

Budget Impact Analysis of Insulin 40 and Insulin 100 units in the Egyptian diabetic patients

Health Technology Appraisal

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• بيانات المستحضر محل الدراسة:

Intervention	Insulin 100 units
Company name	Novo Nordisk
Comparator	Insulin 40 units

• الهدف:

تحليل الآثار المترتبة على ميزانية نتيجة تداول **Insulin 100 units** في علاج مرضي السكر بدلاً من ٤٠ وحدة. وذلك لضمان أفضل النتائج العلاجية بالنسبة للمريض وبأقل تكلفة ممكنة من خلال الالتزام بالخطوط العلاجية الاسترشادية العالمية وفي ضوء الممارسة الإكلينيكية المحلية.

• توصية لجنة اقتصاديات الدواء:

في ضوء ما أفادت به الدراسات من أضرار مرتبة علي استخدام تركيزان من الأنسولين في السوق من كزيادة حدوث أخطاء علاجية، وعليه دراسة التحول إلى استخدام تركيز واحد من الأنسولين وهو (١٠٠ وحدة) كما هو متبع في العديد من الدول، لذا قامت وحدة اقتصاديات الدواء بعمل دراسة اقتصادية للآثار المترتبة لتحليل الآثار المترتبة على ميزانية الدولة نتيجة تداول وتغطية الأنسولين ١٠٠ وحدة بدلاً من ٤٠ وحدة. وقد أسفرت الدراسة عن أن استخدام مستحضر الأنسولين ١٠٠ وحدة يوفر لميزانية الدولة ٦٧٨,٣٦٤,٨٣ جنيه مصري لجميع مرضي السكري (Type I & II) المُعالجين بمستشفيات وزارة الصحة على مدار عام من مقدار الإنفاق على علاج الأنسولين بوزارة الصحة، وذلك عند مقارنته كبديل لمستحضر الأنسولين ٤٠ وحدة.

- علما ان الدراسة التي قامت باجرائها وحدة اقتصاديات الدواء شملت الآتي:

١- بيانات التكلفة الخاصة بالمستحضرين، والتي تم تجميعها من مستندات أسعار الترسية بقسم مناقصات الأدوية بوزارة الصحة، وهذا بالإضافة إلى مستندات أسعار التوريد إلى الشركة المصرية المتواجدة بإدارة الدعم ونواقص الأدوية. كما تم احتساب باقي التكلفة المرتبطة بالإقامة بالمستشفى والأدوية والتبعاات المحتملة من علاج الأخطاء العلاجية لاستخدام كل تركيز على حدة والناجئة عن عدم الوعي الكافي للمرضى، فقد تم تجميع هذه التكلفة طبقاً لأسعار الخدمات بمستشفيات وزارة الصحة.

٢- كما تم تجميع البيانات الخاصة بنسب انتشار مرض السكري في جمهورية مصر العربية من النوعين (Type I & II) والذين في حاجة إلى الأنسولين من ال(International Federation for Diabetes, 2013). والاستناد على آخر تحديث لإحصائيات البنك الدولي في تحديد عدد السكان بمصر، وفئاتهم العمرية ليتم حساب جرعات الأنسولين المستخدمة في كل فئة عمرية.

٣- تم الاعتماد على بيانات ال(IMS International Market Share) وتجميع احتياجات مستشفيات وزارة الصحة من قسم مناقصات الأدوية بوزارة الصحة في تحديد مقدار التغطية للأنسولين بالسوق المصري (محلي ومستورد). وكذلك الاعتماد على احدي الدراسات المنشورة في استنباط الفرق في تكلفة الإقامة بالمستشفى بين تركيز كل مستحضر على حدة.

Budget Impact Analysis of Insulin-40 and Insulin-100 units in the Egyptian diabetic patients

• Introduction

Diabetes is now one of the most common non-communicable diseases globally. It is the fourth or fifth leading cause of death in most high-income countries and there is substantial evidence that it is epidemic in many low- and middle-income countries. Complications from diabetes (such as Coronary Artery Disease, neuropathy, and others) are resulting in increasing disability, reduced life expectancy, and enormously healthcare costs for all societies especially those in middle- and low-income countries. Diabetes is certain to be one of the most challenging health problems in the 21st century.

Studies estimate that by 2030, Egypt will be the 10th leading country worldwide in terms of number of diabetic patients, which will approximate 9 million patients. This composes a strong financial burden, on which if plans and actions were put, will impose a vital area for investment.

Although Type 1 diabetes usually accounts for only a minority of the total burden of diabetes in a population (10-15%), yet still it's the predominant form of the disease in younger age groups. This type is increasing in incidence in both rich and poor countries, and there's an indication of a shift towards type 1 diabetes developing in children at earlier ages.

Insulin constitutes the sole and primary treatment for this type of diabetes, but somehow it seems ineffective in Egypt. Among the most important causes of this inefficacy problem is the presence of two concentration of Insulin at the Egyptian Market, Insulin 40 and Insulin 100 units. This study was conducted taking into consideration the following facts; first, since the late Seventies, the usage of insulin 40 units has been halted in most countries of the world and replaced by insulin 100 units. This was done as a consequence to the frequent medication errors and side effects that lead to an increase in both hospital stay periods and medications costs that are associated with Insulin 40 units more frequently than Insulin 100 units. Second, results of survey studies performed in USA, UK and Canada have shown preferences for Insulin-100 over Insulin-40, and made recommendations for the switch from Insulin 40 and 80 units to Insulin 100 units.

Third, other studies recommend switching as a solution to avoid the increase in wastage accompanying Insulin-40, and for the purpose of dose unification. Fourth, as indicated in some studies, administration of Insulin-100 in Insulin-40 syringes results in an unexpected drop in the blood glucose, whereas administration of Insulin-40 in Insulin-100 syringes leads to insulin resistance.

- **Objective**

The objective of this study was to assess the budget impact analysis of Insulin-40 and Insulin-100 using a static Model over a time horizon of 5 years.

- **Economic evaluation Key Features:** ^[3]

Key Features:	
Title and year of the document	July 2014
Affiliation of authors	Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs
Purpose of the document	Assess the budget impact analysis of Insulin-40 and Insulin-100 using in Egyptian Diabetic Patients
Standard reporting format included	yes
Disclosure	yes
Target audience of funding/ author's interests	Public, healthcare industries and clinicians
Perspective	The Insurer Perspective
Indication	Treatment of type I and type II diabetes
Target population	Those who are insured by the Egyptian health care system
Subgroup analysis	Only for those whom clinical and cost effectiveness may be expected to differ from that of the overall population
Choice of comparator	Insulin-40
Time horizon	over 5-year period
Assumptions required	yes
Analytical technique	Budget impact analysis
Costs to be included	Total costs include costs of treatment and managing strategies according to the Egyptian current practice.
Source of costs	Official sources of unit cost data for products (e.g. Tender lists)
Systematic review of evidences	yes
Preference for effectiveness over efficacy	yes
Outcome measure	Reduction in hospitalization
Method to derive utility	No utility is derived
Equity issues stated	All lives, life years are valued equally, regardless of age, gender, or socioeconomic status of individuals in the population

Discounting costs	A discount rate of 3.5 % per year is used for costs.
Discounting outcomes	A discount rate of 3.5 % per year is used for outcomes.
Sensitivity analysis-parameters and range	Critical component(s) in the calculation is varied through a relevant range or from worst case to best case.
Sensitivity analysis-methods	one-way sensitivity analysis is performed
Presenting results	The total budget for diabetes following U100 insulin use were cost-saving in comparison to U40 insulin
Incremental analysis	yes
Total costs vs. effectiveness (cost/effectiveness ratio)	NA
Portability of results (Generalizability)	The generalizability and extent to which the clinical efficacy data and the economic data are representative is identified and discussed.

• Committee Discussion

The main objective of this study was to evaluate the budget impact of U100 insulin over a time horizon of 5 years. In a hypothetical 85,294,388 member plan, 1,234,380 patients were expected to be candidates for U100 insulin treatment in type I and type II diabetes. The total budget impact after 5 years post-U100 insulin was EGP -0.04 per member per month [PMPM] (pharmacy budget: EGP -0.046 PMPM; medical budget: EGP -0.002 PMPM), assuming 53.59% of the target population would switch to U100 insulin.

The total budget for diabetes following U100 insulin use was cost-saving in comparison to U40 insulin. Conversion to U100 insulin would result in lower overall treatment costs in patients with diabetes from the healthcare system's perspective.

• Conclusion

It is important to address both the clinical and the economic implications of a new therapy from the payer perspective before deciding on public reimbursement of new therapies. Budget impact analysis helps inform the health care decision in allocation of health care system resources and achieving better health for the Egyptian population.

As it's obvious from the results, the switch to insulin 100 units will have the dual benefits of the overall budget savings across the 5 years, and the reduction in hospitalizations rate. Medication errors and side effects will be reduced leading to savings of LE 1,342,567,994 across the Egyptian population in hospitalization and medications costs that are associated with Insulin 40 units more frequently than Insulin 100 units.

An intensive information campaign providing detailed advice for patients, physicians and pharmacists is essential for the prevention of medication errors and reduction of overall costs.

- **Declaration of interest**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

- **Appraisal Committee members**

Each technology appraisal is appraised by the PE Committee, which is one of CAPA's standing advisory committees and consist of members who represent different specialties such as statistics, clinical evidence, economics, medicine, clinical pharmacy and Pharmacoeconomics. A list of the Committee members who took part in the discussions for this appraisal appears below:

- **Prof. Ahmed Hassouna**, Consultant of clinical trials.
- **Prof. Ashraf Nabhan**, Associate Editor, Cochrane Collaboration.
- **Dr. Abd Allah Mohammed**, Expert at National Authority for the control of Biopharmaceuticals.
- **Prof. Randa El-Dessoki**, Scientific director of global initiatives of the Organization of the economics of medicine management and research outputs.
- **Dr. Mahmoud El-Mahdawy**, General director of Hospital pharmacy administration, Central Administration for Pharmaceutical Affairs, Ministry of Health.
- **Dr. Gihan Hamdy**, Head of Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health.
- **Dr. Rasha Hassan**, director of pricing administration Central Administration for Pharmaceutical Affairs, Ministry of Health.
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- **PEU project team**

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- **Andrew Metry**, Team member of Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health.

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4. World bank economy; 2013.