



**SHARP CKD-CVD outcomes model (beta version)**

**USER MANUAL**

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Iryna Schlackow and Borislava Mihaylova

Health Economics Research Centre (HERC)  
Nuffield Department of Population Health  
University of Oxford, UK

<http://dismod.ndph.ox.ac.uk/kidneymodel/app/>

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# Introduction

## Background and aims

The SHARP CKD-CVD outcomes model is developed using the individual participant data from the Study of Heart and Renal Protection and external data. It is a computer simulation model designed to project health outcomes and healthcare costs of adult populations with moderate-to-severe chronic kidney disease (CKD), ie CKD stages 3B or more advanced. The model requires a range baseline data, including prior disease history of individuals.

The model projects risks of vascular or nonvascular mortality, major vascular events and initiation of renal replacement therapy (RRT) at 5 and 10 years as well as over model simulation duration or lifetime. It also allows to evaluate life expectancy, quality-adjusted life expectancy, healthcare costs and cost-effectiveness of a cardiovascular disease prevention treatment with provided efficacy, compliance and cost.

The SHARP CKD-CVD outcomes model is intended for use in moderate-to-severe CKD patients 40 years old or older to project:

- major cardiovascular event risk
- risk of progression to renal replacement therapy
- (quality-of-life-adjusted) life expectancy
- Hospital care costs
- absolute effects and cost-effectiveness of interventions to modify CVD risk

## How to cite

When referring to this program in publications, please cite the following references:

1. Schlackow I, Kent S, Herrington W, Emberson J, Haynes R, Reith C, Wanner C, Fellström B, Gray A, Landray MJ, Baigent C, Mihaylova B, on behalf of the SHARP Collaborative Group. *A lifetime model of health outcomes in moderate-to-severe chronic kidney disease: the SHARP CKD-CVD outcomes model*. Under review.
2. Schlackow I, Mihaylova B. *The SHARP CKD-CVD outcomes model*. 2016; available at <http://dismod.ndph.ox.ac.uk/kidneymodel/app/>

## Contact

The manual and referenced publications contain detailed description of the SHARP CKD-CVD outcomes model and its appropriate use. If you have further queries please email [kidneymodel@ndph.ox.ac.uk](mailto:kidneymodel@ndph.ox.ac.uk). We will be grateful to hear about any problems you might encounter or further suggestions.

## Acknowledgements

We thank Oliver Verran and Seamus Kent for their contribution to the development of the first version of the model and providing further feedback. We also thank the IT team of the Oxford

University's Nuffield Department of Population Health for their support in installing and running the software.

## References

- [1] Schlackow I, Kent S, Herrington W, Emberson J, Haynes R, Reith C, Wanner C, Fellström B, Gray A, Landray MJ, Baigent C, Mihaylova B on behalf of the SHARP Collaborative Group. *A lifetime model of health outcomes in moderate-to-severe chronic kidney disease: the SHARP CKD-CVD outcomes model*. Under review.
- [3] Kent S, Schlackow I, Lozano-Kühne J, Reith C, Emberson J, Haynes R, Gray A, Cass A, Baigent C, Landray MJ, Herrington W, Mihaylova B on behalf of the SHARP Collaborative Group. *What is the impact of chronic kidney disease stage and cardiovascular disease on the annual cost of hospital care in moderate-to-severe kidney disease?* BMC Nephrology 2015; 16:65.
- [3] Baigent C, Landray MJ, Reith C, Emberson J, Wheeler DC, Tomson C, et al. *The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial*. Lancet. 2011; 377(9784):2181-92.
- [4] *Study of Heart and Renal Protection (SHARP). Final protocol (Version 5: 12<sup>th</sup> July 2005)*. [http://www.ctsu.ox.ac.uk/~sharp/download\\_protocol\\_en\\_v5.pdf](http://www.ctsu.ox.ac.uk/~sharp/download_protocol_en_v5.pdf)

## Disclaimer

The web interface for the SHARP CKD-CVD outcomes model is freely available for use.

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# Model Interface

## Getting started

The SHARP CKD-CVD outcomes model is executed under a Shiny web interface using R. The interface can be accessed at <http://dismod.ndph.ox.ac.uk/kidneymodel/app/>. *The webpage is currently password-protected, please enter username: shinydemo and password: entrance-develop*

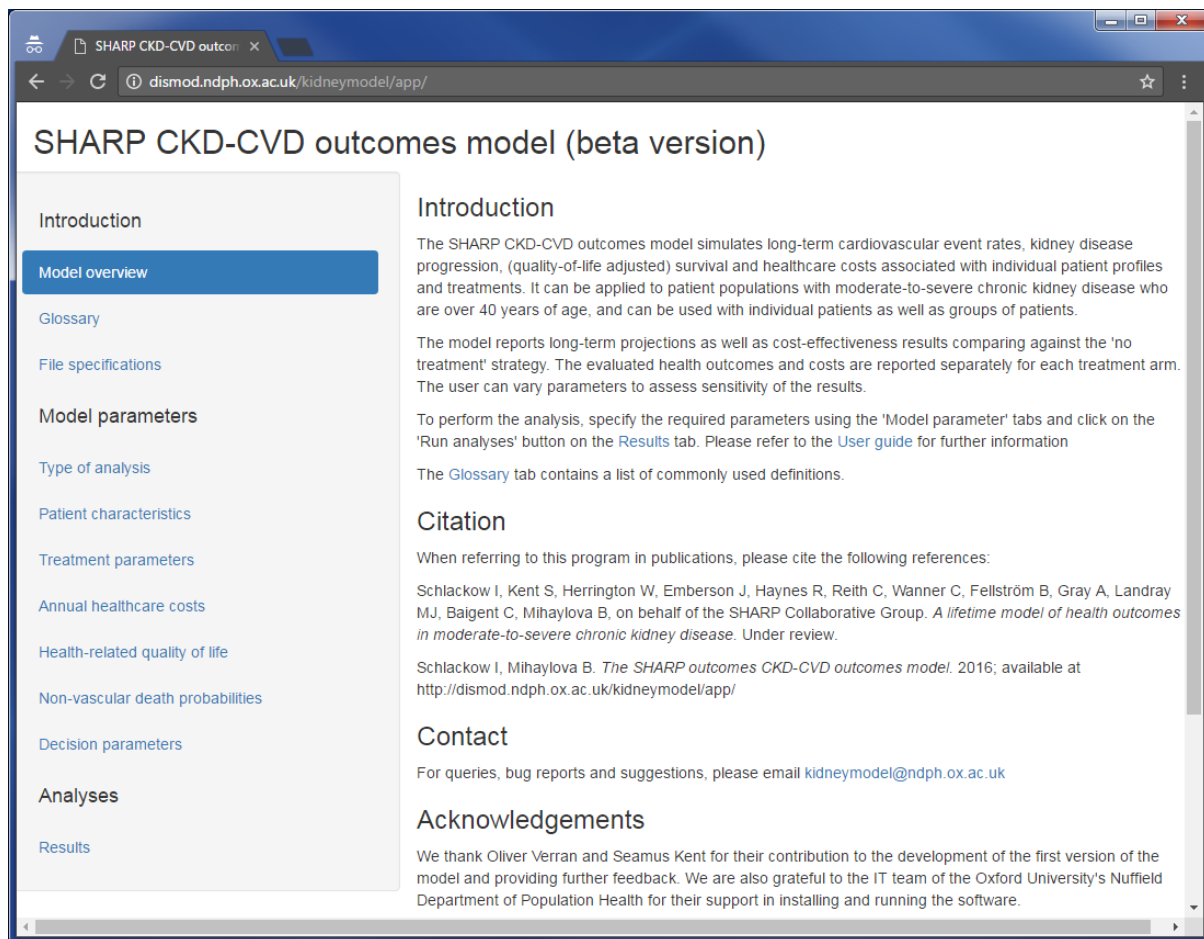
The next sections describes in detail each section of the model interface. A screenshot of each webpage is presented, followed by explanatory text.

## Introduction

This section provides a brief overview of the model together with a glossary of relevant specialist terms and links to specification of files used.

## Model overview

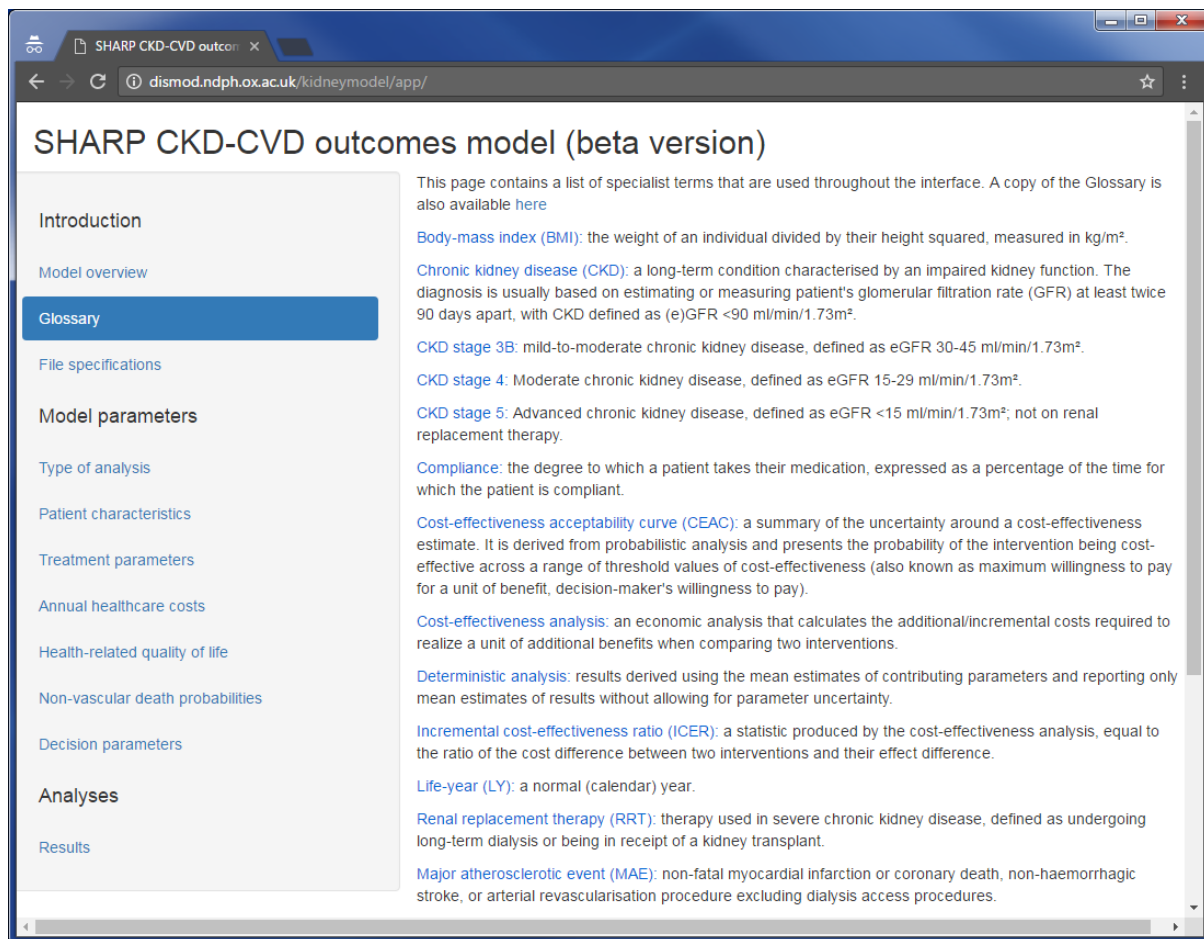
Figure 1 Screenshot of the model overview page



This is the opening screen of the user interface. It briefly introduces the model and provides relevant references and support information.

## Glossary

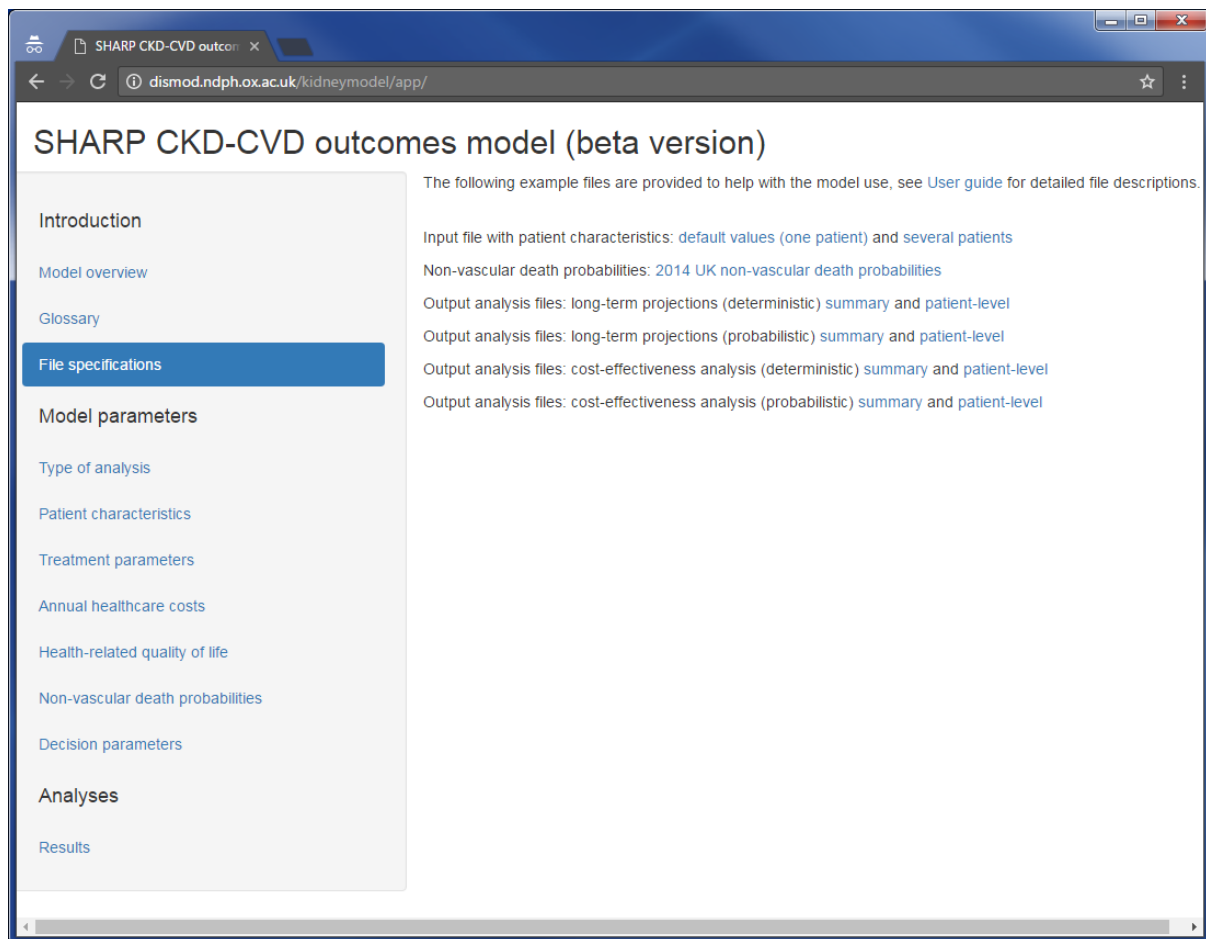
Figure 2 Screenshot of the Glossary page



This section contains a list of specialist terms that are used throughout the interface.

## File specifications

Figure 3 Screenshot of the file specifications page



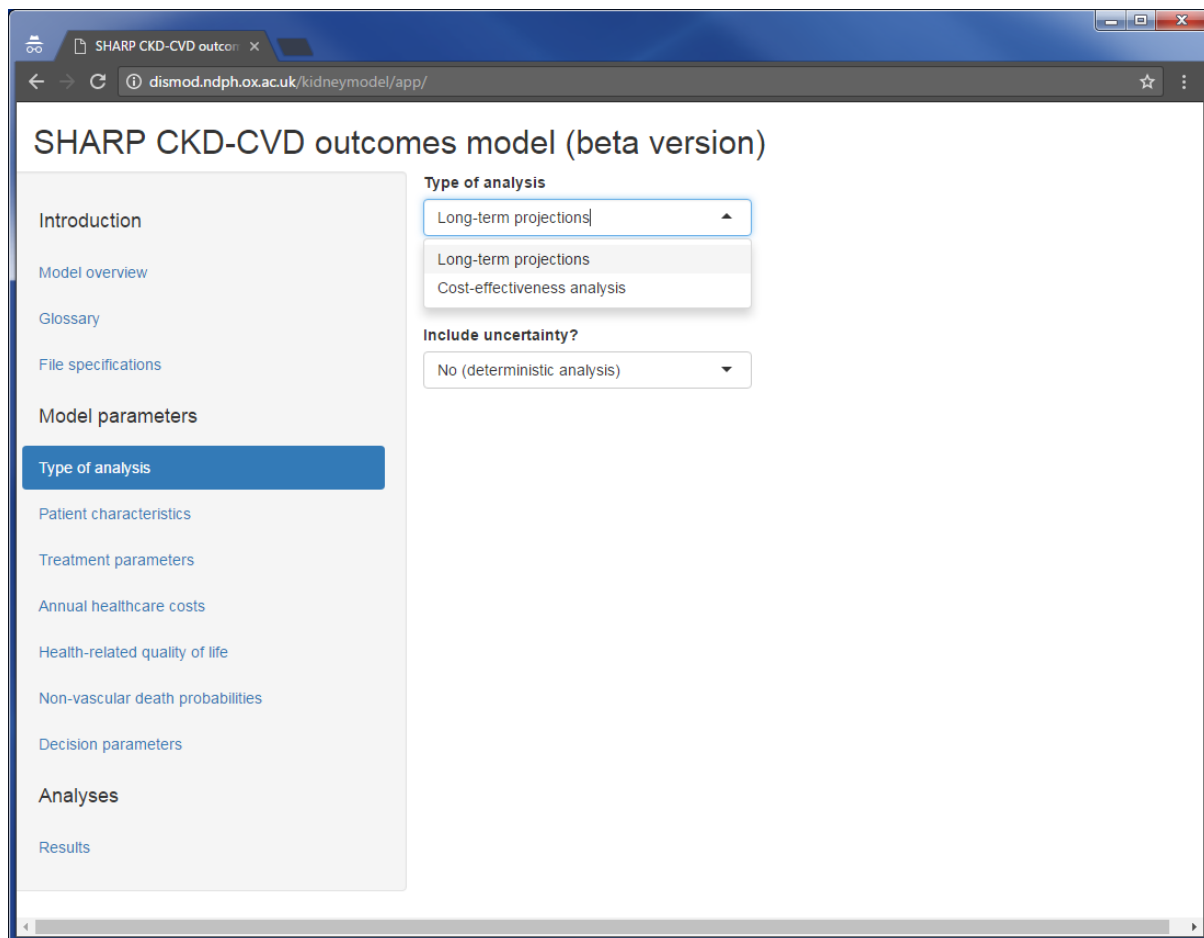
This page contains links to the specifications of files to help the user use the model. Full file specifications are provided in the respective sections of this User guide.



## Model parameters

### Type of analysis

Figure 4 Screenshot of the Type of analysis page



Two types of analysis are enabled. The **Long-term projections** option estimates the probabilities of adverse events at 5 and 10 years and – if the simulation is requested over a fixed number of years - over the simulation duration, and calculates (quality-adjusted) life expectancy and hospital costs over the simulation duration. It is also possible to add a cardiovascular risk modification intervention in this analysis. **Cost-effectiveness analysis** evaluates the probabilities of adverse events at 5 and 10 years and – if the simulation is requested over a fixed number of years - over the simulation duration. Projections are performed with and without a given intervention. Additionally, the simulation predicts and compares (quality-adjusted) life expectancy and hospital costs in the treatment and control groups, and calculates the incremental cost-effectiveness over the simulation duration.

The default analysis is Long-term projections without cardiovascular risk modifying intervention and without the uncertainty estimates.

Figure 5 Screenshot of the Type of analysis page, when the “probabilistic analysis” option is selected

The screenshot shows a web browser window with the address bar displaying `dismod.ndph.ox.ac.uk/kidneymodel/app/`. The page title is "SHARP CKD-CVD outcomes model (beta version)".

**Left Sidebar:**

- Introduction
- Model overview
- Glossary
- File specifications
- Model parameters
  - Type of analysis (selected)
  - Patient characteristics
  - Treatment parameters
  - Annual healthcare costs
  - Health-related quality of life
  - Non-vascular death probabilities
  - Decision parameters
- Analyses
  - Results

**Main Content Area:**

**Type of analysis**  
Long-term projections

**Include uncertainty?**  
Yes (probabilistic analysis)

**Number of samples**  
A slider control is shown with a range from 100 to 1,000. The slider is currently positioned at 100.

The probabilistic sensitivity analysis is currently implemented for treatment effects, disease risks and hospital care costs. The default coefficients from the risk equations are derived from the SHARP data using the bootstrap method.

For each option, it is possible to run **deterministic analysis** (with all parameters fixed at their mean values; without parameter uncertainty) and **probabilistic sensitivity analysis (PSA)**. For the PSA, the number of parameter samples should be specified (between 100 and 1000). Note that model processing time might be substantial depending on number of patient profiles and PSA parameter samples.

## Patient characteristics

Figure 6 Screenshot of the patient characteristics page

SHARP CKD-CVD outcomes model (beta version)

Select characteristics for a single patient or import a text file with these characteristics for one or more patients.

☐ Import a file with patient characteristics

Reset inputs

**Demographic and socio-economic characteristics**

<b>Age (years)</b> <input type="text" value="65"/>	<b>Gender</b> <input type="text" value="Female"/>	<b>Ethnicity</b> <input type="text" value="White"/>
<b>Highest educational attainment</b> <input type="text" value="Any post-secondary education"/>	<b>Adult dependants</b> <input type="text" value="No"/>	<b>Smoking status</b> <input type="text" value="Never smoked"/>
<b>Alcohol drinker</b> <input type="text" value="No"/>	<b>Body mass index</b> <input type="text" value="25-29 kg/m²"/>	

**Clinical factors**

<b>Diastolic blood pressure</b> <input type="text" value="75-84 mmHg"/>	<b>Systolic blood pressure</b> <input type="text" value="130-149 mmHg"/>	<b>HDL cholesterol</b> <input type="text" value="0.9-1.1 mmol/L"/>
<b>Albumin</b> <input type="text" value="3.9-4.1 g/dL"/>	<b>Haemoglobin</b> <input type="text" value="11.6-12.9 g/dL"/>	<b>Phosphate</b> <input type="text" value="1.2-1.4 mmol/L"/>
<b>Urinary albumin:creatinine ratio</b> <input type="text" value="30-300 mg/g"/>		

Footnote: To move vertically across the screen, the users should use the scrollbar on the left. The Urinary albumin:creatinine ratio field is only visible if a pre-RRT CKD stage is selected. Likewise, there are two fields that are only visible if an RRT CKD stage is selected: RRT duration (years) and Previous (failed) transplant.

The user should specify patient characteristics for which to simulate outcomes. This can be done by either (1) specifying characteristics for a particular patient using the drop-down menus, or (2) by importing a .csv file. The latter is useful particularly where simulations for multiple patient profiles are of interest. An example CSV file with 4 patient profiles is provided to guide the specification of the file needed. Note that all of these characteristics are needed for the execution of the model and **missing values are not allowed**. The “Reset inputs” button resets all patient characteristics to the default values in the Interface, as described in Table 1.

The description of the required patient characteristics together with the list of allowable values is provided in the Table 1 below. Each characteristic has a default value, which will be assigned if the user has not clicked the corresponding screen and has not provided any input values. The SHARP CKD-CVD outcomes model is to be used in patients in CKD stage 3B or more advanced, as there were

very few patients at earlier stages of CKD in SHARP and the model performance in these earlier disease stages is uncertain.

Table 1 Required patient characteristics together with their allowed and default values.

Column name	Description	Allowed values	Default value
<b>Demographic and socio-economic characteristics</b>			
id	Patient's id	Numeric should be unique for each patient	1
age	Age (in years)	Numeric between 40 and 90	65
sex	Gender	Numeric 0 = female; 1 = male	0
ethnicity	Ethnicity	Numeric 0 = white; 1 = Asian, lives in China; 2 = Asian, lives outside China; 3 = black; 4 = other	0
education	Highest educational attainment	Numeric 0 = any post-secondary education; 1 = completed secondary education; 2 = below secondary education	0
adultDep	Adult dependants	Numeric 0 = No; 1 = Yes	0
smoker	Smoking status	Numeric 0 = never smoked; 1 = ex-smoker; 2 = current smoker	0
currentAlc	Alcohol drinker	Numeric 0 = No; 1 = Yes	0
BMI_quant	Body mass index	Numeric 0 = 25-29 kg/m <sup>2</sup> ; 1 = <25 kg/m <sup>2</sup> ; 2 = ≥30 kg/m <sup>2</sup>	0
<b>Clinical factors</b>			
DBP_quant	Diastolic blood pressure	Numeric 0 = 75-84 mmHg; 1 = <75 mmHg; 2 = ≥85 mmHg	0
SBP_quant	Systolic blood pressure	Numeric 0 = 130-149 mmHg; 1 = <130 mmHg; 2 = ≥150 mmHg	0
CholHDL_quant	HDL cholesterol	Numeric 0 = 0.9-1.1 mmol/L;	0

		1 = <0.9 mmol/L; 2 = ≥1.2 mmol/L	
Albumin_quant	Albumin	Numeric 0 = 3.9-4.1 g/dL; 1 = <3.9 g/dL; 2 = ≥4.2 g/dL	0
Haemoglobin_quant	Haemoglobin	Numeric 0 = 11.6-12.9 g/dL; 1 = <11.6 g/dL; 2 = ≥13.0 g/dL	0
Phosphate_quant	Phosphate	Numeric 0 = 1.2-1.4 mmol/L; 1 = <1.2 mmol/L; 2 = ≥1.5 mmol/L	0
ACR_quant	Urinary albumin:creatinine ratio	Numeric <i>For pre-RRT patients:</i> 0 = 30-300 mg/g; 1 = <30 mg/g; 2 = >300 mg/g <i>For RRT patients:</i> 3 = RRT	0
<b>Disease history</b>			
CVD	Latest cardiovascular event	Numeric 0 = None; 1 = Major atherosclerotic event in the last year; 2 = Major atherosclerotic event 1-2 years ago; 3 = Major atherosclerotic event >2 years ago; 4 = No MAE, but haemorrhagic stroke; 5 = No MAE, but haemorrhagic stroke 1-2 years ago; 6 = No MAE, but haemorrhagic stroke >2 years ago; 7 = Another cardiovascular event	0
DM	Diabetes	Numeric <i>For patients without Diabetic nephropathy:</i> 0 = No; 1 = Yes <i>For patients with Diabetic nephropathy:</i> 1 = Yes	0
CKDStage	CKD stage	Numeric 0 = CKD 3B; 1 = CKD 4; 2 = CKD 5, not RRT; 3 = dialysis; 4 = transplant	0
CKDDuration	CKD duration (years)	Numeric between 0 and the participant's age	10
renalDiagnosis	Renal diagnosis	Numeric 0 = Diabetic nephropathy; 1 = Cystic kidney disease;	2

		2 = Other known or unknown cause	
RRTDuration	RRT duration (years)	Numeric <i>For pre-RRT patients:</i> 0 <i>For RRT patients:</i> between 0 and patient's CKD duration	0
TX	Previous (failed) transplant	Numeric <i>For pre-RRT patients:</i> 0 = No; <i>For RRT patients:</i> 0 = No; 1 = Yes	0

## Effects of an intervention to modify cardiovascular risk

Figure 7 Screenshot of the Treatment parameters page

SHARP CKD-CVD outcomes model (beta version)

Introduction

Model overview

Glossary

File specifications

Model parameters

Type of analysis

Patient characteristics

**Treatment parameters**

Annual healthcare costs

Health-related quality of life

Non-vascular death probabilities

Decision parameters

Analyses

Results

Hazard ratios should correspond to full compliance with treatment for each of the outcomes below. The rates should be on the exponential scale.

Reset inputs

**Treatment effects**

Treatment effects for the probabilistic sensitivity analyses are sampled from log-normal distributions using the correlation matrix from the SHARP study. Enter the estimates for the hazard ratios together with the 95% confidence interval (CI) on the exponential scale.

**Cardiovascular death**

Hazard ratio	Lower 95% CI	Upper 95% CI
0.9	0.8	1

**Cardiovascular death or non-fatal major atherosclerotic event**

Hazard ratio	Lower 95% CI	Upper 95% CI
0.9	0.8	1

**Cardiovascular death or non-fatal major vascular event**

Hazard ratio	Lower 95% CI	Upper 95% CI
0.9	0.8	1

Compliance (%)

100

Daily treatment cost (full use)

1

Footnote: The 95% CI fields only appear if probability sensitivity analyses are being performed.

The required parameters include:

**Treatment effects** of an intervention to modify cardiovascular risk on the specified cardiovascular endpoints (cardiovascular death, cardiovascular death or non-fatal major atherosclerotic event or cardiovascular death or non-fatal major fatal event), presented as **hazard ratios of effects of treatment compared to no treatment** and, if probabilistic analysis is selected, their 95% confidence intervals. In the PSA, the log-normal distribution is used to sample treatment effects using provided parameters together with the correlation matrix from the SHARP study. Note that the three endpoints are nested, and therefore the three hazard ratios are not independent. The default hazard ratios for all three endpoints are 1.0 (95% CI 0.9-1.1) in the long-term projections option and 0.9 (95% CI 0.8-1.0) in the cost-effectiveness analysis option.

**Compliance** with the intervention, expressed as a percentage (between 0 and 100), corresponds to proportion of time individual is using the intervention; the default is 100%. The compliance affects the effects of the intervention on cardiovascular outcomes, hospital care costs and the cost of the drug (which is scaled proportionately to use).

**Daily treatment cost;** the default is 1.00. Note that the program does not differentiate between different currencies and interprets all prices and costs provided at their numeric value; care should be taken to ensure these are provided consistently in the currency and price year of interest.



## Annual healthcare costs

Figure 8 Screenshot of the Annual healthcare costs page

SHARP CKD-CVD outcomes model (beta version)

The default values are based on SHARP data and UK 2014 prices.

[Reset inputs](#)

The default costs for the probabilistic sensitivity analyses are derived from the SHARP data using the bootstrap method. To provide alternative costs, enter the means and the standard errors below, and the costs will be sampled from gamma distributions. The displayed values are based on SHARP data and UK 2014 prices [1].

### Annual cost of CKD

CKD stage	mean estimate	standard error
CKD stage 3B	427	32
CKD stage 4	417	27
CKD stage 5	556	41

On dialysis, for year of dialysis initiation

mean estimate	standard error
20112	198

On dialysis, not for year of dialysis initiation

mean estimate	standard error
24709	51

Footnote: The standard error fields only appear if probability sensitivity analyses are being performed.

For each year in the model, annual healthcare costs are projected for each person, depending on their characteristics. The default values correspond to the UK annual hospital care costs of CKD patients, derived from the SHARP study data [1] and inflated to year 2014. The user can specify alternative costs to be used. If the PSA option is selected, both mean estimates and standard errors are required. In the PSA the costs are sampled from gamma distributions. The “Reset inputs” button will reset all costs to their default values.

Note that the program does not differentiate between different currencies and interprets all costs provided at their numeric value; care should be taken to ensure these are consistently provided in the currency and price year of interest.

[1] Kent S, Schlackow I, Lozano-Kühne J, Reith C, Emberson J, Haynes R, Gray A, Cass A, Baigent C, Landray MJ, Herrington W, Mihaylova B, on behalf of the SHARP Collaborative Group., *What is the impact of chronic kidney disease stage and cardiovascular disease on the annual cost of hospital care in moderate-to-severe kidney disease?* BMC Nephrology 2015; 16:65.



## Health-related quality of life

Figure 9 Screenshot of the Health-related quality of life section

The screenshot shows a web browser window with the URL `dismod.ndph.ox.ac.uk/kidneymodel/app/`. The page title is "SHARP CKD-CVD outcomes model (beta version)". On the left is a navigation menu with the following items: Introduction, Model overview, Glossary, File specifications, Model parameters, Type of analysis, Patient characteristics, Treatment parameters, Annual healthcare costs, **Health-related quality of life** (highlighted), Non-vascular death probabilities, Decision parameters, Analyses, and Results. The main content area has a heading "SHARP CKD-CVD outcomes model (beta version)" and a sub-heading "The default values are UK quality of life (QoL) utilities estimates derived from the SHARP data." Below this is a paragraph: "Baseline QoL is the quality of life utility of a 60 year old female, non-smoker, with above secondary education, with BMI 25-30 kg/m<sup>2</sup>, pre-RRT CKD and without diabetic nephropathy or vascular disease." A "Reset inputs" button is located below the paragraph. The "Baseline QoL" input field contains the value "0.86". Under the heading "Additional effects", there is a sub-heading "Demographic and socio-economic characteristics". Below this are several input fields arranged in two columns: "Age (per 10 years)" with value "-0.048", "Male" with value "0.059", "Completed secondary education" with value "-0.017", "Below secondary education" with value "-0.036", "Ex-smoker" with value "-0.009", "Current smoker" with value "-0.037", "BMI <25 kg/m<sup>2</sup>" with value "0.011", and "BMI ≥30 kg/m<sup>2</sup>" with value "-0.043". At the bottom of the main content area is the heading "Disease history".

SHARP CKD-CVD outcomes model (beta version)

The default values are UK quality of life (QoL) utilities estimates derived from the SHARP data.

Baseline QoL is the quality of life utility of a 60 year old female, non-smoker, with above secondary education, with BMI 25-30 kg/m<sup>2</sup>, pre-RRT CKD and without diabetic nephropathy or vascular disease.

Reset inputs

Baseline QoL

0.86

Additional effects

Demographic and socio-economic characteristics

Age (per 10 years)

-0.048

Male

0.059

Completed secondary education

-0.017

Below secondary education

-0.036

Ex-smoker

-0.009

Current smoker

-0.037

BMI <25 kg/m<sup>2</sup>

0.011

BMI ≥30 kg/m<sup>2</sup>

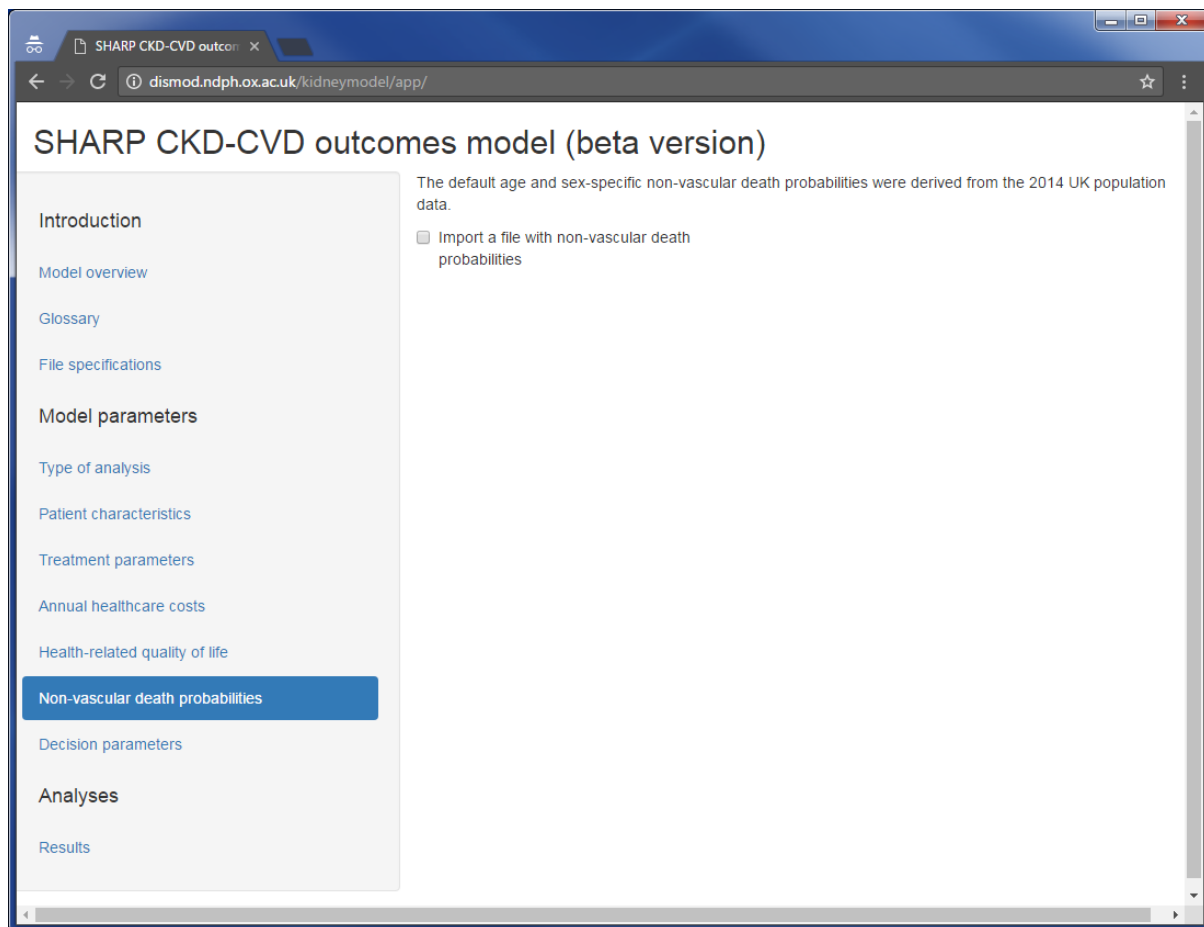
-0.043

Disease history

For each year in the model, the health-related quality of life (HRQoL) utility is calculated for each participant, depending on their characteristics, using the standard linear regression. The user can use the default values, which are derived from the SHARP study data with UK EQ-5D -3L utility values [1], or specify their own utility values. The projected annual quality of life must be above the user-specified minimum value (default value -0.594, which is the lowest possible value using UK EQ-5D-3L tariffs) and below 1. The "Reset inputs" button will reset all patient characteristics to their default values.

## Non-vascular death probabilities

Figure 10 Screenshot of the Non-vascular death probabilities page



Default age and sex-specific annual non-vascular death probabilities were derived from 2014 UK population data [1]. The user can use different probabilities by providing a .csv file following the format described in Table 2.

Note that the age ranges in the user file could vary (e.g. 40-50, 50-60 etc also possible) but should cover the full range from 0 to “Inf” (i.e. infinity). The names of columns as well as the names of CKD stages should be preserved.

Table 2 Required entries in the file for non-vascular death probabilities

Column name	Description	Allowed values
CKDstage	CKD stage	Numeric 0 = CKD 3B; 1 = CKD 4; 2 = CKD 5, not RRT; 3 = dialysis; 4 = transplant All five values must be present
ageBand	Age range	An age range [y1, y2) should be recorded as a string of y1-y2. An Interval of the form y1+ is recorded as y1-Inf
sex	Gender	Numeric

		0 = female; 1 = male Both values must be present
P_NVD	Annual probability of non-vascular death	Numeric between 0 and 1

[1] Schlackow I, Kent S, Herrington W, Emberson J, Haynes R, Reith C, Wanner C, Fellström B, Gray A, Landray MJ, Baigent C, Mihaylova B, on behalf of the SHARP Collaborative Group. *A lifetime model of health outcomes in moderate-to-severe chronic kidney disease: the SHARP CKD-CVD outcomes model*. Under review.

## Decision parameters

Figure 11 Screenshot of the Decision parameters page

The screenshot shows a web application interface for decision parameters. On the left is a sidebar menu with the following items: Model overview, Glossary, File specifications, Model parameters (highlighted), Type of analysis, Patient characteristics, Treatment parameters, Annual healthcare costs, Health-related quality of life, Non-vascular death probabilities, Decision parameters, Analyses, and Results. The main content area is titled 'Decision parameters' and includes a 'Reset inputs' button at the top. Below this are two sliders: 'Discount rate: costs' and 'Discount rate: health outcomes', both with a range from 0 to 10 and a current value of 3.5. Underneath the sliders is a dropdown menu for 'Duration of model execution' with options: 'Simulation for a fixed number of years' (selected), 'Lifetime simulation', and 'Simulation for a fixed number of years'. At the bottom is a text input field for 'Number of years of analysis' with the value '30'.

The user can specify the annual **discount rates** to be applied to future costs and health outcomes (default values are 3.5% for both) as well as the **duration of model execution**.

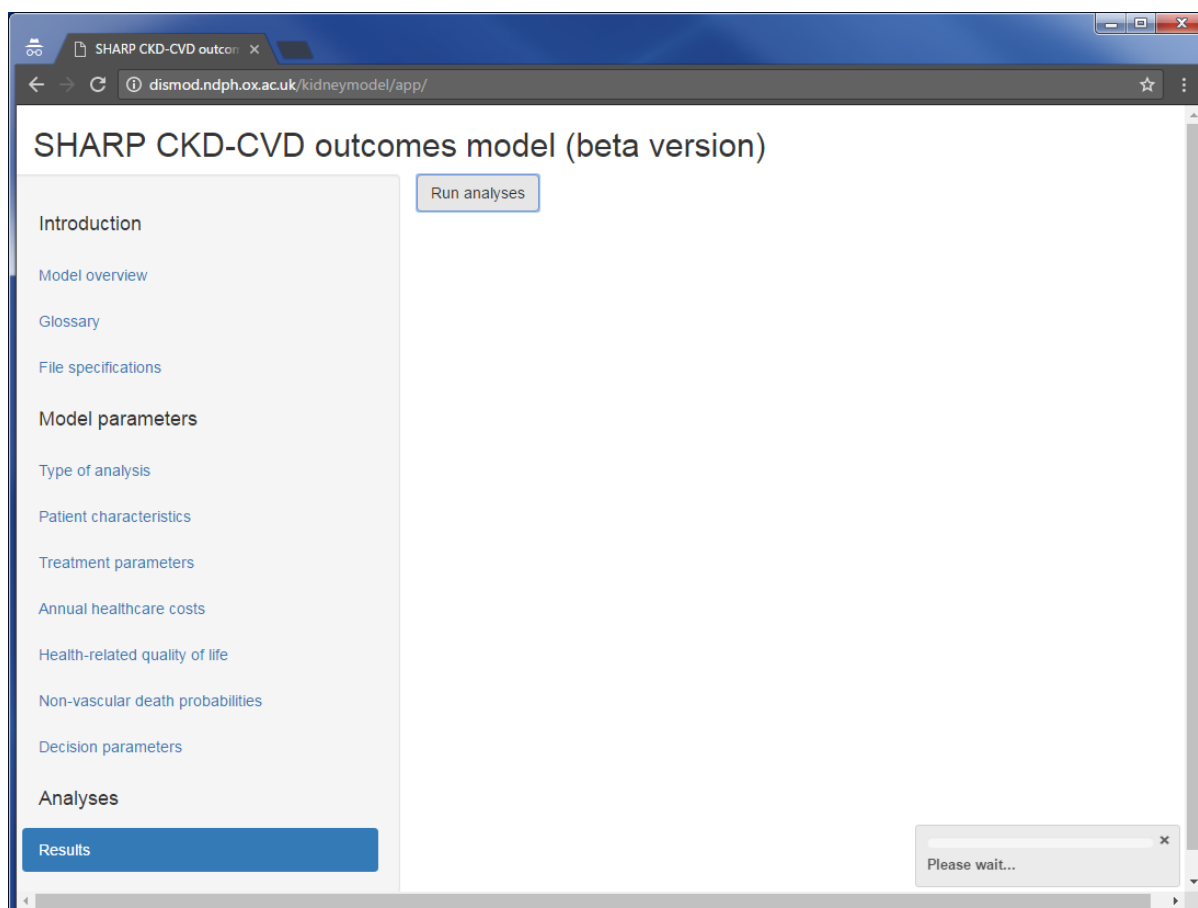
**As to the duration of model execution**, the user can choose between (1) the fixed number of years over which model is executed and the outcomes are calculated (e.g. 30 years, default value), and (2) lifetime simulation, defined as the maximum participant's age for which the simulation should be run. Predictions cannot be made beyond 100 years of age. The "Reset inputs" button will reset all characteristics to their default values.

## Analyses

### Results

The results will be updated every time the 'Run analyses' button is pressed. A "Please wait..." message is shown while the model is being executed.

Figure 12 Screenshot of the "Run analyses" button and "Please wait..." message.



The model produces results at patient level, which are subsequently averaged to produce a group summary. Both summaries are available to download into a .csv file but only the group summary is displayed on the screen. The cumulative event probabilities by the end of year Y are calculated using the Kaplan-Meier product

$$1 - \prod_{y=1}^Y \left( 1 - \frac{\#\{\text{events in year } y\}}{\#\{\text{people at risk at start of year } y\}} \right)$$

If the probabilistic sensitivity analysis has been selected, point estimates are displayed together with the 95% confidence intervals for all outcomes, calculated using the bootstrap method. Note that execution of probabilistic sensitivity analysis might take substantial time. If substantive use of the model is envisaged please contact developers.

The next two sections describe in more detail outputs for each possible scenario.

### Long-term projections

The results produced in this analysis include cumulative probabilities of first vascular event or vascular death, initiation of renal replacement therapy (for pre-RRT participants), vascular deaths and all deaths. Cumulative probabilities are calculated at 5 and 10 years and – if the simulation is run over a fixed number of years – over simulation duration. Additionally, hospital and treatment costs are calculated over the simulation duration. A detailed description of the output .csv file is provided in Table 3 below.

If the probabilistic sensitivity analysis has been selected, all estimates are presented with the 95% confidence intervals. The format of the output .csv file is exactly the same as that described in Table 3, but for each outcome there are now three columns: one for the point estimate (eg LY), one for the lower 95% CI (with the “\_l” suffix, eg “LY\_l”) and one for the upper 95% CI (with the “\_u” suffix, eg “LY\_u”).

Figure 13 Screenshot of the Results section page (long-term projections, deterministic analysis)

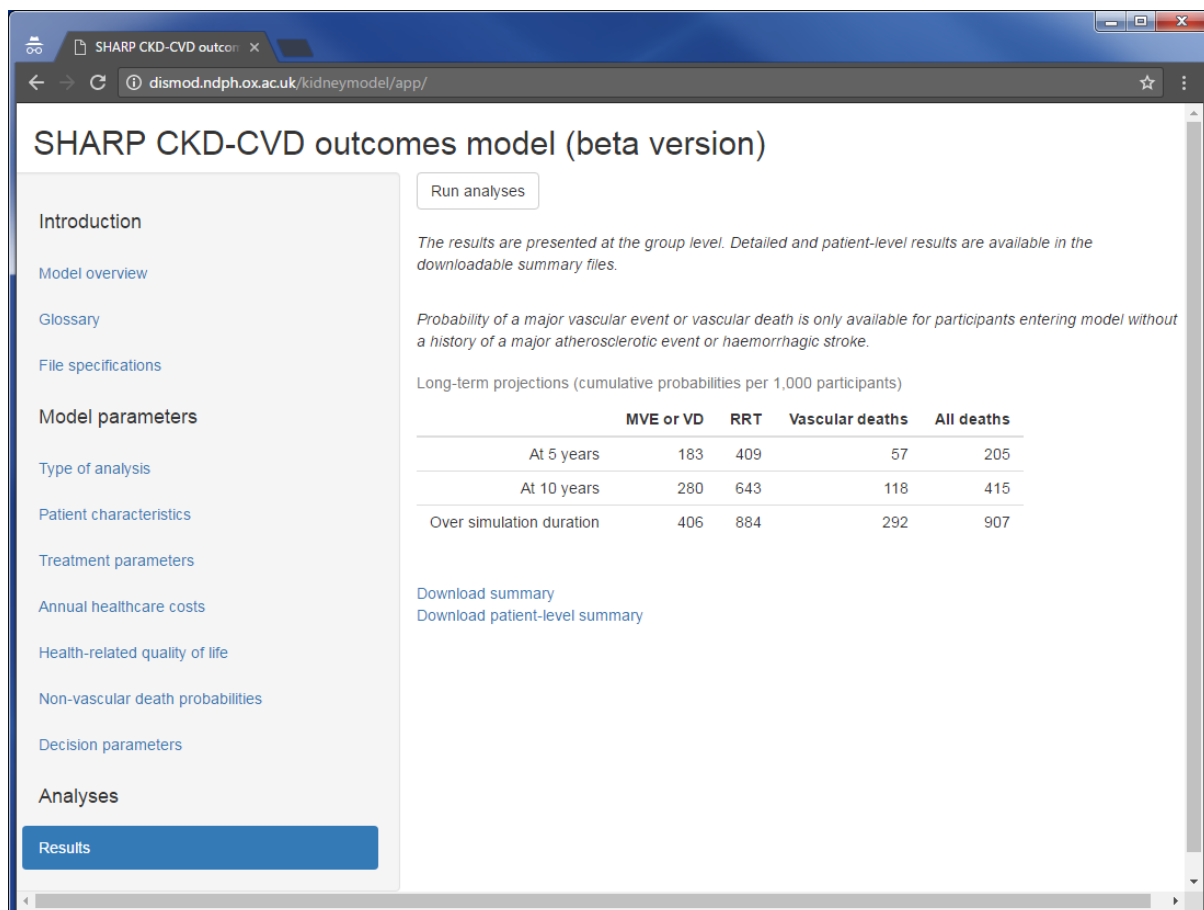




Figure 14 Screenshot of the Results section page (long-term projections, probabilistic analysis)

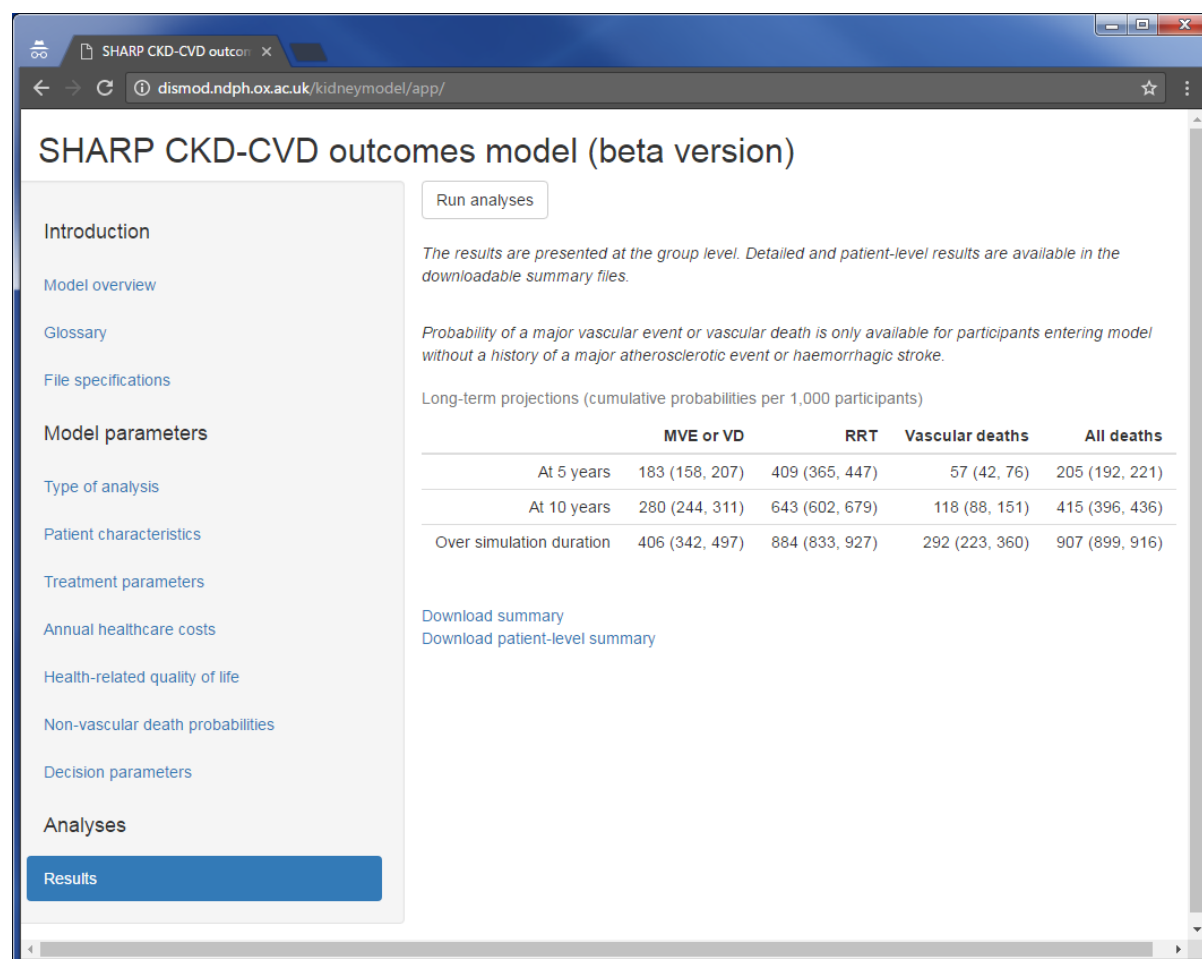


Table 3 Format of the output .csv file in the lifetime projections analysis (deterministic)

Column name	Description
<b>Baseline characteristics</b>	
<b>(only produced for the patient-level summary)</b>	
Id, age, sex, ..., TX	See Table 1 for detail.
<b>Cumulative event probabilities at 5 years</b>	
<b>(NA produced if the simulation is run for less than 5 years)</b>	
MVEorVD_first_5	First major vascular event or vascular death
RRT_first_5	Start of the renal replacement therapy
VD_5	Vascular death
D_5	Any death
<b>Cumulative event probabilities at 10 years</b>	
<b>(NA produced if the simulation is run for less than 10 years)</b>	
MVEorVD_first_10	As above
RRT_first_10	
VD_10	
D_10	
<b>Cumulative probabilities probabilities over simulation duration</b>	
<b>(not available for lifetime simulations)</b>	

MVEorVD_first_all	As above
RRT_first_all	
VD_all	
D_all	
Outcomes calculated over simulation duration	
cost_hosp, cost_hosp_disc	Hospital costs, undiscounted and discounted
cost_tx, cost_tx, disc	Treatment costs, undiscounted and discounted
LY, LY_disc	Life-years, undiscounted and discounted
QALY, QALY_disc	Quality-adjusted life-years, undiscounted and discounted

### *Cost-effectiveness analysis*

In the cost-effectiveness analyses, the same outcomes are presented separately for the control and the intervention group, and incremental cost-effectiveness of the intervention is calculated and both undiscounted (default) and discounted values are presented.

The format of the output .csv file is very similar to that in Table 3, with the following amendments:

- a) Every outcome described in Table 3 is presented for the control group (and has suffix “\_C”, eg “LY\_C”) and the intervention group (and has suffix “\_T”, eg “LY\_T”)
- b) Incremental values are presented for hospital and treatment costs, as well as life-years and QALYs. These have suffix “\_inc”, eg “LY\_inc”.
- c) Incremental cost-effectiveness outcomes are calculated. These are
  - a. Incremental cost per life-year gained, undiscounted and discounted (cost\_LY, cost\_LY\_disc)
  - b. Incremental cost per QALY gained, undiscounted and discounted (cost\_QALY, cost\_QALY\_disc)

If the probabilistic sensitivity analysis has been selected, all estimates are presented with the 95% confidence intervals. Consequently, as in the long-term projections option, there are three columns in the output .csv file: one for the point estimate (eg LY), one for the lower 95% CI (with the “\_l” suffix, eg “LY\_l”) and one for the upper 95% CI (with the “\_u” suffix, eg “LY\_u”). Additionally, the cost-effectiveness acceptability curve is displayed.

Figure 15 Screenshot of the Results section page (cost-effectiveness, deterministic analysis)

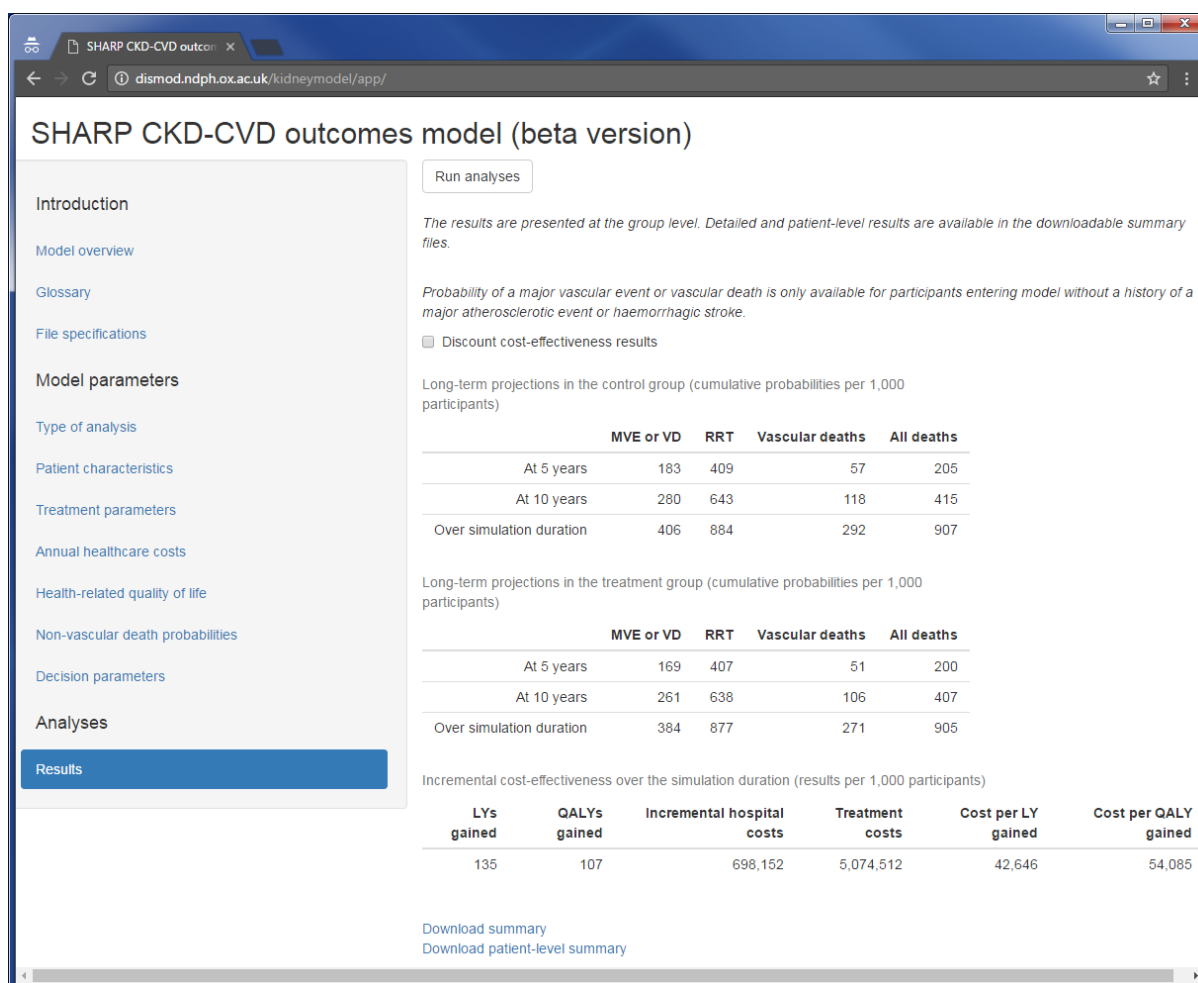


Figure 16 Screenshot of the Results section page (cost-effectiveness, probabilistic analysis)

