A forecasting model for drug utilization and expenditure integrating a Cellular Automata model with the Budget Impact Analysis approach. Preliminary results.

Roberta Joppi(1)*, Elisa Cinconze(2), Luca Demattè(2), Renato Guseo(3), Claudio Jommi(4), Cinzia Mortarino(3) Daniela Pase(1), Chiara Poggiani(1), Alessandro Roggeri(4), Daniela Roggeri(4)

(1) Italian Horizon Scanning Project, Azienda ULSS 20, Verona, Italy *roberta.joppi@ulss20.verona.it (2) Consorzio Interuniversitario CINECA, Bologna, Italy
(3) Department of Statistical Sciences, University of Padova, Italy (4) Department of Pharmaceutical Sciences, University of Piemonte Orientale, Novara, Italy
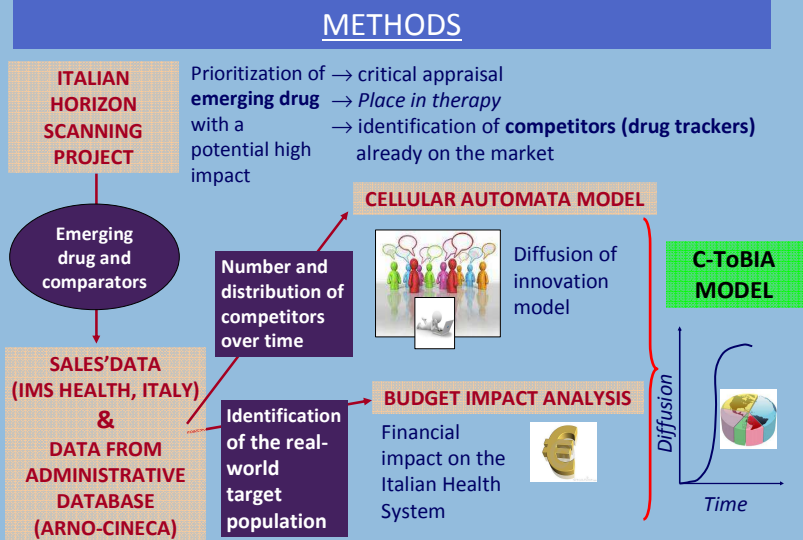
Background. The considerable pressure on healthcare systems, exerted by increasing expenditures for new drugs, urges specific initiatives, including the development of new models, to optimize the managed entry of new medicines and guarantee their sustainability.

Objectives. To develop a Forecasting Model for drug utilization and expenditure of emerging medicines identified, prioritized and critically assessed by the Italian Horizon Scanning Project (IHSP), integrating a Cellular Automata (CA) model describing the diffusion process on the market with the Budget Impact Analysis (BIA), performed before the market entry of a new drug.

Methods. Selection and critical evaluation of high-impact emerging medicines. Development of CA and BIA models for emerging drugs, using medical prescription data from the administrative ARNO-CINECA databases and sales data from IMS Health, Italy.

Results. The first-in-class emerging anti-diabetic dapagliflozin was selected and critically evaluated by the IHSP about 12 months before the European Marketing Authorization (MA). Other competitors already on the market were identified. A CA model describing the diffusion process of more than 200 Italian antidiabetic products (ATC A10B) (new molecules and new formulations, dosages and packs of already existing drugs) sold between 2000-2014 has been developed and validated. A protocol for the identification of the real-world target population in the ARNO-CINECA database was set up on the grounds of the expected indication for dapagliflozin. The estimation of budget impact of dapagliflozin is ongoing based on the estimation of market shares, through the application of CA Model, the analysis of the identified target population, and the analysis of the potential variations in related healthcare costs for the treatment of type 2 diabetes, after the introduction of dapagliflozin.

Conclusions. The proposed Forecasting Model (C-ToBIA Model) predicts the impact of emerging drugs on the National Health System (NHS), under the sufficient conditions for estimability. The originality of the C-ToBIA Model is basically related to the assessment of emerging drugs 12 months before the MA date, and the estimation of the diffusion process and the potential financial impact before market entry (ex-ante). The C-ToBIA Model will help to timely estimate the possible utilization pattern of new medicines and their potential impact on the National Health System before their market entry.

METHODS

ITALIAN HORIZON SCANNING PROJECT

Prioritization of → critical appraisal
emerging drug → *Place in therapy*
with a → identification of **competitors (drug trackers)**
potential high   already on the market
impact

Emerging drug and comparators

SALES'DATA (IMS HEALTH, ITALY) & DATA FROM ADMINISTRATIVE DATABASE (ARNO-CINECA)

Number and distribution of competitors over time

Identification of the real-world target population

CELLULAR AUTOMATA MODEL

Diffusion of innovation model

BUDGET IMPACT ANALYSIS

Financial impact on the Italian Health System

C-ToBIA MODEL

Diffusion / *Time*

RESULTS

Drug selection and evaluation, through the *ITALIAN HORIZON SCANNING PROJECT* (*IHSP*):

Identification and critical appraisal of **DAPAGLIFLOZIN:**

New Product Information Report

DAPAGLIFLOZIN
Type-2 Diabetes Mellitus

Prioritization Group: 17-12-2010
Update: May 2011

> first-in-class inhibitor of sodium- glucose cotransporter 2 (SGLT2), with glucosuric effect

> the drug was critically evaluated by IHSP about 12 months before the European Marketing Authorization as:

- monotherapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance;
- add-on therapy in combination with other glucose-lowering drugs including insulin, when these, together with diet and exercise, do not provide adequate glycemic control

Identification of **competitors already on the market**: antidiabetic drugs (**ATC A10B**)

Development of CELLULAR AUTOMATA MODEL to describe market behaviour of antidiabetic agents

Analysis of **more than 200 Italian** products sold **between 2000-2014**, and development of the diffusion model for antidiabetic drugs (**ATC A10B**), distinguishing between metformin (I line) and other antidiabetic agents (add-on treatments).

Among add-on treatments, the subgroup of products distributed due to higher price through hospital pharmacies (DHP) – instead of community pharmacies – has been isolated.
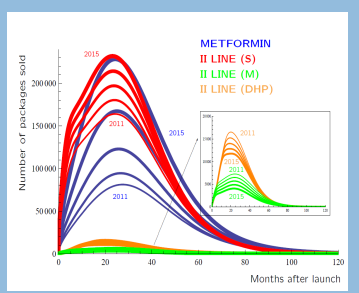
Forecast of the number of new antidiabetic products that will be introduced on the Italian market per month until 2018
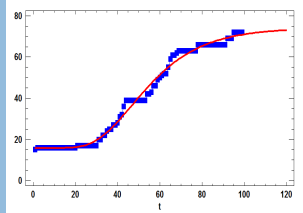
METFORMIN: 7 new products expected until April 2018
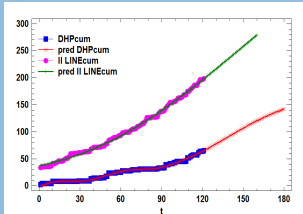
ADD-ON TREATMENTS: 104 (68 DHP) new products expected until April 2018

BUDGET IMPACT ANALYSIS for dapagliflozin before market entry (*ongoing*)

A protocol for the identification of the **real-world target population** in the ARNO database has been set up on the grounds of the expected indication.

The estimation of **budget impact** of dapagliflozin is based on:

1. estimation of expected market shares, through the application of CA model

2. analysis of the identified target population through IMS Health Data and ARNO Database

3. analysis of the potential variations in related healthcare costs for the treatment of type 2 diabetes, after the introduction of dapagliflozin

CONCLUSIONS

The present project proposes an original forecasting model, *C-ToBIA Model*, to predict the impact of emerging drugs on the National Health System, under the sufficient conditions for estimability. The originality of the C-ToBIA Model is basically related to two elements:
(i) the assessment of emerging drugs 12 months before the European Marketing Authorization date
(ii) the estimation of the diffusion process and the potential financial impact before market entry (ex-ante)

The C-ToBIA Model will help to timely estimate the possible utilization pattern of new medicines and their potential impact on the National Health System before their market entry.

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