Budget Impact Analysis of Gaucher Disease Pharmacologic Treatment in Colombia

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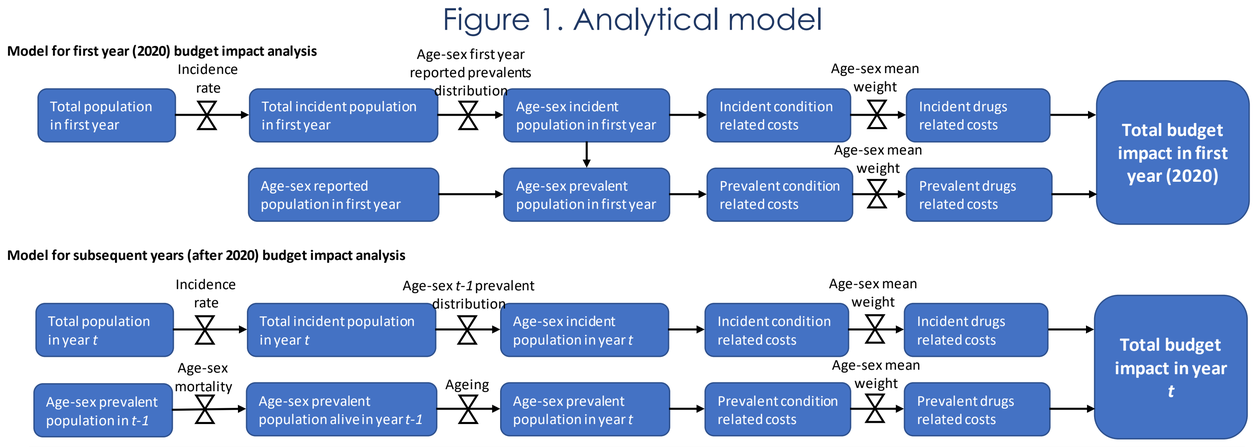
OBJECTIVE

Gaucher Disease is a rare disease in Colombia with a low prevalence. Nonetheless, healthcare treatment costs related to it remain high, representing a burden on the health system. This study developed a Budget Impact Analysis of including Enzyme Replacement Therapy - ERT (Imiglucerase, Taliglucerase, Velaglucerase) and Substrate Reduction Therapy - SRT (Eliglustat) for type I Gaucher Disease (GDI) from the health system perspective over a 3-year time horizon in enrolled Colombian population.

MODEL

A population model over age-sex mean weight was used to calculate drugs dose (dose depends on weight) through the modelled time-horizon. Incident population was determined through whole population incidence and afterwards distributed according to prevalence distribution as no age-sex incidence rates were available. Costs for incident population were calculated separately from prevalent as diagnostic related services are incurred only once. From total enrolled population in each year incident population was calculated. Costs for incident in each year were calculated and added to costs of prevalent. General age-sex population mortality was assumed at each age and sex. As reported prevalent contain incident during the first year, estimated age-sex incident in the first year were subtracted from age-sex prevalent reported population (in the first year), thus maintaining consistency in total reported population in the first period.

Figure 1. Analytical model



INPUTS

POPULATION

Total population for each year is obtained from Colombian health third-payer or state enrolled population from the Health Ministry's enrollee database *Base de Datos Única de Afiliados* (BDUA). Population living with the condition by age and sex, were obtained from prescriptions data in Colombia (no population data or estimates for Gaucher disease in Colombia were available). Incidence per year was calculated from Nalysnyk (2017) and adjusted using Pinto (2008). Mean weight, was calculated from the Demographic and Health Surveys (DHS) of 2005 for Colombia and Tocaruncho L. (2015) Colombia's Health Ministry technical report. General population age-sex probabilities of dying are obtained from an abridged life-table built from age-sex population projections in 2020 and deceased data in 2020 (vital statistics microdata) from the National Statistics Administrative Department (DANE) of Colombia. Linear interpolations between the abridged age-sex groups are applied to obtain probabilities for each age.

Table 1. Incidence and total enrolled population in each year

Year	Incidence per 1'000,000	Total enrolled population
2020	0.300	47,169,293
2021	0.300	48,478,768
2022	0.300	49,164,040

Table 2. Death probabilities by age-sex group

Age group	Female probability of dying	Male probability of dying
0	0.73%	0.90%
1-4	0.14%	0.18%
5-9	0.08%	0.11%
10-14	0.11%	0.17%
15-19	0.21%	0.61%
20-24	0.27%	1.05%
25-29	0.33%	1.13%
30-34	0.40%	1.15%
35-39	0.57%	1.26%

Age group	Female probability of dying	Male probability of dying
40-44	0.77%	1.49%
45-49	1.10%	1.91%
50-54	1.63%	2.76%
55-59	2.41%	4.22%
60-64	3.83%	6.76%
65-69	5.92%	10.30%
70-74	9.09%	15.71%
75-79	14.74%	23.72%
80-84	27.22%	37.71%

TREATMENT MIX

Treatment mix was determined from prescriptions data in Colombia (MiPres) from the Health Ministry, assuming population prescribed as the eligible population, as no Gaucher disease population data or estimates in Colombia were available. Treatment mix in each year was obtained by applying calculated trends of treatment mix from prescriptions data in each year.

Table 3. Treatment mix and changes through time

Drug	Year 1	% change year 2	% change year 3	Year 1	Year 2	Year 3
Imiglucerase	64.73%	3.44%	-1.58%	64.73%	66.96%	65.90%
Velaglucerase alfa	20.77%	-21.53%	-2.40%	20.77%	16.30%	15.91%
Taliglucerase alfa	9.66%	4.87%	16.31%	9.66%	10.13%	11.78%
Eliglustat	4.83%	36.78%	-3.08%	4.83%	6.61%	6.40%
Total	100%			100%	100%	100%

COSTS

Treatment related costs for each drug were obtained from Colombia's Health Ministry drugs system (SISMED). From this system, reported laboratory drugs sales, quantities and minimum, mean and maximum price were obtained, along with descriptions on dosage forms, drug concentration and drug units per product. Using this information, minimum units of concentration prices were obtained. From the latter, together with per patient expected dosage, costs were obtained in per patient per kilogram, as dosage depends on the individuals' weight (except for Eliglustat). Condition related costs were obtained from information provided from claims of insurers reported to the health ministry, from which estimates for interventions or medical procedures are given in Colombia during a specific year. For this study, data for 2020 was used.

Table 4. Treatment related costs per individual in each year

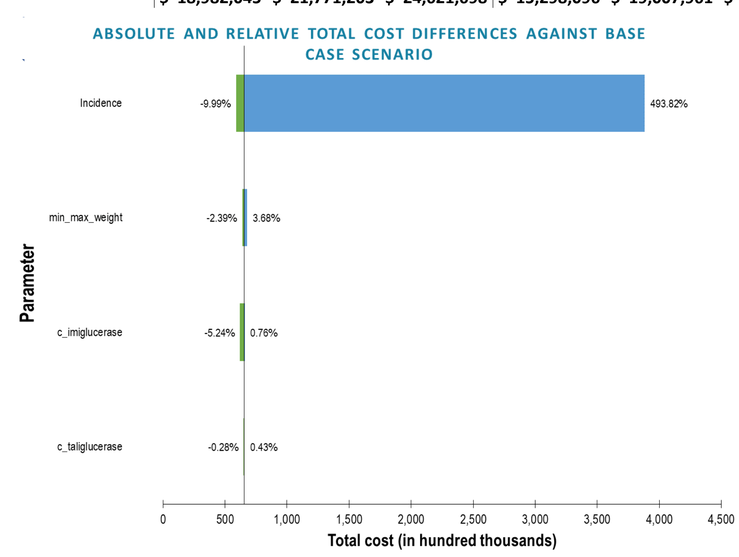
Active principle	Cost
Imiglucerase	$ 3,530 per Kg
Velaglucerase Alfa	$ 3,426 per Kg
Taliglucerase Alfa	$ 2,191 per Kg
Eliglustat	$ 104,825

Table 5. Condition related costs per individual in each year

Age group	Incident	Prevalent
Under 14 years old	$ 1,533	$ 1,441
14 to 17 years old	$ 1,537	$ 1,444
18 to 49 years old	$ 1,532	$ 1,448
Over 49 years old	$ 1,529	$ 1,444

RESULTS

	Base case scenario			Nalysnyk treatment mix change		
	2020	2021	2022	2020	2021	2022
Market share						
Imiglucerase	64.73%	66.96%	65.90%	38.84%	40.18%	39.54%
Velaglucerase Alfa	20.77%	16.30%	15.91%	12.46%	9.78%	9.55%
Taliglucerase Alfa	9.66%	10.13%	11.78%	9.66%	10.13%	11.78%
Eliglustat	4.83%	6.61%	6.40%	39.03%	53.39%	51.75%
Costs related to treatment						
Imiglucerase	$ 13,105,891	$ 15,720,602	$ 17,607,092	$ 7,863,535	$ 9,432,361	$ 10,564,255
Velaglucerase Alfa	$ 4,081,287	$ 3,713,592	$ 4,124,684	$ 2,448,772	$ 2,228,155	$ 2,474,811
Taliglucerase Alfa	$ 1,214,316	$ 1,476,704	$ 1,954,474	$ 1,214,316	$ 1,476,704	$ 1,954,474
Eliglustat	$ 450,695	$ 705,238	$ 768,662	$ 3,641,617	$ 5,698,321	$ 6,210,790
Total	$ 18,852,189	$ 21,616,136	$ 24,454,913	$ 15,168,240	$ 18,835,541	$ 21,204,330
Costs related to health condition						
Imiglucerase	$ 84,062	$ 99,388	$ 109,915	$ 50,437	$ 59,633	$ 65,949
Velaglucerase Alfa	$ 26,975	$ 30,833	$ 26,533	$ 16,185	$ 18,500	$ 15,920
Taliglucerase Alfa	$ 12,546	$ 15,039	$ 19,654	$ 12,546	$ 15,039	$ 19,654
Eliglustat	$ 6,273	$ 9,808	$ 10,682	$ 50,688	$ 79,249	$ 86,309
Total	$ 129,856	$ 155,068	$ 166,785	$ 129,856	$ 172,420	$ 187,832
Budget impact	**$ 18,982,045**	**$ 21,771,203**	**$ 24,621,698**	**$ 15,298,096**	**$ 19,007,961**	**$ 21,392,162**



CONCLUSIONS

The highest economic burden falls in treatment related costs due to medications costs and treatment mix. Considering Pichon-Riviere's suggested threshold for BIA technologies, these should not be financed using health plan payment resources (UPC). Finally, need for orphan diseases' data collection and availability would give more precise estimates for incidence.

REFERENCES

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