# RESTRICTIVE VS NON-RESTRICTIVE DRUG REIMBURSEMENT SYSTEMS: EVIDENCE FROM EUROPEAN COUNTRIES*

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***Jornadas de Economía de la Salud (AES), Barcelona, 6th September 2017***

** Research funded by the CRES-UPF, as part of the research agreement with the Obra Social de la Caixa.*

# 1. Background and motivation

- Since the 80s, Health Technology Assessment has been an increasingly important concept in the field of health care. All health care systems need to make choices regarding which services and products are to be paid for from public resources.

- As a result, most developed countries have HTA procedures for informing drug reimbursement decisions.

- There are three possible final decision outcomes regarding the adoption of the technology: **Favourable, Favourable with restrictions and Non-Favourable.**

- *Countries make different decisions regarding which treatments to provide. These differences provide the motivation for this paper.*

# 1. Background and motivation

- **Motivation: previous work in Advance-HTA**

- The main ***aim is to link the result of these decisions with health outcomes*** (i.e. life expectancy, healthy life years and cancer mortality rates).

- The principal hypothesis is that health outcomes will differ across countries depending on the level of access to drugs (across time and per country).

# 2. Objective

- ***The principal objective of this research is to model the impact of drug reimbursement decisions on health outcomes.***

- In particular, this paper looks at countries that have different acceptance rates for drug reimbursement decisions (restrictive vs non-restrictive).

- Existing literature, i.e. Lichtenberg (2005, 2011a, 2011b, 2014a, 2014b, 2014c, 2014d), has looked at the impact of pharmaceutical innovation on health outcomes (+) and medical expenditure (-).

# 3. Contribution

- To the best of my knowledge, this is the first paper to examine the specific relationship between drug reimbursement decisions and health outcomes using an empirical approach.

- This paper shows evidence that *even if a country's drug reimbursement system is designed to be more restrictive in terms of access; it does not necessarily lead to worse health outcomes than in a less restrictive country.*

- As a result, this paper contributes to the HTA literature, but also sheds light on potential criticisms of a restrictive system.

# 4. Methods. 4.1. Dataset

The current study is based on a longitudinal dataset with data from nine European countries from 2002 to 2014: Belgium, Germany, France, Spain, Sweden, Portugal, Poland, England and Scotland.

1) **primary data** on drug reimbursement decisions (cancer drugs) collected as part of the ADVANCE-HTA project

2) **secondary data** on life tables and indicators of health and socioeconomic status (Eurostat and World Bank)

# 4.1. Dataset

***1) Primary data***

- It included the technology appraisals for cancer drugs from January 2002 to December 2014 for the selected countries (formal HTA). Collected during the ADVANCE-HTA project

- In total, 161 drug-indications were considered for each country.

- Variables created for this study: **rate of acceptance, restriction and rejection for each year and country + rate of non-assessment**.

## Descriptive statistics: variables of interest (2002-2014)

| Country | Rate of acceptance | Rate of restriction | Rate of rejection | Rate of non-assessment |
|---|---|---|---|---|
| **Belgium** | 65.79 (24.06)[1] | 32.10 (21.06) | 2.11 (4.21) | 19.25 |
| | (12.5, 100)[2] | (0, 75) | (0, 12.5) | |
| **France** | 90.93 (12.00) | 2.88 (4.76) | 6.19 (11.07) | 4.35 |
| | (60, 100) | (0, 12.5) | (0, 40) | |
| **Germany** | 100 (0) | 0 (0) | 0 (0) | 0 |
| | (100, 100) | (0, 0) | (0, 0) | |
| **Portugal** | 86.28 (17.27) | 5.13 (11.04) | 8.59 (12.49) | 72.67 |
| | (50, 100) | (0, 33.33) | (0, 33.33) | |
| **Poland** | 60.27 (43.52) | 25.76 (31.50) | 13.97 (15.49) | 41.61 |
| | (0, 100) | (0, 87.5) | (0, 44.44) | |
| **Spain** | 87.74 (23.35) | 12.26 (23.35) | 0 (0) | 9.94 |
| | (16.67, 100) | (0, 83.33) | (0, 0) | |
| **Sweden** | 87.13 (17.52) | 6.76 (11.14) | 6.11 (9.39) | 68.32 |
| | (55.56, 100) | (0, 33.33) | (0, 22.22) | |
| **Scotland** | 25.00 (18.69) | 47.84 (31.08) | 27.17 (21.02) | 7.2 |
| | (0, 50) | (7.14, 100) | (0, 54.55) | |
| **England** | 46.27 (30.46) | 25.91 (20.52) | 27.82 (28.41) | 36.36 |
| | (0, 100) | (0, 66.67) | (0, 87.5) | |

*[1]mean (standard deviation), [2] (max,min). Source: created by the author*

# 4.1. Dataset

***2) Secondary data***

- From **Eurostat and World Bank.**

- Problem: England and Scotland separately --- need regional variables.

- Eurostat has NUTS II data, but England is not considered a single region for NUTS II (unlike Scotland); it is composed of nine “sub-regions”.

- To get the value for England, I used weighted average measurements based on population. For some variables, however, the only information available was country level.

These variables were chosen based on the longevity model (Lichtenberg, 2014a).

+ additional variables (e.g. cancer mortality rate)

- variables not included due to data availability problems (e.g. risk factors or urbanisation).

| *Variables* |
| --- |
| *Life expectancy at birth (male and female)* |
| *Healthy life years at birth (male and female)* |
| *Cancer mortality rate (male and female)* |
| *GDP capita (PPP)* |
| *Population, total* |
| *Unemployment rate* |
| *Education attainment level (%)* |
| *Population over 65 (%)* |
| *Population with illness (%)* |
| *Patents (per million inhabitants)* |
| *Health Expenditure, public (% GDP)* |

# 4.2. Longevity model

- Longevity model ----- used in Lichtenberg (2014a). His variable of interest (X) was pharmaceutical innovation.

- In this analysis, the variables of interest are the different rates relating to drug reimbursement decisions (i.e. rate of acceptance, restriction and rejection).

- The model specification is a fixed-effects panel data specification for nine countries (i) and for year (t) from 2002 to 2014

$$LONGEVITY_{it} = \beta X_{it} + \gamma Z_{it} + \alpha_i + \pi_t + e_{it}$$

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where $LONGEVITY_{it}$ denotes the different measures for longevity per country (i) and per year (t); $X_{it}$ corresponds to the variables of interest per country and per year; $Z_{it}$ is a vector of other determinants of longevity per country and year; $\alpha_i$ is a fixed-effect for country (i); $\pi_t$ is a fixed-effect for year (t) and $e_{it}$ is the disturbance term

- ***β* parameter** shows how the rate of restriction or rejection affects longevity outcomes holding the other factors constant (rate of acceptance -- base category).

- If ***β* parameter is negative and significant**, it indicates that a country, which tends to restrict or reject more than it accepts, has a worse longevity outcome.

# 5. Results. 5.1. Descriptives

- 6 dependent variables (LE, HLY, Cancer mortality) broken down by gender.
- Females have a higher life expectancy than males and males have a higher cancer mortality rate.
- The rest of explanatory variables show enough variability, across country and year.
- ***Main concern: low number of observations. As a result, I do not claim causality.***

| *Variables* | N | Mean (SD) | Min | Max |
|---|---|---|---|---|
| *Life expectancy at birth male (LEM)* | 117 | 76.35 (2.45) | 70.3 | 80.4 |
| *Life expectancy at birth female (LEF)* | .117 | 82.53 (1.78) | 78.8 | 86.2 |
| *Healthy life years at birth male (HLYM)* | 94 | 62.51 (3.41) | 54.5 | 73.6 |
| *Healthy life years at birth female (HLYF)* | 94 | 62.96 (3.52) | 52.4 | 73.6 |
| *Cancer mortality rate male (100,000 inhabitants)* | 107 | 369.67 (41.31) | 282.37 | 484.3 |
| *Cancer mortality rate female (100,000 inhabitants)* | 107 | 209.09 (29.57) | 159.98 | 260.1 |
| *GDP capita (PPP)* | 117 | 25445.65 (5618.11) | 9900 | 34500 |
| *Population, total* | 117 | 3.51e+07 (2.63e+07) | 5064592 | 8.25e+07 |
| *Unemployment rate* | 117 | 9.17 (4.32) | 4.48 | 26.1 |
| *Education attainment 0-2 (%)* | 117 | 30.90 (17.61) | 9.5 | 79.4 |
| *Education attainment 3-4 (%)* | 117 | 40.88 (15.73) | 11.2 | 68.3 |
| *Education attainment 5-8 (%)* | 117 | 28.21 (7.57) | 9.4 | 46.5 |
| *Population over 65 (%)* | 117 | 16.95 (1.71) | 12.58 | 20.87 |
| *Population with illness (%)* | 96 | 32.92 (4.69) | 22.9 | 50.1 |
| *Patents (per million inhabitants)* | 99 | 113.28 (98.88) | 2.19 | 310.22 |
| *Health Expenditure, public (% GDP)* | 117 | 7.15 (1.31) | 4.24 | 10.05 |

# 5.2. Econometric model results

| | Ln (Life Exp Male) | Ln (Life Exp Female) | Ln (HLY Male) | Ln (HLY Female) | Cancer Mortality male | Cancer Mortality female |
|---|---|---|---|---|---|---|
| Rate of rejection | 0.00002 | 0.00002 | 0.00036* | 0.00038 | 0.00007 | -0.05912** |
| | (0.000) | (0.000) | (0.000) | (0.000) | (0.061) | (0.025) |
| Rate of restriction | -0.00002 | -0.00001 | 0.00019 | 0.00028* | 0.01816 | 0.00997 |
| | (0.000) | (0.000) | (0.000) | (0.000) | (0.043) | (0.018) |
| constant | 4.26757*** | 4.30867*** | 3.72108*** | 4.14234*** | 93.874 | 213.85221*** |
| | (0.081) | (0.060) | (0.722) | (0.841) | (193.946) | (79.459) |
| country fixed-effects | X | X | X | X | X | X |
| year fixed-effects | X | X | X | X | X | X |
| *N* | 115 | 115 | 93 | 93 | 105 | 105 |
| within $R^2$ | 0.97518 | 0.97460 | 0.53585 | 0.51647 | 0.92087 | 0.87167 |
| between $R^2$ | 0.09665 | 0.16503 | 0.16059 | 0.61387 | 0.25987 | 0.36388 |
| overall $R^2$ | 0.07097 | 0.01406 | 0.07275 | 0.37913 | 0.03741 | 0.26179 |

*Main result --- the variables of interest (rate of restriction and rejection) are not statistically significant for the life expectancy model, whereas they show significant coefficients for the two other dependent variables.*

# 5.2. Econometric model results

For the rest of the explanatory/control variables, some results are unexpected.

1. **Unemployment rate** --- positively related to life expectancy at birth

   *This relationship ---- highest life expectancy outcome is found in Spain and, at the same time, it is the country with the highest unemployment rate.*

2. **Health expenditure (%GDP)** ---- negative related to life expectancy/ healthy life years.

   *Same explanation (Spain)*

# 5.2. Econometric model results

3. **Education attainment 5-8 (%)** ----- negative on healthy life years
   ----- positive on cancer mortality rate

*No clear pattern across countries*

4. The **year fixed-effects** follows the expected results; showing that health outcomes improve with time.

# 6. Conclusion

- Aim ---- **link the results of drug reimbursement decisions with health outcomes.**

- The main hypothesis was that health outcomes would differ across countries depending on the level of access to drugs.

- In order to achieve that goal:
  - Data from primary and secondary sources
  - Longitudinal dataset of nine European countries over 13 years.
  - Methodology was based on the longevity model defined by Lichtenberg (2014a).
  - The final model specification was a fixed-effects panel data model.

# 6. Conclusion

- Summing up, *a more restrictive drug reimbursement system is not related with worse health outcomes*; it is either associated with a positive outcome or no relationship is found.

- This conclusion thus indicates that, contrary to beliefs that may well be held by the general population or even policy-makers, *a more restrictive system is not synonymous with poorer health outcomes.*

# 7. Limitations

- **Assembling the database** was complicated by the fact that data was not always available for the entire study period and it was not always possible to separate England and Scotland.

- As a result, some **assumptions** needed to be made in order to combine all these data in a single analysis.

- Moreover, due to the **small number of observations**, the models are not robust and efficient enough to be taken as evidence of causality.

- However, the variables included as explanatory variables controlled for the potential **omitted variable bias and for some sources of endogeneity**.

# THANKS FOR YOUR ATTENTION

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