EE532

Budget Impact Analysis of Hemoglobin A_{1c} and Lipid Panel Point-of-Care Testing with Afinion™ 2 in Italy and Canada

Garcia, David, MSc, MD[1]; Ruffolo, Antonio, MSc, MD[2]; Walczyk Mooradally, Alicyia, PhD[1]; Zhou, Anna, MSc[1]; Lazaridis, Emmanuel, BA[3]; Laurelli, Barbara, Dott. Mag.[4]
[1]EVERSANA, Burlington, ON, Canada; [2]Abbott Rapid Diagnostics, Köln, NW, Germany; [3]Abbott Rapid Diagnostics, Ottawa, ON, Canada; [4]Abbott Rapid Diagnostics, Sesto San Giovanni, MI, Italy

Background and Objectives

- Diabetes and dyslipidemia are two prevalent chronic conditions that require regular blood biomarker testing for diagnosis or to track disease progression.[1,2]
- In Canada and Italy, the current testing process for patients usually involves going to their primary care physician (PCP) to obtain a blood test requisition, then visiting a central laboratory testing facility to have the test conducted. Dependent on the test results, patients may need to reconsult with their PCP to initiate or modify treatment.[3]
- This process is associated with high administrative burden for PCPs, resulting in longer wait times, as well as high indirect costs for patients, resulting in low adherence to testing guidelines.[4]
- There is a need to streamline the diagnostic and monitoring pathway for hemoglobin A_{1c} (HbA_{1c}) and lipids to improve identification of diabetic and dyslipidemia patients and ensure those who are diagnosed adhere to testing guidelines to reduce the risk of disease-related complications.[5]
- This study assessed the budget impact of introducing Afinion™ 2 point-of-care testing (POCT) to screen and monitor patients with diabetes or dyslipidemia attending primary care (PC) from the Canadian and Italian societal perspectives.

Methods

- A Budget Impact Analysis (BIA) was developed to estimate both direct costs (HbA_{1c} and lipid panel testing, healthcare provider consultations) and indirect costs (productivity loss, transportation) of Afinion™ 2 POCT vs. traditional lab testing in Canada and Italy with a time horizon encompassing a one-year baseline period (2024) and a five-year forecast period (2025 to 2029).
- The anticipated market share for Afinion™ 2 POCT in the future scenario (i.e., world with Afinion™ 2 POCT) was assumed to increase from 0% in the baseline year to 5 % in the first year, and then increase 10% each year from years two to five.
- An epidemiological approach was undertaken to determine the number of patients eligible for HbA_{1c} or lipid panel testing. The eligible population was separated into two categories, a diagnosed diabetic or dyslipidemia population being monitored by PCP, and patients eligible for diabetes or dyslipidemia screening.
- The monitored population was further sub-categorized to inform the number of PCP consultations and tests required annually (**Table 1**).[3,6,7]

Table 1: Healthcare Resource Use Inputs in the Monitoring Population

Subgroup	Number of Consultations		Number of Tests	
	Lab Testing	Afinion 2 POCT	Lab Testing	Afinion 2 POCT
HbA_{1c}				
Patients with optimal glycemic control	2	2	2	2
Patients with suboptimal glycemic control	6	4	4	4
Patients not adhering to testing guidelines	2	1	1	1
Lipid Panel				
Stable patients	1	1	1	1
Patients with uncontrolled lipid levels	5	3	3	3
Newly diagnosed patients initiating treatment	4	2	2	2
Patients not adhering to testing guidelines	1	0.5	0.5	0.5

- It was assumed that patients utilizing lab testing with suboptimal glycemic control or uncontrolled lipid levels will incur additional consultations to initiate or modify treatment.
- For screening, conservative assumptions were made where the request for a test is provided while the patient is consulting for another reason and no follow-up consultation was assumed. Therefore, only testing cost was considered.
- No consultation cost was assumed for the Italian healthcare system as they operate under a per-capita billing system and therefore do not charge the public system per PC consultation.[8]
- To explore how changes in key assumptions affect the BIA results, several scenario analyses were conducted.
  - The first scenario analysis considered a healthcare payer perspective which only included direct costs.
  - The second and third scenario analysis were included to understand how the BIA would be affected if a proportion of patients are tested and treated at a community pharmacy.
  - The fourth scenario analysis was conducted to understand how the BIA would be affected if all patients utilizing traditional lab testing had one follow-up consultation per monitoring test, and that 10% of screening patients had a follow-up consultation.

Results

Incremental Budget Impact

- The five-year cumulative incremental budget impact of introducing Afinion™ 2 POCT is presented in **Table 2**, showing overall cost savings for both HbA_{1c} and lipid panel POCT over the time horizon.
- The annual incremental budget impact and disaggregated cost categories for Afinion™ 2 POCT is detailed in **Table 3** and **Table 4** for HbA_{1c} and lipids, respectively.

Table 2: Five-Year Cumulative Incremental Budget Impact of Afinion 2 POC HbA_{1c} and Lipid Panel Testing for the Screening and Monitoring of Patients Attending PC

	HbA_{1c}	Lipid Panel
Canada	-$758,006,692	-$726,452,755
Italy	-€ 1,380,658,764	-€ 851,792,115

Table 3: Disaggregated Results by Cost Category for Budget Impact of Afinion™ 2 POC HbA_{1c} Testing for the Screening and Monitoring of Patients with Diabetes Attending PC

Cost Category	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	5-Year Total
Canada						
Testing	$3,175,592	$9,644,471	$16,265,643	$23,033,170	$33,267,882	$85,386,759
Consultation	-$5,061,531	-$15,372,183	-$25,925,574	-$36,712,238	-$53,025,198	-$136,096,723
Indirect – Consultation	-$3,373,692	-$10,246,111	-$17,280,326	-$24,470,024	-$35,343,197	-$90,713,351
Indirect – Laboratory Testing	-$22,931,160	-$69,643,354	-$117,455,277	-$166,324,030	-$240,229,556	-$616,583,377
Total	-$28,190,791	-$85,617,177	-$144,395,534	-$204,473,121	-$295,330,069	-$758,006,692
Italy						
Testing	-€ 247,289	-€ 740,604	-€ 1,231,813	-€ 1,720,412	-€ 2,451,837	-€ 6,391,954
Consultation	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Indirect – Consultation	-€ 10,663,563	-€ 31,936,219	-€ 53,118,090	-€ 74,187,388	-€ 105,727,785	-€ 275,633,044
Indirect – Laboratory Testing	-€ 42,503,433	-€ 127,293,185	-€ 211,721,083	-€ 295,700,282	-€ 421,415,781	-€ 1,098,633,765
Total	-€ 53,414,285	-€ 159,970,008	-€ 266,070,986	-€ 371,608,081	-€ 529,595,403	-€ 1,380,658,764

Table 4: Disaggregated Results by Cost Category for Budget Impact of Afinion™ 2 POC Lipid Testing for the Screening and Monitoring of Patients with Dyslipidemia Attending PC

Cost Category	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	5-Year Total
Canada						
Testing	$4,976,823	$15,114,920	$25,491,694	$36,097,835	$52,137,788	$133,819,060
Consultation	-$4,877,003	-$14,811,759	-$24,980,407	-$35,373,821	-$51,092,060	-$131,135,049
Indirect – Consultation	-$3,012,957	-$9,150,538	-$15,432,614	-$21,853,548	-$31,564,099	-$81,013,758
Indirect – Laboratory Testing	-$24,104,141	-$73,205,769	-$123,463,379	-$174,831,879	-$252,517,841	-$648,123,009
Total	-$27,017,278	-$82,053,147	-$138,384,706	-$195,961,413	-$283,036,212	-$726,452,755
Italy						
Testing	€ 2,165,066	€ 6,484,138	€ 10,784,778	€ 15,062,562	€ 21,466,335	€ 55,962,879
Consultation	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Indirect – Consultation	-€ 3,711,920	-€ 11,116,801	-€ 18,490,079	-€ 25,824,172	-€ 36,803,189	-€ 95,946,161
Indirect –Laboratory Testing	-€ 31,406,883	-€ 94,060,219	-€ 156,446,171	-€ 218,500,567	-€ 311,394,993	-€ 811,808,833
Total	-€ 32,953,738	-€ 98,692,881	-€ 164,151,472	-€ 229,262,177	-€ 326,731,848	-€ 851,792,115

Number of Consultations

- To determine the potential healthcare efficiencies, the reduction in PCP consultations achievable through the implementation of Afinion™ 2 POCT was analyzed. The model demonstrated that both HbA_{1c} (**Figure 1**) and lipid panel testing (**Figure 2**) led to a significant decrease in PCP consultations.

Figure 1: Difference in Total Number of HbA_{1c} Consultations for the Screening and Monitoring of Patients with Diabetes Attending PC

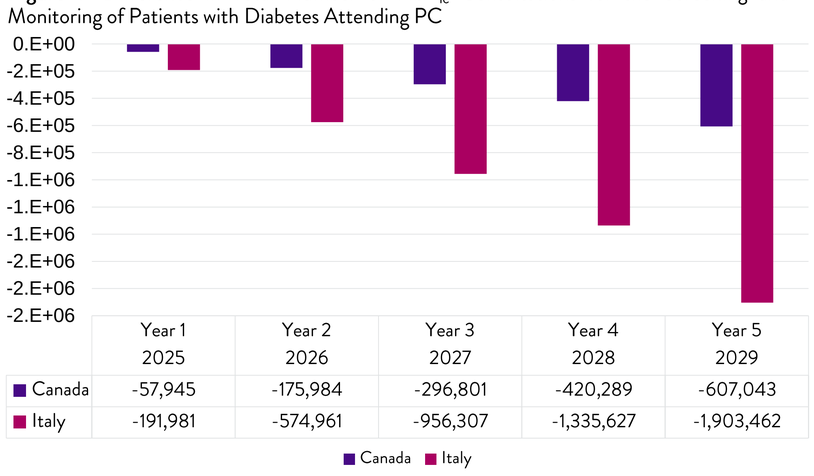
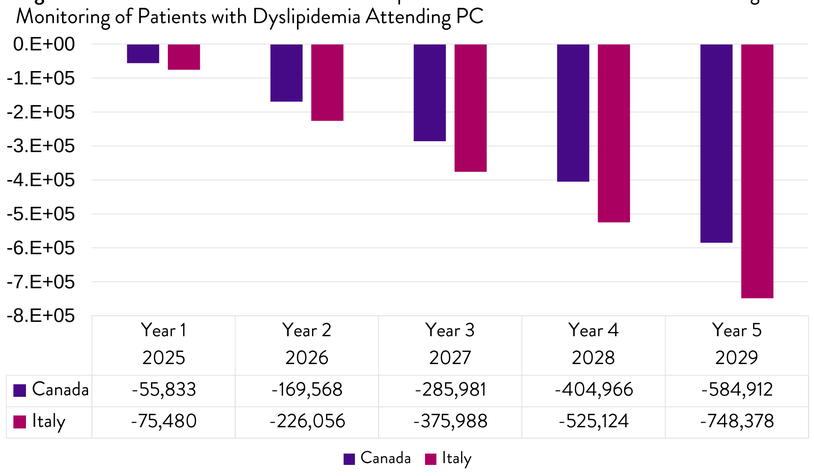


Figure 2: Difference in Total Number of Lipid Panel Consultations for the Screening and Monitoring of Patients with Dyslipidemia Attending PC



Scenario Analysis

- A summary of scenario analysis results is presented in **Table 5**.

Table 5: Summary of Scenario Analyses

Scenario	Canada	Italy
	5-Year Incremental Budget Impact	5-Year Incremental Budget Impact
HbA_{1c} Base Case	-$758,006,692	-€ 1,380,658,764
Scenario #1: Healthcare Payer Perspective	-$50,709,964	-€ 6,391,954
Scenario #2: Pharmacy Administration of Afinion™ 2 POCT HbA_{1c} (25%)	-$830,063,927	-€ 1,424,151,456
Scenario #3: Pharmacy Administration of Afinion™ 2 POCT HbA_{1c} (100%)	-$1,046,235,633	-€ 1,554,629,533
Scenario #4: Increased Number of Consultations for Patients Using Central Lab	-$1,164,108,278	-€ 1,770,709,221
Lipid Panel Base Case	-$726,452,755	-€ 851,792,115
Scenario #1: Healthcare Payer Perspective	+$2,684,011	+€ 55,962,879
Scenario #2: Pharmacy Administration of Afinion™ 2 POCT HbA_{1c} (25%)	-$791,000,584	-€ 873,991,183
Scenario #3: Pharmacy Administration of Afinion™ 2 POCT HbA_{1c} (100%)	-$984,644,070	-€ 940,588,386
Scenario #4: Increased Number of Consultations for Patients Using Central Lab	-$1,238,636,250	-€ 1,140,383,969

Discussion

Implementation of Afinion™ 2 POCT can address many of the unmet testing needs amongst patients with diabetes or dyslipidemia, as this technology can facilitate on-site testing, providing rapid test results and allowing medical decision-making to be expedited in one PC visit. Afinion™ 2 POCT can transform the healthcare system by decentralizing access at the PC and pharmacy level, empowering patients and fundamentally shifting the healthcare paradigm towards more accessible and patient-centered care options. **This study demonstrates that the adoption of Afinion™ 2 POCT can provide efficiencies to different types of healthcare systems through reducing PC consultations, saving time and money for patients, and providing cost savings for payers.**

Abbreviations BIA = budget impact analysis; HbA_{1c} = hemoglobin A_{1c}; PC = primary care; PCP = primary care physician; POCT = point-of-care testing.

References
1. WHO (2016). *Global Report on Diabetes*.
2. Arvanitis M, Lowenstein CJ (2023). Dyslipidemia. *Annals of Internal Medicine* 176 (6): ITC81-ITC96.
3. Chadee A, Blackhouse G, Goeree R (2014) Point-of-Care Hemoglobin A1c Testing: A Budget Impact Analysis. *Health Technology Assessment*.
4. Schnell O, Crocker JB, Weng J (2017) Impact of HbA1c Testing at Point of Care on Diabetes Management. *J Diabetes Sci Technol* 11 (3): 611-617.
5. Trenti T (2021) Synergy Between Point-of-Care Testing and Laboratory Consolidations. *EJIFCC* 32 (3): 328-336.
6. Berard LD, Siemens R, Woo V (2018) Monitoring Glycemic Control. *Can J Diabetes* 42 Suppl 1 S47-S53.
7. Pearson GJ, Thanassoulis G, Anderson TJ, Barry AR, Couture P et al. (2021) 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in Adults. *Can J Cardiol* 37 (8): 1129-1150.
8. Giulio de Belvis A, Meregaglia M, Morsella A, Adduci A, Perilli A et al. (2022) Italy: Health System Review. *Health Syst Transit* 24 (4): 1-236.

EVERSANA®

Abbott