



ORI  
*Osservatorio Regionale per l'Innovazione*

# Matching research with decisions: how rapid HTA based on patients' outcomes can support EB-DM

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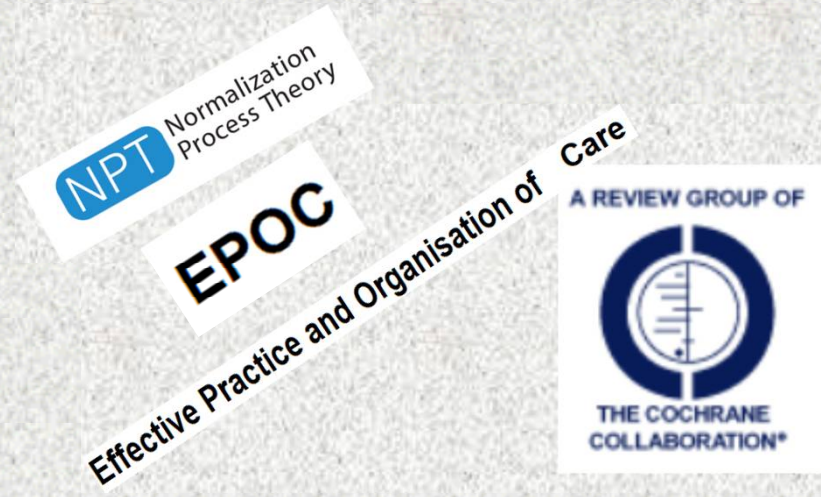
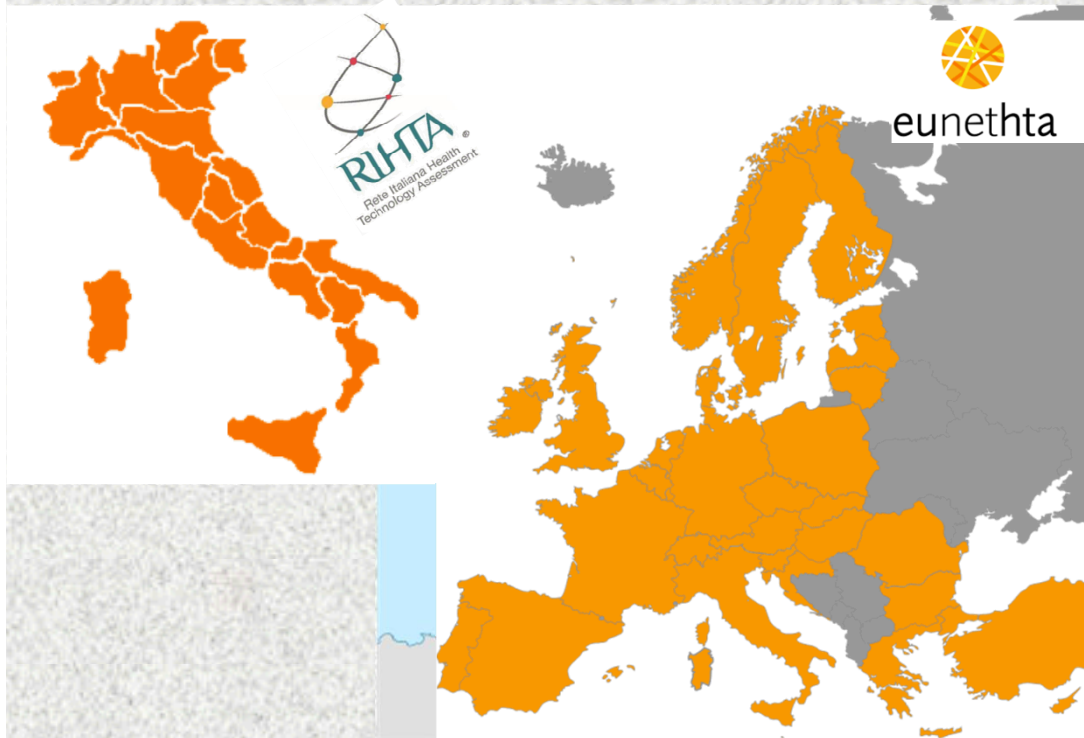
Emilia-Romagna, Italy





# ORI – Regional Observatory for Innovation: who we are

We give support to Local Health Trusts and to Regional Ministry of Health in managing health innovations, using methods and tools of EBM and HTA





# Background

Charming and promising rationale

Decision-makers are used to and (usually) forced to take decisions with an incomplete evidence profile

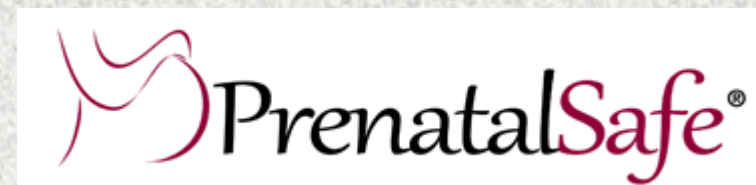
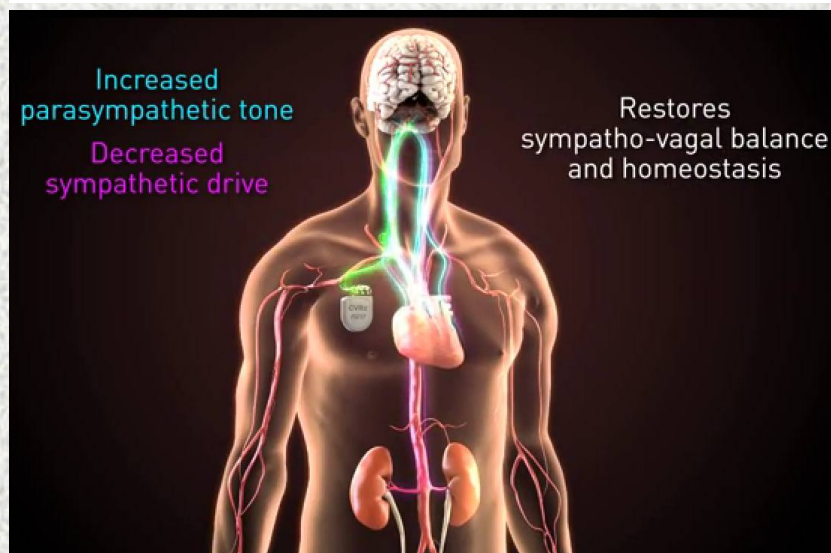
Need to be rapid

How to identify technologies potentially useful for regional health system?

# Some examples



## Approval for Rheos® Baroreflex Hypertension Therapy™ System



**NO LEAD. NO POCKET.  
NO COMPROMISE.**



**Promising** rationale + pressure from patients, clinicians, manufacturers on decision-makers



HTA agencies



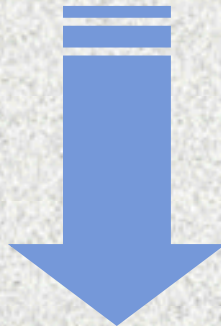


Theoretical rationale:  
the idea

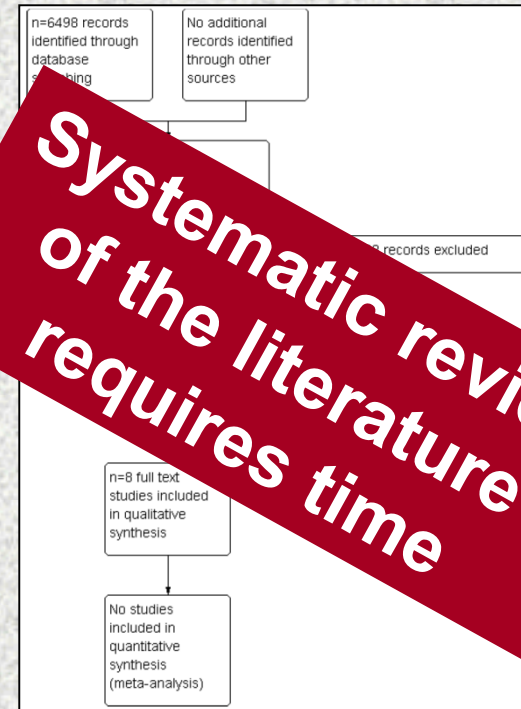
no



yes



Empirical knowledge:  
the evidence  
**Does it work?**



**Systematic review  
of the literature  
requires time**



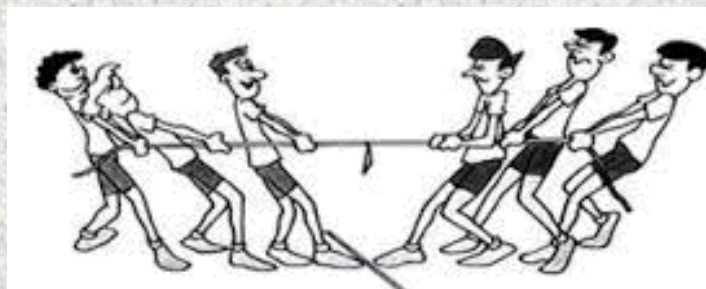
## Health innovations and HTA process

### HTA process

- ∅ based on empirical data
- ∅ needs time
- ∅ rationality and prudence

### Emerging technologies

- ∅ scientifically "immature"
- ∅ rapid diffusion
- ∅ enthusiasm and impatience



Production and diffusion of HTA reports require **time** whilst innovative technologies tend to spread over very **quickly**



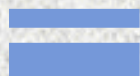


Theoretical rationale:  
the idea

no



yes



Do we need it?  
Context analysis



Empirical knowledge: the  
evidence

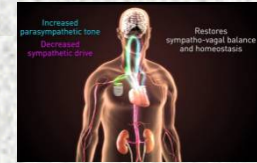
Does it work?

Systematic  
review of the  
literature  
requires time





# Rheos® Baroreflex Hypertension Therapy™ System



2009

**Proposed indication:** treatment of patients with treatment-resistant hypertension

**Treatment-resistant hypertension** = blood pressure that remains above goal in spite of concurrent use of three antihypertensive agents of different classes (Calhoun 2008; Mancia 2013)

How many patients with treatment-resistant hypertension?  
From the literature: **15% of treatment compliant patients receiving 4 or more drugs** for hypertension (ALLHAT 2002)



# Rheos® Baroreflex Hypertension Therapy™ System



2009

How many **possible candidates** to the treatment with Rheos system for resistant hypertension **in Emilia-Romagna region?**

From the database of drug consumption of the Emilia-Romagna Region: **2 695** patients received at least 3 of the following drugs, with a compliance above 75%: b-blockers, ACE inhibitors, diuretics, calcium-channel blockers.

If the Rheos technology should prove effective, **about 400** (15%) of these patients could be eligible for its implantation

**We potentially need it!**



# Innovative medical devices for diabetes (CSII, CGM, SAP)



2012

## Proposed indication:

Patients (adults and children/adolescents) with type 1 or 2 diabetes mellitus undergoing multi-daily injective (MDI) insulin therapy

## Main expected benefits

1. better glycaemic control
2. reduction in hypoglycaemic episodes
3. improvement in QOL and other health status measures (such as weight reduction)
4. **reduction of both short and long-term complications**



## Innovative medical devices for diabetes (CSII, CGM, SAP)



2012

**How many patients** with type 1 or 2 in **Emilia-Romagna region?**

208.738 patients (4,98% of regional population)

How many **possible candidates** in Emilia-Romagna region?

From the regional pharmaceutical database (year 2011):

- selection of patients assuming MDI
- estimate of type 1 DM (patients assuming insulin and not assuming oral antidiabetics neither in 2011 nor in the four previous years)

### Results:

- total number of diabetic patients treated with MDI: 45.109 (2011-cohort of diabetic patients)
- number of type 1 diabetic patients: 17.748 (836 children or adolescents, 16.912 adults)

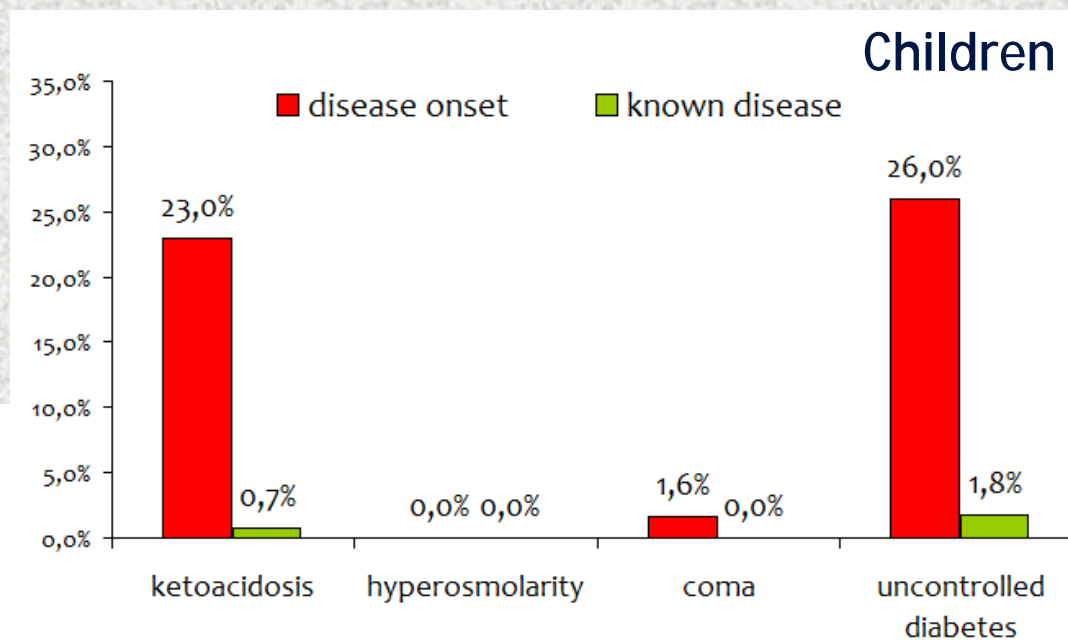
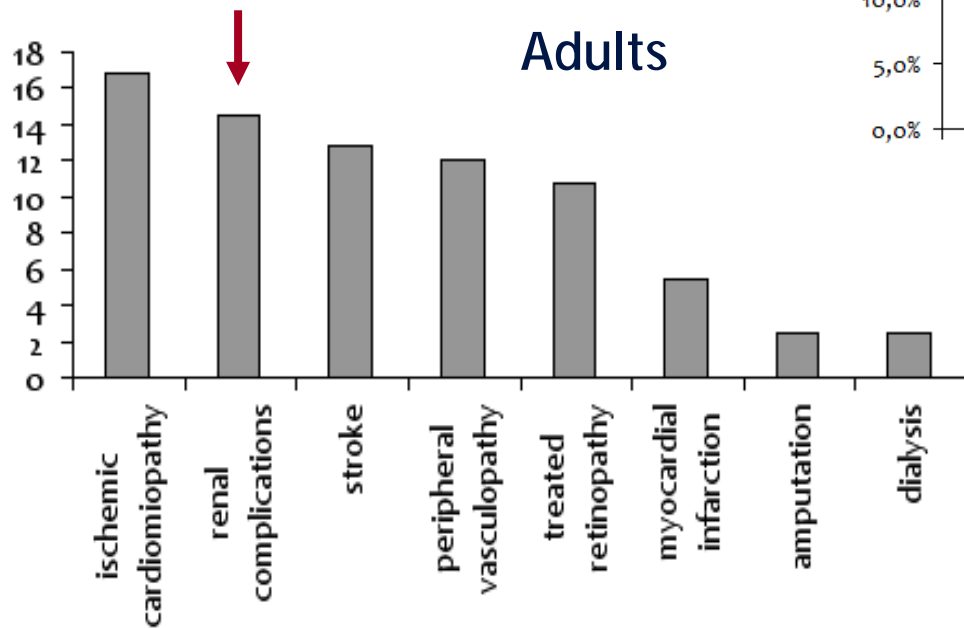


# Do we need it?

How is **diabetes management** in Emilia-Romagna region?

Look at the complications and establish the **size of expected benefit**

Range EU  
11.5 – 38.2



Perhaps we do not need it

## Proposed indication:

Breast cancer: to predict individual risk of developing metastasis.

The test classifies the patients in two categories: low and high risk of metastasis and suggest the need for chemotherapy accordingly



## Main expected benefits

- more accurate test than guideline criteria or electronic calculators for the estimate of individual risk for metastasis
- better identification of low and high risk patients
- expected decrease in number of women undergoing unnecessary adjuvant chemotherapy and adverse effects



## Do we need it?

### How many candidates in our context?

In the year 2005 according to the Emilia-Romagna Region Registry, the number of incident cases of women surgically treated for stage 1 or stage 2 breast cancer was **2 630** (LN negative: 1 950; LN 1-3: 680)\*

Out of the 2 630 women with breast cancer eligible for MammaPrint®: **887 (33.7%)** high risk of metastasis and treated with adjuvant chemotherapy



\*data source: Registro Tumori Emilia-Romagna, 2005

# Do we need it?

## Simulation in our context

Population		
women surgically treated for stage 1 or stage 2 breast cancer: 2 630		
	Index Test	Comparator
	<b>MammaPrint® (expected)</b> - Sensitivity (range): 72-100% - Specificity (range): 21-77%	<b>Current practice (observed)</b>
Assigned to <b>low</b> risk	<b>1418 - 608</b>	<b>1743</b>
Assigned to <b>high</b> risk	<b>1 212 - 2 022</b>	<b>887</b>



**We'd better not use it**





Theoretical rationale

no

STOP

yes

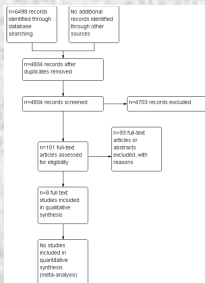


Context analysis

no

STOP

yes



Empirical knowledge

Available

**Not** available:

How long do we have to wait for better results (ongoing studies)?

or... can we fund the research that we need (regional research fund)?

**Decision**



**THANKS FOR YOUR  
ATTENTION**

Conference, October 2014



*Under the patronage of the Italian Ministry of Health*



Conference website: [www.eunetha2014.it](http://www.eunetha2014.it)