



HAUTE AUTORITÉ DE SANTÉ

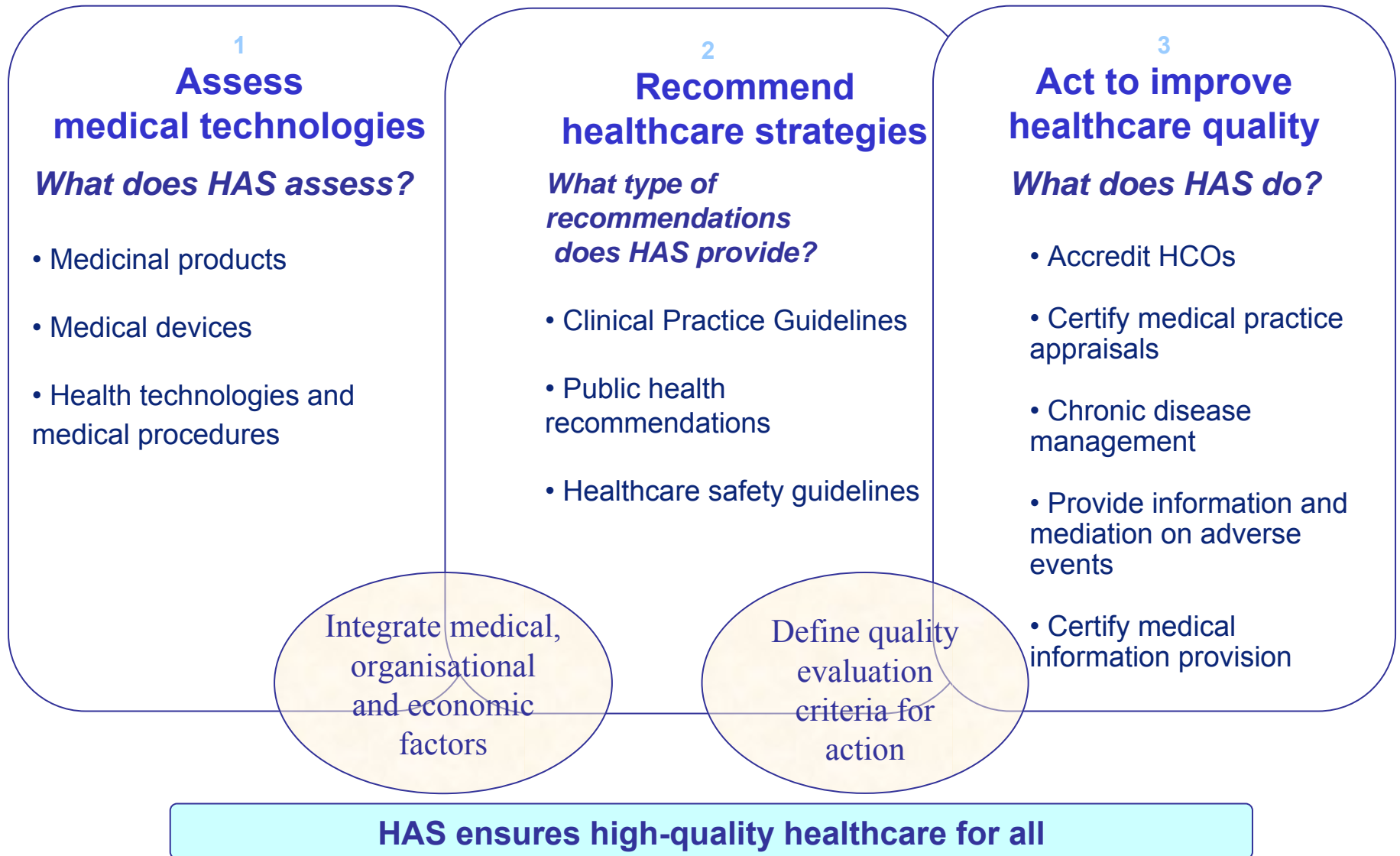
# **Benefit of health technologies :**

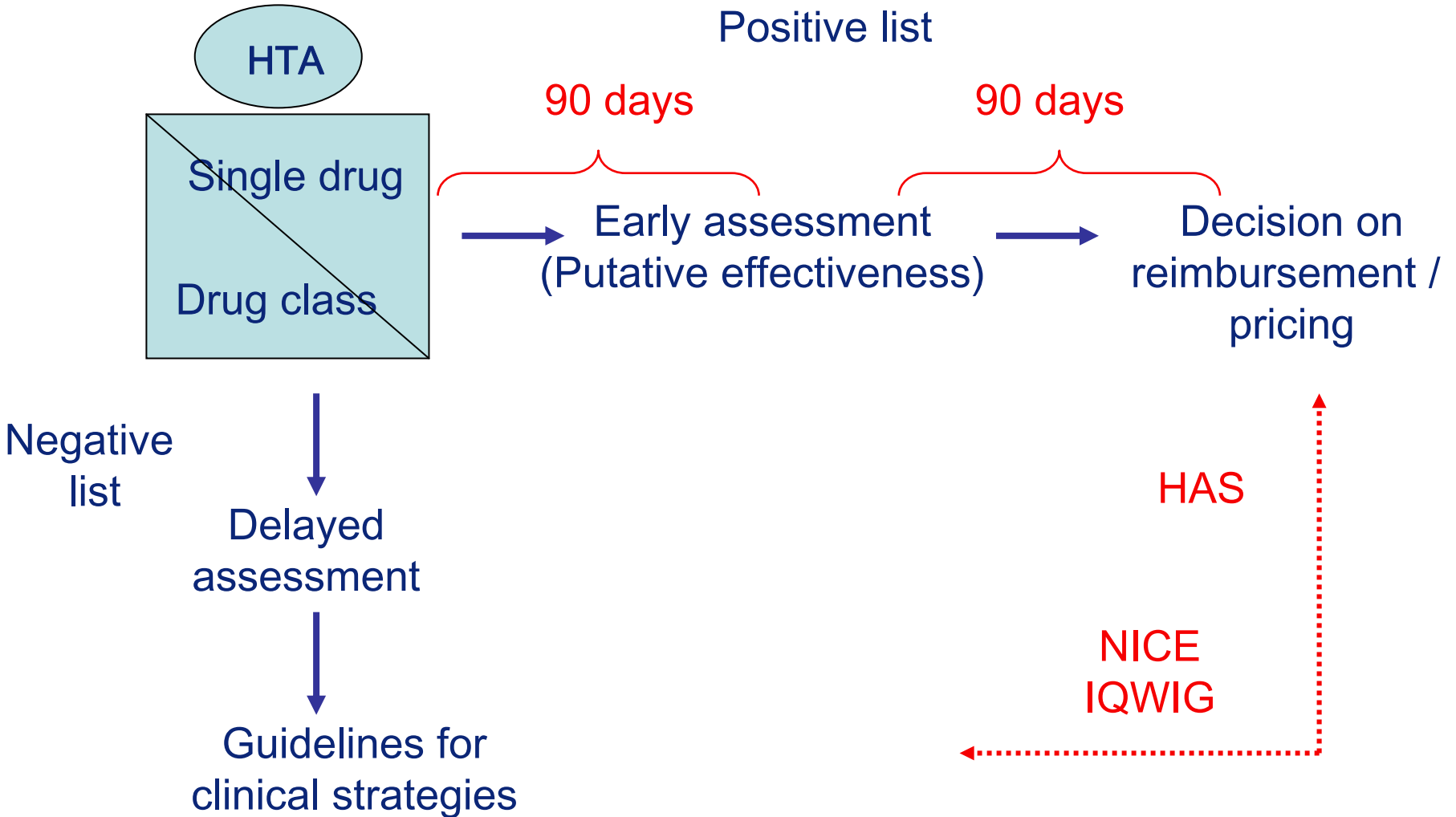
**Where do we come from,  
Where are we now,  
where do we go ?**

**Professor Laurent Degos**

**IWQIG, 24 Nov. 2007**

# 1 – Where have we come from?





	<b>Assessment</b>	<b>Decision</b>
<b>Approval</b>	<b>AFSSAPS = EMEA</b>	
<b>Reimbursement</b>	<b>HAS</b> <b>Actual Benefit (AB)</b>	<b>Ministry of Health</b>
<b>Pricing</b>	<b>HAS</b> <b>Improvement in</b> <b>Actual Benefit (IAB)</b>	<b>Ministry of Health,</b> <b>CEPS (Pricing Committee)</b> <b>&amp; Industry</b>

## 1. Single drug assessment

- Immediately after marketing approval
- 1 000 opinions/year

## 2. Positive list for reimbursement

- 0% / 35% / 65% / 100%

## 3. Agreement between CEPS & industry

- Price & reimbursement rate

- **Actual benefit (AB) and medical indication**

Substantial / Moderate / Low / Insufficient

→ if insufficient, no reimbursement

- Severity of the disease
- No other treatments available
- Public health burden (Epidemiology)

- **Improvement in Actual Benefit (IAB) = added value**

Major / Significant / Moderate / Minor / None

→ lower price if no IAB

## HAS

- **reassesses drugs every 5 years**
  - **revisits a class of drugs at any time** (e.g. drugs for Alzheimer's disease)
  - **meets Ministry of Health requests** (e.g. venotonics, vasodilators)
- **Delisting** - 380 drugs were delisted in 2006-7
- **Price cut**
- **Reimbursement rate reduced**



## Early assessment

Different reimbursement rates

- based on Actual Benefit

Specified indications qualifying for reimbursement

- “Proper use of drugs” leaflets
- overseen by NHI

Negotiated price

- based on Improvement in Actual Benefit

## Delayed assessment

Agreement between NHI and physicians' unions

- proposed by NHI
- assessed by HAS

e.g. aspirin *versus* clopidogrel

## **2 – Where are we now ?**

- **International trend**

**Growing interest in full Health Technology Assessments (that include medical, health-economic, organisational, social and ethical aspects)**

- Experience of NICE (UK) and National Board of Health (DK)
- Discussions ongoing in several national agencies

- **In France**

**HAS' mandate to be modified by law (Dec. 2007)**

- Competency in health economics
- Separate criteria (and steps) to assess medical effectiveness and health-economic issues (efficiency)

**... But this raises a range of difficult issues for HAS**

## ✓ **Efficacy**

- explanatory trials
- highly selected populations
- comparator: often placebo
- outcomes: clinical, often surrogates, adverse effects

→ *Is the treatment effective*

## ✓ **Effectiveness**

- pragmatic trials
- few exclusions
- comparator: current ('best') practice
- outcomes: patient-focused, downstream resources

→ *What is the real-life added value*

## ✓ **Role of post-approval studies**

- Observational studies and statistics ?
- Public, private, public/private ?

- **Will society accept health economics assessments?**  
*e.g. reactions to NICE guidance on drugs for Alzheimer's disease*
- **Which method should be used to assess economic efficiency?**
  - Cost-efficacy
  - Cost-benefit
  - Cost-utility

- **Threshold of the cost/benefit ratio?**
- **How to take social values into account in the decision-making process?**
- **How to identify possible ethical dilemmas *ex ante*?**
- **Separate or composite criteria?**

## Impact on

- **everyday life of patients and families**
- **professional skills**
- **organisation of care**
- **equal access to innovation**
- **existing public health policies**

## **3 – Where do we go from here ?**



## Preparing the new law: How to assess benefit for the community?

A technology undergoing a full HTA should be:

- part of an overall medical strategy
- in competition with other medical / non-medical strategies

A full HTA should address clinical AND community benefit

- Medical effectiveness (real-life)
- Health economics (efficiency)
- Impact on organization of care
- Social choice
- Ethical issues

**Community benefit (SERC)**

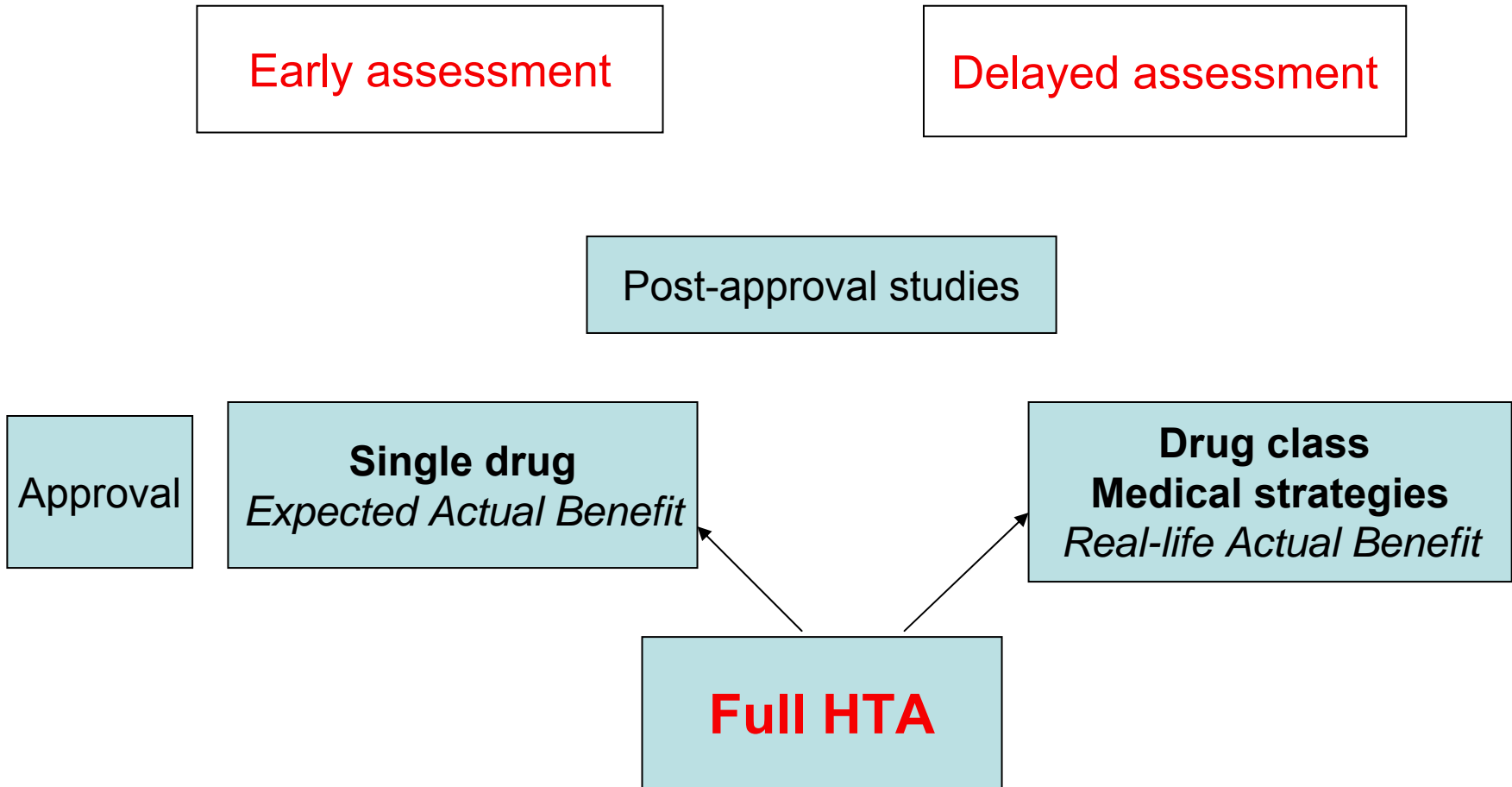
## Consider clinical benefit AND community benefit

- **Clinical benefit**
  - Intrinsic value + indication
  - Severity and burden of the disease
  - No alternative treatment
- **Community benefit (SERC)**
  - Health economics (efficiency)
  - Impact on organization of care
  - Social choice
  - Ethical issues

## **Before implementing a full HTA, need to consider:**

1. when should a full HTA take place?
2. which products / procedures should undergo a full HTA?
3. which assessment criteria should be used?
4. what types of analysis should be performed?
5. who are the stakeholders ?
6. impact on decision-making

# 1. Timing of a full HTA



# 1. Timing of a full HTA (contd)

## ✓ **Early assessment** (single drug)

## ✓ **Delayed assessment** (drug class)

**Clinical HTA**

**Before** pricing and reimbursement

**After** pricing and reimbursement

- Expected Actual Benefit
- Positive list
- Horizon scanning
- Rapid assessment (3 months)
- Stringent selection

- Real-life Actual Benefit
- Negative list
- Selected according to HAS' work programme or integrated activities

**Full HTA**

- **Impact on pricing & reimbursement**
- **Impact on efficient practices**

### ✓ **Early assessment**

#### **Clinical HTA**

- Systematic (1000/year)

#### **Full HTA**

- When major issues raised:
  - health-economic
  - organisational
  - social and ethical
- Next best alternative strategies:
  - opportunity cost

### ✓ **Delayed assessment**

- Systematic (every 5 years)

- Revision because of
  - new data
  - new competitor drug
- Due to HAS work programme
- Direct interaction with efficient prescription and practices (continuous professional development, certification...)

## Clinical effectiveness, relative efficacy

- Intrinsic value
  - Actual Benefit
  - Improvement in Actual Benefit
- Good practices
  - Indication
  - Alternative treatment
  - Professional skills
  - Ethics
- Disease
  - Severity
  - Prevalence

## Community benefit

- Health economics assessment
- Organisational issues, accessibility
- Public health policy
- Epidemiology
- Social and ethical aspects

## 4. Types of analysis

### **Clinical benefit (relative efficacy)**

- Meta-analysis
- 'Area under the curve' comparison
- Utility (QALY)

### **Community benefit**

- Costs and health-economic evaluation
  - cost-efficacy
  - cost-benefit
  - cost-utility
- Assessment of impact on organisation of care
- Identification of relevant social values
- Identification of possible ethical dilemmas



- **Cost-utility? QALY ?**  
No composite criteria accepted to date
- **Cost-benefit (willingness to pay) ?**  
A patient is not a standard customer
- **Cost-efficacy**  
Comparable numbers for efficacy assessment ?  
(Amplitude of difference, time-dependent)

- **Expertise**
- **Citizen councils**
- **Public debates (internet)**

### ✓ **Early assessment (positive list)**

- Rejected
- Temporarily accepted  
Post-approval studies (private, public, shared)?
- Accepted

### **Impact on reimbursement**

- Price control
- Price reference
- Payback

### ✓ **Delayed assessment**

- Delisted
- Revisited pricing/reimbursement
- Modified prescribing strategy

### **Impact on efficient practices**

- Guidelines
- Control
- Measures

### Separate or composite criteria ?

- One composite criterion = close to the decision
  - No accepted composite criteria yet
- Several criteria = open decision
  - Less impact in the decision-making process ?
- Scenarios combining clinical and collective benefit

- **Health economics included in a full HTA**
- **Single drug – Early Assessment - Positive list**
  - Direct impact on pricing and reimbursement
  - Strong selection for full HTA (clinical, health-economic, organisational, public health policy, social and ethical aspects)
  - Combined criteria: Leaflets on the ‘Proper use of technologies’
    - Professional expertise
- **Drug class – Delayed Assessment – Negative list (rare) & Efficient practice**
  - Tools for implementation = guidelines
  - Promotion: incentives, constraints, control, comparison, contracts
  - Link with colleges of professionals
    - Professional practice