prostate, Lung, Colorectal, and Ovarian cancer screening trial, and the contributions of screening and treatment toward declines in mortality. He has also developed models to study the impact of changes in obesity on incidence and mortality patterns, the harm-benefit tradeoffs of screening, and comparative effectiveness of candidate screening programs for the BC Cancer Agency. He is currently using models to investigate differences in prostate cancer natural history in blacks and whites, project the impact of delaying treatment for low-risk prostate cancers, and identify smarter strategies for prostate cancer screening that preserve benefit while reducing harms and costs.

Iris Lansdorp-Vogelaar, PhD, originally trained in Econometrics, has been a cancer modeler at the Department of Public Health of Erasmus MC since 2003. In April 2009, she received her PhD for her research estimating the effects of colorectal cancer screening on population health, using microsimulation modelling. Her research interests include model building and validation, prediction and evaluation, optimizing the choice of interventions, and cost-effectiveness analyses. She is the primary modeler for the MISCAN-Colon and UW-MISCAN microsimulation models. Her modelling work informed the 2008 US Preventive Services Task Force recommendations, Medicare reimbursement decisions on CTC and Stool DNA screening and the Dutch national colorectal cancer screening program. Her work has been published in several authoritative medical journals. She is a member of the European Cancer Network and lead author of a chapter in the European Guidelines for Quality Assurance in Colorectal Cancer Screening. In 2012, she received a career development award of the Department of Public Health to determine efficient and effective methods for model validation and calibration. Her current research further focuses on explaining colorectal cancer disparities, on individualizing colorectal cancer screening recommendations, and on surveillance of trends in esophageal adenocarcinoma.

Mt Hood 2012
Challenges

Challenge #1: VALIDATION CHALLENGE

PREDICTION OF CVD EVENTS ACROSS DIFFERENT COUNTRIES AND USING OBSERVATIONAL DATA

Background:

Cardiovascular disease (CVD) is the single-largest source of death and disability in Type 2 diabetes mellitus (T2DM). Accurately predicting the occurrence of cardiovascular events is crucial, thus, to the usefulness of health economic modelling in the estimation of the cost-effectiveness of treatments for T2DM. Rates of CVD differ considerably across countries, however, posing a challenge to modellers who frequently conduct analyses in multiple geographical and treatment settings.

Previous Mt. Hood Challenges have tested the ability of the models to replicate the results of specific clinical trials (even estimating treatment effects observed in the trials). Large international trials consist of selected patients, are subject to strict protocols, and often represent primarily industrialized countries, however. Consequently, validations based on RCT data provide information only about certain aspects of model performance.

Objective:

The aim of this validation challenge is to test the ability of participating models to replicate CVD and survival/mortality patterns across a number of very different country settings and using primarily naturalistic data.

Methods:

Modeling groups will attempt to predict the major CVD and survival/mortality rates using information on the baseline characteristics of T2DM patients in 6 different patient populations: the Kaiser Permanent insured patient population in the US, T2DM patients in the (nearly encompassing) Swedish National Diabetes Registry, and 3 subgroups (Asia, Eastern Europe, and the Established Market Economies) plus all patients together in the ADVANCE study.

Initial (baseline) patient characteristics data are provided on a separate Excel worksheet. If additional data are required to simulate your model, please use the most suitable complementary data and document the source. Note also, if groups have access to additional information that is not public (e.g., patient level data), this should not be used to produce the primary results but can be used to produce an additional set of results to examine whether model performance could be improved with access to additional data. ‘

Please enter the results in the accompanying Excel document for outcomes and mail to Philip Clarke by Sunday, the 27th of May (philip.clarke@unimelb.edu.au). Please submit results for as many of the validation exercises as possible. We recognize the limited time remaining, however, and if choices must be made suggest that we prioritize the Kaiser and Swedish NDR analyses and omit the ADVANCE validation challenges if necessary. In the not unlikely event that clarifications are required, please send your inquires to either mw@ihe.se or philip.clarke@unimelb.edu.au (or both).

Challenge #1: Kaiser Permanente

- Input values:
  - Country-specific values for demographics, biomarkers, T2DM duration, smoking rates, and existing co-morbidities at baseline are provided in the accompanying workbook titled "Input Data--Mt Hood Challenge 6.xlsx"
  - Use a 5-year time horizon
  - Please simulate each of the age intervals separately. If your model is stochastic, set initial age to the mean age in the age interval. While there are, unfortunately, not gender-specific input data, please simulate the outcomes again separately for males and for females (for each of the age groups) using the combined input data.
  - Make what you feel are realistic assumptions. Please document them and report the average time paths for each variable. If you have time, also run an model with "Parameter Drift" in which HbA1c increase at the level seen in the UKPDS (0.15/year) but hold other key covariates constant (e.g., SBP, lipid values, and BMI).
- Outcomes:
  - The modelling groups will compute cumulative incidences (as % of initial cohort) and/or event rates per 1,000 individuals (depending on model capabilities) of myocardial infarction (MI), any ischemic heart disease, stroke/cerebrovascular disease, any cardiovascular disease, heart failure, and all-cause mortality. The definitions are provided in the accompanying worksheet ("Input Data--Mt Hood Challenge 6.xlsx"). Please note whenever your health states do not align with the definitions of the outcomes.
  - Enter the results in the accompanying workbook "Output Data--Mt Hood Challenge 6.xlsx".

Challenge #2: Swedish NDR

- Input values:
  - Country-specific values for demographics, biomarkers, T2DM duration, smoking rates, and existing co-morbidities at baseline are provided in the accompanying workbook titled "Input Data--Mt Hood Challenge 6.xlsx"
  - Use a 5-year time horizon
  - Please simulate each of the age- and gender-specific sub-groups separately. If your model is stochastic, set initial age to the mean age in the age interval.
  - Make what you feel are realistic assumptions. Please document them and report the average time paths for each variable. If you have time, also run an model with "Parameter Drift" in which HbA1c increase at the level seen in the UKPDS (0.15/year) but hold other key covariates constant (e.g., SBP, lipid values, and BMI).
- Outcomes:
  - The modelling groups will compute cumulative incidences (as % of initial cohort) and/or event rates per 1,000 individuals (depending on model capabilities) of MI, IHD (including stable and non-stable angina), stroke/cerebrovascular disease, and congestive heart failure (CHF). The definitions are provided in the accompanying worksheet ("Input Data--Mt Hood Challenge 6.xlsx"). Please note whenever your health states do not align with the definitions of the outcomes.
  - Enter the results in the accompanying workbook "Output Data--Mt Hood Challenge 6.xlsx".

o Challenge #3: ADVANCE

- Overview:
  - Simulate separately the 3 cohort sub-groups (Asia, Eastern Europe, and Established Market Economies) as well as the overall group
  - There are two treatment arms:
    - Intensive
    - Standard Care
- Input values:
  - Sub-group-specific and overall values for demographics, biomarkers, T2DM duration, smoking rates, and existing co-morbidities at baseline are provided in the accompanying workbook titled "Input Data--Mt Hood Challenge 6.xlsx".
  - The inclusion/exclusion criteria are rather complicated (see ADVANCE study PDF). Please account for them as best as possible within the constraints of your model.
  - Please simulate the following initial treatment effects for the biomarkers:
    - Standard Treatment Arm:
      - HbA1c: decrease 0.24
      - SBP: decrease 7 mmHg
      - LDL cholesterol: 0.46 mmol/liter
      - HDL: no effect
      - TGL: 0.05 mmol/liter
      - Weight: no change
    - Intensive Treatment Arm:
      - HbA1c: decrease 0.99
      - SBP: decrease 9.5 mmHg
      - LDL cholesterol: 0.48 mmol/liter
      - HDL: no effect
      - TGL: 0.15 mmol/liter
      - Weight: no change
  - Use a 5-year time horizon
  - Distribution of anti-diabetes and other drug use are presented in the workbook titled "Input Data--Mt Hood Challenge 6.xlsx". To make the simulations as comparable as possible, <u>please ignore</u> the modeling of treatment sequence if possible as it adds an additional source of uncertainty. Instead, model the bio-marker evolution directly as follows:
    - Use the material provided in the ADVANCE publications to make assumptions about time paths
    -

- .If this is not possible with your model, please use the closest approximation and then document any deviations.

- Outcomes:
  - The modelling groups will compute cumulative incidences (as % of initial cohort) of combined micro- and macrovascular outcomes, macrovascular disease, microvascular disease, all-cause mortality, CVD-related death, major coronary events, major cerebrovascular events, new or worsening nephropathy, new microalbuminuria, and new or worsening retinopathy for each cohort and treatment arm. The definitions are provided in the accompanying worksheet ("Input Data--Mt Hood Challenge 6.xlsx"). Please note whenever your health states do not align with the definitions of the outcomes.
  - Enter the results in the accompanying workbook "Output Data--Mt Hood Challenge 6.xlsx".

Results Reporting:

The modelling groups will enter and submit the results in a prepared Excel document. A Word document explaining the results and any assumptions or deviations that were needed should accompany the results.

Questions:

Please address any questions to either Michael Willis (mw@ihe.se) or to Philip Clarke (philip.clarke@unimelb.edu.au)

Mt Hood2012Uncertainty challenge.pdf

CHALLENGE #2

STOCHASTIC UNCERTAINTY (FIRST ORDER MONTE CARLO SIMULATION)

Background:

Micro-simulation models use Monte Carlo methods to estimate an empirical distribution of outcomes for an individual patient and/or a cohort of patients. This entails using a random process to simulate identical patients one at a time through a mathematical structure that simulates the pathways of disease while recording the outcome(s) of each simulation. Due to the random nature of Monte Carlo, the outcome(s) of interest could be different every time a patient goes through the model. This random process is sometimes called 'first order Monte Carlo simulation'.

If several replicates are conducted for the same identical patient it becomes possible to estimate measures such as mean and variation (i.e., stochastic uncertainty) for the different outcomes. The variation between the replicates can be quite large due to its randomness. This random noise is called **Monte Carlo error** and can be measured as the standard error of the mean outcome. It is desirable to minimise Monte Carlo error to obtain precise estimates of the expected model outcomes. Just take a simple example, the average risk of having a stroke for a patient with given characteristics is estimated at 10% with 10 replicates (i.e., patient experienced a stroke in 1 of 10 simulations), 5% with 100 replicates (i.e., patient experienced a stroke in 5 of 100 simulations), eventually converging towards the mean value of 4% above 100,000 replicates.

Ideally, many replicates should be conducted (especially when there are events with low probability but high impact) so as to reduce the Monte Carlo error to zero (achievable only if we ran an infinite number of replicates), but there is a trade-off with computing time (often results are desired quickly). Nonetheless, the Monte Carlo error can be used to ascertain how many simulations are required to achieve a specified level of accuracy.

The aim of this challenge is to understand how many replicates are required for the participating models in order to reduce the Monte Carlo error to acceptable levels (and avoid unnecessarily long simulations). Note, the point at which the results tend to converge may vary by endpoint (e.g., common events vs. rare but high impact events), though for many economic evaluations, it would only be necessary to know when the

primary endpoint(s) converge (e.g., total costs and QALYs). Note, though, other outcomes may provide complementary information and it may be useful in many economic evaluations to ensure that these have stabilized as well.

Objective: For each of the models participating in Mt. Hood 2012, to estimate the mean and Monte Carlo error across a series of outcomes and a pre-defined number of replicates.

Methods: Simulate a single treatment arm with the following inputs:

Initial Patient Characteristics	**Value**
Current age	55
Gender	Male
Ethnicity	White
Duration since diagnosis of T2DM (years)	5
% HbA1c	7.49
Total cholesterol (mg/dl)*	200
LDL cholesterol (mg/dl)*	100
HDL cholesterol (mg/dl)*	47
Triglycerides (mg/dl)*	265
Systolic blood pressure (mmHg)	133.6
BMI (kg/m2)	30
Smoker	No; never
Atrial fibrillation	No
Diabetic retinopathy	No
Microalbuminuria or other renal disease	No
Neuropathy	No
Foot ulcer	No
History of ischemic heart disease	No
History of Stroke	No
History of myocardial infarction	No
History of congestive heart failure	No
History of peripheral vascular disease	No

** The lipids inputs in mmol/l are: Total 5.172; LDL 2.586; HDL 1.215; Triglycerides 2.992.*

Initial treatment effects	Value
HbA1c (percentage points)	-0.5
BMI	0
Systolic blood pressure	0
All lipid components (total, HDL, LDL triglycerides)	0

Risk factor trajectories (same for both treatment arms)*	Value
HbA1c (annual drift in percentage points)	0.1
BMI	No change
Systolic blood pressure	No Change
All lipid components (total HDL LDL triglycerides)	No change

* If you cannot fix the risk trajectories as described here in risk factors are defined in your model.

Treatment parameters	Value
HbA1c treatment targets (if present)	Disable
Anti-Diabetes treatment switching	Disable
Hypertension*	Disable
Dyslipidemia*	Disable
Therapies/procedures for treating cardiovascular disease**	Optional
Therapies/procedures for treating microvascular disease**	Optional

* e.g., do not include statins, ACE inhibitors etc. in the model.

** If modelling treatment explicitly, please explain details of how you do it.

	Costs	
Event	**Event Year**	**Subsequent Years**
Anti-hyperglycemic treatment	$1,500	$1,500
Blindness	$1,358	$575
ESRD	$30,000	$30,000
Amputation	$10,354	$598
IHD	$2,696	$891
Myocardial infarction	$3,282	$856
Stroke	$3,596	$601
CHF	$3,007	$1,054
Year with no complications	$374	$374

All other costs should be set to 0.

Quality of life	**Value**
Baseline	0.785
Decrements:	
IHD	0.09
MI	0.055
Stroke	0.164
CHF	0.108
Blindness	0.074
ESRD	0.263
Amputation	0.28

Simulations

- Switch off any parameter (2nd-order) uncertainty to the extent possible (i.e., run each patient through exactly the same risk equations)
    - The only variation between runs of hypothetical patients should be due tothe Monte Carlo simulation (i.e., whether a patient experiences an event given the risk of event)
    - If you use the UKPDS equation, apply the mean values for the coefficients as published in UKPDS 68 (and not the iterations from Philip Clarke's Excel spreadsheet).

- Set up the number of replicates (Monte Carlo draws/simulations/inner loops) to be 1 per patient simulated.

- Simulate 10,000 initially identical, individual patients with characteristics defined above (i.e., the patients are really identical and not drawn from a population with standard deviation around the above means). This corresponds to 10,000 replicates (Monte Carlo draws/simulations) of the same patient.

- Record the following outcomes over the 20-year time horizon with 100, 1000, 5000, and 10000 (all) replicates:
    - Total costs (discounted)
    - Total QALYs (discounted)
    - Total life-years (both discounted and undiscounted)
    - Proportion of patients out of initial cohort (i.e., the cumulative incidence)
    - who have experienced[1]:
        - Myocardial infarction
        - Stroke
        - IHD
        - CHF
        - At least one of the above 4 macrovascular events

Other Simulation Settings	**Value**
Discount rate for Costs	3%
Discount rate for health outcomes*	3%
Time Horizon	20 years

* Note: LY (life expectancy) should also be reported undiscounted

- Blindness
- ESRD
- Amputation

- At least one of the above events (macro- or microvascular)
- Death

[1] If your health states do not align with the UKPDS health states, please describe how yours are defined.

Estimating Monte Carlo error for each outcome

- Separately, for each outcome estimate the mean, $\overline{X_n}$ using 100, 1000, 5000, and 10000 replicates:

  $$\overline{X_n} = \sum_{i=1}^{n} \frac{x_i}{n}$$ for i=1,…,*n* number of replicates
- Estimate the standard deviation for each outcome, SD_n, using 100, 1000, 5000, and 10000 replicates:

  $$SD_n = \sqrt{\left[\frac{1}{n-1}\sum_{i=1}^{n}(x_i - \overline{X_n})\right]}$$ for i=1,…,*n* number of replicates
- Estimate the Monte Carlo error for each outcome, ____, using 100, 1000, 5000, and 10000 replicates:

  $$MCE_n = \frac{SD_n}{\sqrt{n}}$$ for i=1,…,*n* number of replicates
- Now, separately for each outcome, divide the Monte Carlo error by the estimated mean using 100, 1000, 5000, and 10000 replicates. This will give you a measure of the accuracy for the mean.

CHALLENGE #2: Identifying Model Uncertainty

PARAMETER UNCERTAINTY (SECOND ORDER MONTE CARLO SIMULATION)

Background:

Monte Carlo error measures the variability between replicates at the individual level when 'first order Monte Carlo simulation' is performed. The aim is then to reduce the noise, by increasing the number of replicates, and obtain accurate means of the outcome(s) of interest.

Parameter uncertainty is very different. The parameters upon which simulation models are built often come from samples (with sampling variability) and are seldom known with complete certainty. Parameter uncertainty reflects the incomplete knowledge about the true value of the model parameters. Unlike Monte Carlo error, it cannot be reduced by increasing the number of replicates. The only way to decrease uncertainty is by undergoing further research.

Uncertainty is represented as an empirical distribution of 'true' mean values of the parameter(s) of interest (i.e. standard error of the mean rather than standard deviation). Parameter uncertainty is propagated through the decision model by randomly drawing values from these distributions and recording the outcomes of the model.

In the context of Micro-simulations, the process used to propagate parameter uncertainty is sometimes called 'second order Monte Carlo simulation'. At the individual level, it involves two steps or loops:

1) Reducing variability between replicates (inner loop/1st order MC simulation)
2) Propagating parameter uncertainty (outer loop/2nd order MC simulation)

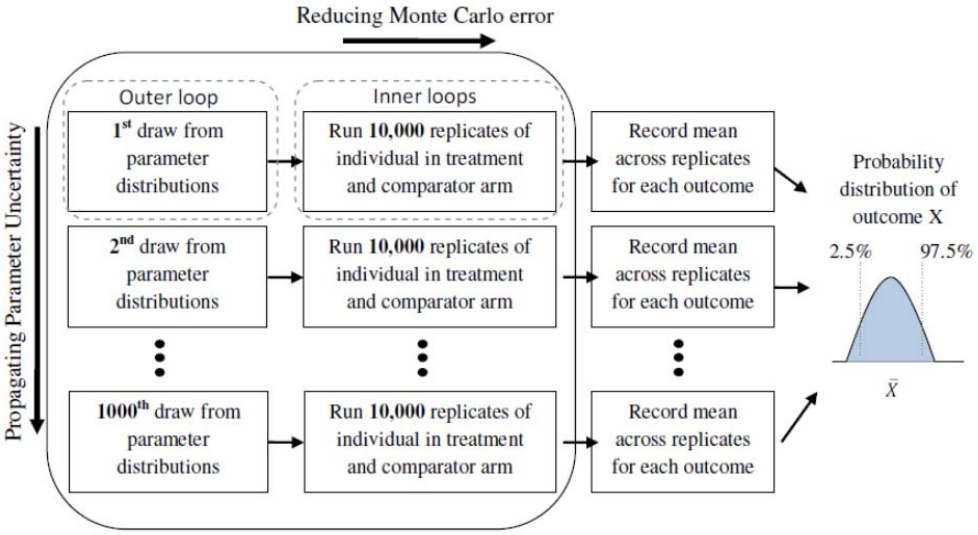
Objective:
To identify the extent of parameter uncertainty in the different models participating in Mt. Hood 2012 by simulating and analysing 20-year model outcomes.
Methods:

- We will compare two treatment arms, one with an experimental treatment that lowers HbA1c by 0.5 % points and one that does nothing
- Simulation Inputs
    - Fix all inputs as in Challenge 1. The only difference between the two arms should be the following:

Initial Treatment Effects	Value
HbA1c (percentage points): Experimental treatment	-0.5
HbA1c (percentage points): Comparator	0

Costs	Value
Experimental treatment	1500/year
Comparator	0

- Simulation
    - Activate all sources of parameter uncertainty.
    - Follow the steps:
        1) Draw a value from all model parameters;
            - Use mean values for those parameters for which uncertainty is not being modelled. If you use the UKPDS equation, draw jointly from the iterations reported in Philip Clarke's Excel spreadsheet.
        2) Run 10,000 replicates of the same individual in each treatment arm (i.e., 10,000 initially identical individuals) over 20 years using the parameter values from step 1;
        3) Record the following outcomes:
            - Total costs (discounted)
            - Total QALYs (discounted)
            - Total life-years (discounted and undiscounted)
            - Proportion of patients out of initial cohort (i.e., cumulative incidence) who have experienced:
                - Myocardial infarction
                - Stroke
                - IHD
                - CHF
                - Blindness
                - ESRD
                - Amputation
                - Death
        4) Repeat steps (1) to (3) 1000 times (i.e., use 1000 sets of different parameter values);
        5) Make a probability distribution of the individual outcomes at step 4. This will capture both stochastic and parameter uncertainty.
- The figure below demonstrates graphically the steps described above:


Reducing Monte Carlo error
Propagating Parameter Uncertainty
Outer loop
Inner loops
1st draw from parameter distributions
Run 10,000 replicates of individual in treatment and comparator arm
Record mean across replicates for each outcome
2nd draw from parameter distributions
Run 10,000 replicates of individual in treatment and comparator arm
Record mean across replicates for each outcome
1000th draw from parameter distributions
Run 10,000 replicates of individual in treatment and comparator arm
Record mean across replicates for each outcome
Probability distribution of outcome X
2.5%
97.5%
$\bar{X}$

Models Participating in Challenges:

Cardiff Model

CDC-RTI Diabetes Cost-Effectiveness Model

Diabetes Modelling and Analysis Framework (DMAF)

IHE/ECHO-T2DM Model

IMS CORE Model

MICADO: Modelling Integrated Care for Diabetes based on Observational Data

Reference Model

UKPDS Outcomes Model

Cardiff Model

Lead Presenter: Phil McEwan, Swansea University
Other team members attending: Hayley Bennett, Swansea Centre for Health Economics

The Cardiff Model is a stochastic simulation model programmed in C++ and Visual Basic for Applications, embedded in Microsoft Excel. It is designed to evaluate the impact of new therapies in a population of T2DM patients, modelling disease progression through implementation of the UK Prospective Diabetes Study (UKPDS) 68 outcomes equations.

The model requires specification of age, sex, ethnicity, smoking status and duration of diabetes and models changes to modifiable risk factors: total cholesterol, HDL cholesterol, systolic blood pressure, weight and glycosylated haemoglobin (HbA1c). Time-dependent risk factor profiles are simulated through implementation of equations reported in the UKPDS 68 study.On entering the simulation patients are initialised to first-line therapy. Following the modification of each patient's HbA1c in line with treatment effect, the model projects HbA1c over time. Pre-specified HbA1c threshold values may be used to invoke escalation to second- and third-line therapies.Costs are applied to all predicted complications in the year of occurrence. Healthcare maintenance costs are applied in all subsequent years following non-fatal events. The costs of diabetes-related complications are drawn primarily from UKPDS 65. Baseline utility is modelled using age-dependent mean EQ-5D values in subjects with no major complications obtained from the Health Survey for England 2003. Utility decrements associated with predicted complications are drawn primarily from UKPDS 62.

Model output includes the incidence of microvascular (retinopathy, neuropathy, nephropathy) and macrovascular complications (congestive heart failure, myocardial infarction, stroke, ischaemic heart disease), hypoglycaemia, diabetes-specific mortality and all-cause mortality and point estimates and probabilistic output for cost-effectiveness.

Key Publications:

Erhardt W, Bergenheim K, Duprat-Lomon I, McEwan P. Cost Effectiveness of Saxagliptin and Metformin versus Sulfonylurea and Metformin in the Treatment of Type 2 Diabetes Mellitus in Germany: A Cardiff Diabetes Model Analysis. Clin Drug Investig. 2012 Jan 31.

Granström O, Bergenheim K, McEwan P, Sennfält K, Henriksson M. Cost-effectiveness of saxagliptin (Onglyza(®)) in type 2 diabetes in Sweden. Prim Care Diabetes. 2011 Oct 14

McEwan P, et al. A population model evaluating the costs and benefits associated with different oral treatment strategies in people with T2DM. Diabetes Obes Metab. 2010 Jul; 12(7):623-30.

McEwan P, Evans M, Kan H, Bergenheim K. Understanding the inter-relationship between improved glycaemic control, hypoglycaemia and weight change within a long-term economic model. Diabetes Obes Metab. 2010 May; 12(5):431-6.

McEwan P, et al. Assessing the relationship between computational speed and precision: a case study comparing an interpreted versus compiled programming language using a stochastic simulation model in diabetes care. Pharmacoeconomics. 2010; 28(8):665-74.

CDC-RTI Diabetes Cost-Effectiveness Model

Lead Presenter: Xiaohui Zhuo, Division of Diabetes Translation, Centers for Disease Control

Other team members attending: Ping Zhang, Centers for Disease Control

The CDC-RTI Diabetes Cost-Effectiveness Model is a Markov simulation model of disease progression and cost-effectiveness for type 2 diabetes. The model has four modules: the main diabetes module, diabetes screening module, pre-diabetes module, and pre-diabetes screening module. The main diabetes module follows patients from diagnosis to either death or age 95 years and simulates development of diabetes related complications on three micro-vascular disease paths (nephropathy, neuropathy, and retinopathy) and two macro-vascular disease paths for diabetes screening and pre-diabetes. Model outcomes include disease complications, deaths, costs, and quality-adjusted life years (QALYs).

In the model, progression between disease states is governed by transition probabilities that depend on risk factors—including glycemic level (measured by HbA1c levels), blood pressure, cholesterol, and smoking status—and duration of diabetes. Interventions affect the transition probabilities and resulting complications. For example, tight glycemic control lowers HbA1c, slowing progression on the micro-vascular complication paths. With slower progression, fewer micro-vascular complications occur, deaths are delayed, QALYs increase, and the costs of complications are reduced. The model has been used to estimate the cost-effectiveness of treatment interventions for patients with diagnosed diabetes, evaluate optimal resource allocation across interventions, assess whether screening for diabetes is cost-effective, show that lifestyle modification is cost-effective in delaying or preventing diabetes among persons with pre-diabetes, and estimate the cost-effectiveness of screening for pre-diabetes.

Key Publications:

Hoerger, T.J., Segel, J.E., Zhang, P., and Sorensen, S.W. (2009). Validation of the CDC-RTI Diabetes Cost-Effectiveness Model. RTI Press publication No. MR-0013-0909. Research Triangle Park, NC: RTI International. http://www.rti.org/pubs/mr-0013-0909-hoerger.pdf

William H. Herman, MD, MPH; Thomas J. Hoerger, PhD; Michael Brandle, MD, MS; Katherine Hicks, MS; Stephen Sorensen, PhD; Ping Zhang, PhD; Richard F. Hamman, MD, DrPH; Ronald T. Ackermann, MD, MPH; Michael M. Engelgau, MD, MS; and Robert E. Ratner, MD. The Lifetime Cost-Utility of Lifestyle Intervention or Metformin for the Prevention of Type 2 Diabetes Mellitus. Annals of Internal Medicine. 2005; 142:323-332.

Diabetes Modelling and Analysis Framework (DMAF)

Lead Presenter: Nicolas M. Furiak, Medical Decision Modelling Inc.

Other team members attending: Robert W. Klein, Vice President, Healthcare Engineering, Medical Decision Modelling Inc.

The Diabetes Modelling and Analysis Framework (DMAF) outlined here uses established methods to develop the central simulation engine (CSE) that lies at the nucleus of DMAF. However, the architecture of DMAF has been designed such that emerging evidence reported in the literature can be efficiently incorporated into the framework and evaluated for their potential impact on immediate and long term outcomes. The architecture is particularly obliging of published trial data and capable of efficiently producing the comprehensive sensitivity analysis required for state of the art decision making. DMAF captures events occurring in routine patient care through an A1c sub model bridging between patient-specific A1c and the incidence of complications. Transitions are modified amongst health states based on the hemoglobin A1c of the patient (A1c) which may be reduced by per-cycle, multiplicative reductions specific to each stratum of treatment (oral antidiabetics only (OADs), multiple OADs, OADs+basal insulin, OADs+basal insulin+bolus insulin). The multiplicative factors are taken from A1c vs. time curves from published head-to-head studies of the treatments considered. DMAF also contains treatment transition and scheduling based, by default, the treatment consensus algorithm published by Nathan et al. The transitions between treatment strata are modifiable for sensitivity analysis including the functionality to randomly sample a range of start times for additional treatment.

This is a new model. Mount Hood 2012 is the first publication venue.

IHE/ECHO-T2DM Model

Lead Presenter: Michael Willis, IHE, Sweden

Other team members attending: Christian Asseburg, ESiOR Oy; Pierre Johanssen, IHE; Cheryl Neslusan, Janssen Global Services; Jianming He, Janssen Global Services

ECHO-T2DM is a (2nd order) stochastic, micro-simulation model that consists of Markov health states representing the development and consequences of key micro- and macrovascular complications. Specifically, a cohort of hypothetical T2DM patients is generated from a probability distribution of initial patient characteristics (both demographic and health-related). HbA1c is the core driver of the model, affecting both outcomes and changes in treatment. These patients are initially treated with one of two user-specified treatment paradigms and their evolving health and treatment needs are simulated annually until the end of the user-defined time horizon or death. Patient health is recorded using health states that capture the existence and severity of retinopathy, of nephropathy, of neuropathy, and of CVD (as defined in the UKPDS), updated on an annual basis.

Diabetes treatment is governed by an algorithm that seeks to maintain user-defined HbA1c treatment thresholds. User-defined inputs control the algorithm, which is, thus, quite flexible. Treatment affects HbA1c, but can also affect BMI, SBP, and lipid values. Treatments can be escalated or discontinued and new agents added to meet HbA1c goals. Treatments can also cause AE's, including importantly hypoglycemic events, which can lead to discontinuation or non-compliance. The model applies costs to both blood glucose control and to treatment of the diabetic complications that arise, both event costs and state costs. The model also calculates QALYs for each of the simulated patients, using QALY decrements for each of the diabetic complications. The model outcomes consist of incidence rates for each of the complications and AEs, ICERs, Net Monetary Benefits, and the Cost-Effectiveness Acceptability Curve.

Key Publications:

Asseburg C, Willis M, Persson U, et al, "Validation of the IHE/J&J Economic Simulation Model of Type 2 Diabetes Mellitus", Presented at 14th Annual ISPOR Intl Meeting 18/5/2009

Willis M, Assesburg C, Neslusan C, et al, "The Economic Importance of Metabolic Memory in the Treatment of Type 2 Diabetes Mellitus", Presented at the ADA Annual Congress, 2010.

Asseburg C, Willis M, He J, et al, "The Impact of Adherence on the Costs And Benefits of Intensive lifestyle Management (ILM) in Overweight and Obese Patients at High risk for Type 2 Diabetes Mellitus (T2DM)", Presented at the 14th Annual ISPOR Intl Meeting Orlando 2009

Willis M, Asseburg C, Neslusan C,et al, "The Economic Impact of Weight Loss for Patients with Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in the US", Presented at the 15th Annual ISPOR International Meeting, Atlanta, USA, 2010.

He J, Willis M, Asseburg C, et al, "Simulation of the Chinese Diabetes Treatment Guideline Using IHE/JJPS Type 2 Diabetes Model", Presented at the 7th world Congress, iHEA, Beijing, 2009.

IMS CORE Diabetes Model

Lead Presenter: Volker Foos, IMS Health, Health Economics and Outcomes Research (HEOR), Phil McEwan, IMS Health and Swansea University,

Other team members attending: David Grant, IMS Health, HEOR; Mark Lamotte, IMS Heath HEOR; Adam Lloyd, IMS Health, HEOR; James Palmer, IMS Health, HEOR,

The IMS CORE Diabetes Model is a non-product-specific, diabetes policy analysis tool that performs real-time simulations. The model evaluates intensive or conventional insulin therapy, concomitant oral antidiabetic agents and lipid-lowering therapies, aspirin and angiotensin-converting enzyme inhibitor usage, and screening and treatment strategies for microvascular and end-stage complications. Disease progression is based on a series of inter-dependent Markov sub-models that simulate diabetes-related complications (angina, myocardial infarction, congestive heart failure, stroke, peripheral vascular disease, diabetic retinopathy, macular edema, cataract, hypoglycemia, ketoacidosis, nephropathy and end-stage renal disease, neuropathy, foot ulcer and amputation). Each sub-model uses time-, state- and diabetes type-dependent probabilities derived from published sources, and utilizes tracker variables to overcome the memory-less properties of standard Markov models. The progression of relevant physiological parameters (e.g. glycohemoglobin, systolic blood pressure, triglycerides, body mass index, etc.) is simulated, based on long-term epidemiological data, and event risk is continuously updated based on these risk factors. Analyses, including first- and second-order Monte Carlo simulations, can be performed on patient cohorts with either type 1 or type 2 diabetes, defined in terms of age, gender, baseline risk factors, pre-existing complications and comorbidities. The model is adaptable, allowing the inclusion of new clinical and economic data as it becomes available, and facilitates the investigation of new hypotheses. The creation of country-, health maintenance organization- or provider-specific versions of the model is possible. The reliability of simulated clinical outcomes has been tested, with results validated against those reported by clinical trials and epidemiological studies.

Key Publications:

Beaudet A, Palmer JL, Timlin L, Wilson B, Bruhn D, Boye KS, Lloyd A. Cost-utility of exenatide once weekly compared with insulin glargine in patients with T2DM in the UK. J Med Econ. 2011;14(3):357-66.

Davies MJ, et al., Cost-utility analysis of liraglutide compared with sulphonylurea or sitagliptin, all as add-on to metformin monotherapy in T2DM. Diabet Med. 2011 Aug 29.

Guillermin AL, Samyshkin Y, Wright D, Nguyen T, Villeneuve J. J Med Econ. 2011;14(2):207-16. Epub 2011 Mar 2. Modelling the lifetime costs of insulin glargine and insulin detemir in type 1 and T2DM patients in Canada: a meta-analysis and a cost-minimization analysis.

Cummins E, et al. . Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. Health Technol Assess. 2010 Feb;14(11):iii-iv, xi-xvi, 1-181.

Palmer AJ, Roze S, Valentine WJ, *et al*. Validation of the CORE Diabetes Model against epidemiological and clinical studies. Current Medical Research and Opinion 2004; 20: S27-S40.

MICADO: Modelling Integrated Care for Diabetes based on Observational Data

Lead Presenter: Amber van der Heijden, EMGO Institute for Health and Care Research VU University Medical Center, The Netherlands

Other team members attending: Talitha Feenstra Ph.D,RIVM, Dept for Prevention and Health Services Research, UMCG, dept of epidemiology, The Netherlands

The MICADO model aims to estimate long-term effects of preventive interventions in persons with and without diabetes. MICADO links several risk factors to micro- and macrovascular diseases in a diabetes population. It is closely connected to the RIVM Chronic Disease model that links the same risk factors to incidence of chronic diseases. Thus, interventions can be evaluated in diabetes populations and in general populations.

MICADO contains modules on the development of diabetic foot, nephropathy and retinopathy. MICADO and the RIVM chronic disease model both distinguish several cardiovascular complications, namely coronary heart disease, stroke, chronic heart failure, and myocardial infarction. All transitions are specified by to age, gender and the risk factors: smoking status, BMI, physical activity level, blood pressure, total cholesterol, and $HbA_{1c.}$

An important strength is the combination of a similar model for persons with and without diabetes, which allows comparing the long-term effects of interventions targeting at persons with and without diabetes. Both model variants include parameter uncertainty. That is, probabilistic sensitivity analysis can be carried out, varying model parameters based on distributions that reflect the uncertainty introduced when estimating these input parameters from data. Outcomes are prevalence of complications, quality of life, costs and cost-effectiveness. It can be applied for projections as well as scenario analyses to evaluate the long-term (cost-) effectiveness of diabetes-related and cardiovascular interventions.

Key Publications:

Van der Heijden AA, Feenstra TL, Hoogenveen RT, Niessen LW, de Bruijne MC, Dekker JM, Baan, CA, Nijpels G. Modelling integrated care for diabetes based on observational data: the MICADO model. (under review)

Feenstra TL, et al.. Targeted versus universal prevention. a resource allocation model to prioritize cardiovascular prevention. Cost Eff Resour Alloc. 2011 Oct 6;9(1):14.

Jacobs-van der Bruggen MA,et al. Cost-effectiveness of lifestyle modification in diabetic patients. Diabetes Care. 2009 Aug;32(8):1453-8.

PHM van Baal,et al. “Lifetime medical costs of obesity: Prevention no cure for increasing health expenditure”, PLoS Medicine 2008, 5 (2), pp. 0242-0249 /e29.

Jacobs-van der Bruggen MA, Bos G, Bemelmans WJ, Hoogenveen RT, Vijgen SM, Baan CA. Lifestyle interventions are cost-effective in people with different levels of diabetes risk: results from a modelling study. Diabetes Care. 2007 Jan;30(1):128-34.

Reference Model

Lead Presenter: Jacob Barhak, University of Michigan

The reference model is composed of building blocks that are published in the scientific literature. The model reuses existing risk equations and populations with a traceable reference to the data source, hence the model name.

The model is a state transition model with multiple parallel processes. State transitions are governed by risk equations from the literature. Initial population data is generated from distributions found in publications. In case of missing information, defaults are used or an assumption is recorded.

The model combines different risk equations with different populations under a unified framework. Moreover it allows assessing compatibility of multiple risk equation combinations. Better combinations can then be located by comparing simulation results.

Results are obtained through micro-simulation with the aid of parallelization enabled by computing power.

The model is scalable and has the potential to expand to include more risk equations and populations.

This is a new model. Mount Hood 2012 is the first publication venue.

UKPDS Outcomes Model

Lead Presenter: Alastair Gray, University of Oxford

Other team members: Jose Leal, University of Oxford; Philip Clarke, University of Melbourne

The UKPDS Outcomes Model is based on patient data from 3642 patients participating in the UK Prospective Diabetes Study. It is a computer simulation model for forecasting the likely first occurrence of major diabetes-related complications and death in patients with diagnosed T2DM. The UKPDS-OM was designed to assess the total burden of disease over an extrapolated lifetime for populations with T2DM.

The UKPDS-OM is a probabilistic discrete-time model with annual cycles that is based on a system of parametric survival equations simulating patient-level outcomes. The model predicts an individual's absolute risk of first of seven complications (ischaemic heart disease, myocardial infarction, heart failure, stroke, blindness, renal failure and amputation) and death, conditional on the patient's characteristics (age, ethnicity, sex and duration of diabetes) and annual values for time-varying clinical risk factors (systolic blood pressure, HbA1c, lipid levels, smoking status and history of previous complications).

The UKPDS-OM outputs are estimated Life Expectancy, Quality Adjusted Life Expectancy, complication rates, and costs for each member of a given population. It was developed primarily to facilitate economic evaluations of diabetes related interventions by simulating their impact on clinical risk factors and assist with sample size trial calculations but has also been applied to health service planning and used as a long-term prognostic tool. The UKPDS-OM was shown to have good internal validity and to closely match diabetes-related complications in observational studies and the impact of interventions assessed through randomized controlled trials.

Key Publications:

Clarke P, Gray A, Holman R. Estimating utility values for health states of T2DM patients using the EQ-5D (UKPDS 62) Medical Decision Making 2002; 22: 340-349

Clarke P, Gray A, Legood R, Briggs A, Holman R. The impact of diabetes-related complications on healthcare costs: results from the United Kingdom Prospective Diabetes Study (UKPDS 65). Diabetic Medicine 2003; 20 (6): 442-50.

Clarke PM, Gray AM, Briggs A, et al. A model to estimate the lifetime health outcomes of patients with type 2 diabetes: UKPDS Outcomes Model. Diabetologia 2004; 47: 1747-59

The Mount Hood 4 Modelling Group. Computer Modelling of Diabetes and Its Complications. Diabetes Care 2007;30: 1638-1646.

Conference Sessions

Instructions for Presenters in Conference sessions

- All Presenters will have around 20 minutes each (including 5 minutes questions).
- A laptop computer and projector will be provided for your presentation, using Microsoft PowerPoint software.
- The time allocated for presentation will be 15 minutes. Allow a minimum of one minute per slide, preferably 2–3 minutes.
- Arrive at the meeting room before the session begins and contact the session convener for last-minute instructions or changes in the schedule.
- During your presentation, state the purpose and objectives of the paper, the main concepts and results, and the conclusions. Avoid too much detail.
- Do not exceed the allocated time for your presentation.
- Presenters will be given an opportunity to make a pdf of a paper or slides available on the conference website.

Parallel Conference Sessions for Economics, Modelling and Diabetes: The Mt Hood Six Challenge Economics, Modelling, Baltimore, 2012

Conference Session 1: Type 2 diabetes model

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Session Chairperson: Prof Andrew Palmer, University of Tasmania

Presentations:

1. An improved model to estimate lifetime health outcomes of patients with Type 2 diabetes using long-term follow-up data from the United Kingdom Prospective Diabetes Study (UKPDS)

   Presenter: Alison Hayes, University of Sydney, Australia.

2. The Importance of HbA1c Evolution in Cost-Effectiveness Modelling of Type 2 Diabetes Mellitus (T2DM)

   Presenter: Michael Willis, Swedish Institute for Health Economics, Sweden

3. Correlating cost effectiveness output with patient level data input via the IMS Core Diabetes Model

   Presenter: Phil McEwan, Swansea University. UK

4. Development and Validation of a New Coronary Heart Disease Model for Type 2 Diabetes
   Presenter: Ye Wen, University of Michigan, United States

Parallel Conference Sessions for Economics, Modelling and Diabetes: The Mt Hood Six Challenge Economics, Modelling, Baltimore, 2012

Conference Session 2: Cost of diabetes and diabetes complication

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 202

Session Chairperson: : Dr Ping Zhang, Centres for Disease Control and Prevention, USA

Presentations:

1. The cost of diabetes complications in Belgium

   Presenter: Mark Lamotte, Health Economic and Outcomes Research Belgium

2. Inpatient costs for people with diabetes in England: An economic analysis

   Presenter: Marion Kerr, NHS Diabetes, Insight Health Economics, UK

3. Estimating the costs of prescribed medicines attributable to people with diabetes in Scotland.

   Presenter: Lindsay Govan, University of Glasgow. UK

4. Implications of non-normality in cost distributions for health economic modelling in type 2 diabetes mellitus (t2dm)

   Presenter: Anna Teschemaker, Janssen Global Services, United States

Parallel Conference Sessions for Economics, Modelling and Diabetes: The Mt Hood Six Challenge Economics, Modelling, Baltimore, 2012

Conference Session 3: Cost-effectiveness of interventions

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 18

Session Chairperson: A/ Prof John Bridges, John Hopkins Uniervsity

1. Screening and treatment change for patients with monogenic diabetes: a two-stage decision model

   Presenter: Jaime Peters, University of Exeter, UK

2. Modelling decision-making for therapy for type 2 diabetes using the Analytic Hierarchy Process (AHP)

   Presenter: Nisa Maruthur, The Johns Hopkins University, United States

3. Impact of Delaying Blood Pressure Control in Patients with Type 2 Diabetes: Results of a Decision Analysis

   Presenter: Neda Laiteerapong, University of Chicago, United States

4. Modelling the cost-effectiveness of diabetes genetic testing

   Presenter: Priya John, University of Chicago, United States

Parallel Conference Sessions for Economics, Modelling and Diabetes: The Mt Hood Six Challenge Economics, Modelling, Baltimore, 2012

Conference Session 4: Type 1 diabetes and GDM models

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Session Chairperson: Neda Laiteerapong, University of Chicago

Presentations:

1. Development and validation of a cost-utility model for type 1 diabetes mellitus

   Presenter: S. Wolowacz , RTI Health Solutions, United States

2. Cost-effectiveness of renal screening strategies and treatment options for patients with type 1 diabetes in the united kingdom

   Presenter: Tom Lung, University of Sydney, Australia

3. The cost-effectiveness of screening and treatment of gestational diabetes including prevention of Type-2 Diabetes Mellitus: Application of a new model in India and Israel

   Presenter: Elliot Marseille, Health Strategies International, United States

4. Modelling the Effects of Gestational Diabetes Mellitus on Maternity Care and Costs in Ireland

   Presenter: Paddy Gillespie, NU, Ireland

Parallel Conference Sessions for Economics, Modelling and Diabetes: The Mt Hood Six Challenge Economics, Modelling, Baltimore, 2012

Conference Session 5: Technical aspects of diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 202

Session Chairperson: David Grant, IMS HEOR, Belgium

Presentations:

1. Inpatient and Outpatient resource utilization of type-2 diabetes patients

   Presenter: Maria Alva, University of Oxford, UK

5. Adapting and validating diabetes simulation models across settings: Accounting for mortality differences using administrative data from Australia

   Presenter: Clarke Philip University of Melbourne, Australia

6. Minimum run-time requirements to reduce Monte Carlo error in stochastic simulations

   Presenter: Volker Foos, IMS Health, Switzerland

7. Using computing power to aid chronic disease modelling

   Presenter: Jacob Barhak

Parallel Conference Sessions for Economics, Modelling and Diabetes: The Mt Hood Six Challenge Economics, Modelling, Baltimore, 2012

Conference Session 6: Patient preferences in diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 18

Session Chairperson: Priya John, University of Chicago

Presentations:

1. Identifying the treatment preferences of patients with type 2 diabetes: A systematic review

   Presenter: Susan Joy Johns Hopkins University, United States

2. How to account for psychological determinants of treatment response in simulation models of behavioral interventions for diabetes

   Presenter: J. Kruger, University of Sheffield, UK

3. Simulating Randomized Clinical Trials with the SimCare Patient Model

   Presenter: Ryan McCabe, University of Minnesota

4. Expenditure variation in diabetes care in Danish general practice clinics

   Presenter: Camilla Sortsoe, University of Southern Denmark, Denmark

Conference Session 1: Type 2 diabetes model

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 1: An improved model to estimate lifetime health outcomes of patients with Type 2 diabetes using long-term follow-up data from the United Kingdom Prospective Diabetes Study (UKPDS)

Authors: Alison Hayes, Philip Clarke, Jose Leal, Maria Alva, Ruth Coleman, Alastair Gray and Rury Holman

Abstract:

Background and Aims: To extend and enhance the existing UKPDS Outcomes simulation model for type 2 diabetes by using additional patient-level data from the ten-year post-trial monitoring phase of the UKPDS in the re-estimation of risk equations for diabetes complications and death.

Methods Using individual patient data from the UKPDS and up to 10 years of post trial monitoring (PTM) data, parametric proportional hazards models were estimated to predict absolute and relative risk associated with nine diabetes-related complications and death. This included re-estimation of equations for death and the six complications in the original Outcomes model (1st MI, 1st stroke, 1st amputation, ischaemic heart disease, heart failure, blindness and renal failure) and estimation of new equations for diabetic ulcer and second events for myocardial infarction, stroke and amputation. In addition to classical risk factors, new risk factor covariates included micro/macro albuminurea, heart rate, white blood cell count, haemoglobin, and eGFR.

Results Event equations were based on up to 77941patient years of data. For each of the outcomes we have approximately twice as many events as used in the estimation of the previous risk equations, enabling greater precision and a larger number of siginifcant co-variates. Of the new covariates, Micro/macro albuminurea was a significant covariate in 9 of the equations, and eGFR in five. The equations reliably predicted the cumulative incidence of major events over 3 decades of calendar time.

Conclusion: The new equations can simulate a wider range of long-term outcomes and more reliably estimate risk for older people with diabetes.

Conference Session 1: Type 2 diabetes model

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 2: The Importance of HbA1c Evolution in Cost-Effectiveness Modelling of Type 2 Diabetes Mellitus (T2DM)

Authors: Michael Willis, Jianming He, Cheryl Neslusan, Pierre Johansen1

Abstract:

INTRODUCTION: Owing to the progressive nature of T2DM, HbA1c tends to drift up over time. In addition, the extent to which alternative anti-hyperglycemic agents can maintain their initial glucose lowering effect (or durability) varies. HbA1c evolution is an important determinant of future outcomes and costs. Currently there is no consensus in the modelling community on how to account for the natural upward drift in HbA1c or the durability of treatments.

OBJECTIVE: Review different approaches to modelling HbA1c evolution and assess their impact on economic evaluations of T2DM interventions.

METHODS: We reviewed the ways in which HbA1c evolution has been modelled. To assess alternative approaches, lifetime simulations were performed that compared two hypothetical treatments using ECHO-T2DM, a validated micro-simulation model. The two profiles were specified: 1) initial HbA1c reduction of 1.25% and annual cost of $250 and 2) initial HbA1c reduction of 1% and annual cost of $200. Treatment was intensified in both arms when HbA1c exceeded 7.0%, first by adding basal insulin and subsequently by adding 3x daily short-acting insulin.

RESULTS: Four different approaches were identified: (1) no HbA1c evolution; (2) constant increase in HbA1c, irrespective of treatment; (3) constant treatment-specific increase in HbA1c; and (4) non-linear increase in HbA1c, irrespective of treatment. The simulations confirmed that these assumptions are critical. While the incremental life-years (LY's) and Quality-Adjusted LYs (QALYs) were similar in the first 3 scenarios, the absolute values were highest for (1). Cost-savings were largest in (3), which allowed HbA1c to drift apart over time in each arm, and lowest in (2) (because treatment intensification reduced the HbA1c gap). (4) could not be implemented in this version of ECHO-T2DM.

CONCLUSION: Assumptions used to model HbA1c evolution have important consequences for estimates of cost-effectiveness and should be addressed with sensitivity analysis in health economic evaluations

Conference Session 1: Type 2 diabetes model

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 3: Correlating cost effectiveness output with patient level data input via the IMS Core Diabetes Model (CDM)

Authors: Phil McEwan, Volker Foos, Adam Lloyd, James Palmer, Mark Lamotteand, David Grant

Abstract

Introduction: The use of patient level data (PLD) within cost-effectiveness models offers the potential to analyse the relationship between individual input profiles and predicted output. The objective of this study was to ascertain if particular PLD input profiles were predictive of cost effectiveness sub-groups in Type 2 diabetes mellitus (T2DM) subjects.

Methods: This study used the IMS Core Diabetes Model (CDM), a validated and established diabetes model to evaluate the cost effectiveness of a new 2nd line oral therapy (Treatment) compared to metformin+ sulphonylurea (Control). Delta treatment effects (favouring Treatment) were a 0.5% HbA1c reduction, 2kg weight change and a difference in symptomatic hypoglycaemia of 0.9/100 patient years. Annual diabetes specific therapy cost was £455 (Treatment) versus £70 (Control). A PLD extract was obtained from NHANES over the period of 1999 to 2008 of T2DM subjects treated with oral therapy only. Costs (2010 UK£) and benefits were discounted at 3.5%. Analysis if input/output data was undertaken using R.

Results: PLD for 1,858 T2DM subjects from NHANES were obtained with mean age 63.6 years of which 53% were male. Mean estimated cost per QALY of Treatment versus Control was £6,111. Multivariate logistic regression identified age ($p<0.05$), SBP ($p<0.001$) and HbA1c ($p<0.001$) as model input variables significantly associated with cost effectiveness at a WTP threshold of £20,000. HbA1c was linearly and negatively correlated with incremental cost (-£569 per 1% increase ($p<0.001$)). Subjects with baseline HbA1c>7.4% had significantly lower incremental costs compared to those $\leq$ 7.4% (£ 1,205 versus £3,462 respectively) and higher incremental QALY benefits (0.18 versus 0.15 respectively.

Conclusion: The identification of patient characteristics associated with greater potential for health gain and reduced cost is an important goal. The analysis of PLD alongside simulation model output provides an additional mechanism for informing healthcare decision-making.

Conference Session 1: Type 2 diabetes model

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 4: Development and Validation of a New Coronary Heart Disease Model for Type 2 Diabetes

Authors: Wen Ye, Michael Brandle, Morton Brown, and William Herman

Abstract:

Coronary heart disease (CHD) is a major comorbidity of diabetes and the leading cause of death among people with diabetes. At least 60 percent of people with diabetes die from heart disease. A valid sub-model for CHD that reflects current treatments is essential for the success of any diabetes simulation model.

In the past decade, medical practice has been changed dramatically with respect to screening for and treatment of hypertension, dyslipidemia, and cardiovascular disease. We updated the CHD sub-model in the Michigan Diabetes Model to reflect these changes.

We have modified the structure of the new CHD model to accommodate revascularization procedures before and after the first myocardial infarction (MI), to model heart failure as the most severe and costly stage of CHD before death, and to allow repeated MI and repeated revascularizations. To account for heterogeneity among diabetic patients, we have incorporated risk equations from the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model for the events of ischemic heart disease, myocardial infarction, and fatality after MI. We modified these equations to adjust for additional benefits of beta-blockers, ACE-inhibitors, and statin medications. We calibrated all the model parameters (including baseline hazard parameters in the UKPDS outcome model equations) to more recently published studies.

To assess the validity of this new CHD model, we performed internal and external validation exercises comparing the model-simulated outcomes with the outcomes from published observational studies and clinical trials

Conference Session 2: Cost of diabetes and diabetes complication

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 1: Inpatient and Outpatient resource utilization of type-2 diabetes patients

Authors: Maria Alva , Alastair Gray PhD 1, Borislava Mihaylova DPhil 1, Rury R Holman FRCP

Abstract

Reliable estimates of the impact of complications on resource use and healthcare costs are important for researchers studying cost-effectiveness of interventions. We provide new estimates of the cost of diabetes complications using 10 years of additional data from the landmark UK Prospective Diabetes Study (UKPDS). We analyse inpatient and outpatient utilisation, using six questionnaires administered between 1997 and 2007 resulting in 3,589 responders and 10,920 questionnaires and hospitalization records for England for 2866 patients. Resources use measured includes home, clinic, and telephone contacts with general practitioners, nurses, podiatrists, opticians, and dieticians, eye and other hospital out-patient clinics, and all in-patient stays and procedures.

We estimated the immediate and long term impact on impatient and outpatient costs of myocardial infarction, ischemic heart disease, stroke, heart failure, amputation, blindness in one eye, retinal photocoagulation, cataract extraction and vitreous haemorrhage, controlling for patient specific characteristics.

The panel structure of our dataset allows us to differentiate cost variations due to heterogeneity between patients and patient-specific increases in the underlying utilization resulting from diabetes-related complications. We demonstrate that people who have an event are on a higher level of expenditure before the event actually occurs.

For patients having no complications, routine outpatient care costs increased by 54% over the 10-year follow-up, and particularly between 1997 and 2003. This period corresponded with the publication of UKPDS results demonstrating the benefits of intensive therapy and the subsequent changes in treatment guidance and protocols.

Conference Session 2: Cost of diabetes and diabetes complication

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 2: The cost of diabetes complications in Belgium**.**

Authors: Mark Lamotte, Pierre Chevalier, Volker Foos, Phil McEwan, Adam Lloyd, James Palmer, and David Grant

Abstract

Background: The risk of cardiovascular risk is higher in patients with diabetes but what with the cost of this complication?

Objectives: The aim of this study was to compare the cost of cardiovascular events in patients with and without diabetes in Belgium.

Methods: Cost of cardiovascular events among hospitalized patients were estimated using the longitudinal IMS Hospital Disease Database (2008), including data on 34.3% of Belgian hospital beds, combined with Belgian population data. Stays were identified based on ICD-9 or DRG coding. Cardiac disease included myocardial infarction (MI; ICD-9:410), angina (ICD-9: 413) and heart failure (ICD-9: 428). Cerebrovascular disease (CVD) was defined as stroke (APR-DRG:045;046) and Transient Ischemic Attack (TIA; DRG:047). Diabetes was defined with the ICD-9 codes 249 and 250. Cost comparisons were made using a Wilcoxon non-parametrical test.

Results: An MI in a diabetic patient was 35% more expensive compared to a non diabetic (€7,483 vs. €5,549; $p<0.001$). In angina and heart failure the difference was less pronounced, nevertheless the cost was respectively 22% and 13% higher (angina: €2,570 vs. €2,101; $p=0.01$, heart failure: €8,776 vs. €7,757; $p<0.001$). Stroke was 8% more expensive and TIA 17% more expensive (stroke: €9,508 vs. €8,804; TIA: €4,802 vs. €4,109; both $p<0.001$). Reason for this higher cost is the longer length of stay varying from 1 day in angina to 3 days in MI. The percentage of women was higher in the diabetic group (50% vs. 47%; $p<0.05$) and diabetic patients were on average 1.8 years older (72.8 vs. 71.0; $p<0.01$). A regression analysis learned that age was the most important cost driver for all outcomes and diabetes was an independent driver for MI and stroke.

Conclusions: Patients with diabetes do not only have a higher risk of cardiovascular events, in case they have an event this event is significantly more expensive.

Conference Session 2: Cost of diabetes and diabetes complication

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 3: Inpatient costs for people with diabetes in England: An economic analysis

Authors: Kerr M**.**

Abstract

Objective: To estimate total and excess expenditure on inpatient care for people with diabetes in the English NHS.

Methods: NHS Hospital Episode Statistics for 2009-10 were examined to identify all admissions to English NHS hospitals with a recorded diabetes diagnosis. Total expenditure on inpatient care for this patient group was estimated using Healthcare Resource Group (HRG) tariffs. Admission rates and elective day case rates were then calculated, and compared with those for people of the same quinary age band and gender without diabetes. The impact of diabetes diagnosis on length of stay was examined using generalised linear model regression analysis. Excess expenditure in diabetes was estimated, relative to patients of the same age and gender without diabetes. The distribution of excess admissions across HRG chapters was examined.

Results: It is estimated that the NHS in England spent £2.3 billion-£2.5 billion on inpatient care for people with diabetes in 2009-10, around eleven per cent of total NHS inpatient expenditure. Of this sum, £573 million-£686 million was excess expenditure, above the level for people of the same age and gender without diabetes. Three quarters of this excess was accounted for by excess non-elective admissions. The non-elective admission rate was 70% higher, and the elective admission rate 15% lower, than the rates for people of the same age and gender without diabetes. Length of stay was longer for people with diabetes, and elective day case rates were lower. One fifth of excess elective admissions were for hyperglycaemia, hypoglycaemia or lower limb complications. Of the remainder, more than half occurred in three clinical areas: Cardiac, Digestive System, and Renal.

Summary: Absolute and excess costs in inpatient care for people with diabetes are substantial. The bulk of excess expenditure is accounted for by high non-elective admission rates for diabetes complications and comorbidities.

Conference Session 2: Cost of diabetes and diabetes complication

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 4: Estimating the costs of prescribed medicines attributable to people with diabetes in Scotland

Authors: L Govan, O Wu, A Briggs, RS Lindsay on behalf of the Scottish Diabetes Research Network Epidemiology Group

Abstract

Background: Previous studies show approximately 25% of the expenditure attributable to people with diabetes is incurred by prescriptions. In this study, we assessed the prescription costs in people with type 1 and type 2 diabetes in Scotland.

Methods: Data on prescribed medications were available via the Scottish Care Information – Diabetes Collaboration (SCI-DC) clinical system: a dynamic national register of diagnosed cases of diabetes in Scotland. Standard NHS costs for prescribed medications were estimated using the Prescription Cost Analysis (2007/2008). These data sources were linked using drug name, strength and formulation; linkage was achieved in 96% of records in SCI-DC.

Results: In Scotland during 2005–2007, 22,257 people with type 1 and 187,373 people with type 2 diabetes were observed for prescriptions, accounting for approximately 4.1% of the total Scottish population (5.1 million). The number of prescriptions observed in the type 1 population increased from 20,793 to 21,664 (4% increase) and in type 2, from 158,317 to 174,972 (10%). The corresponding prescription expenditure was between £21-£24m for type 1 diabetes (13% increase) and £153-£172m for type 2 diabetes (13%), approximately 20% of the total Scottish expenditure on prescriptions (£967m). Overall, 50% of prescription expenditure in type 1 diabetes was accounted for by endocrine system related drugs (insulin prescriptions make up 96% of these costs) and a further 20% by cardiovascular related drugs. In type 2 diabetes, 48% of prescription costs were accounted for by cardiovascular related drugs, 18% by endocrine system related drugs (37% accounted for by insulin, 55% by oral antidiabetic drugs), and 11% by central nervous system drugs.

Discussion: Diabetes accounts for a substantial proportion of health spending. Work is ongoing and we intend to investigate the effects of characteristics such as age, sex, diabetes duration, deprivation and HbA1c on costs of prescription.

Conference Session 3: Cost-effecitveness of interventions

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 1: Screening and treatment change for patients with monogenic diabetes: a two-stage decision model

Authors: Jaime L Peters, Rob Anderson, Chris Hyde

Abstract

Background: Monogenic diabetes resulting from mutations in the HNF1A, HNF4A and GCK genes shows marked differences in treatment response compared to patients with Type 1 and Type 2 diabetes, with patients usually discontinuing insulin and replacing it with sulphonylurea tablets. Such a treatment change is likely to have large impacts on costs to the National Health Service (NHS) in England and Wales and the quality of life of people with monogenic diabetes. However, the impact of this pharmacogenetic knowledge is currently limited by the failure to diagnose monogenic diabetes. Genetic testing of all diabetes patients is likely to be costly, but clinical, biochemical and immunological criteria are available to help diagnosis of monogenic diabetes.

Methods: We have developed a decision tree to evaluate the short-term costs and quality-adjusted life years associated with five alternative pathways for the diagnosis and subsequent treatment change for patients with monogenic diabetes. These results will feed into the CORE diabetes outcome model allowing a life-time horizon for the calculation of the cost-effectiveness of the screening strategies. The five screening strategies are all realistic options for the NHS: (1) no genetic testing of any individuals, (2) referral for genetic testing based on clinical features (defined as current practice), (3) referral for genetic testing based on a clinical prediction model, (4) referral for genetic testing based on biochemical and immunological test results, (5) genetic testing of all diabetes patients under the age of 30 years.

Results: Preliminary results will be presented, highlighting the main areas of uncertainty in model structure, in particular for linking the decision tree with the CORE diabetes outcome model. Estimating the costs of prescribed medicines attributable to people with diabetes in Scotland.

Conference Session 3: Cost-effecitveness of interventions

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 2: Modelling decision-making for therapy for type 2 diabetes using the Analytic Hierarchy Process (AHP)

Authors: Nisa M. Maruthur, John F. P. Bridges, Susan M. Joy, Emily Little, Sonal Singh

Abstract

Background: Modelling treatment decisions in medicine requires identification of the relevant criteria (benefits and harms), values to weigh the criteria and simulation of the deliberative process.

Objective: To model the decision for the treatment of type 2 diabetes using the Analytic Hierarchy Process (AHP) taking a regulatory perspective with a goal of determining the safest and most effective medication.

Methods: We enumerated the treatment alternatives and criteria (benefits and risks) using published studies and FDA medication labels. As part of the iterative process of model and process refinement, we conducted content validation during two in-person one-hour group sessions and piloted the AHP process with generalist and specialist diabetes experts. Web-based ExpertChoice software was used to elicit treatment-related preferences. A total of 130 comparisons were performed. Relative differences between treatment alternatives >1.1 were considered significant.

Results: The AHP model included the following criteria: Benefits of glucose control such as prevention of diabetes-related complications; treatment-related risks such hypoglycemia; and treatment-related quality of life. Treatment alternatives were from seven non-insulin medication classes and placebo/lifestyle. Aggregated weights for preferences were 0.41, 0.35, and 0.23 for maximizing benefits, minimizing harms, and minimizing treatment burden, respectively. Relative differences were <1.1 comparing diabetes medications to one another and were >1.1 when medications were compared with placebo. Priorities for treatment alternatives ranged from 0.17 to 0.22 and were generally similar, and the priority for placebo was 0.11.

Conclusions: Treatment priorities are similar for the non-insulin diabetes medications and higher than that for placebo. Expert input can be used to elicit preferences for treatment-related outcomes and support transparent treatment decisions about benefit and risk. In future work, we will engage patients to understand whether patient preferences for treatment-related outcomes are concordant with those of experts and determine preference heterogeneity.

Conference Session 3: Cost-effectiveness of interventions

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 3: Impact of Delaying Blood Pressure Control in Patients with Type 2 Diabetes: Results of a Decision Analysis

Authors: Neda Laiteerapong, Priya M. John, David O. Meltzer, Elbert S. Huang,

Abstract

Background: In patients with diabetes, delays in controlling blood pressure are common, but the harms of delays have not been quantified.

Objective: To estimate the harms of delays in controlling systolic blood pressure in middle-aged adults with newly diagnosed Type 2 diabetes.

Design: Decision analysis using diabetes complication equations from the United Kingdom Prospective Diabetes Study (UKPDS).

Participants: Hypothetical population of adults aged 50 to 59 years old with newly diagnosed Type 2 diabetes based on characteristics from the National Health and Nutrition Examination Surveys

Intervention: Delays in lowering systolic blood pressure from 150 (uncontrolled) to 130 mmHg (controlled).

Main Measures: Lifetime complication rates (amputation, congestive heart failure, end-stage renal disease, ischemic heart disease, myocardial infarction, and stroke), average life expectancy and quality-adjusted life expectancy (QALE).

Key Results: Compared to a lifetime of controlled blood pressure, a lifetime of uncontrolled blood pressure increased complications by 1855 events per 10,000 patients and decreased QALE by 332 days. A 1-year delay increased complications by 14 events per 10,000 patients and decreased QALE by 2 days. A 10-year delay increased complications by 428 events per 10,000 patients and decreased QALE by 145 days. Among complications, rates of stroke and myocardial infarction increased to the greatest extent due to delays. With a 20-year delay in achieving controlled blood pressure, a baseline blood pressure of 160 mmHg decreased QALE by 544 days, whereas a baseline of 140 mmHg decreased QALE by 163 days.

Conclusions: Among middle-aged adults with diabetes, the harms of a 1-year delay in controlling blood pressure may be small; however, delays of ten years or more are expected to lower QALE to the same extent as smoking in patients with cardiovascular disease.

Conference Session 3: Cost-effecitveness of interventions

Time: 1:30-3:00pm, Thursday 7th June 2012

Location: Room 18

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Conference Session 4: Type 1 diabetes and GDM models

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 1: Development and validation of a cost-utility model for type 1 diabetes mellitus

Authors: Wolowacz S, Pearson I, Roskell N, Shannon P, Chubb B, Gundgaard J, Davies M, Briggs A

Abstract

Objective: A simple, transparent cost-utility model was developed to evaluate type 1 diabetes mellitus (T1DM) treatments, predicted from their effect on mean glycosylated haemoglobin (HbA1c) levels and the risk of hypoglycemic events.

Methods: Data describing the incidence of T1DM complications and the effect of HbA1c and other risk factors were identified by a systematic review. The Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) study were identified as the primary sources as they uniquely provide long-term follow-up (now over 23 years) of patients managed using strategies that are reasonably representative of contemporary T1DM management. Parametric survival functions were fitted to published cumulative incidence curves for the following endpoints: cardiovascular disease, peripheral neuropathy, microalbuminuria, end-stage renal disease, proliferative retinopathy, and ketoacidosis. Data for complications not reported in DCCT/EDIC (including cataract and adverse birth outcomes) were taken from other publications. Published hazard ratios for HbA1c, age, and duration of diabetes were used to develop risk equations for each complication. An individual patient-simulation model was developed in Excel. Internal validation was performed with respect to outcomes for the DCCT/EDIC intensive treatment group; external validation was performed with respect to the DCCT/EDIC conventional treatment group and other studied populations (e.g., the Epidemiology of Diabetes Complications study), based on differences in HbA1c, age and disease duration.

Results: Model predictions were within 2% of expected values for the DCCT intensive group, within 4% of expected values for the DCCT conventional treatment group, and within 8% of expected values for external validation studies. The model predicted mean total expected life-years, quality-adjusted life-years and costs.

Conclusions: This simple, patient-simulation model utilises high-quality, recently reported data specific to T1DM patients. Internal and external validation of the model demonstrated a deviation of less than 8% from expected values.

Conference Session 4: Type 1 diabetes and GDM models

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 2: Cost-effectiveness of renal screening strategies and treatment options for patients with type 1 diabetes in the United Kingdom

Authors: Thomas Lung,

Abstract

Objectives: To evaluate the cost-effectiveness of alternative renal screening strategies and implications for blood pressure treatment in patients with type 1 diabetes. This required development of a discrete time simulation model for type 1 diabetes patients to estimate quality-adjusted life years (QALYs).

Methods: We synthesized evidence on type 1 diabetes patients using several published sources. The simulation model was based on eleven equations to estimate transitions between health states. Screening identified patients with impaired renal function whom were then assigned angiotensin-converting enzyme inhibitors (ACE-I) to lower blood pressure and improve renal function. Screening intervals were varied from 1 year to 10 yearly intervals and compared to current UK guidelines of annual screening. Outcomes were expressed in QALYs based on utilities of different diabetes complications obtained from a meta-analysis. Costs of the monitoring program, treatment and hospitalisation from diabetes-related complications were included. 1000 patients (mean age 15 years) were simulated for 85 years and cost-effectiveness analyses performed. Costs and effects were discounted at standard rates. Uncertainty surrounding these results was also calculated.

Results: When comparing annual screening to biennial screening, the reduction in the number of patients on ACE-I reduces both costs and QALYs, showing an incremental cost-effectiveness (ICER) ratio of £9,718 per QALY. Increasing the screening interval to 5 years resulted in further reductions in both costs and QALYs, and an ICER well within the National Institute of Health and Clinical Excellence's (NICE) recommended threshold. Sensitivity analyses showed universal treatment increased survival rates when compared to annual screening and no treatment by an additional 4.4 years and 5.5 years, respectively.

Conclusions: Renal screening for people with type 1 diabetes is cost-effective in the UK context compared to other funded health interventions. Further research is required to determine whether universal treatment is a policy that is worth pursuing in the long term.

Conference Session 4: Type 1 diabetes and GDM models

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 3: The cost-effectiveness of screening and treatment of gestational diabetes including prevention of Type-2 Diabetes Mellitus: Application of a new model in India and Israel

Authors: Elliot Marseille, Nicolai Lohse, Aliya Jiwani, Moshe Hod , V. Sheshiah, C.V. Yajnik, G. AroraV, Balaji, Ole Henriksen, Nicky Lieberman, Rony Chen, Peter Damm, Boyd Metzger, James G. Kahn

Abstract

Background: Gestational diabetes mellitus (GDM) is associated with elevated risks of perinatal complications and type 2 diabetes (T2DM). GDM screening and management can reduce these adverse outcomes, but little is known about the cost-effectiveness of intervening when T2DM benefits are considered. We assessed the cost-effectiveness of GDM interventions in two settings.

Methods: We developed a spreadsheet-based decision-analysis tool (the GDModel®) to assess the cost and health impact of GDM screening and treatment. Using local prevalence and cost data, combined with literature-based estimates of incidence and efficacy, we applied the model for the Government Corporation Hospital (GCH) in Chennai, India, and Clalit, a large HMO in Israel. We computed intervention and net costs, averted disability-adjusted life years (DALYs), and net cost per DALY averted. We performed one-way and multivariate sensitivity analyses.

Results: For 1,000 pregnant women, GDM intervention costs in discounted international dollars, are estimated at $259,139 for GCH (India) and $259,929 for Clalit (Israel). Net costs (adjusted for averted medical care) are $194,358 and $76,102, respectively. The intervention averts 120 discounted DALYs in GCH and 42 in Clalit. The cost per DALY averted is $1,626 and $1,830 at the Indian and Israeli sites, respectively. Inputs with the greatest influence on cost-effectiveness were T2DM reduction and incidence in GDM-affected mothers and the cost of postpartum interventions to reduce T2DM. In multivariate simulations, the range of findings was $628 - $3,681 for GCH and net savings of $72,420, to $8,432 per DALY averted for Clalit.

Conclusion: Our study suggests that GDM interventions are highly cost-effective in Indian and Israeli settings. Given large differences between these countries in GDM prevalence and health care costs, GDM interventions may be cost-effective in varied settings. GDM screening and management presents an important opportunity to reduce GDM health consequences such as T2DM and their attendant societal costs.

Conference Session 4: Type 1 diabetes and GDM models
Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Pullen Plaza

Presentation 4: Modelling the Effects of Gestational Diabetes Mellitus on Maternity Care and Costs in Ireland

Authors: Paddy Gillespie, Ciaran O'Neill, John Cullinan, Fidelma Dunne, For the ALANTIC DIP Collaborators

Abstract

Given the increasing prevalence of gestational diabetes mellitus (GDM), as well as its implications for maternal and neonatal outcomes, a growing literature explores economic issues relating to GDM. This study models the effects of GDM on maternity care and costs in Ireland, based on a sample of 4372 women from the ATLANTIC DIP Study who had a 75g OGTT at 24–28 weeks during pregnancy. Adopting the International Association of Diabetes and Pregnancy Study Group criteria, 354 women or 8.1% of the sample had a positive GDM diagnosis. Mode of delivery was recorded as normal vaginal delivery (NVD), assisted vaginal delivery (forceps and/or ventose) (AVD), elective caesarean section (ELCS), and emergency caesarean section delivery (ERCS). Neonatal unit admission (NUA) was recorded as whether or not an infant was admitted for neonatal intensive care. Unit cost estimates in 2009 Euros were applied to value resource use. Multinomial logistic, logistic, and generalised linear model multivariate regression analysis was used to explore the effects of GDM and other independent variables (age, body mass index, primiparous, family history of diabetes, previous miscarriage, ethnicity, and delivery week) on three dependent variables: mode of delivery, neonatal unit admission, and cost. After controlling for other factors, the odds ratio for an ERCS relative to a NVD was 1.75 (95% CIs: 1.08, 2.81, $P < 0.05$) for GDM relative to non-GDM cases. The odds ratio for a NUA was 3.14 (95% CIs: 2.27, 4.34, $P < 0.01$) for GDM relative to non-GDM cases. The mean cost per non-GDM case was €4117 (SD: 3019) compared to €6039 (SD: 4378) per GDM case. The incremental cost of GDM was €1597 (95% CIs: 1086, 2108, $P < 0.01$). GDM poses a significant burden on maternity care services which is independent of the effects of other factors including overweight or obesity during pregnancy.

Conference Session 5: Technical aspects of diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 1: Implications of non-normality in cost distributions for healtheconomic modelling in type 2 diabetes mellitus (T2dm)

Authors: Anna Teschemaker, Michael Willis, Chyi-Hung Hsu, Cheryl Neslusan, Jianming He

Abstract

Background: Macro- and micro-vascular complications are important cost drivers in T2DM. Often the costs of these complications vary considerably across patients and their distributions are skewed, which can lead to biased cost estimates and the degree of uncertainty in the results. Although statistical techniques to address these issues are available, they have not been routinely applied in the economic modelling of T2DM.

Objective: To illustrate the importance of using appropriate statistical techniques to generate cost data for use in economic modelling of T2DM.

Methods: Patients with T2DM were identified in the IMS LifeLink™ Health Plan Claims Database between 2000 and 2010 using an algorithm based on ICD-9 codes and medication usage. Index dates were defined as the date of first occurrence of the following events: myocardial infarction (MI), congestive heart failure (CHF), stroke, and angina pectoris (AP). Annual physician and hospitalization costs associated with each event were computed over the year following the index dates. For each complication type, the costs were tested for whether they were distributed according to normal, lognormal, and gamma distributions using the Kolmogorov-Smirnov test and CDF plots. If the assumption of normality was rejected, bootstrapped standard errors were calculated.

Results: We identified 5,090, 10,696, 5,316, and 8,079 patients with T2DM with a diagnosis of MI, CHF, stroke and AP, respectively. The distribution of costs for each complication was positively skewed and the hypothesis of normality was rejected. The CDF plots were consistent with the finding. Bootstrapped mean cost (SE) estimates were $11,922 ($406), $10,850 ($344), $4,225 ($191) and $2,367 ($81) for MI, CHF, stroke, and AP, respectively.

Conclusion: These results suggest that techniques that address variability and skewness in costs should be considered in cost-effectiveness modelling of T2DM to avoid bias.

Conference Session 5: Technical aspects of diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 2: Adapting and validating diabetes simulation models across settings: Accounting for mortality differences using administrative data from Australia

Authors: Alison Hayes, Wendy Davis, Timothy Davis, and Philip Clarke

Abstract

Objectives. To develop age and sex-specific risk equations for predicting mortality following major complications of diabetes, using a large linked administrative dataset from Western Australia (WA)(n=13884 patients) and to incorporate these into the UKPDS Outcomes Model. To compare the original and adapted models in predictions of survival and life expectancy following complications, and of incremental benefits associated with changes in common risk factors.
Methods: We estimated a multivariate logistic regression model for the probability of death in the year of a complication, and a multivariate semi-parametric survival model (Gompertz) for years beyond the year of the complication. Using representative input data and clinical risk factors for Australian patients, we ran Monte Carlo simulations of the original and adapted models. Parameter uncertainty was evaluated using 1000 bootstrapped coefficients of all model risk equations.
Results: The two versions of the model generated differences in life expectancy following specific events; for example life expectancy of a 74 year old following myocardial infarction was 2.74 (95% CI 2.07-3.42) years for UK versus 4.33 (3.85-4.72) years for WA. However there was little impact of using alternative mortality equations on incremental QALYs gained as a result of reducing HbA1c or systolic blood pressure, or on outcomes of life expectancy for a cohort initially free of complications.
Conclusion: Mortality following major complications varies across diabetic populations and this can impact on estimates of life expectancy, but it appears to have less impact on incremental benefits of interventions that are commonly used in pharmoeconomic analysesAn improved model to estimate lifetime health outcomes of patients with Type 2 diabetes using long-term follow-up data from the United Kingdom Prospective Diabetes Study (UKPDS).

Conference Session 5: Technical aspects of diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 3: Minimum run-time requirements to reduce Monte Carlo error in stochastic simulations

Authors: Volker Foos, Phil McEwan, Adam Lloyd, James Palmer, Mark Lamotte and David Grant

Abstract

Backgrounds: In HEOR the role of probabilistic sensitivity analysis (PSA) is to assess the uncertainty of model predictions with respect to the underlying parameter uncertainty. However, in Monte Carlo simulation parameter uncertainty coincides with and cannot be distinguished from random noise (Monte Carlo error). The objective of this study was to quantify the minimum run time requirements to reduce Monte Carlo error to acceptable levels.

Methods: A established and validated model, the IMS CORE diabetes model (CDM), was used to compare outcome variability of bootstrap simulations with 1000 repetitions and increasing number of patients ranging from 2500 to 100000. Model projections were defined to evaluate the cost effectiveness of two hypothetical interventions with differences in clinical effectiveness of 0.5% HbA1c and a 2kg weight change in favour of the treatment- vs. control arm. Each simulation was performed in three ways; 1st where no parameter sampling was applied, 2nd and 3rd where parameters were sampled around 5% (SE based PSA) and 25% (SD based PSA) of their mean values, respectively. The degree of Monte Carlo error was determined according to the ratio of the confidence ranges (ICER per QALY) of the non-sampling analyses versus PSA.

Results: The proportion of Monte Carlo error contained in overall ICER variability for simulations with increasing number of patients (2500, 5000, 10000, 25.000, 50.000 and 100.000) was found at 110%, 107%, 73%, 54%, 45% and 32% for SE based PSA and 80%, 80%, 37%, 13%, 9%, and 6% for SD based PSA.

Conclusion: Run time requirements to reduce Monte Carlo error are lower whenever the uncertainty of included parameters is increased. Hypothesizing that not more than 40% of overall outcome variability should be attributable to Monte Carlo error, the minimum run time requirement was found at 100.000- and 10.000 patients for SE- and SD based PSA, respectively.

Conference Session 5: Technical aspects of diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 202

Presentation 4: Using computing power to aid chronic disease modelling

Authors: Jacob Barhak

Abstract:

Simulations of disease models test many combinations of parameters and individuals. This requires computational power. Chronic diseases have practically no interaction between individuals. Therefore, it is possible to solve the problem for each individual separately in parallel using Monte Carlo micro-simulation. Moreover, the simulation is typically repeated many times to reduce Monte-Carlo error, which is also parallelizable. Since so many pieces of the problem can be solved in parallel, it is categorized as embarrassingly parallel.

Embarrassingly parallel simulations have recently received support through a boost in computing power. Multi-core CPUs are now common in household computers and in servers at reasonable costs. Moreover, computer clusters are easier to build and operate and cloud solutions are also available.

An overview of techniques will be provided to aid the use of computing power for chronic disease modelling tasks.

Conference Session 6: Patient preferences in diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 1: Identifying the treatment preferences of patients with type 2 diabetes: A systematic review

Authors: Susan M., Joy Sonal Singh, Nisa M. Maruthur, Emily Little, John F. P. Bridges

Abstract

Background: Multicriteria decision analysis (MCDA) models are one promising method for performing quantitative benefit-risk analyses. Such decision models require information about patient preferences, both in terms of identifying which criteria should be included in the model and to develop important weights for various criteria included in the decision model. Currently, there are no best-practices for identifying and synthesizing such preference data, but a systematic review is one possible method.

Objectives: To determine the feasibility of using systematic review methods to identify the treatment preferences and treatment-related quality of life of adult patients with type 2 diabetes. We also aimed to determine sources of heterogeneity, if present, affecting patient preferences.

Methods: In March 2012, we searched PubMed, EMBASE, CINAHL and EconLit to identify studies reporting on treatment-related preferences or quality of life for patients with type 2 diabetes, without restriction on the type of measurement used. Titles identified were stored in EndNote. Articles not meeting the inclusion criteria were excluded through sequential review of titles, abstracts, and then full text articles. Marginal decisions were made by consensus. Data were abstracted into standardized forms in Excel.

Results: The initial search produced 4582 articles after removal of duplicates. Preliminary results identified a wide range of preference measurement methods such as conjoint analysis and a range of instruments measuring treatment-related satisfaction and quality of life, limiting conclusions about treatment-related preferences across studies. Few studies systematically identified the relative weights of treatment attributes or sources of heterogeneity in patient preferences.

Conclusions: The lack of consistency in treatment-related quality of life and preference measurement presents difficulties for synthesizing published results and for including such treatment-related preferences in diabetes management models. Future studies should collect preference measures in a standardized fashion both in studies designed to measure treatment-related preferences and in diabetes treatment trials.

Conference Session 6: Patient preferences in diabetes modelling
Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 2: How to account for psychological determinants of treatment response in simulation models of behavioural interventions for diabetes

Authors: J. Kruger and A. Brennan

Abstract

Health economic modelling of diabetes has paid limited attention to the effects patients' psychological characteristics can have on the effectiveness of an intervention. The objective of this study was to incorporate psychological prediction models of heterogeneous glycaemic response to the Dose Adjustment For Normal Eating (DAFNE) diabetes structured education programme into a diabetes simulation model.

Regression models were used to investigate the relationships between patients' psychological characteristics and 12-month HbA1c response to DAFNE. The resulting prediction models were integrated with a patient-level simulation model of type 1 diabetes by assigning psychological labels to patient entities and simulating individual HbA1c change as dependent on these labels. The integrated model was used to evaluate the cost-effectiveness of two new DAFNE service delivery policies (providing DAFNE only to predicted responders and offering a follow-up intervention to predicted non-responders) compared with current practice. The model estimated costs and quality-adjusted life-years over a 50-year time horizon from a UK National Health Service perspective. Deterministic sensitivity analyses were conducted.

Psychological predictors of treatment response were successfully integrated with the health economic simulation model, allowing new treatment policies to be evaluated. The results suggest that providing DAFNE only to predicted responders is dominated by current practice. This result was insensitive to the majority of sensitivity analysis assumptions tested. The results suggest that providing a follow-up intervention to predicted non-responders dominates current practice. This result was sensitive to model assumptions regarding the cost and effectiveness of the follow-up intervention.

By collecting data on psychological variables before and after a diabetes intervention we can construct predictive models of treatment response to behavioural interventions and incorporate these into health economic simulation models. This allows the simulation models to better represent the observed system and permits investigation of more complex treatment policies. Recommendations are made for future research using this methodology.

Conference Session 6: Patient preferences in diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 3: Simulating Randomized Clinical Trials with the SimCare Patient Model

Authors: Ryan M McCabe, Paul E Johnson, George Biltz, Patrick J O'Connor, JoAnn Sperl-Hillen, William A Rush, Autri Dutta, Mohamed Elidrisi, Georg Meyer

Abstract

Background: The SimCare Patient Model is a computational model of individual patients with type 2 diabetes. The model – constructed for physicians to interact with simulated patients – represents patients as a series of health states responding to treatments, referrals and disease progression over time. States are comprised of attributes representing patient health, individual and treatment characteristics; patient health attributes: A1c, SMBG, lipids panel, blood pressure, weight, creatinine; individual attributes: biophysical responsiveness to treatments, adherence (compliance) to treatment, disease progression; treatments: formularies of oral drugs, insulins and referrals to a nurse educator or psychologist. Each attribute is modeled independently by functional expressions derived from literature and clinical data.

Method: Cohorts of patients are generated from modeled clinical databases. Treatment regimens are modeled as rule sets. The patient model is parameterized by the initial state of a patient, the regimen is administered, the health state is recorded at each clinical encounter, and the next patient from the cohort is simulated. This study simulated three randomized clinical trials, each focusing on a major component associated with type 2 diabetes and predictive of cardiovascular disease – A1c, LDL, and SBP: ADVANCE (A1c arm), CARDS, and ADVANCE (SBP arm), respectively. These trials were not used to build the model.

Results: Comparisons are made for each reporting period (e.g., each 6 month cohort data point) for intermediate outcomes, relative differences between cohorts and total macrovascular event rates (generated by the UKPDS Risk Engine). R2-calculations measure the goodness of fit for model predictions within each comparison: A1c, SBP, LDL, Relative Differences, CVD Total Event Rates; 0.92, 0.89, 0.97, 0.86, 0.97, respectively (N = 24, 24, 10, 44, 12, respectively).

Conclusions: The SimCare Patient Model generated outcomes highly correlated with published outcomes. Limitations include generating representative initial patient states for individuals in cohorts and representing treatment regimens as rule sets.

Conference Session 6: Patient preferences in diabetes modelling

Time: 3:30-5:00pm, Thursday 7th June 2012

Location: Room 18

Presentation 4: Expenditure variation in diabetes care in Danish general practice clinics

Authors: Troels Kristensena, Kim Rose-Olsena, Camilla Sortsøa, Charlotte Ejerstedc, Anders Halling,

Abstract:

Background In several countries, morbidity burdens have changed the system to allocate resources among patients from a demographic based to a morbidity-based casemix system. In Danish GP clinics, no differentiation of capitation or fee-for-service (FFS) expenditures is made according to morbidity status.

Aims: We analysed FFS expenditure of diabetic patients visiting Danish GP clinics and aimed to assess what proportion of FFS expenditure variation are explained by patient morbidity and GP clinic characteristics.

Methods and data: We use patient morbidity characteristics such as diagnostic markers and multi-morbidity case-mix adjustment based on adjusted clinical groups (ACGs) and FFS expenditure for a sample of primary care patients for the year 2010. Our sample included 6,706 patients in 59 general practices. We applied a multi-level approach.

Results: The average annual FFS expenditure of caring for diabetes in general practice was about 400 euro per patient. Much of the variation in the expenditures was driven by multi-morbidity characteristics. Expenditures increased progressively with the degree of multi-morbidity. In addition, expenditures were higher for patients who suffered from diagnostic makers based on ICPC-2 (body systems and/or components such as infections and symptoms). Nevertheless, 14-18% of the variation in expenditure was related to the clinic in which the patient was cared for, with the number of diagnoses per visit, the number of visits per patient and clinic specific proportions of multi-morbidities and diagnostic markers being the main reason for this variation. The volume of patients did not explain the variation in expenditure.

Conclusion: Patient morbidity and GP clinic characteristics are significant patient related FFS expenditure drivers in diabetes care. Increasing proportions of a number of diabetes comorbidity diagnoses (such as infections) across clinics imply significantly lower FFS remuneration per patient. Thus, it may be relevant to introduce differentiated FFS tariffs to allocate resources according to morbidity status.