MAFEIP

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

United4Health

SERGAS

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Executive summary

Description of the intervention

The United4Health project (U4H)[2] tested telehealth services targeting the three main chronic diseases found among the EU population: diabetes, COPD[3], and CHF[4]. This case covers the telehealth service for patients living with COPD, which has the aim to provide an alternative way to support self-management through the provision of an appropriate level of tele-monitoring that is flexible and can respond with fluctuations in their health status and thus avoid future emergency hospital admissions due to a COPD exacerbation. The intervention and follow-up duration for an individual patient is up to 12 months. This use case focuses on the trial in Galicia implemented by SERGAS[5], the regional health department. Participants were people who had been hospitalised for exacerbation of COPD. Their age ranged from 34 to 86 years, and most participants were males. The evaluation was conducted using the MAST multidimensional evaluation methodology (Kidholm et al., 2012)[6]. The study had an observational design, with intervention and comparator groups.

Model input

Defining the health states and the transition probabilities

The definition of states is based on the number of admissions for exacerbation of COPD. *Baseline health* is defined as not having been admitted to the hospital in the last 12 months, and having had at least one additional admission is considered as belonging to the *deteriorated health state*. Among the patients in the intervention group, 70 were in the baseline and 56 in the deteriorated state before the implementation of the services. At the end of the treatment, 34 had moved from the baseline to the deteriorated state, and 7 had done the opposite. Therefore, the incidence rate for the intervention group is 48.6% and the recovery rate 12.5% (Table 1). The project results estimated that patients in the comparator group were 3.6 times more likely to be hospitalised (odds ratio) than those receiving tele-monitoring. Using this value, assuming that patients in the control group have the same initial distribution than those in the intervention group, and converting the odds ratio to probabilities, we obtain the transition probabilities for the control group, which are 77% and 4% for the incidence rate and the recovery rate respectively. On the other hand, we use a relative risk of COPD-related death of 1.98 for the control group, obtained from a report by the World Health Organisation (Shibuya, Mathers, & Lopez, 2001)[7]. The values for the intervention group are constructed using the annual mortality rates collected during the U4H study (Table 1).

[2] http://united4health.eu/
[3] Chronic Obstructive Pulmonary Disease
[4] Congestive Heart Failure
[5] https://www.sergas.es/
[6] Kidholm, K., Pedersen, C. D., Jensen, L. K., Ekeland, A. G., Bowes, A., Flottorp, S., & Bech, M. (2012). A model for assessment of telemedicine applications – MAST. International Journal of Technology Assessment in Health Care, 28(1), 44–51.
[7] Shibuya, K., Mathers, C. D., & Lopez, A. D. (2001). Chronic obstructive pulmonary disease (COPD): Consistent Estimates of Incidence, Prevalence, and Mortality by WHO Region. Global Programme on Evidence for Health Policy. World Health Organization.

Computing the costs

The one-off costs related to the intervention include the costs of management, education and training, estimated to be 7€ per patient. On the other hand, the recurring costs comprise the costs related to the telehealth services, including the rent of telemedicine devices, and those related to the staff, which gives a total annual cost of 147€/patient. The project estimated the healthcare costs which covered GP visits, Emergency Department (ED) visits, and outpatient visits. Those in the baseline health state had higher costs related to outpatient visits and to GP visits, but lower costs related to ED visits. On the other hand, the costs related to admissions to the hospital are zero, by definition, in the baseline health states. The costs for the deteriorated state are based on the average number of admissions during treatment of patients in the deteriorated state (intervention group) and the mean of admissions in the 12 months before the implementation of the telehealth services for those that were initially in the deteriorated state (control group) (Table 1). Societal costs would include time used by patients and relatives, but this was not calculated in U4H. Therefore, in this case societal costs are equivalent to healthcare costs.

Utility

Table 1 also shows the value for utility. The EQ-5D for the deteriorated state are obtained from a similar project undertaken in Spain (Jódar-Sánchez et al., 2014)[8]. The improvement in utility for the intervention group is calculated through the COPD Assessment Test (CAT) [9] used in the U4H project.

Table 1. Input data used to populate the MAFEIP model

	Control Group	Intervention Group
Transition Probabilities		
Incidence	77%	48.6%
Recovery	4%	12.5%
Relative Risk		
Baseline State	1.98	0.88
Deteriorated State	1.98	2.20
Costs		
One-off cost per patient (Intervention)	-	7€
Recurring cost per patient/year (Intervention)	-	147€
Healthcare cost – Baseline	0€	746€
Healthcare cost – Deteriorated	18,979€	17,741€
Societal cost – Baseline	0€	746€
Societal cost – Deteriorated	18,979€	17,741€
Utility		
Baseline State	0.55	0.58
Deteriorated State	0.49	0.52

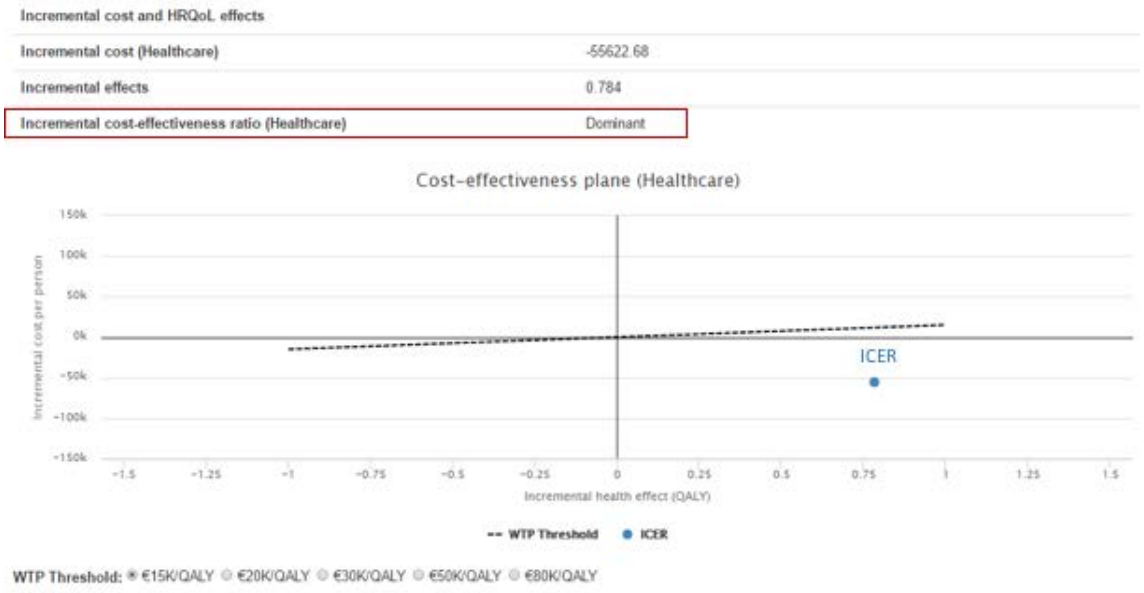
Model output

The figure below shows the overall impact of the intervention on the costs and effects of the whole target population. The incremental cost-effectiveness ratio (ICER) is located in the lower-

[8] Jódar-Sánchez, F., Ortega, F., Parra, C., Gómez-Suárez, C., Bonachela, P., Leal, S., … Barrot, E. (2014). Cost-utility analysis of a telehealth programme for patients with severe chronic obstructive pulmonary disease treated with long-term oxygen therapy. Journal of Telemedicine and Telecare, 0(0), 1–10.
[9] http://www.catestonline.org/

right quadrant. This means that the U4H treatment is dominant (i.e. both cheaper and more effective than the current care option), and that its implementation would be acceptable. The same figure shows that the savings per patient in the intervention compared to usual care amount to 55,622.68€.

Figure 1. Cost-effectiveness



1. Description of the intervention

The **United4Health** project[10], UNIversal solutions in TElemedicine Deployment for European HEALTH care (U4H), tested telehealth services targeting the three main chronic diseases found among the EU population: diabetes, COPD[11], and CHF[12]. Concretely, the 3 services offered were: life–long management of diabetes, short-term follow-up after hospital discharge for COPD patients, and remote monitoring of congestive heart failure. This case covers the telehealth service **for patients living with COPD**, which has the aim to provide an alternative way to support self-management through the provision of an appropriate level of tele-monitoring that is flexible and can respond with fluctuations in their health status and thus avoid future emergency hospital admissions due to a COPD exacerbation. The project aims at assessing the benefits that the tele-monitoring service can bring to patients suffering from this condition, their informal carers, and healthcare professionals, as well as the return on investment that it can provide to health authorities and health insurers.

United4Health included a total of 13 trial sites across Europe, but the COPD service was deployed in six of them: Wales and Scotland in the UK; Galicia in Spain; Berlin in Germany; and both North and South Norway. This use case focuses on the trial from **Galicia** implemented by SERGAS[13], the regional health department. The age of the participants in this pilot ranged from 34 to 86 years. The service targets both males and females, but most participants were males (90.3%). Participants were people who had been hospitalised for exacerbation of COPD and most of them indicated that they had co-morbidities. The most prevalent were diabetes (22%), a tumour (17%), atrial fibrillation and flutter (14%), peripheral vascular disease (13%), and anxiety/depression (12%).

The U4H **treatment** includes 3 phases, corresponding to three levels of intensity of tele-monitoring. The patient admitted with a COPD exacerbation is discharged from hospital and provided with a tele-monitoring package including video conferencing and a pulse oximeter. In the first phase (High Level TMon) there is daily teleconsultation with the GP nurse (via video-consultation or telephone if not possible). The patient answers the symptom management questions and records their pulse oximetry reading, which are uploaded prior to the teleconsultation. This phase is supposed to last approximately 10 working days, but its duration can range from 5 to 30 days, depending on the decision of the clinician. Moreover, if there are worrying clinical features, the patient can be referred for physician assessment and, depending on the conditions, the person can be readmitted to hospital. In this case, they remain within the study and are discharged again with High Level TMon. In the moderate level, the patients updates daily the pulse oximetry and symptom questions for up to 12 weeks (minimum of 4 weeks) after discharge. The GP nurse receives this data and responds to any alerts and seeks advice from the GP and hospital specialists as required. Finally, in the low level tele-monitoring, there are optional symptom management questions and text message behaviour prompts or website links sent to a mobile phone for up to 12 months after discharge. In total, the intervention and follow-up duration (including the three intensity levels of tele-monitoring) for an individual patient can last a maximum of 12 months (and a minimum of three), based on the treating physician's prescription.

[10] http://united4health.eu/
[11] Chronic Obstructive Pulmonary Disease
[12] Congestive Heart Failure
[13] https://www.sergas.es/

The evaluation was conducted using the MAST multidimensional evaluation methodology (Kidholm et al., 2012)[14]. The study had an observational design, with intervention and comparator groups. The comparator group consisted of patients, different from those in the intervention group, who fulfilled the eligibility criteria and had been treated and followed for at least one year before the implementation of the telehealth service, from the same health units as the intervention group. Patients in the **comparator group** received usual care. Usual care is undertaken by the patients themselves supported predominantly by their GP and GP nurse who do home visits depending on the patient's health status. Clinical information is recorded in the shared EHR. Patients can have scheduled appointments to review their treatment and self-management plan. If necessary, they can be referred to medical and nursing COPD specialists. Eight success indicators were assessed: hospital admissions, access to emergency room, GP consultations, total cost of treatment, acceptance, organisational changes, non-participation reasons, and differences in clinical outcomes. The intervention is currently in routine use because SERGAS has integrated the tele-monitoring as one of the treatments available upon discharge.

2. Model input

2.1. Defining the health states and the transition probabilities

The definition of states is based on the primary outcome of the intervention, the number of admissions for exacerbation of COPD. First, we look at the number of admissions for exacerbation of COPD in the 12 months preceding the start of the intervention, in order to examine the distribution between states before the implementation. *Baseline health* is defined as not having been admitted to the hospital in the last 12 months, except for the admission that caused the start of the treatment, which is an eligibility criteria to enter the study. On the other hand, having had at least one additional admission is considered as belonging to the *deteriorated health state*.

Among the patients in the intervention group in Galicia, 70 were in the baseline and 56 in the deteriorated state before the implementation of the services. At the end of the treatment, 34 had moved from the baseline to the deteriorated state, and 7 had done the opposite. Therefore, the incidence rate for the intervention group is **48.6%** and the recovery rate **12.5%.** The project evaluation for the whole COPD sample (including all pilots) estimated the probability of being re-admitted to hospital due to COPD. They used a logistic regression analysis controlling by gender, smoking, age, and admissions in the 12 months preceding the start of the treatment. The results revealed that the comparator patients were 3.6 times more likely to be hospitalised (odds ratio) than those receiving tele-monitoring for the duration of the study ($p<0.05$). Using this value, assuming that patients in the control group have the same initial distribution than those in the intervention group, and converting the odds ratio to probabilities, we obtain the transition probabilities for the control group, which are **77%** and **4%** for the incidence rate and the recovery rate respectively.

[14] Kidholm, K., Pedersen, C. D., Jensen, L. K., Ekeland, A. G., Bowes, A., Flottorp, S., & Bech, M. (2012). A model for assessment of telemedicine applications – MAST. International Journal of Technology Assessment in Health Care, 28(1), 44–51.

Table 2. Transition probabilities

	Period 0[15]		End of intervention		Transition probabilities	
			Baseline	Deteriorated		
Intervention group	Baseline	70	36	**34**	48.6%	Incidence Rate
	Deteriorated	56	**7**	49	12.5%	Recovery Rate
Control group	Baseline	70	16	**54**	77%	Incidence Rate
	Deteriorated	56	**2**	54	4%	Recovery Rate

The **risk for mortality** for people with COPD may be higher than for the general population. A report from the World Health Organisation estimated the relative risks of COPD-related death by age and sex (Shibuya, Mathers, & Lopez, 2001)[16]. The one for the EURO A region, where Spain belongs, for males aged 60-69[17] was **1.98**. We will use this as the value for the control group and for both states since it does not differentiate by severity.

The values of the intervention are based on the results of the U4H study, which calculated the annual mortality rates. The data from Galicia shows that from those that started the intervention in the baseline health state (202[18]), 6 deceased, which represents a 2.97%. From those that started the intervention in the deteriorated health state (135), 10 deceased, which represents a 7.41%. The annual mortality rates should be transformed into the relative risk ratio (RR), which is the mortality rate of the studied population compared to a reference mortality rate. Considering as the reference mortality rate the value extracted from the control group, we get a RR of **2.2** for the intervention group, deteriorated state; and of **0.88** for the intervention group, baseline state (Table 2).

Table 3. Mortality

	Control	Intervention
Baseline	1.98	0.88
Deteriorated	1.98	2.20

2.2. Computing the costs

The one-off costs refer to the investment in the telemedicine application. These include the physical change of buildings, the technical infrastructure, and the training for the staff. This is computed at group level and later divided in order to get the cost per patient. In Galicia, the end-to-end telehealth solution was leased on a monthly cost per patient irrespective of the length of time the patient required tele-monitoring as part of their care plan (thus, this is included in the recurring costs). Therefore, the investment in the technical solution and the technical infrastructure are zero. For future deployment, patients will probably have their own smartphone or tablet and pulse oximeter. The costs of management, education and training were estimated to be **7€** per patient.

[15] Period 0 refers to the period before the implementation of U4H.
[16] Shibuya, K., Mathers, C. D., & Lopez, A. D. (2001). Chronic obstructive pulmonary disease (COPD): Consistent Estimates of Incidence, Prevalence, and Mortality by WHO Region. Global Programme on Evidence for Health Policy. World Health Organization.
[17] This is more representative of our sample: the mean age is 67 years old and most participants are male.
[18] In order to calculate mortality we use as reference point the number of those who started the treatment, not of those who finalised it, as was the case in the previous table.

The recurring costs include several items: time used by staff at the call centre, tele-consultations, rent of telemedicine devices, staff time used by home care nurse, time used by relatives. This is computed at patient level. In Galicia, the costs related to the telehealth services were 72€ per patient and those related to the staff 75€. This gives a total annual cost of **147€/patient**.

Table 4. Intervention costs (one-off)

Intervention one-off costs (per patient)	
Devices	0
Technical infrastructure, software, etc.	0
Management, education, training	7
TOTAL	7

Table 5. Intervention costs (recurring)

Intervention recurring costs (per patient)	
Telehealth devices	72
Staff	75
TOTAL	147

The final evaluation report of the project includes the healthcare costs for Galicia. It was estimated that the intervention increased the cost per patient of GP visits by 200€, the cost of Emergency Department (ED) visits by 225€, and the cost of outpatient visits by 166€. We calculated the differences in these costs between the baseline and deteriorated states, which revealed that those in the baseline had higher costs related to outpatient visits (71€) and to GP visits (84€), but lower costs related to ED visits (-213€). We add these differences to the values previously mentioned[19] in order to get the final values that appear in Table 5. The costs related to admissions to the hospital are zero, by definition, in the baseline health states. For the deteriorated state in intervention we calculate the mean of admissions during treatment of patients in this state (1.89). For the control group, we use the average number of admissions in the 12 months before the implementation of the telehealth services, for those that were initially in the deteriorated state (2.12). Both numbers were multiplied by the cost per admission to hospital (8,942). Societal costs would include time used by patients and relatives, but this was not calculated in U4H. Therefore, in this case societal costs are equivalent to healthcare costs.

[19] These are added to the baseline or the deteriorated states depending on which of them is more expensive

Table 6. Healthcare Costs (per patient and year in €)

Control Group baseline health	
Cost of hospital admissions	0
TOTAL	**0**
Control Group deteriorated health	
Cost of hospital admissions	18,979
TOTAL	**18,979**
Intervention Group baseline health	
Costs of GP visits	284
Costs of ED visits	225
Costs of outpatient visits	237
Cost of hospital admissions	0
TOTAL	**746**
Intervention Group deteriorated health	
Costs of GP visits	200
Costs of ED visits	438
Costs of outpatient visits	166
Cost of hospital admissions	16,937
TOTAL	**17,741**

2.3. Utility

MAFEIP recommends using EQ-5D to calculate utility, but U4Health did not use this questionnaire. However, the EQ-5D was computed in a similar project undertaken Spain, a cost-utility analysis of a telehealth programme for patients with severe COPD (Jódar-Sánchez et al., 2014)[20]. These values were calculated for the group testing the telehealth programme (intervention) and for those in the control group. Utility was calculated at baseline and at 4 months (thus, the annual improvement could be higher). People in the control group started with higher values, which could undermine the effect of the intervention. In order to address this issue, we focused on the double difference, this is the difference between the improvement in the intervention and the improvement in the control group. This gives an increase in utility of **0.03** for those in the intervention. The average utility for the whole sample before the implementation of the telehealth programme was **0.49**, which we use for the control group. Adding to this the estimated increase in utility for the intervention (0.03), we obtain the value of **0.52** for the intervention group. We input these values in the deteriorated state because the participants in the study had severe COPD.

The U4H project used the COPD Assessment Test (CAT) [21], which is composed by 8 items ranging from 0 to 5, being 5 the one in which the person has more difficulties. The total CAT score in Galicia was computed at baseline, and we use this to estimate the differences in utility between the two health states. The average CAT for those in the baseline health state was **17.21** and for the deteriorated **19.24**. Mapping these values into the 0-1 range and inverting them, gives 0.57 and 0.51 respectively. Thus, the difference between states is 0.06, which we add to the values in the deteriorated state for both groups (Table 6).

Table 7. Utility

	Control	Intervention
Baseline	0.55	0.58
Deteriorated	0.49	0.52

[20] Jódar-Sánchez, F., Ortega, F., Parra, C., Gómez-Suárez, C., Bonachela, P., Leal, S., … Barrot, E. (2014). Cost-utility analysis of a telehealth programme for patients with severe chronic obstructive pulmonary disease treated with long-term oxygen therapy. Journal of Telemedicine and Telecare, 0(0), 1–10.
[21] http://www.catestonline.org/

3. Model output

The figure below shows the incremental costs by age. They are negative, implying that the U4H intervention brings savings, as it is cheaper than usual care. Moreover, the intervention is also more effective, with the incremental Quality-adjusted life years (QALYs)[22] ranging from 0.474 to 1.97 depending on age, gender and discount rate (Figure 2). Both things place the incremental cost-effectiveness ratio (ICER)[23] in the lower-right quadrant (Figure 3). This means that the U4H treatment is dominant (i.e. both cheaper and more effective than the current care option), and that its implementation would be acceptable. The same figure shows that the savings per patient in the intervention compared to usual care amount to 55,622.68€.

Figure 2. Incremental cost by age

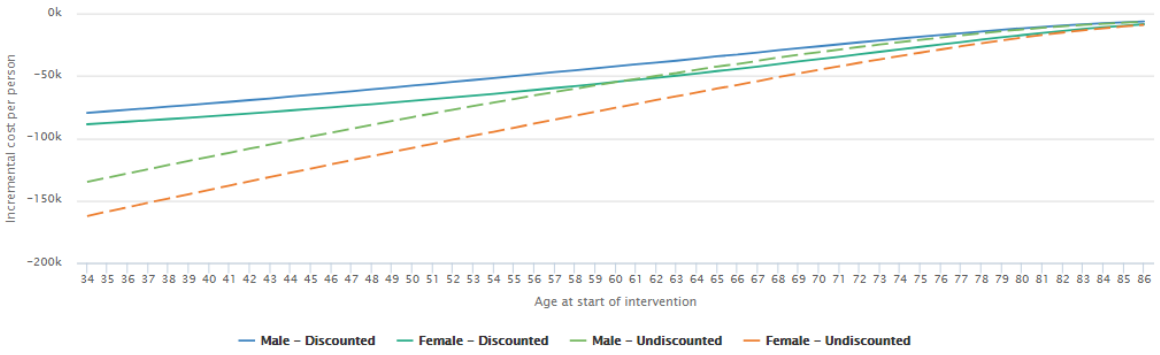
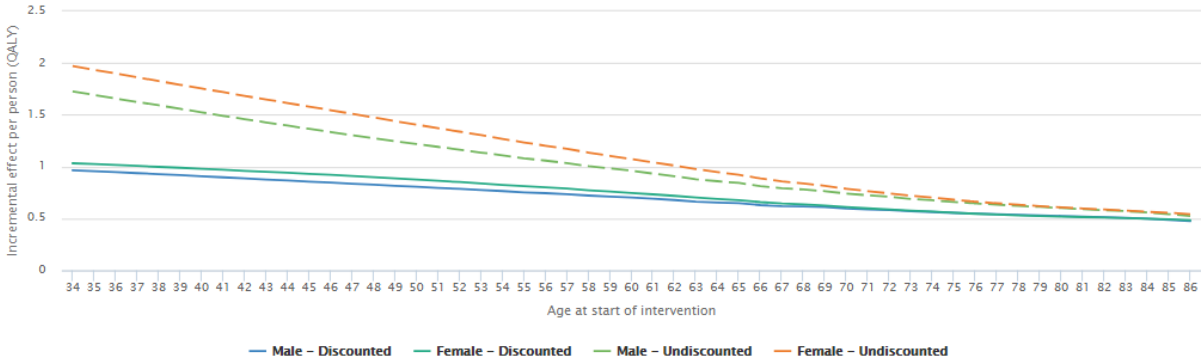


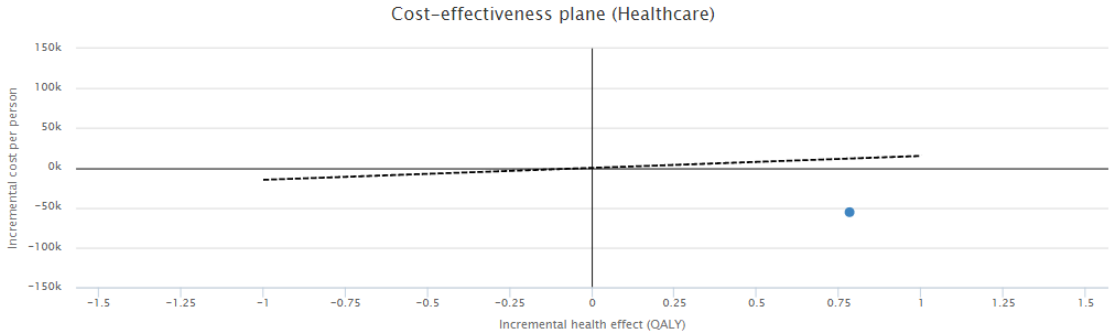
Figure 3. Incremental effects by age



[22] https://www.nice.org.uk/glossary?letter=q
[23] This is the ratio between incremental costs and incremental effects.

Figure 4. Cost-effectiveness plane (healthcare costs)

Incremental cost and HRQoL effects	
Incremental cost (Healthcare)	-55622.68
Incremental effects	0.784
Incremental cost-effectiveness ratio (Healthcare)	Dominant

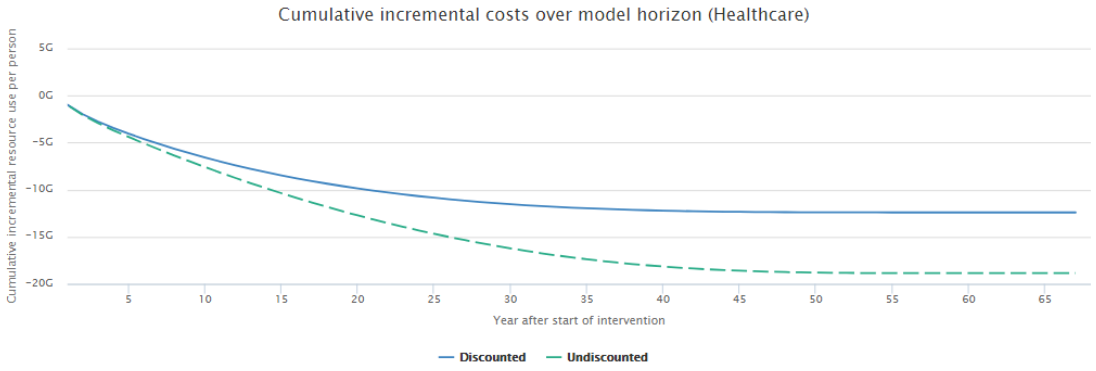


WTP Threshold: €15K/QALY €20K/QALY €30K/QALY €50K/QALY €80K/QALY

The following figures show the cumulative costs and effects for a population of 223,085 (the population of Galicia multiplied by the prevalence of COPD in the region, which represents the target population of U4H). Savings (negative costs) and effects increase yearly until approximately 35 years after the start of the intervention when the lines are rather flat (looking at the discounted values[24]).

Figure 5. Cumulative incremental costs

Population-level impact	Population: 223085 Reset
Population-level impact on incremental cost (Healthcare)	-12408585783.75
Population-level impact on incremental HRQoL	174984.86



[24] The discount rate is 3% for both costs and effects.

Figure 6. Cumulative incremental effects

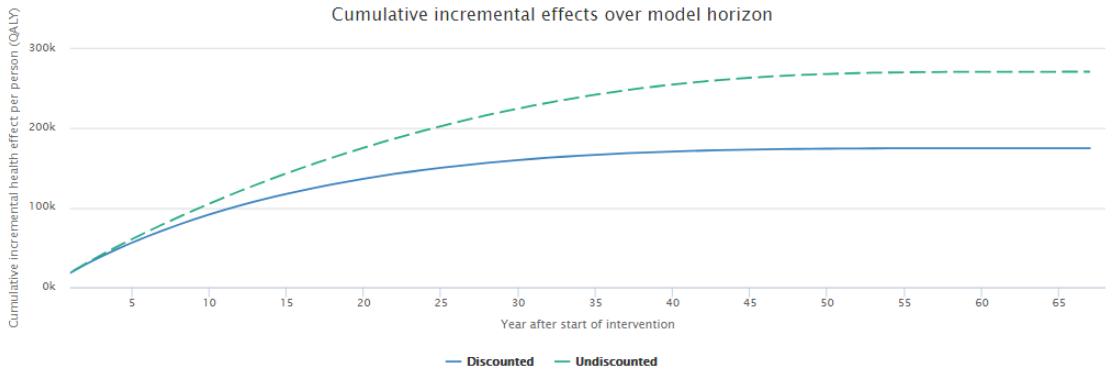


Figure 6 shows the flow of a reference person (in this case a 34 years old male) between the baseline and the deteriorated states through his lifetime. This person has a high probability of spending time in the deteriorated state because, as explained above, the incidence rates are large. Nonetheless, this probability is lower if the patient is treated with the telehealth service (intervention). As the patient becomes older, the probability of moving to the dead state increases (Figure 7).

Figure 7. Patient flow through model states (Alive states)

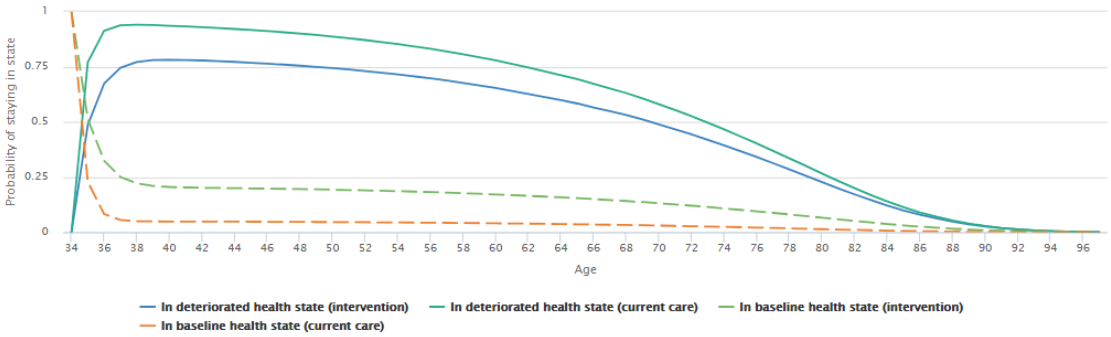
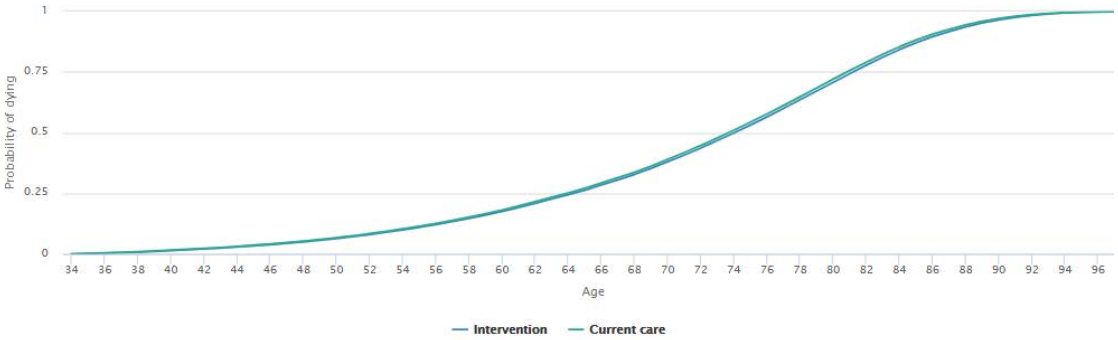


Figure 8. Patient flow through model states (Dead state)



The **sensitivity analysis** allows us to assess how the output varies when one parameter changes. Since, it is possible that mortality was underestimated (due to lack of information on some of the drop-outs), we test what happens when we increase the RR in the baseline health for the intervention group (from 0.88 to 2.00). As Figure 8 shows, the ICER remains in the dominant quadrant, hence, the intervention is still regarded as cost-effective. On the other hand, a large

increase in the costs of the intervention (from 147 to 4,000€), hypothetically caused by technical issues or and underestimation of the costs could move the ICER to the upper-right quadrant (Figure 9), where cost-effectiveness depends on the willingness to pay (WTP). In this case, the solution would be anyway acceptable because the ICER is below the WTP threshold.

Figure 9. Univariate sensitivity analysis with a change in the relative risk of mortality in baseline health for the intervention group

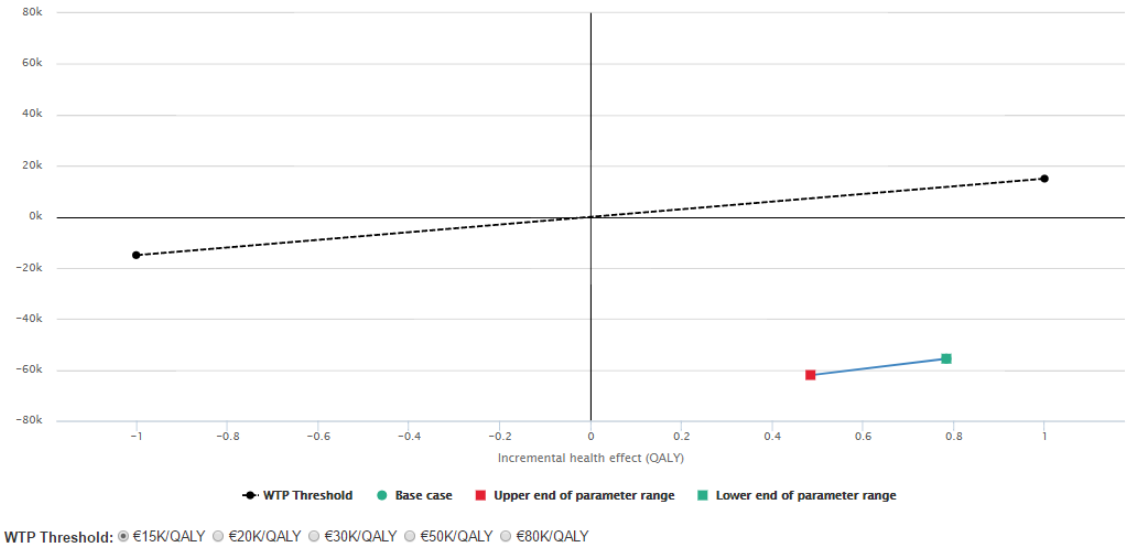
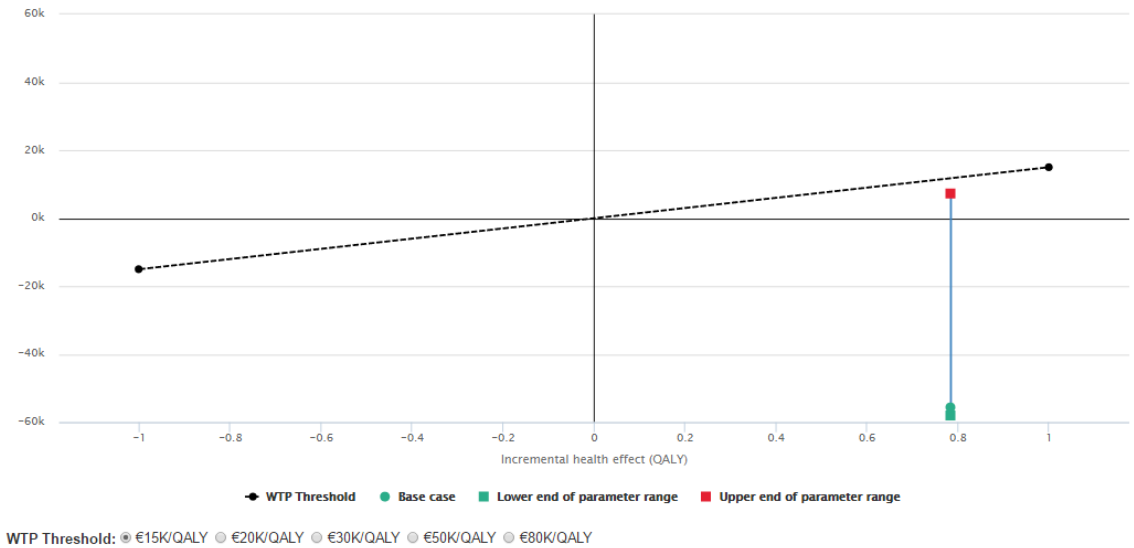


Figure 10. Univariate sensitivity analysis with a change in intervention costs



The figures below show how a change in several parameters affect the incremental costs (Figure 10) and the incremental effects (Figure 11), when applying a ±10% change in the main parameters. The element that has a larger impact on costs is clearly the healthcare costs in the deteriorated state, probably due to the high costs of hospital admissions (which are characteristic of this health state). On the contrary, the impact of the healthcare costs in the baseline health, where there are no hospital admissions, is very small. Utility in the deteriorated state (where the

population spends a larger amount of time), is the element that has a higher impact on incremental effects.

Figure 11. Parameter impact on incremental costs

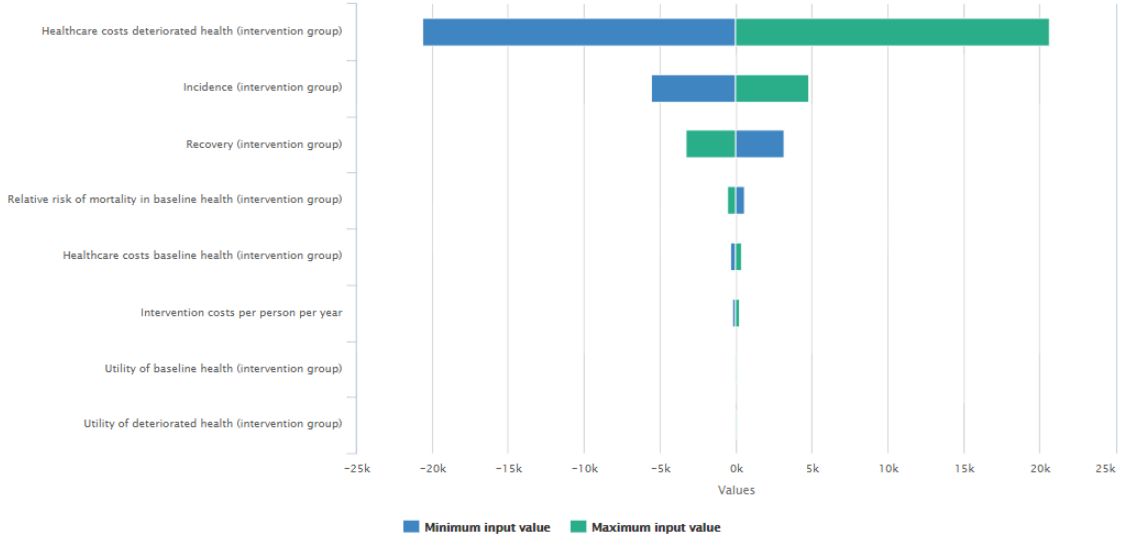
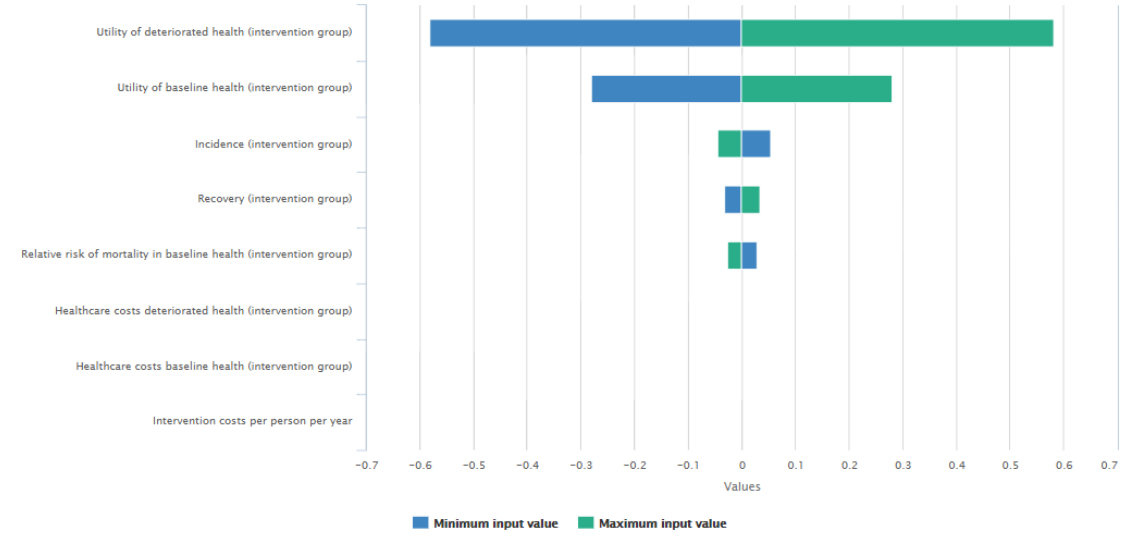


Figure 12. Parameter impact on incremental effects



4. Lessons learned

This section summarises the main difficulties we have encountered in adapting the intervention performed in United4Health to the Markov model used in MAFEIP. These difficulties are detailed below:

- The tool does not allow to input negative numbers in the costs related to the intervention, which would indicate savings. If the costs are recurring this can be solved by adding the value in the section for the healthcare cost for the control group.
- In order to identify the parameters for mortality and utility, it was convenient to use input from relevant articles in the scientific literature.

These lessons learned can be applied for the further development of the MAFEIP tool.