

Evidence from pilot application from selected therapeutic areas



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Report Details	
Project Title	Improved methods and actionable tools for enhancing HTA
Project Acronym	IMPACT HTA
Grant Number	779312
Start Date	1 January 2018
End Date	30 June 2021
Report Date	31 May 2021
Contributing WP and Deliverable	9; D9.2
Dissemination level	Public
No. of Pages	13

Authors

Organisation	Name
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Executive summary

This report constitutes deliverable D9.2 of WP9 of the IMPACT HTA project.

Work Package 9 (WP9) has focused on an area where use of economic evaluation for HTA is not used and valued, as we focus a lot on choices based on expense items or at most indirect costs. The overarching objective of this WP is to define a consistent methodology to incorporate fiscal impact in economic evaluations, focusing on productivity gains, consumption increases and potential tax revenues, deriving from health gains of new healthcare interventions.

The ambition of WP9 is to establish a standardized method to assess the fiscal impact deriving from health gains (i.e. consumption increases, productivity gains) in order to support decision-making for pricing and reimbursement of new drugs, vaccines, and other health technologies by providing an integrated view of the economic and social impact of new healthcare interventions. In doing so, it will take a public decision maker perspective into account when assessing new technologies. While some evidence exists in this field, this remains sporadic and heterogeneous. The WP will propose and validate a replicable methodology, coupled with an algorithm and simple software that can be used immediately by decision-makers in Europe and beyond.

We built an algorithm for the estimation of the fiscal impact of new technologies. The development of the algorithm is based on results from a systematic literature reviews, multiple interviews and case studies.

We used the algorithm for the estimation of the fiscal impact (algorithm) for medical technologies involving in different diseases/ therapeutic areas. Setting/ Area:

- Patients with Type 2 Diabetes in Italy;
- Ostomy and continence care in Italy.

First setting: Type 2 diabetes (T2D)

Type 2 diabetes (T2D) represents, worldwide, 90% of cases of diabetic pathology (ISS, 2020), with an estimated prevalence of about 5% (AMD, 2018).

Diagnosis is usually quite late, more commonly after the *age of 40* (AMD, 2018) and can occur randomly or at the time of the onset of *complications* or stressful situations that make it evident.

According to the latest data presented in the Osservasalute Report, 2018 Edition (Osservasalute, 2019), in Italy, the disease affects 5.7% of the population, with over 90% represented by cases of DM2.

Slightly higher is the prevalence of diabetes reported in the latest ARNO Report, Edition 2019, equal to 6.2% (ARNO, 2017).

Hospitalizations cause hard productivity losses. Easy to associate hospitalizations with days of absence from work -> *good field to investigate the fiscal impact.*

In order to estimate the fiscal impact of type 2 diabetes in Italy, a questionnaire was developed to investigate the current scenario of type 2 diabetes in Italy. The questionnaire involved a representative sample of the population with type 2 diabetes and has 132 total respondents.

The analysis focuses on a population of working age.

The average age of the respondents is 53 years:

- male gender (60%);
- female gender (40%).
- The level of education among the respondents to the survey is characterized as follows:
- 36% have a high school diploma;
- 28% have obtained a degree;
- 26% had a primary and / or secondary education diploma;
- 9% obtained a post-graduate training qualification (Master, PhD,...).

Our model estimates that, based on 3 million people with T2D per year, the current fiscal impact and social costs associated are EUR 205 million and EUR 2.99 billion, respectively.

The implementation of a specific home telehealth programme able to increase the adherence to the treatments in the target population, reducing the incidence of the hospitalizations (-18%) resulting in a reduction of the number of infected people by 500,000 would result in a decrease in

productivity loss of EUR 172 million and an increase in tax revenue of nearly EUR 1.6 million in the first year.

Table 1 - Baseline scenario results (T2D)

MEAN AGE	NUMBER OF PATIENT	FISCAL IMPACT	SOCIAL COSTS	TOTAL (FISCAL IMPACT + SOCIAL COSTS)	INCREASE IN TAX REVENUE (CUMULATIVE)	DECREASE IN PRODUCTIVITY LOSS (CUMULATIVE)
53	3,059,608	€ 205,764,143.31	€ 2,996,295,842.97	€ 3,202,059,986.28		
54	2,508,879	€ 204,163,926.05	€ 2,823,784,918.69	€ 3,027,948,844.73	€ 1,600,217.26	€ 172,510,924.29
55	2,057,281	€ 167,414,419.36	€ 2,315,503,633.32	€ 2,482,918,052.68	€ 38,349,723.95	€ 680,792,209.65
56	1,686,970	€ 137,279,823.87	€ 1,898,712,979.33	€ 2,035,992,803.20	€ 68,484,319.43	€ 1,097,582,863.65
57	1,383,316	€ 112,569,455.58	€ 1,556,944,643.05	€ 1,669,514,098.62	€ 93,194,687.73	€ 1,439,351,199.93
58	1,134,319	€ 92,306,953.57	€ 1,276,694,607.30	€ 1,369,001,560.87	€ 113,457,189.73	€ 1,719,601,235.67
59	930,141	€ 75,691,701.93	€ 1,046,889,577.98	€ 1,122,581,279.91	€ 130,072,441.38	€ 1,949,406,264.99
60	762,716	€ 62,067,195.58	€ 858,449,453.95	€ 920,516,649.53	€ 143,696,947.72	€ 2,137,846,389.02
61	625,427	€ 50,895,100.38	€ 703,928,552.24	€ 754,823,652.61	€ 154,869,042.93	€ 2,292,367,290.74
62	512,850	€ 41,733,982.31	€ 577,221,412.83	€ 618,955,395.14	€ 164,030,161.00	€ 2,419,074,430.14
63	420,537	€ 34,221,865.49	€ 473,321,558.52	€ 507,543,424.02	€ 171,542,277.81	€ 2,522,974,284.45
64	344,840	€ 28,061,929.71	€ 388,123,677.99	€ 416,185,607.69	€ 177,702,213.60	€ 2,608,172,164.98
65	282,769	€ 23,010,782.36	€ 318,261,415.95	€ 341,272,198.31	€ 182,753,360.95	€ 2,678,034,427.02

A multi-way bootstrap analysis is conducted in order to investigate the variability and the generalizability of the results. One-thousand iterations are performed where all the covariates of the model are subject to a resampling procedure assuming a normal distribution.

One-way bootstraps are performed in order to observe the elasticity of the fiscal impact estimation according to the variation of age and number of episodes.

In all bootstrap simulations 10th, 25th, 50th, 75th and 90th percentiles are presented in tabular format.

Table 2 - Bootstrap analyses (T2D)

MEAN AGE	FISCAL IMPACT (BASE CASE)	10TH percentile	25TH percentile	50TH percentile	75TH percentile	90TH percentile
53	€ 205,764,143.31	€ 153,024,671.31	€ 178,006,982.18	€ 205,764,143.31	€ 233,521,304.43	€ 258,503,615.30
54	€ 204,163,926.05	€ 151,834,606.24	€ 176,622,630.95	€ 204,163,926.05	€ 231,705,221.14	€ 256,493,245.86
55	€ 167,414,419.36	€ 124,504,377.11	€ 144,830,557.38	€ 167,414,419.36	€ 189,998,281.34	€ 210,324,461.60
56	€ 137,279,823.87	€ 102,093,589.23	€ 118,761,057.05	€ 137,279,823.87	€ 155,798,590.70	€ 172,466,058.52
57	€ 112,569,455.58	€ 83,716,743.17	€ 97,384,066.78	€ 112,569,455.58	€ 127,754,844.37	€ 141,422,167.98
58	€ 92,306,953.57	€ 68,647,729.40	€ 79,854,934.76	€ 92,306,953.57	€ 104,758,972.38	€ 115,966,177.75
59	€ 75,691,701.93	€ 56,291,138.11	€ 65,481,046.50	€ 75,691,701.93	€ 85,902,357.36	€ 95,092,265.75
60	€ 62,067,195.58	€ 46,158,733.25	€ 53,694,458.13	€ 62,067,195.58	€ 70,439,933.03	€ 77,975,657.92
61	€ 50,895,100.38	€ 37,850,161.26	€ 44,029,455.67	€ 50,895,100.38	€ 57,760,745.09	€ 63,940,039.49
62	€ 41,733,982.31	€ 31,037,132.24	€ 36,104,153.65	€ 41,733,982.31	€ 47,363,810.97	€ 52,430,832.38
63	€ 34,221,865.49	€ 25,450,448.43	€ 29,605,405.99	€ 34,221,865.49	€ 38,838,325.00	€ 42,993,282.55
64	€ 28,061,929.71	€ 20,869,367.72	€ 24,276,432.91	€ 28,061,929.71	€ 31,847,426.50	€ 35,254,491.69
65	€ 23,010,782.36	€ 17,112,881.53	€ 19,906,674.99	€ 23,010,782.36	€ 26,114,889.73	€ 28,908,683.19

In all bootstrap simulations 10th, 25th, 50th, 75th and 90th percentiles, the analysis demonstrates there are no substantial differences in terms of fiscal impact, considering different percentiles.

Second setting: Ostomy and continence care

An ostomy is an artificial opening that surgeons make in the abdomen of some patients. It allows waste materials to be transported out of the body. Depending on the type of ostomy, an organ is connected to the opening (also called a stoma) so that other organs can be skipped in the waste removal system.

Intermittent catheterization (IC) is the emptying of the bladder using a thin disposable catheter and represents the treatment of choice in the rehabilitation of vertebra-medullary trauma as it allows adequate drainage of the urine with respect to the anatomical-functional integrity of the vesicourethral complex.

In the present analysis, regarding the IC we are considering only patients with vertebro-medullary injuries.

The ostomy patient population is made up of approximately 71,787 people, of which 55,794 are enterostomies and 15,993 urostomies (F.A.I.S., 2010).

From a demographic point of view, all age groups are affected, 62% of people are over 70, 35% are between 41 and 70 and only 3% of people are under 40. years. Regarding gender, *60% are men and 40% are women.*

The incidence of traumatic vertebro-medullary injuries, nationwide, is estimated at 20-25 new cases per year per million inhabitants (AGENAS, 2015). The ratio of males to females is 4:1 in traumatic injuries, while the average age at the time of the injury is 38 (median 34) years in the traumatic injury group (GISEM, 2000).

In order to estimate the fiscal impact of Ostomy and continence care in Italy, a questionnaire was developed to investigate the current scenario of Ostomy and continence care in Italy.

The questionnaire has 752 total respondents.

The average age of the respondents is 51 years:

The gender distribution is:

- male (67%);
- female (33%)

Our model estimates that, based on 100,000 people with Ostomy and continence care per year, the current fiscal impact and social costs associated are EUR 39 million and EUR 423 million, respectively.

Assuming a different percentage in the distribution methods of ostomy and incontinence devices in the Italian clinical setting, the implementation of a specific policy which increase in the 5% of the home distribution which affect the indirect costs in the target population resulting in a reduction of the number of infected people by 5,000 would result in a decrease in productivity loss of EUR 21 million and an increase in tax revenue of nearly EUR 1.9 million in the first year.

Table 3 - Baseline scenario results (Ostomy and continence care)

MEAN AGE	NUMBER OF PATIENT	FISCAL IMPACT	SOCIAL COSTS	TOTAL (FISCAL IMPACT + SOCIAL COSTS)	INCREASE IN TAX REVENUE (CUMULATIVE)	DECREASE IN PRODUCTIVITY LOSS (CUMULATIVE)
50	101,235	€ 38,937,879.79	€ 422,862,381.92	€ 461,800,261.71		
51	96,174	€ 36,990,985.80	€ 401,719,262.82	€ 438,710,248.63	€ 1,946,893.99	€ 21,143,119.10
52	91,365	€ 35,141,436.51	€ 381,633,299.68	€ 416,774,736.19	€ 3,796,443.28	€ 41,229,082.24
53	86,797	€ 33,384,364.69	€ 362,551,634.70	€ 395,935,999.38	€ 5,553,515.11	€ 60,310,747.22
54	82,457	€ 31,715,146.45	€ 344,424,052.96	€ 376,139,199.42	€ 7,222,733.34	€ 78,438,328.96
55	78,334	€ 30,129,389.13	€ 327,202,850.32	€ 357,332,239.44	€ 8,808,490.66	€ 95,659,531.60
56	74,417	€ 28,622,919.67	€ 310,842,707.80	€ 339,465,627.47	€ 10,314,960.12	€ 112,019,674.12
57	70,696	€ 27,191,773.69	€ 295,300,572.41	€ 322,492,346.10	€ 11,746,106.10	€ 127,561,809.51
58	67,162	€ 25,832,185.00	€ 280,535,543.79	€ 306,367,728.79	€ 13,105,694.79	€ 142,326,838.13

59	63,804	€ 24,540,575.75	€ 266,508,766.60	€ 291,049,342.35	€ 14,397,304.04	€ 156,353,615.32
60	60,613	€ 23,313,546.97	€ 253,183,328.27	€ 276,496,875.24	€ 15,624,332.82	€ 169,679,053.65
61	57,583	€ 22,147,869.62	€ 240,524,161.86	€ 262,672,031.47	€ 16,790,010.17	€ 182,338,220.06
62	54,704	€ 21,040,476.14	€ 228,497,953.76	€ 249,538,429.90	€ 17,897,403.65	€ 194,364,428.16
63	51,968	€ 19,988,452.33	€ 217,073,056.08	€ 237,061,508.41	€ 18,949,427.46	€ 205,789,325.84
64	49,370	€ 18,989,029.71	€ 206,219,403.27	€ 225,208,432.99	€ 19,948,850.08	€ 216,642,978.65
65	46,902	€ 18,039,578.23	€ 195,908,433.11	€ 213,948,011.34	€ 20,898,301.56	€ 226,953,948.81

One-way bootstraps are performed in order to observe the elasticity of the fiscal impact estimation according to the variation of age and number of episodes.

In all bootstrap simulations 10th, 25th, 50th, 75th and 90th percentiles are presented in tabular format.

Table 4 – Bootstrap analysis (Ostomy and continence care)

MEAN AGE	FISCAL IMPACT (BASE CASE)	10TH percentile	25TH percentile	50TH percentile	75TH percentile	90TH percentile
50	€ 38,937,879.79	€ 28,957,699.63	€ 33,685,239.63	€ 38,937,879.79	€ 44,190,519.95	€ 48,918,059.95
51	€ 36,990,985.80	€ 27,509,814.65	€ 32,000,977.65	€ 36,990,985.80	€ 41,980,993.96	€ 46,472,156.95
52	€ 35,141,436.51	€ 26,134,323.92	€ 30,400,928.76	€ 35,141,436.51	€ 39,881,944.26	€ 44,148,549.11
53	€ 33,384,364.69	€ 24,827,607.72	€ 28,880,882.33	€ 33,384,364.69	€ 37,887,847.05	€ 41,941,121.65
54	€ 31,715,146.45	€ 23,586,227.33	€ 27,436,838.21	€ 31,715,146.45	€ 35,993,454.69	€ 39,844,065.57
55	€ 30,129,389.13	€ 22,406,915.97	€ 26,064,996.30	€ 30,129,389.13	€ 34,193,781.96	€ 37,851,862.29
56	€ 28,622,919.67	€ 21,286,570.17	€ 24,761,746.48	€ 28,622,919.67	€ 32,484,092.86	€ 35,959,269.18
57	€ 27,191,773.69	€ 20,222,241.66	€ 23,523,659.16	€ 27,191,773.69	€ 30,859,888.22	€ 34,161,305.72
58	€ 25,832,185.00	€ 19,211,129.58	€ 22,347,476.20	€ 25,832,185.00	€ 29,316,893.81	€ 32,453,240.43
59	€ 24,540,575.75	€ 18,250,573.10	€ 21,230,102.39	€ 24,540,575.75	€ 27,851,049.12	€ 30,830,578.41
60	€ 23,313,546.97	€ 17,338,044.44	€ 20,168,597.27	€ 23,313,546.97	€ 26,458,496.66	€ 29,289,049.49
61	€ 22,147,869.62	€ 16,471,142.22	€ 19,160,167.41	€ 22,147,869.62	€ 25,135,571.83	€ 27,824,597.01
62	€ 21,040,476.14	€ 15,647,585.11	€ 18,202,159.04	€ 21,040,476.14	€ 23,878,793.24	€ 26,433,367.16
63	€ 19,988,452.33	€ 14,865,205.86	€ 17,292,051.09	€ 19,988,452.33	€ 22,684,853.57	€ 25,111,698.81
64	€ 18,989,029.71	€ 14,121,945.56	€ 16,427,448.53	€ 18,989,029.71	€ 21,550,610.90	€ 23,856,113.87
65	€ 18,039,578.23	€ 13,415,848.28	€ 15,606,076.11	€ 18,039,578.23	€ 20,473,080.35	€ 22,663,308.17

In all bootstrap simulations 10th, 25th, 50th, 75th and 90th percentiles, the analysis demonstrates there are no substantial differences in terms of fiscal impact, considering different percentiles.

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