

# **Virtual Mount Hood Challenge 2020:**

## **Quality-of-Life - Reference Challenge**

### **Motivation:**

In 2018, a reference simulation was created based in part on the ADVANCE study population and participants in the 9<sup>th</sup> Mount Hood Diabetes Challenge were asked to apply it using their models and the results were uploaded onto the Mount Hood Diabetes Network homepage. Modelers were asked to upload new results of this benchmark simulation when their models were modified. In 2019, this reference simulation (with some modifications to the instructions based on misunderstandings) was part of the Asian Mount Hood Diabetes Challenge in Korea. The purpose is to provide a benchmark simulation that examines the magnitude of impact of different aspects of quality of life on incremental health economics outcomes associated with common diabetes interventions, which can facilitate model evaluation by users and stakeholders alike. The simulation was intentionally simple, given the diversity of structures and features in the many available diabetes models. A limitation of this simplicity, however, is that a number of key model features are not activated in this scenario (including treatment intensification and the simulation of high-risk patient populations). It was decided, thus, that the reference simulation would be supplemented an additional reference simulation that examine additional model features.

This Mount Hood Diabetes Network Challenge consists of 2 scenarios. For models that completed the original reference simulation and have not been modified, the original results can be used but a new scenarios should be applied.

***An Excel spreadsheet accompanying these instructions (MH VIRTUAL CHALLENGE – QOL.xlsx) is provided for the documentation of inputs and simulated outcomes.***

### **Model Description:**

We acknowledge that different models incorporate utilities in different ways (e.g. some assume additive effect, while others assume a multiplicative effect). However, for the purpose of this challenge, the **additive** quality-of-life (QoL) model is recommended when populating the health utility values into the simulation model. Suggestions on how utility values are applied are described in Appendix 1. If the additive QoL model is not feasible in your model, please document your assumptions how the health utility values are populated in your model.

For transparency it would be useful to describe how utilities are incorporated into different diabetes models. Please provide the following information in the accompanying Excel spreadsheet (in tab labelled “Model Description”).

- (i) What health states can be assigned a utility in your model;
- (ii) What values are typically assumed for each health state (provide point estimates and/or ranges). If these have varied over time, what values were used in the most recent published economic evaluation that involved a QALY simulation of the model. Please provide references of the source of the utilities where available.
- (iii) In 150 words (or less) succinctly describe how quality of life is modelled (e.g. are changes in utilities assumed to have an additive or multiplicative effect on QALY outcomes).

For models that have previously submitted this documentation (and Mount Hood 9 and/or at Mount Hood Asia Challenge) and have not been modified, the original documentation is sufficient.

## **Model Inputs:**

### ***Utility Values***

To examine the effect of different assumptions regarding quality of life’s impact on outcomes, we will run the same simulation with a variety of different assumptions regarding the utility associated with health states (such as diabetes-related complications). These values have been chosen to reflect average values from the literature (and high/low value as well). Utility values (Figure 1) from a recent systematic review (Beaudet et al., 2014) should be used for this challenge [Note: some models will require a utility value for renal transplant, which can be found in Appendix 1]. In this challenge, it would be adequate to use point estimates and not model 2<sup>nd</sup> order uncertainty if the model allows it.

If you require additional utility weights for health states not listed, please include these using values you currently use. Please document your sources and assumptions in the “Utility values” tab in the accompanying Excel spreadsheet.

**Figure 1: Utility values used to populate model**

Parameter	Proposed reference	Proposed utility value	95% CI	Range of candidate values
T2DM without complication	Clarke et al. [21]	0.785	0.681–0.889	0.690–0.940
Myocardial infarction	Clarke et al. [21]	-0.055	-0.067 to -0.042	-0.059 to -0.007
Ischemic heart disease	Clarke et al. [21]	-0.090	-0.126 to -0.054	-0.090 to -0.027
Heart failure	Clarke et al. [21]	-0.108	-0.169 to -0.048	-0.108 to -0.051
Stroke	Clarke et al. [21]	-0.164	-0.222 to -0.105	-0.164 to -0.070
Severe vision loss	Clarke et al. [21]	-0.074	-0.124 to -0.025	-0.070 to -0.012
Amputation event	Clarke et al. [21]	-0.280	-0.389 to -0.170	-0.280 to -0.063
Peripheral vascular disease	Bagust and Beale [22]	-0.061	-0.090 to -0.032 <sup>*</sup>	-0.186 to -0.061
Proteinuria	Bagust and Beale [22]	-0.048	-0.091 to -0.005 <sup>*</sup>	One reference identified
Neuropathy	Bagust and Beale [22]	-0.084	-0.111 to -0.057 <sup>†</sup>	
Active ulcer	Bagust and Beale [22]	-0.170	-0.207 to -0.133 <sup>*</sup>	-0.206 to -0.016
Excess BMI (each unit above 25 kg/m <sup>2</sup> )	Bagust and Beale [22]	-0.006	-0.008 to -0.004 <sup>*</sup>	-0.006 to -0.002
Hemodialysis	Wasserfallen et al. [23]	-0.164	-0.274 to -0.054 <sup>*</sup>	One reference identified
Peritoneal dialysis	Wasserfallen et al. [23]	-0.204	-0.342 to -0.066 <sup>*</sup>	
Renal transplant	Kiberd and Jindal [26]	0.762	0.658–0.866	0.762–0.820
Cataract	Lee et al. [32]	-0.016	-0.031 to -0.001 <sup>*</sup>	One reference identified
Moderate nonproliferative background diabetic retinopathy	Fenwick et al. [24]	-0.040	-0.066 to -0.014 <sup>‡</sup>	
Moderate macular edema	Fenwick et al. [24]	-0.070	-0.099 to -0.041 <sup>‡</sup>	One reference identified
Vision-threatening diabetic retinopathy	Fenwick et al. [24]	-0.047	-0.012 <sup>‡</sup>	
Major hypoglycemia event	Currie et al. [18]	-0.014	-0.004 <sup>‡</sup>	-0.020–0.005 <sup>‡</sup> -0.031 to -0.001 <sup>‡</sup>
Minor hypoglycemia event	Currie et al. [18]	-0.012 <sup>‡</sup>	-0.004 <sup>‡</sup>	
CI, confidence interval; T2DM, type 2 diabetes mellitus. <sup>*</sup> Estimated from the standard error values provided. <sup>†</sup> Estimated from the interquartile range values provided. <sup>‡</sup> Disutilities converted into annual values.				

Source: Table 3 from Beaudet et al. "Review of utility values for economic modeling in type 2 diabetes." Value in Health 17.4 (2014): 462-470

[https://www.valueinhealthjournal.com/article/S1098-3015\(14\)00054-0/pdf](https://www.valueinhealthjournal.com/article/S1098-3015(14)00054-0/pdf)

Note: please make sure to avoid confusion with utility/disutility terminology in loading the models and in reporting results. The proposed “utility values above” column in Figure 1 reports “utility” only for T2DM without complication (which is positive). The remaining items (all negative) are disutility and are incremental.

### **Patient Baseline Characteristics**

To allow for consistent comparisons across all models, baseline patient characteristics should follow the values as listed in Table 1. Any other baseline patient characteristics that your model may require can be sourced from publicly available literature (but please document this including sources in “Baseline Characteristics” tab in the accompanying Excel spreadsheet).

**Table 1: Characteristics of a representative patient to be used in the simulations**

<b>Patient Characteristics</b>	<b>Scenario 1*</b> <b>(Original)</b>		<b>Scenario 2</b>
	<b>Men</b>	<b>Women</b>	<b>Men/Wome n</b>
<i>Current age</i>	66	66	66 (6)
<i>Duration of diabetes</i>	8	8	8 (6)
<i>Sex (Female)</i>	0%	100%	50%
<i>Current/former smoker</i>	N	N	N
<i>HbA1c %</i>	7.5	7.5	7.5 (1.5)
<i>Systolic Blood Pressure mmHg</i>	145	145	145 (22)
<i>Diastolic Blood Pressure mmHg</i>	80	80	80 (11)
<i>Total Cholesterol mmol/l</i>	5.2	5.2	5.2 (1.2)
<i>HDL Cholesterol mmol/l</i>	1.3	1.3	1.3 (0.4)
<i>LDL Cholesterol mmol/l</i>	3.0	3.0	3.0 (1.0)
<i>BMI</i>	28	28	28 (5)
<i>Albumin: creatinine ratio</i>	14.2	14.2	14.2 (1.4)
<i>PVD</i>	N	N	N
<i>Micro or macro albuminuria (albuminuria <math>\geq</math>50)</i>	N	N	N
<i>Atrial fibrillation</i>	N	N	N
<i>eGFR (ml/min/1.73 m<sup>2</sup>)</i>	70	70	70 (15)
<i>WBC (x10<sup>9</sup>/l)</i>	7	7	7 (1.9)
<i>Heart rate (bpm)</i>	79	79	79 (12)
<i>Haemoglobin (g/dl)</i>	14	14	14 (1.5)
<i>Prior history of macrovascular disease</i>	N	N	N
<i>Prior history of microvascular disease</i>	N	N	N

\*Source: [ADVANCE—Action in Diabetes and Vascular Disease: patient recruitment and characteristics of the study population at baseline](#); see Appendix 2 for summary table

\*\*Repeated separately for 100% MI, 100% stroke, 100% renal failure, and 100% LEA

The main outputs required will be incremental **undiscounted** QALYs. As such, please set the discount rate to 0% for QALYs prior to running the simulations.

## **Challenge Simulations – Scenario 1:**

**Step 1: Run a simulation using the baseline characteristics in Table 1 held constant over a 40-year period, separately for males and for females**

It is important in each simulation all other factors are kept constant between simulations and limit variation to the utility weights as per instructions in the steps below. This includes assumptions around biomarker evolution; i.e. HbA1c and systolic blood pressure should be kept constant over time and not allowed to change over time (i.e., drift).

Extract the results and enter input values in a transparent manner in the accompanying Excel workbook in tab labelled “Time paths & Outcomes” (modify the workbook to fit your outcomes if necessary, but please try to preserve the basic structure). Do not forget to include traces (risk factor time paths) for input values of all the above risk factors; rates (or counts) of all major health states in the model (e.g. MI; stroke; renal failure, etc.), and life-expectancy.

For microsimulation models, please ensure that the number of replications is sufficient to generate stable results.

**Step 2: Simulate four common interventions (plus all combined), separately for males and females**

Re-run the simulation with four individual interventions (one-at-a-time and then all combined) that capture initial and permanent reductions in common risk factors from time paths modelled in Step 1. Reductions from these interventions should only be applied to post-baseline cycles and baseline values should remain unchanged.

- (i) 0.5%-point reduction in HbA1c;
- (ii) 10mm Hg reduction in Systolic Blood Pressure;
- (iii) 0.5 mmol/l (19.33 mg/dl) reduction in LDL Cholesterol
- (iv) 1-unit reduction in BMI (kg/m<sup>2</sup>)
- (v) All 4 of the interventions above applied simultaneously

Extract the results and add to the accompanying Excel workbook (in tab labelled “Time paths & Outcomes”). Report outcomes and inputs in a transparent manner. Do not forget to include traces (numerical or curves) for input values of all the above risk factors; cumulative rates (or counts) of all major health states in the model (e.g. MI; stroke; renal failure, etc.) and life expectancy.

**Step 3: Estimate incremental QALYs, separately for males and females**

Using the “Proposed Utility Value” from Figure 1 run the baseline simulation and estimate expected QALY, assuming that decrements apply to the year of the event and are similarly applied to each subsequent year. However, if temporary events/states such as hypoglycaemia are modelled, it is likely that these decrements only apply to the year of the event. If so, please document this.

Run each of the four interventions listed in Step 2 to estimate the expected QALYs and calculate the incremental QALYs compared to the baseline (control). Extract the results and add to the accompanying Excel workbook (in tab labelled “Time paths & Outcomes – SC 1”).

Be sure to report incremental QALYs so that a negative value indicates worse QALYs (not inverting to account for a positive value indicating more disutility)

**Step 4: Estimate incremental QALYs under different assumption regarding utility, separately for males and females**

Keeping the baseline utility value at 0.785 for people without complications, repeat the simulation in Step 3 using different utility weights:

**4.1 Low estimates of QALY disutility:** Use the lower limits of the 95% CIs for **All** utility values listed in Column 4 of Figure 1. Note: the lower limits for disutility means that overall utility will be higher (i.e., less disutility).

**4.2 High estimates of QALY disutility:** Use the upper limits of the 95% CIs for **All** utility values listed in Column 4 of Figure 1. Note: the upper limits for disutility means that overall utility will be lower (i.e., more disutility).

**Step 5: Identify how much each utility value contributes to incremental QALYs**

The final set of estimates will involve **only the first intervention (0.5%-point reduction in HbA1c)**. It will involve varying each of the health state utility values in your model one at a time using the lower and upper limits of the 95% CIs to determine the sensitivity of incremental QALYs to changes in the utility value associated with each health state. Please keep the baseline utility value at 0.785 for people without complications for this step.

**Step 6: (Optional)**

Re-run Steps 1 and 2, but instead of using 0.785 for people without complications, use 0.681 (the lower limit of the 95% CI). Repeat this simulation for an intervention involving **0.5%-point reduction in HbA1c**. Record incremental QALYs for each change in utility compared to baseline (control).

Repeat the above in a second simulation using 0.889 (the upper limit of the 95% CI) and record incremental QALYs as per above.

### **Summary of findings:**

Compile a summary of your findings in the accompanying Excel spreadsheet (in tab labelled “Summary—Sc 1”). Please complete the following.

- A) Based on your results in Step 3, which intervention evoked the greatest change in incremental QALY?
- B) Based on your results in Step 5, list three health states which evoked the greatest change in incremental QALY and the health state inducing the least change.
- C) Provide an overview of what you learnt from this challenge.

### **Challenge Simulations – Scenario 2:**

**Step 1: Run a simulation using the baseline characteristics in Table 1 over a 40-year period. In line with common usage in real world applications, males and females will not be considered separately but rather will be pooled (50%/50%). This enhanced simulation has been used and reported previously. See “Comparing the Cohort and Micro-Simulation Modeling Approaches in Cost-Effectiveness Modeling of Type 2 Diabetes Mellitus: A Case Study of the IHE Diabetes Cohort Model and the Economics and Health Outcomes Model of T2DM ” (Willis et al, 2020) for a more complete description <https://pubmed.ncbi.nlm.nih.gov/32399797/>).**

This enhanced scenario permits patient-level variation to support micro-simulation modelling. For cohort models, just ignore the standard deviations in baseline patient characteristics. Furthermore, the enhanced scenario also included natural evolution of HbA1c, SBP, and eGFR as well as treatment intensification following uncontrolled HbA1c (>8%).

Annual linear biomarker evolution (as possible with your model):

- HbA1c: 0.14 %/year
- SBP: 0.3 mmHg/year
- eGFR: -2.43 mL/min/1.73 m<sup>2</sup>/year

Apply insulin rescue therapy to maintain glycemic control (HbA1c < 8.0%) as best as possible with your models. To standardize across models, please use the following sequence of first basal and later basal + bolus insulin using treatment effects in line with Willis et al. (2020).

Specifically, use to the extent possible the treatment effects in the table below. If your models allow, please apply the HbA1c evolution on top of these treatment effects.

Treatment	Basal		Basal and Bolus	
	Mean	SE	Mean	SE
$\Delta\text{HbA1c, \%}$	-1.196	0.095	-2.224	0.357
$\Delta\text{BMI, kg/m}^2$	0.735	0.111	1.605	0.487

Source: Willis et al. (2020) <https://pubmed.ncbi.nlm.nih.gov/32399797/>

For models that do not have pre-programmed values for metabolic factors the file INPUTVALUES\_MT2020.xlsx can be used.

Extract the results and enter input values in a transparent manner in the accompanying Excel workbook in tab labelled “Time paths & Outcomes – Sc 3” (modify the workbook to fit your outcomes if necessary, but please try to preserve the basic structure). Do not forget to include traces (risk factor time paths) for input values of all the above risk factors; rates (or counts) of all major health states in the model (e.g. MI; stroke; renal failure, etc.), and life-expectancy.

For microsimulation models, please ensure that the number of replications is sufficient to generate stable results.

### **Step 2: Simulate four common interventions (plus all combined)**

Re-run the simulation with four individual interventions (one-at-a-time and then all combined) that capture initial and permanent reductions in common risk factors from time paths modelled in Step 1. Reductions from these interventions should only be applied to post-baseline cycles and baseline values should remain unchanged.

- (i) 0.5%-point reduction in HbA1c;
- (ii) 10mm Hg reduction in Systolic Blood Pressure;
- (iii) 0.5 mmol/l (19.33 mg/dl) reduction in LDL Cholesterol
- (iv) 1-unit reduction in BMI (kg/m<sup>2</sup>)
- (v) All 4 of the interventions above applied simultaneously

Extract the results and add to the accompanying Excel workbook (in tab labelled “Time paths & Outcomes – Sc 3”. Report outcomes and inputs in a transparent manner. Do not forget to include traces (numerical or curves) for input values of all the above risk factors; cumulative rates (or counts) of all major health states in the model (e.g. MI; stroke; renal failure, etc.) and life expectancy.

### **Step 3: Estimate incremental QALYs**

Using the “Proposed Utility Value” from Figure 1 run the baseline simulation and estimate expected QALY, assuming that decrements apply to the year of the event and are similarly applied to each subsequent year. However, if temporary events/states such as hypoglycaemia are modelled, it is likely that these decrements only apply to the year of the event. If so, please document this.

Run each of the four interventions listed in Step 2 to estimate the expected QALYs and calculate the incremental QALYs compared to the baseline (control). Extract the results and add to the accompanying Excel workbook (in tab labelled “Time paths & Outcomes – SC 3”).

Be sure to report incremental QALYs so that a negative value indicates worse QALYs (not inverting to account for a positive value indicating more disutility)

#### **Step 4: Estimate incremental QALYs under different assumption regarding utility**

Keeping the baseline utility value at 0.785 for people without complications, repeat the simulation in Step 3 using different utility weights:

**4.1 Low estimates of QALY disutility:** Use the lower limits of the 95% CIs for **All** utility values listed in Column 4 of Figure 1. Note: the lower limits for disutility means that overall utility will be higher (i.e., less disutility).

**4.2 High estimates of QALY disutility:** Use the upper limits of the 95% CIs for **All** utility values listed in Column 4 of Figure 1. Note: the upper limits for disutility means that overall utility will be lower (i.e., more disutility).

#### **Step 5: Identify how much each utility value contributes to incremental QALYs**

The final set of estimates will involve **only the first intervention (0.5%-point reduction in HbA1c)**. It will involve varying each of the health state utility values in your model one at a time using the lower and upper limits of the 95% CIs to determine the sensitivity of incremental QALYs to changes in the utility value associated with each health state. Please keep the baseline utility value at 0.785 for people without complications for this step.

#### **Step 6: (Optional)**

Re-run Steps 1 and 2, but instead of using 0.785 for people without complications, use 0.681 (the lower limit of the 95% CI). Repeat this simulation for an intervention involving **0.5%-point reduction in HbA1c**. Record incremental QALYs for each change in utility compared to baseline (control).

Repeat the above in a second simulation using 0.889 (the upper limit of the 95% CI) and record incremental QALYs as per above.

## **Summary of findings:**

Compile a summary of your findings in the accompanying Excel spreadsheet (in tab labelled “Summary—Sc 3”). Please complete the following.

- A) Based on your results in Step 3, which intervention evoked the greatest change in incremental QALY?
- B) Based on your results in Step 5, list three health states which evoked the greatest change in incremental QALY and the health state inducing the least change.
- C) Provide an overview of what you learnt from this challenge.

## **Submission:**

Please submit the Excel spreadsheet (“MH VIRTUAL CHALLENGE QOL \_GROUP”) to Mount Hood at: [mthood2016@gmail.com](mailto:mthood2016@gmail.com) by **14 September, 2020**. Please replace \_GROUP with your modelling group name before submission.

## APPENDIX 1

### Incorporating health utility values for 2018 Mt. Hood Quality of Life challenge

Based on the 2018 Mt. Hood challenge conference call on September 5, 2018, two suggestions were made for the Quality of Life challenge, including:

- 1) The additive quality-of-life (QoL) model is recommended when populating the health utility values into the simulation model. As shown in Table 1 below, if a subject has experienced 2 different complications belonging to 2 different categories of disease (e.g., stroke [in the category of cerebrovascular disease] and myocardial infarction [in the category of coronary heart disease]), the health utility value will be reduced by 0.219 which is the sum of individual decrement for these 2 complications (i.e., 0.164+0.055). However, if a subject has experienced 2 complications within the same category of disease (e.g., myocardial infarction [in the category of coronary heart disease] and congestive heart failure [in the category of coronary heart disease]), the health utility value will be reduced by 0.108 (the decrement for heart failure) which is the largest decrement of these 2 complications. If the additive QoL model is not feasible in your model, please document your assumptions how the health utility values are populated in your model.
- 2) The utility decrement and its 95% confidence interval for renal transplant was assumed to be the half of those for hemodialysis.

**Table 1. Categories of diseases/complications (summary from Figure 1 provided in the instructions for 2018 Mt. Hood Quality of Life challenge)**

Disease category	Complication level provided in Mt. Hood QoL challenge	Utility value or decrement (95% CI) used for Mt. Hood QoL challenge
Baseline utility value	T2DM without complications	0.785 (0.681 to 0.889)
Acute metabolic disorder	Minor hypoglycemia event	-0.014 (-0.004)
	Major hypoglycemia event	-0.047 (-0.012)
Comorbidity	Excess BMI (each unit above 25 kg/m <sup>2</sup> )	-0.006 (-0.008 to -0.004)
Retinopathy	Cataract	-0.016 (-0.031 to -0.001)
	Moderate non-proliferative background diabetic retinopathy	-0.040 (-0.066 to -0.014)
	Moderate macular edema	-0.040 (-0.066 to -0.014)
	Vision-threatening diabetic retinopathy	-0.070 (-0.099 to -0.041)
	Severe vision loss	-0.074 (-0.124 to -0.025)
Nephropathy	Proteinuria	-0.048 (-0.091 to -0.005)
	Renal transplant <sup>1</sup>	-0.082 (-0.137 to -0.027)
	Hemodialysis	-0.164 (-0.274 to -0.054)
	Peritoneal dialysis	-0.204 (-0.342 to -0.066)
Neuropathy	Peripheral vascular disease	-0.061 (-0.090 to -0.032)
	Neuropathy	-0.084 (-0.111 to -0.057)

	Active ulcer	-0.170 (-0.207 to -0.133)
	Amputation event	-0.280 (-0.389 to -0.170)
Cerebrovascular disease	Stroke	-0.164 (-0.222 to -0.105)
Coronary heart disease	Myocardial infarction	-0.055 (-0.067 to -0.042)
	Ischemic heart disease	-0.090 (-0.126 to -0.054)
	Heart failure	-0.108 (-0.169 to -0.048)

Abbreviations: QoL, quality of life; CI, confidence interval; T2DM, type 2 diabetes; BMI, body mass index.

<sup>1</sup>The utility decrement and its 95% confidence interval for renal transplant was assumed to be the half of those for hemodialysis.

### Alternative tables – if not in the above

Parameters	Utility/Disutility Values		
	Control	Lower 95% CI	Upper 95% CI
T2DM without complications	0.785	0.681	0.889
Minor hypoglycemia event	-0.014	-0.004	-0.004
Major hypoglycemia event	-0.047	-0.012	-0.012
Excess BMI (each unit above 25 kg/m <sup>2</sup> )	-0.006	-0.008	-0.004
Cataract	-0.016	-0.031	-0.001
Moderate non-proliferative background diabetic retinopathy	-0.040	-0.066	-0.014
Moderate macular edema	-0.040	-0.066	-0.014
Vision-threatening diabetic retinopathy	-0.070	-0.099	-0.041
Severe vision loss	-0.074	-0.124	-0.025
Proteinuria	-0.048	-0.091	-0.005
Renal transplant <sup>1</sup>	-0.082	-0.137	-0.027
Hemodialysis	-0.164	-0.274	-0.054
Peritoneal dialysis	-0.204	-0.342	-0.066
Peripheral vascular disease	-0.061	-0.090	-0.032
Neuropathy	-0.084	-0.111	-0.057
Active ulcer	-0.170	-0.207	-0.133
Amputation event	-0.280	-0.389	-0.170
Stroke	-0.164	-0.222	-0.105
Myocardial infarction	-0.055	-0.067	-0.042
Ischemic heart disease	-0.090	-0.126	-0.054
Heart failure	-0.108	-0.169	-0.048

## APPENDIX 2

**ADVANCE—Action in Diabetes and Vascular Disease: patient recruitment and characteristics of the study population at baseline <https://doi.org/10.1111/j.1464-5491.2005.01596.x>**

**Table 1** Baseline characteristics of randomized patients (*n* = 11 140)

Characteristic	Mean (SD) or %
Mean age, years	66 (6)
Female, %	43
Mean duration of diabetes, years	8 (6)
Prior vascular disease	
History of major macrovascular disease, %	32
History of major microvascular disease, %	10
Other major risk factors	
Current smokers, %	14
Mean total cholesterol, mmol/l	5.2 (1.2)
Mean HDL cholesterol, mmol/l	1.3 (0.4)
Mean triglycerides, mmol/l	2.0 (1.5)
Mean albumin : creatinine ratio, µg/mg	14.2 [6.4–38.1]*
Mean body mass index, kg/m <sup>2</sup>	28 (5)
Mean waist circumference, cm	99 (13)
Blood pressure control	
Mean systolic blood pressure, mmHg	145 (22)
Mean diastolic blood pressure, mmHg	81 (11)
History of hypertension, %	69
Current blood pressure lowering therapy, %	75
ACE inhibitors, %	43
Angiotensin-receptor blockers, %	5
Beta-blockers, %	24
Calcium antagonists, %	31
Thiazide/thiazide-like diuretics, %	14
Other diuretics, %	11
Other blood pressure lowering drugs, %	12
Glucose control	
Mean haemoglobin A <sub>1c</sub> concentration, %	7.5 (1.5)
Diet-only treated diabetes, %	9
Current oral hypoglycaemic, %	91
Sulphonylurea, %	71
Metformin, %	61
Thiazolidinediones, %	4
Glinides, %	2
Acarbose, %	9
Current insulin†, %	1
Other major current treatments	
Aspirin or other anti-platelet, %	47
Lipid-lowering therapy, %	35

\*Median and interquartile range presented as the distribution is highly skewed.

†Not prescribed as permanent or long-term therapy.