MAFEIP

Support Services for the Management and Utilization of Monitoring and Assessment of the EIP - MAFEIP Tool

Renewing Health: Telemonitoring for Type 2 Diabetes Patients in Thessaly, Greece

Authors:
George Dafoulas, Christianne Lavin, Strahil Birov, Veli Stroetmann,
Ruth Vilar, Francisco Lupiáñez-Villanueva

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Executive summary

Description of the intervention

The objective of Renewing Health was to implement telemedicine services in nine European regions for the validation and subsequent evaluation of these services using a patient-centred approach and a common assessment methodology (MAST). The services should be targeting the telemedicine and treatment of chronic patients suffering from diabetes, Chronic Obstructive Pulmonary Disease (COPD) or Cardio Vascular Diseases (CVD).

The intervention explored specifically in this use case covers remote monitoring and the treatment of chronic patients suffering from diabetes mellitus type 2 (DM2). Type 2 diabetes is usually treated first with weight reduction, a diabetic diet, and exercise. When these measures fail to control the elevated blood sugars, oral medications are used. If oral medications are still insufficient, treatment with insulin is considered (e.g. via pens, injectors or pumps). As part of the intervention group, 74 patients of the region, Thessaly, Greece, were equipped with telemonitoring or measuring devices that were connected to a mobile application and a web-based database. Data were then transmitted to the database and the eHealth centre, giving healthcare personnel the possibility to react and take action at any time.

Based on the study from the Renewing Health Multicentre Trial[1], there is evidence that glycemic control was improved for the Central Greece region. An improved quality of life in terms of the physical or the mental component of the SF-36v2 scale has also been demonstrated. Data from this study is used in the MAFEIP tool for the evaluation of the intervention.

Model input

Defining the health states and the transition probabilities

The MAFEIP 3-state model has been adopted with the following defined health states: (1) the baseline health state (not having DM2), (2) the deteriorated health state (having DM2) and (3) the death state.

Computing the costs

Costs were taken from the average treatment costs in 2011, which was measured throughout the Renewing Health multicentre trial. These costs included the telemedicine

[1] Mavrodi et al. (2015). Cost-utility analysis of long-term telemonitoring of DMT2 patients among different EU health systems: The Renewing Health multicentre trial. Conference Paper at the 8th International Conference of Advanced Technologies & Treatments for Diabetes. <https://www.researchgate.net/profile/Fenia_Mavrodi/publication/273630113_Cost-utility_analysis_of_long-term_telemonitoring_of_DMT2_patients_among_different_EU_health_systems_The_Renewing_Health_multicentre_trial/links/5506dbba0cf26ff55f7b0f45/Cost-utility-analysis-of-long-term-telemonitoring-of-DMT2-patients-among-different-EU-health-systems-The-Renewing-Health-multicentre-trial.pdf>

investment cost (cost of intervention per year) and the running (healthcare) costs for both the intervention group and the control group.

Utility

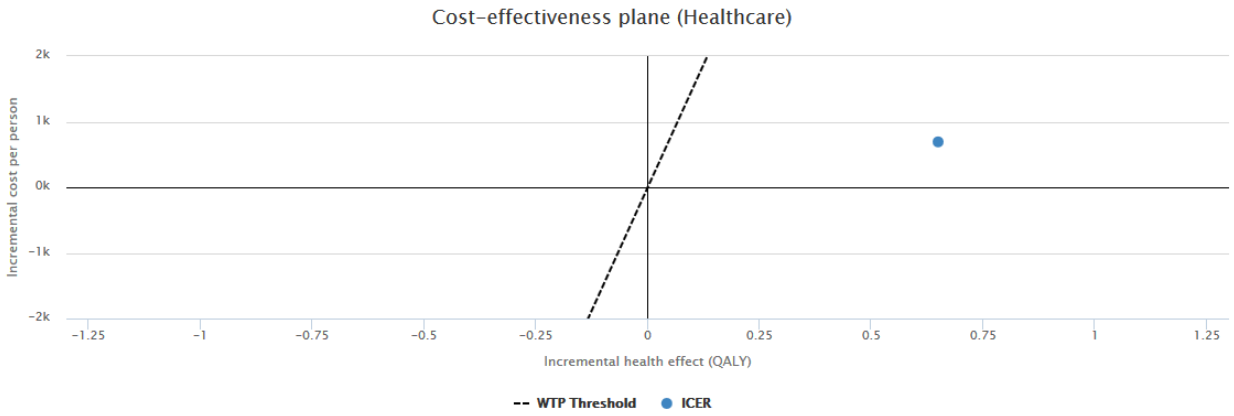
During the trial, a study has also been done to assess health-related Quality of Life (HRQoL) through the use of a generic questionnaire, the SF36v2. Results of this questionnaire were interpreted into quality adjusted life years (QALYs) through the SF-6D classification system.

	Control Group	Intervention Group
Utility of baseline health	1	1
Utility of deteriorated health	0.67	0.78

Model output

A calculation of the incremental cost and effects places the incremental cost-effectiveness ratio (ICER) in the upper-right quadrant. This means that the intervention is better (more effective), and yet more expensive than the current (standard) care. Nevertheless, the intervention is still accepted, as the ICER value (1,066.65) is less than the Willingness to Pay (WTP) threshold value (15,000).

Incremental cost and HRQoL effects	
Incremental cost (Healthcare)	693.05
Incremental effects	0.650
Incremental cost-effectiveness ratio (Healthcare)	1066.65



WTP Threshold: ◉ €15K/QALY ○ €20K/QALY ○ €30K/QALY ○ €50K/QALY ○ €80K/QALY

1. Description of the intervention

The objective of Renewing Health was to implement telemedicine services in nine European regions for the validation and subsequent evaluation of these services using a patient-centred approach and a common assessment methodology (MAST). The services should be targeting the telemedicine and treatment of chronic patients suffering from diabetes, Chronic Obstructive Pulmonary Disease (COPD) or Cardio Vascular Diseases (CVD).

The services provided in Renewing Health are designed to give patients a central role in the management of their diseases, fine-tuning the choice and dosage of medications, promoting compliance to treatment, and helping healthcare professionals to detect early signs of worsening. It is also the intention with the services to provide healthcare professionals with new tools and possibilities for collaboration and communication. During the project period, the services have been scaled up and integrated with mainstream healthcare systems. The services have been grouped into a limited number of clusters, bringing together services showing similar features, trialled and assessed with the use of MAST, and using a common set of primary indicators for pilots belonging to the same cluster.

The intervention explored specifically in this use case covers remote monitoring and the treatment of chronic patients suffering from diabetes mellitus type 2 (DM2). Type 2 diabetes is first treated with weight reduction, a diabetic diet, and exercise. When these measures fail to control the elevated blood sugars, oral medications are used. If oral medications are still insufficient, treatment with insulin is considered (e.g. via pens, injectors or pumps).

For the intervention group, patients are equipped with telemonitoring or measuring devices that (a scale to measure weight, a sphygmomanometer to measure blood pressure and pulse, a device to measure blood sugar) are connected to a mobile application and a web-based database. A different device applied to the wrist of the patient uses a wireless and all-in-one monitoring system which measures blood sugar level. Data are transmitted to the database and the eHealth centre, whereas alarms with different values can be found in the Home Care portal giving healthcare personnel the possibility to react and take action at any time.[2] An overview of the system is depicted in the Figure below.

[2] http://www.renewinghealth.eu/documents/28946/555381f3-9686-4955-8547-76b58be34a04

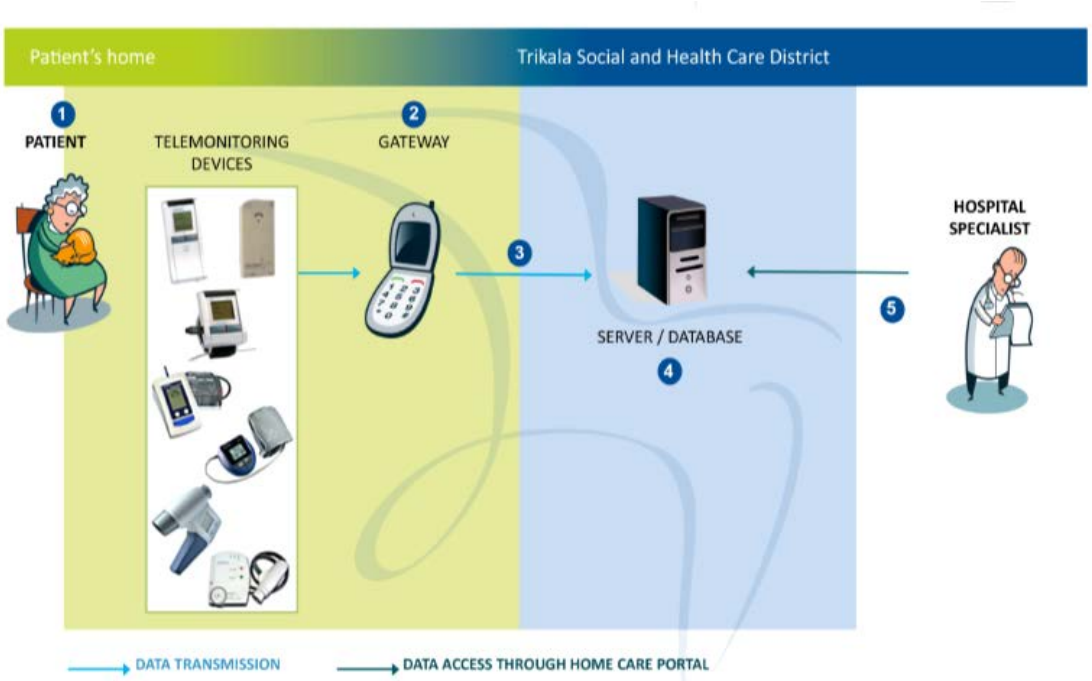


Figure 1. The Renewing Health telemonitoring model established for Thessaly, Greece

Source: Mavrodi et al. Cost-utility analysis of long-term telemonitoring of DMT2 patients among different EU health systems: The Renewing Health multicentre trial[3]

Based on the study by the Renewing Health project, there is evidence that glycemic control was improved for the Central Greece region. An improved quality of life in terms of the physical or the mental component of the SF-36v2 scale has also been demonstrated. Data from the Renewing Health trial study is adopted into the MAFEIP tool in order to reassess the intervention.

[3] Mavrodi et al. (2015). Cost-utility analysis of long-term telemonitoring of DMT2 patients among different EU health systems: The Renewing Health multicentre trial. Conference Paper at the 8th International Conference of Advanced Technologies & Treatments for Diabetes. <https://www.researchgate.net/profile/Fenia_Mavrodi/publication/273630113_Cost-utility_analysis_of_long-term_telemonitoring_of_DMT2_patients_among_different_EU_health_systems_The_Renewing_Health_multicentre_trial/links/5506dbba0cf26ff55f7b0f45/Cost-utility-analysis-of-long-term-telemonitoring-of-DMT2-patients-among-different-EU-health-systems-The-Renewing-Health-multicentre-trial.pdf>

2. Model input

2.1. Defining the health states and the transition probabilities

In the project, the generic Markov-chain disease states were derived from the care pathway and its three general disease states as reflected in the figure below. The baseline health state corresponds to patients without diabetes mellitus 2 (DM2) while the deteriorated health state corresponds to patients that have DM2.

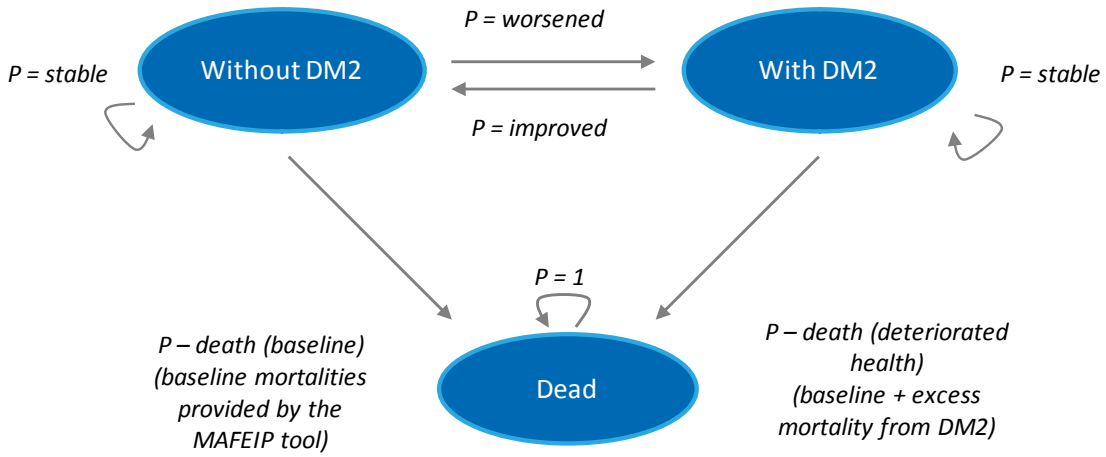


Figure 2. A 3-state model of the patient scenario of this use case

Incidence rates, or the transition rates from the baseline to the deteriorated health state, were taken from an external source.[4] The telemonitoring innovation aims to provide better quality of life as well as an improved glycemic control for DM2 patients rather than attempting to treat the disease, and thus recovery rates have not been of interest and are set to zero in the MAFEIP tool. Similarly, as the intervention provides improved quality of care for patients that already have diabetes mellitus 2, incidence rates remain the same between the two patient groups. These are illustrated in the Table below.

Table 1. Transition probabilities for the control and intervention group

	Control Group	Intervention Group
Incidence Rate (%)	5.5	5.5
Recovery Rate (%)	0	0

As the MAFEIP tool works with a 3-state model with the third state being the dead state, mortality rates are also accounted for.

Baseline mortality for the specified target population (country and age range; here: Greece, ages 58 to 64) comes from the Human Mortality Database. Data input for mortality rates differ from the other transition probabilities above as a relative risk (RR) is specified instead of the actual mortality rate. As described in the MAFEIP tool, the relative risk of mortality is a proportional measure estimating the mortality in a certain

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2515429/

population compared with the mortality in a reference condition. In this use case, the "reference condition" is the all-cause mortality in the general population aged 58 to 64 in Greece. When the RR is greater than one, the mortality is higher compared to all-cause mortality in the general population. When the RR is less than one, the mortality is lower.

The study did not focus on mortalities, and therefore the relative risks of mortalities were kept at the standard value of 1. This means that the tool would then take the baseline mortality rates from the Human Mortality Database

Table 2. Relative risks of mortalities for the control and intervention group

	Control Group	Intervention Group
Relative Risk of Mortality in Baseline Health	1	1
Relative Risk of Mortality in Deteriorated Health	1	1

2.2. Computing the costs

The average cost of telemedicine treatment per patient was measured throughout the Renewing Health Multicentre Trial in 2011. These figures were then simply transferred and adopted into the MAFEIP tool. The average treatment cost per patient for both the intervention and control groups measured in the study are found in the Table below.

Table 3.Average treatment cost per patient for the Intervention and Control Groups

EU Region	Berlin		Central Greece		Veneto	
	Intervention	Control	Intervention	Control	Intervention	Control
SF-6D health utility scores [Mean]						
Mean	0.52	0.53	0.78	0.67	-0.023	-0.004
Mean difference [CI; p-value]	-0.005 [-0.06, 0.05; p=0.863]		0.111 [0.078, 0.144; p=0.000]		-0.019 [-0.054, 0.016; p=0.28]	
Treatment costs (€, 2011 prices)						
Telemedicine investment cost	79.44	n.a.	486.31	n.a.	4.50	n.a.
Running cost	1,697.26	2,990.18	527.17	494.46	3,060.16	2,602.49
TOTAL COSTS	1,776.70	2,990.18	1,013.48	494.46	3,064.66	2,602.49

The costs above are translated adopted into the tool as shown in the Table 4 and Table 5.

One-off intervention costs represent the total cost incurred only once per patient (e.g. the cost of a surgical procedure that happens only once for each patient in the intervention cohort).

The total intervention cost per person per year consists of two components: First, variable costs of the intervention are incurred for each individual and each year and represent, for example, the annual costs for medication, personal devices or delivery of the intervention. Second, the share of annual fixed costs per patient currently treated or targeted by the intervention represents, for example, the annual cost of the

infrastructure used for all patients divided by the number of patients currently treated or targeted by the intervention.

The Renewing Health trial study already have calculated results on the telemedicine investment cost of 2011, which are already given per patient. This is what was then input in the MAFEIP tool under "intervention one-off costs (per patient)".

Table 4. Telemonitoring intervention one-off and recurrent costs

Intervention one-off costs (per patient)	
Intervention one-off costs (per patient)	486.31
Intervention recurrent costs (per patient and year)	0

The running costs were also given for both the intervention group and the control group. These were adopted into the MAFEIP tool as the healthcare costs, which refer to all other resource use within the healthcare system, excluding the costs for the telemonitoring intervention itself (which were input previously). Societal costs include other costs outside the healthcare sector (e.g. out-of-pocket payments and travel costs for patients, productivity losses) added to the healthcare costs. In this use case, no differentiation was made between healthcare costs and societal costs.

A summary of the costs as required by the MAFEIP tool are found below. In this section, only integers are accepted by the tool.

Table 5. Summary of healthcare and societal costs for the control and intervention group

		Control Group	Intervention Group
Healthcare costs, €	Baseline	0	0
	Deteriorated	494	527
Societal costs , €	Baseline	0	0
	Deteriorated	494	527

2.3. Utility

In this section, utility is expressed as health-related quality of life values (HRQoL) of a particular health outcome. The higher this utility value, the higher the quality-of-life associated with that health outcome. A utility of 0 indicates no quality of life or dead, whereas a utility of 1 indicates quality-of-life in perfect health.

In this use case, HRQoL of patients (both in the control and intervention group) was assessed using a generic (SF36v2) questionnaire, and SF-6D was used to calculate quality adjusted life years (QALYs) in the cost-utility analysis. Results from this study were adopted and are summarized below. As the study concentrated only on patients that are already in the deteriorated state (and not in the baseline state), baseline utility values were set to the default value of 1.

Table 6. Utility values for the control and intervention group

	Control Group	Intervention Group
Utility of baseline health	1	1
Utility of deteriorated health	0.67	0.78

3. Model output

3.1. Incremental costs and effects

Incremental costs and effects are calculated per person and are presented in the next two Figures below. The age range first observed is from 58 to 64, which is the approximate age range of the patients in the trial. As shown in Figure 3 below, all incremental costs are above zero. This could be interpreted as the additional costs that the intervention requires compared to standard care and thus also indicates that the intervention is more expensive than the current standard care. It shows a slight downward curve which shows that there are lower accumulated costs involved at a higher age. This may be explained by possible higher mortality rates at higher ages. Once a patient transfers into the dead state, the corresponding cost calculation stops which then reflects the lower incremental cost.

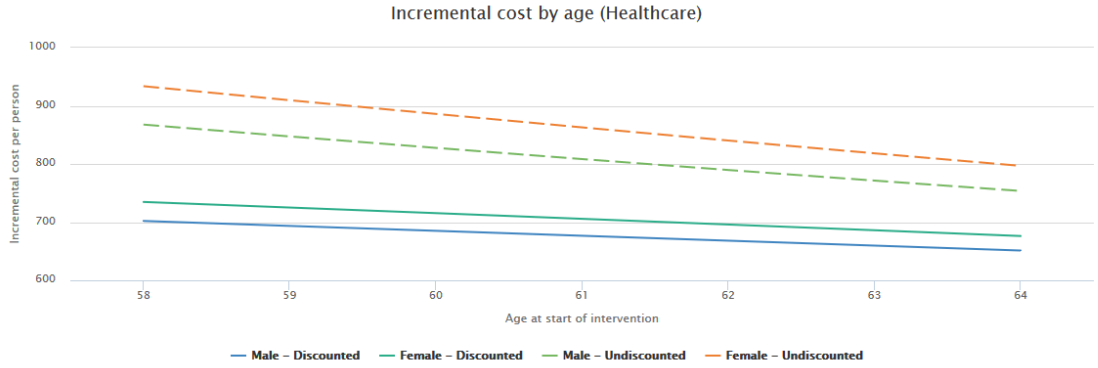


Figure 3. Incremental cost by age

The incremental effects values show how much QALYs are gained when the intervention is used instead of the standard care.

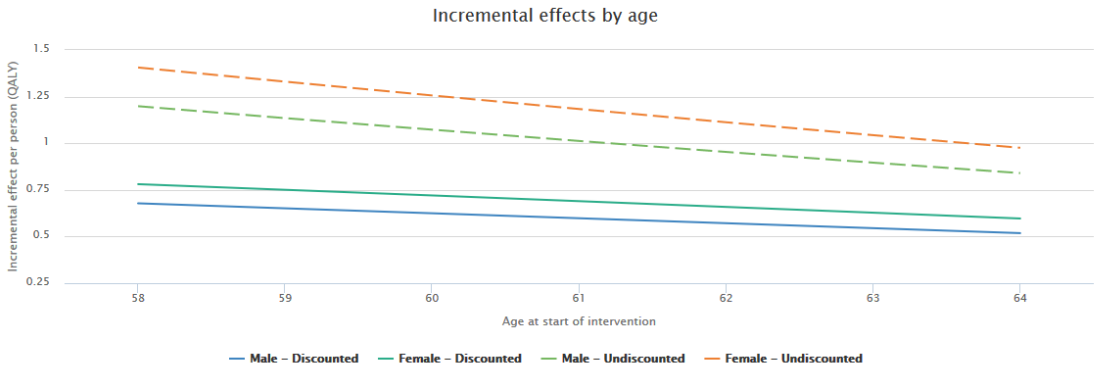


Figure 4. Incremental effects by age

3.2. Cost-effectiveness

Based on the previous graphs, the incremental cost-effectiveness ratio (ICER) is then calculated and plotted in the cost-effectiveness plane as shown in Figure 5 below (ICER indicated by the blue dot).

As shown in the Figure, the ICER is calculated as 1,066.65 and is graphically located in the upper right quadrant. This means that the intervention is better (more effective) and yet more expensive than the current (standard) care. When the ICER is located in the upper right or the lower left quadrant, it is noteworthy to compare the ICER value and the Willingness to Pay Threshold (WTP). Since the ICER, of 1,066.65 is lower than the WTP threshold (set at 15,000 €; location of blue ICER dot is below the WTP plot line), the intervention is accepted.

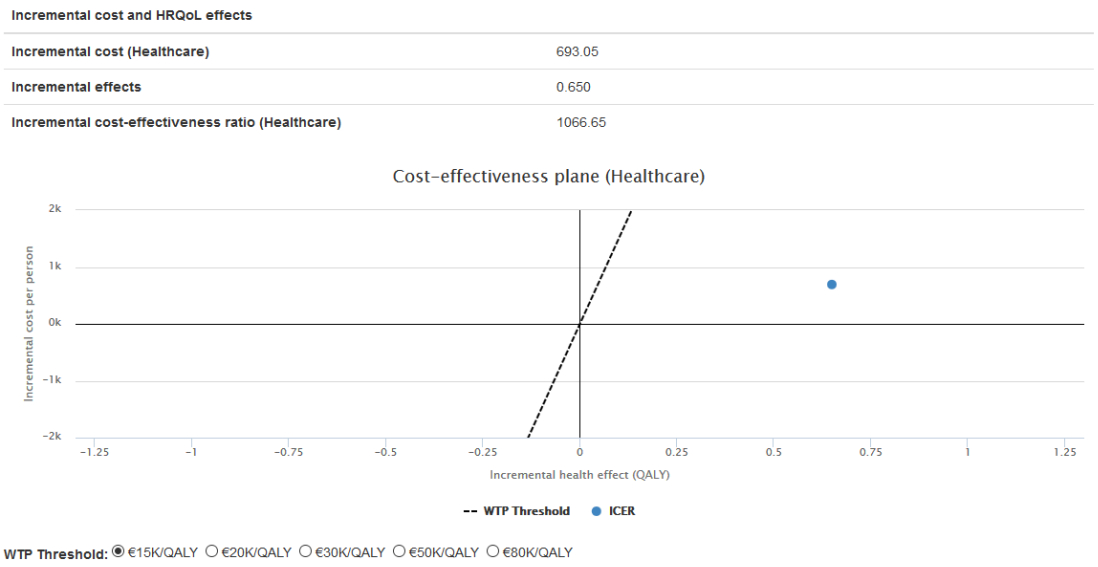


Figure 5. Cost-effectiveness plane

A similar study was done during the Renewing Health trial. They used the Greek GDP capita for 2011 (18,625€) as the indicator equivalent to the WTP threshold, and their calculations led to an ICER of 5,460.11 per QALY. The MAFEIP tool considers the 3 states in its calculations, which may explain the differences in calculated ICER value. Moreover, as 1,066.65 is still less than 18,625, the intervention is accepted and considered a cost-effective choice for the Greek national health system.

3.3. Population Impact

The next Figures illustrate an extension of the results under “Incremental Costs and Effects” by showing a population-level impact (rather than a personal-level impact) on costs and effects over a course of time (45 years). A sample population of 670 was chosen as this was the initial sample size of the trial in the Central Greece region.

Cumulative costs are simply the average amount of costs of the whole population either saved (if the value is negative) or additionally paid for (if the value is positive) by using the intervention instead of the standard care. Similarly, cumulative effects are the averaged, accumulated quality of life gained or lost within a time span of 45 years.

The graph in Figure 6 shows an upward curve with values above zero. This describes how the intervention would lead to more costs along an approximate 45-year time period. On the other hand, the graph in Figure 7 also shows an upward curve, which then illustrates that the intervention also leads to more QALYs (cumulatively gained) along this time period.

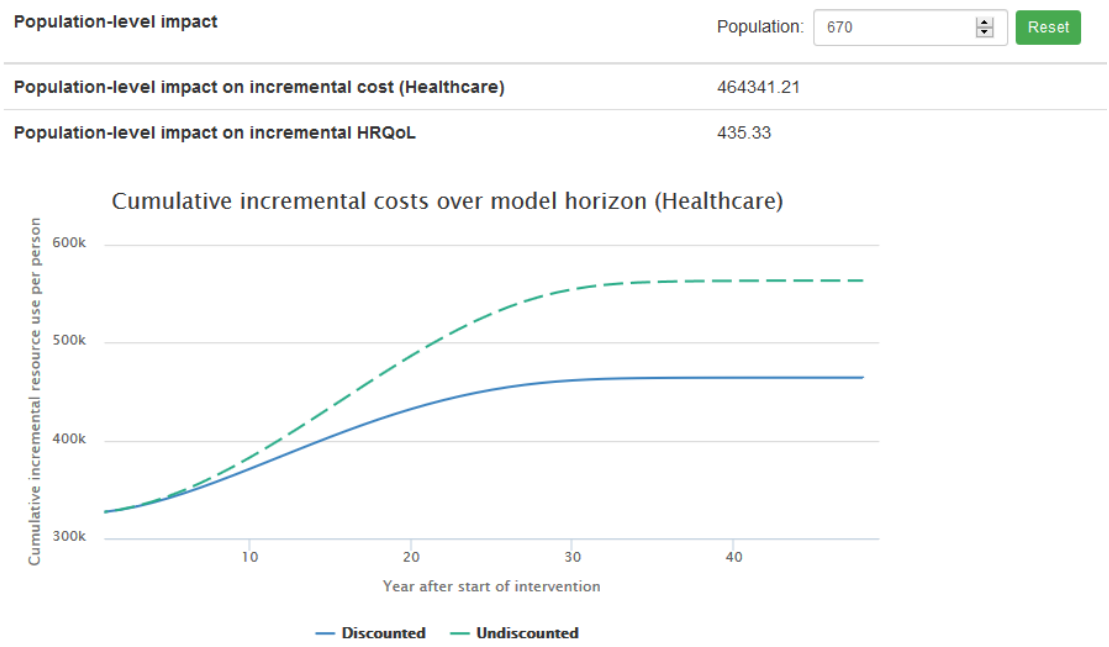


Figure 6. Cumulative incremental cost

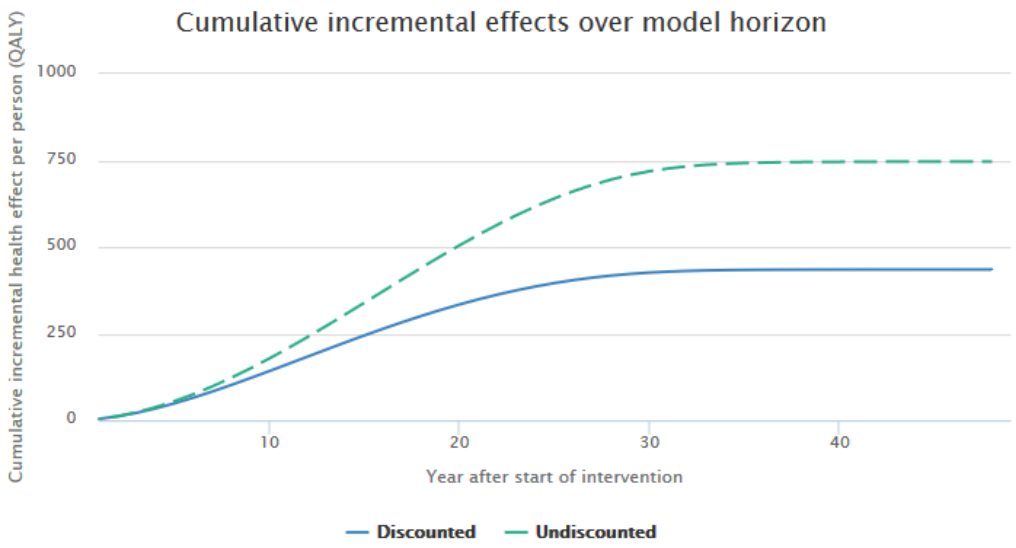


Figure 7. Cumulative incremental effects

3.4. Patient flow through model states

The following Figures (Figure 8, Figure 9) reflect the results based on the transition probabilities defined earlier (Tables 1 and 2). The graphs below illustrate how likely a patient (from a certain age group and health state) will either stay in an alive state (baseline or deteriorated) or will move towards the dead state.

The Figure below shows the likelihood that a patient would stay in the specific alive state, with dotted lines representing the baseline health state and continuous lines representing the deteriorated health state. The current care and intervention scenarios for each the baseline health state and the deteriorated health state have the same plot (overlapping on top of each other), which is why only 2 rather than 4 plot lines seem to be shown. This is because current care and intervention scenarios have the same defined incidence and recovery rates (incidence rate of 5.5, recovery rate of 0).

The graph below shows that there is a high chance of staying in the baseline health state (no DM2) up until the age of 70 (see dotted lines). Afterwards, there is more than a 50% chance of going to another state (e.g. deteriorated or dead).

On the other hand, patients with DM2 (deteriorated health state) have a lower chance of staying in the deteriorated health state at a high age group. This indicates that DM2 patients are more likely to die at an older age.

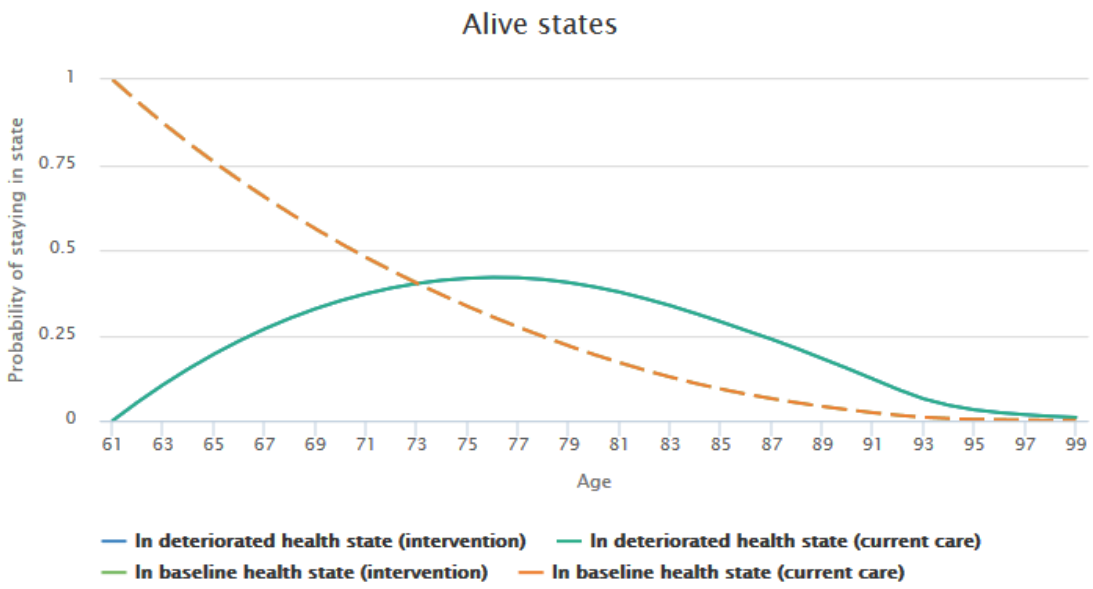


Figure 8. Patient flow through model states (Alive states)

All mortality rates in this use case were set to the default value of 1. In such a case, the plot lines for the current care and intervention scenario will overlap as shown in the Figure below. The Figure shows an upward curve, describing an increasing probability of dying as age also increases. The values used to create this graph were taken from age- and country-dependent, all-cause mortality rates from the Human Mortality Database and therefore do not only represent patients with DM2.

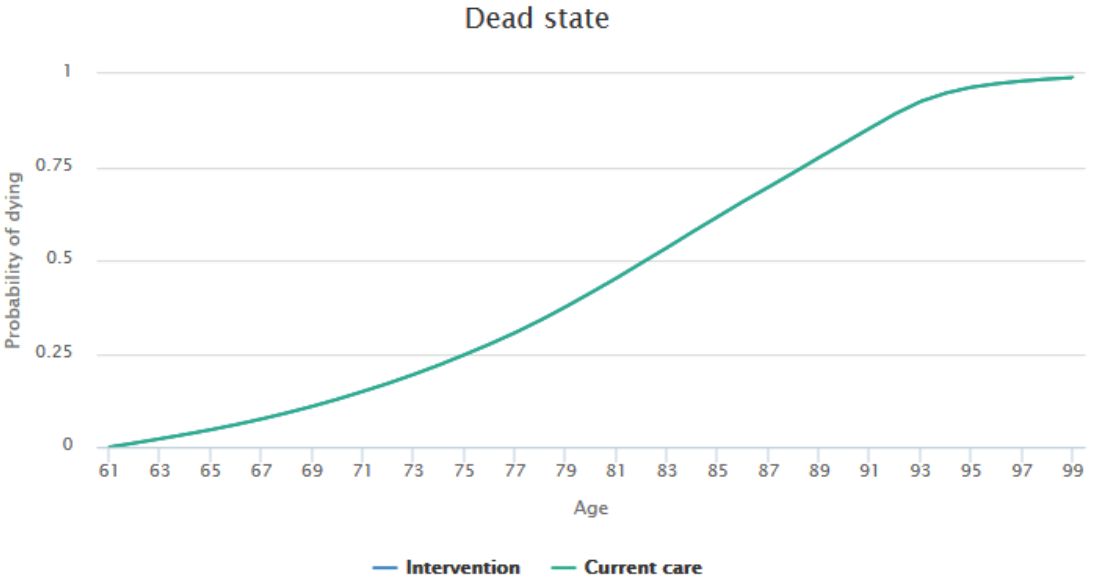


Figure 9. Patient flow through model states (Dead state)

4. Lessons learned

This use case is an example of how the MAFEIP tool can be used to verify or complement results from similar types of studies (that have used other methods). In this use case, a study was already done in which costs, HRQoL, and even ICER were assessed. Both the results from the previous study and from the MAFEIP tool lead to the conclusion that even though the telemonitoring intervention is more expensive, it is still a cost-effective choice for the Greek national health system, especially when considering the QALYs gained by the DM2 patients.