GLYCATED ALBUMIN FOR GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES: AN ITALIAN MULTI-DIMENSIONAL ANALYSIS

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Rational of the study

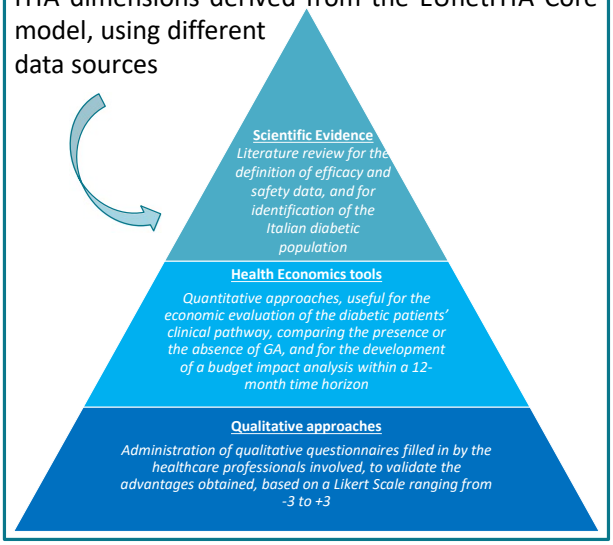
Glycated haemoglobin (HbA1c) is traditionally used to monitor the glycemic control in type 2 diabetes mellitus (T2DM)

Glycated albumin (GA) has emerged as an innovative glycaemic marker, differing from HbA1c because its values are not affected by changes in erythrocyte lifespan nor influenced by interfering conditions

This research activity aims at **defining the impacts of GA introduction, as an add-on marker to the traditional glycaemic monitoring systems**, within insulin naïve T2DM individuals, treated with oral therapies, and T2DM patients with chronic kidney disease (CKD), based on a multidimensional assessment

Methods

A Health Technology Assessment (HTA) was conducted in the two different settings, assuming the Italian NHS perspective and exploring the 9 HTA dimensions derived from the EUnetHTA Core model, using different data sources



Results

Insulin naïve T2DM individuals, treated with oral therapies

Italian eligible population: **1,955,447 individuals**

Efficacy (Shima et al., 2014)	Traditional Instruments	Traditional Instruments + GA
% of patients achieving a therapeutic success after 3 month of therapy	71.6%	97%

Budget Impact analysis	Traditional Instruments	Traditional Instruments + GA	Difference (%)
Clinical pathway of patients experiencing a therapeutic switch	301,455,531 €	429,735,156 €	42.55%
Clinical pathway of patients not experiencing a therapeutic switch	154,319,824 €	17,628,232 €	-88.58%
Total costs	**455,775,355 €**	**447,363,388 €**	**-1.85%**

Qualitative approaches	Traditional Instruments	Traditional Instruments + GA	p-value
Effectiveness	0.53	1.80	0.012
Safety	0.11	0.65	0.043
Equity Impact	0.72	0.13	0.244
Social and Ethical Impact	1.12	1.20	0.236
Legal Impact	0.75	0.29	0.225
Organizational Impact - 12 months	-0.01	-0.27	0.144
Organizational Impact - 36 months	0.01	0.30	0.175

T2DM patients with chronic kidney disease (CKD)

Italian eligible population: **89,960 individuals**

Efficacy (Inaba *et al.*, 2017)	Traditional Instruments	Traditional Instruments + GA
Capability to identify a worst glycemic control	19.2%	52%

Budget Impact analysis	Traditional Instruments	Traditional Instruments + GA	Difference (%)
Clinical pathway	169,727,532 €	163,989,883 €	-3.38%
Dialysis	3,707,817,448 €	3,707,817,448 €	0.00%
Hospitalization	87,594,052 €	66,321,210 €	-24.29%
Adverse events	124,172,687 €	65,587,137 €	-47.18%
Total costs	**4,089,311,720 €**	**4,003,715,679 €**	**-2.09%**

Qualitative approaches	Traditional Instruments	Traditional Instruments + GA	p-value
Effectiveness	1.02	2.12	0.018
Safety	1.01	1.60	0.043
Equity Impact	0.30	0.33	0.124
Social and Ethical Impact	0.44	0.68	0.349
Legal Impact	0.48	0.24	0.369
Organizational Impact - 12 months	0.02	-0.18	0.287
Organizational Impact - 36 months	0.05	0.26	0.230

Conclusions

Results demonstrated the strategic relevance of adding GA to traditional glycemic control instruments, in the optimization of T2DM patients glycaemic monitoring, leading to clinical, economic, and organizational advantages, considering both investigated clinical settings

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