



Budget impact vs cost effectiveness: Implications for personalised cancer therapies.

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no conflict of interest

The aim of the healthcare policy is to *maximise the health* of the population within the *limits of the available means* and within an ethical framework, based on values such as fairness and solidarity.



incremental cost / incremental effect = ICER

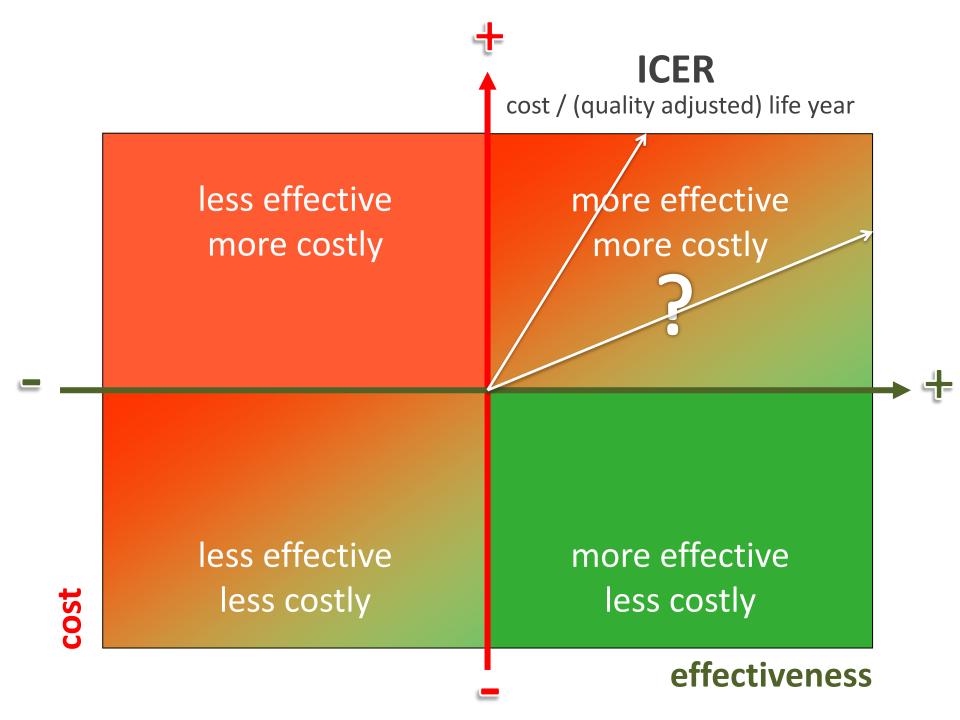
cost per life year gained (LYG)

= incremental cost-effectiveness ratio

cost per quality-adjusted life year (QALY)

= incremental cost-utility ratio





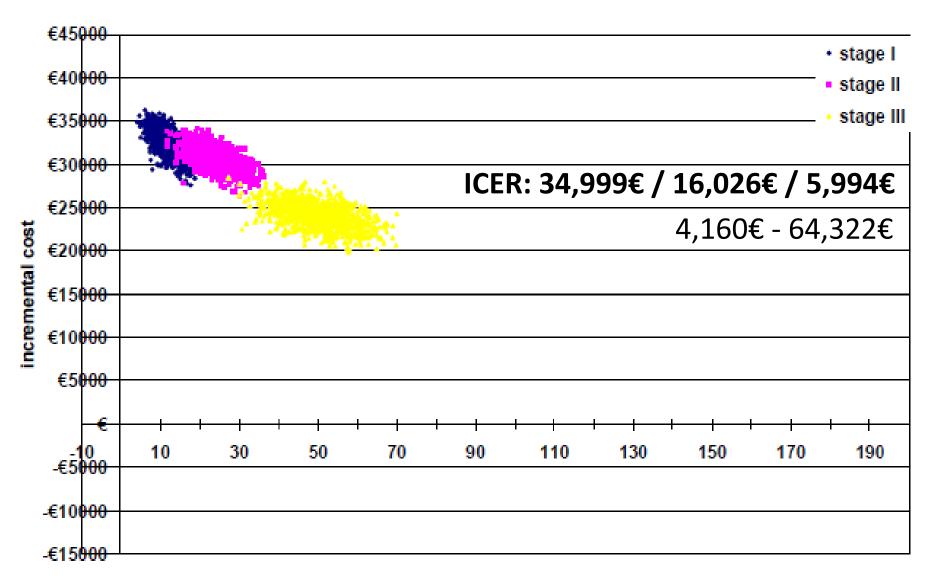
Country	Authors	ICER threshold		
Explicit ICER threshold range				
UK	NICE ¹⁵¹	£20 000 - £30 000 per QALY		
Implicit ICER thresh	Implicit ICER threshold values or ranges based on past allocation decisions			
Australia	Henry et al. and the PBAC ⁹⁵	AU\$69 900 per QALY		
New Zealand	Pritchard et al. and PHARMAC ⁹³	NZ\$20 000 per QALY		
Canada	Rocchi et al. and the CDR ⁹⁴	Range of acceptance: dominant to CAN\$80 000 per QALY		
		Range of rejection: CAN\$31 000 to CAN\$137 000 per QALY		
ICER threshold values or ranges proposed by individuals or institutions				
USA	Weinstein ¹⁴⁰	\$50 000 per QALY		
USA	Braithwaite et al.96	\$109 000 - \$297 000 per QALY		
The	The Council for Public	€80 000 per QALY		
Netherlands	Health and Health Care 156			
Canada	Laupacis et al. 155	CAN\$20 000 to CAN\$100 000 per QALY		
No ICER threshold values or ranges identified				
Finland, Sweden, Norway, Denmark				

- < 1*GDP / capita = cost-effective
- > 3*GDP / capita = cost-ineffective

cost-effectiveness trastuzumab in early stage breast cancer

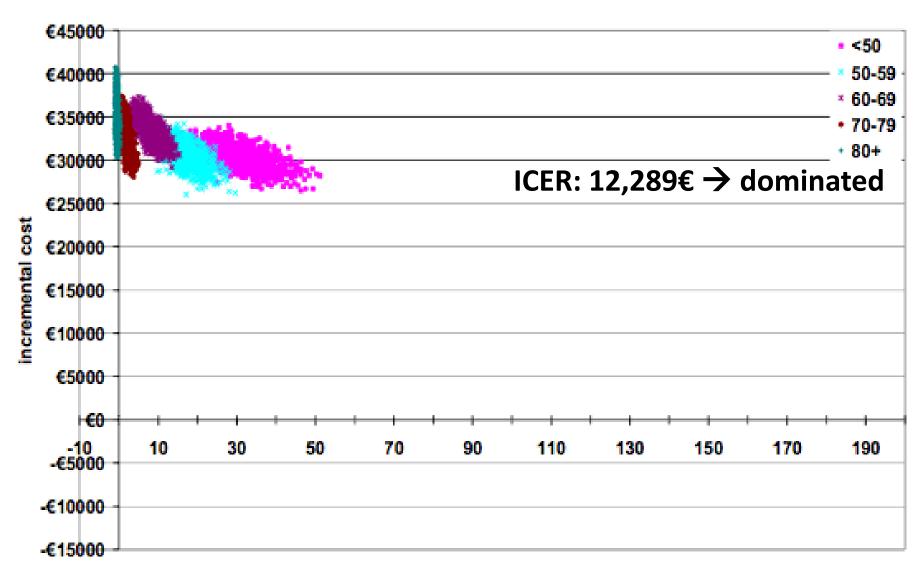


cost-effectiveness trastuzumab in early stage breast cancer

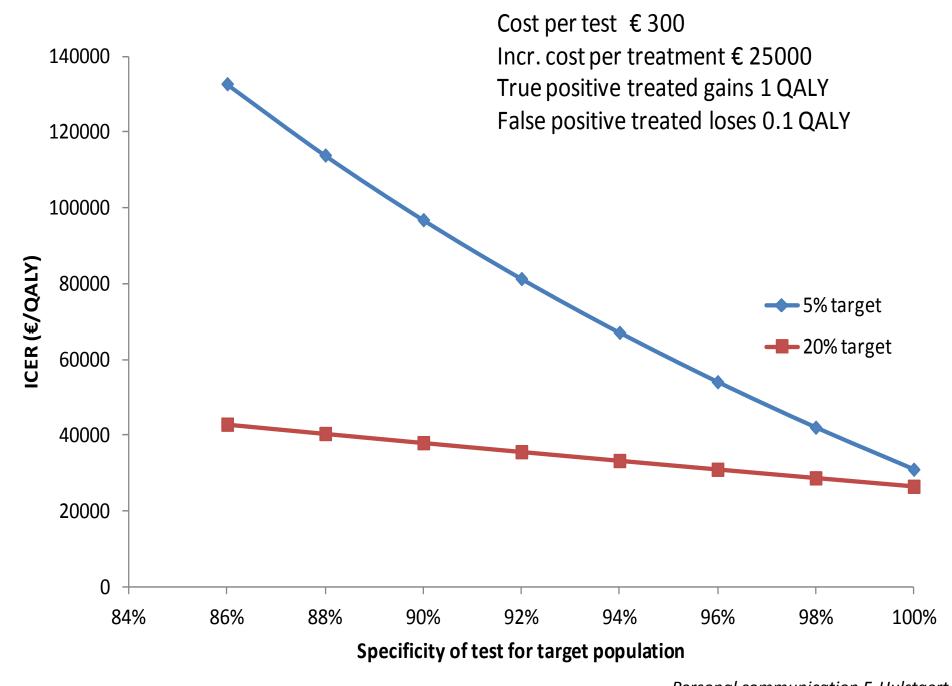


incremental effectiveness (months)

cost-effectiveness trastuzumab in early stage breast cancer

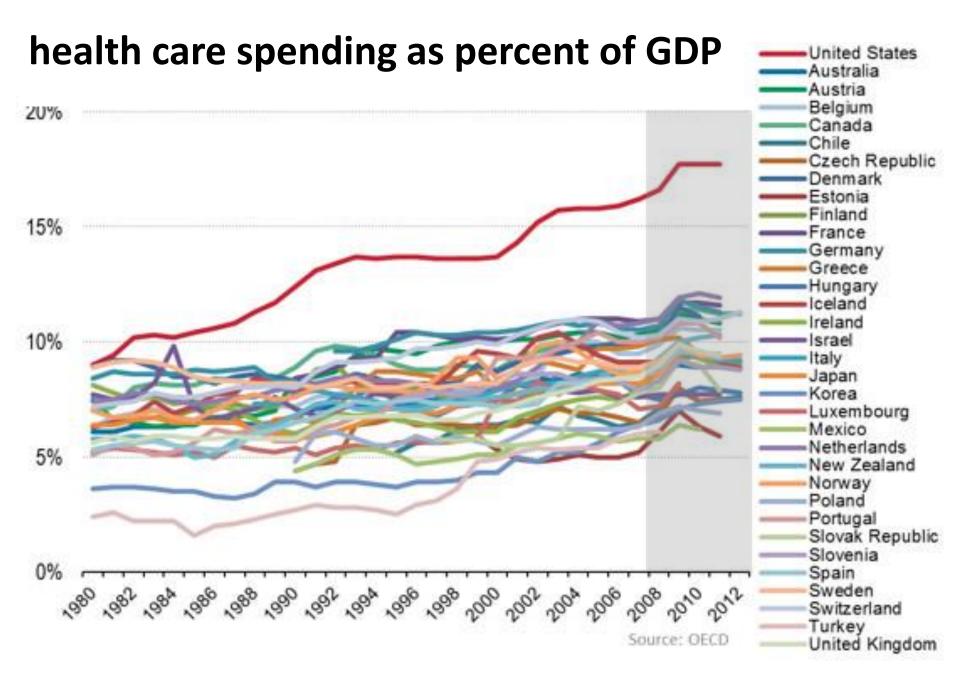


incremental effectiveness (months)



Personal communication F. Hulstaert

acceptable... and affordable?



"How much will Herceptin really cost?"

"On the face of it, the answer to our question is simple—Herceptin will cost our trust £2.3m, but the real cost lies in the services that will be cut to provide this money."

Table 1 Cost and potential benefits of adjuvant cancer treatments in Norfolk and Norwich University Hospital Trust

Treatment	No of patients given treatment	Drug cost (£000)	Proven benefit	Potential benefit at our hospital	Cost per patient cured (£000)
Adjuvant chemotherapy for lung cancer	15	23	5-15% improved 5 year overall survival ^{w3}	1 extra patient cured	23
Oxaliplatin as adjuvant therapy for colon cancer compared with fluorouracil alone	20	137	5% improved 3 year disease-free survival; no benefit to overall survival ^{#4}	1 extra patient without recurrence at 3 years	137
Neoadjuvant chemotherapy for oesophageal cancer	25	8	9% improved 5 year survival ^{w6}	3 extra patients cured	2.67
Rituximab in addition to CHOP for non-Hodgkin lymphoma in patients over 60	25	215	13% improved 2 year overall surviva(^{w6}	3 extra patients cured	71.67
Adjuvant aromatase inhibitors in postmenopausal breast cancer	270	120	3.7% improved disease-free survival compared with tamoxifen; no benefit to overall survival ^{w7}	8 extra patients without recurrence at 5 years	15
Total	355	503		16 extra patients cured	
Herceptin for early stage breast cancer	75	1940	0-4% improved 4 year overall survival ^{w1 w2}	3 extra patients cured	650

acceptability vs. affordability

There is growing recognition that a comprehensive economic assessment of a new health-care intervention at the time of launch requires both a cost-effectiveness analysis (CEA) and a budget impact analysis (BIA).

	CEA	BIA	
Research question	Acceptability	Affordability	
Perspective	Healthcare payers		
Tarret manulation	Consistent with reimbursement request		
Target population	Closed *	Open	
Comparator	On the efficiency frontier	Current situation	
Costs	Direct healthcare related costs		
Costs	No transfers	Transfers	
Health outcomes	Included	Not included **	
Time horizon	As long as incremental costs or outcomes are generated	Up to steady state	
Modelling	Decision tree, Markov model		
Handling uncertainty	Probabilistic and one- or multiple-way probabilistic sensitivity analyses, scenario and subgroup analyses		
Discount rate	Costs: 3%, effects: 1.5%	No discounting	
Presenting results	Incremental cost, incremental effect, ICER, cost-effectiveness plane, CEA-curve, results of the sensitivity analyses	Yearly budget impact, disaggregated impact, results of the sensitivity analyses	

stage	FISH positive	Actual Chemo	Chemo LVEF ≥55%
			T 52 weeks
stage 1	378	100	80 3.25 M€
stage 2	546	331	267 10.86 M€
stage 3	245	179	144 5.85 M€
all	1169	610	491 19.96 M€

Belgian population data, 2005

some issues

many new drugs in the pipeline rapidly evolving and highly complex landscape smaller numbers of potential recipients what is the evidence? higher costs of newer drugs what ICER benchmark to use? allow different prices for different patient groups? value-based pricing? value-based user charges? how to value? how to deal the ever growing health care basket?

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RCT's: time for a paradigm change?

Which populations do really benefit?

RCT's in small and highly selected population?

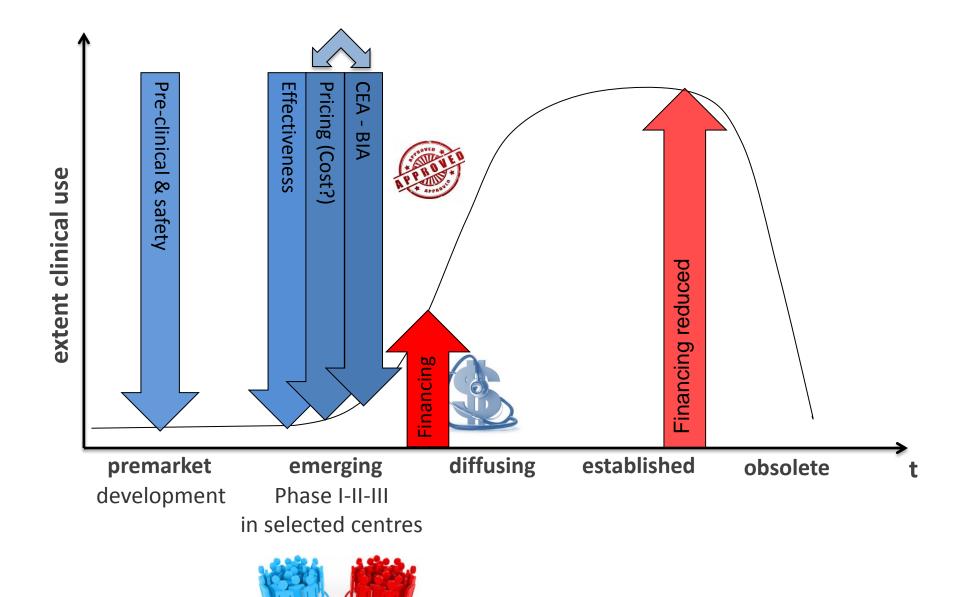


The drug and its companion diagnostic Effectiveness? Value? Timing?

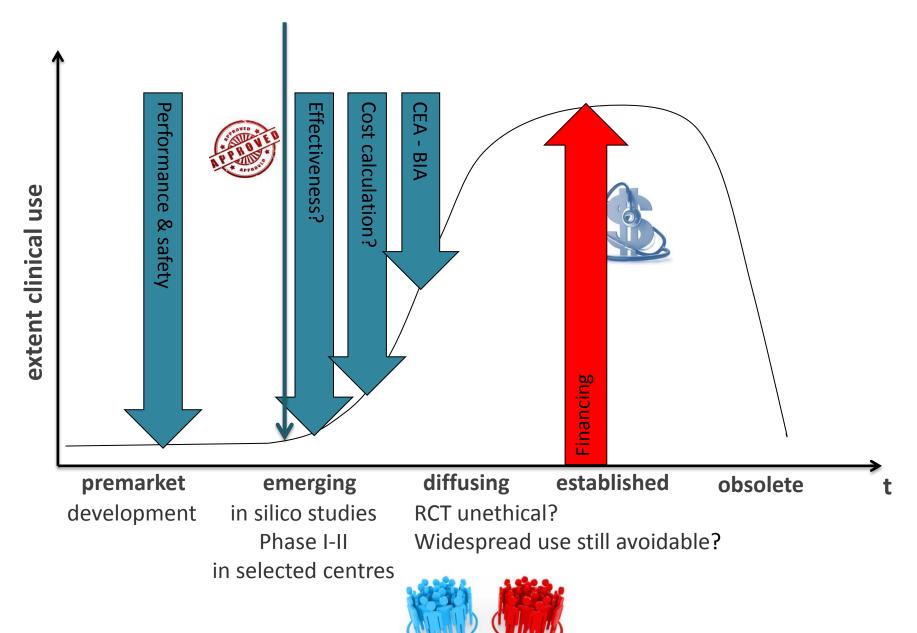
Longer survival versus less side-effects and better QOL New RCT's without cross-over?

New approaches for trial design?
Bayesian adaptive trials, modelling

How to meet the evidence needs of reimbursement authorities? Supplementary support by observational cohorts? Post-authorization data?



investment



similar issues for radiotherapy

many new technologies in the pipeline rapidly evolving and highly complex landscape smaller numbers of potential recipients what is the evidence? higher costs of newer technologies what ICER benchmark to use? allow different prices for different patient groups? value-based pricing? value based user charges? how to value? how to deal the ever growing health care basket?

...

reimbursement for SBRT?

what is

the (level 1) evidence?

the cost?

the value for money?

the budgetary impact?

coverage with evidence development

Innovative radiotherapy techniques



Define the indications

Define the costs to be covered

Define the evidence generation



Evidence generation and follow-up



→ In close collaboration with the radiotherapy departments

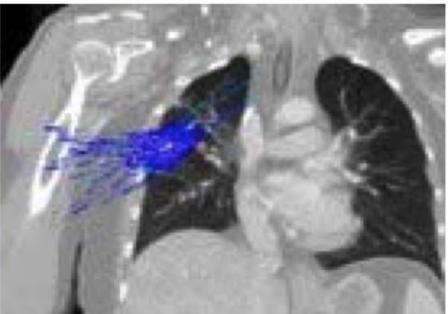


		1,000
Technique	Cancer Indication	Safety monitoring (clinical trial)
APBI	Breast (low risk group only)	No**
APBI	Breast (medium risk)	Yes
Intraoperative boost	Breast	No**
SBRT	Lung	No
SBRT	Prostate	Yes
SBRT	Renal	Yes
SBRT	Pancreatic	Yes
SBRT	Head & Neck	Yes
SBRT	Primary Hepatic	Yes
SBRT	Hepatic Metastases	No
SBRT	Spinal and paraspinal	No
SBRT	Oligometastases (other)	Yes
SBRT	Lung Metastases	No
SBRT	Lymph Node Metastases	Yes



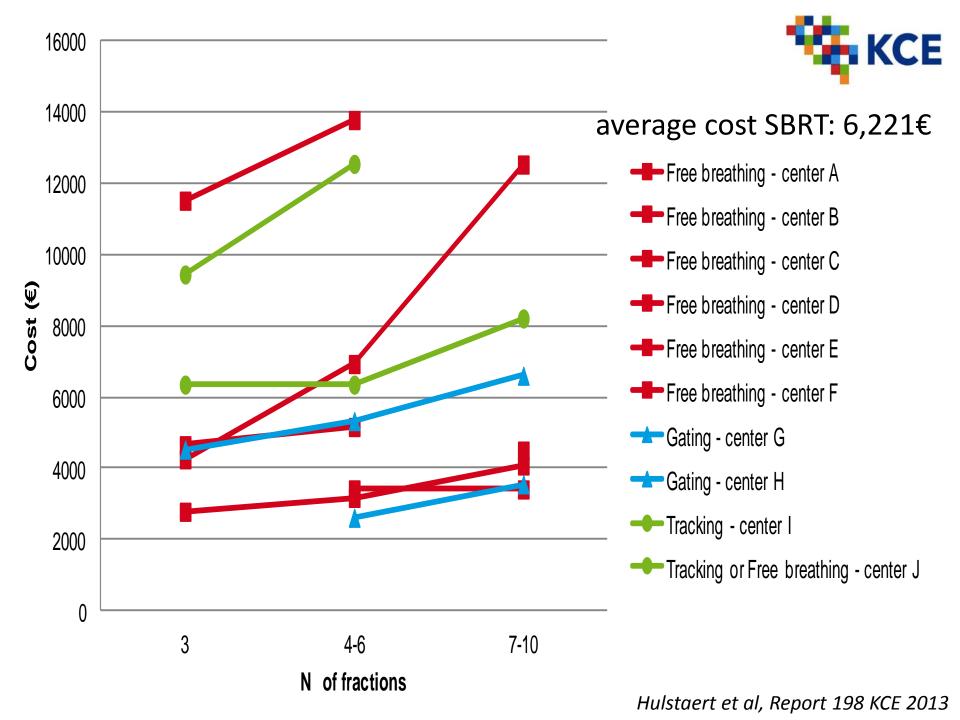
INNOVATIVE RADIOTHERAPY TECHNIQUES: A MULTICENTRE TIME-DRIVEN ACTIVITY-BASED COSTING STUDY

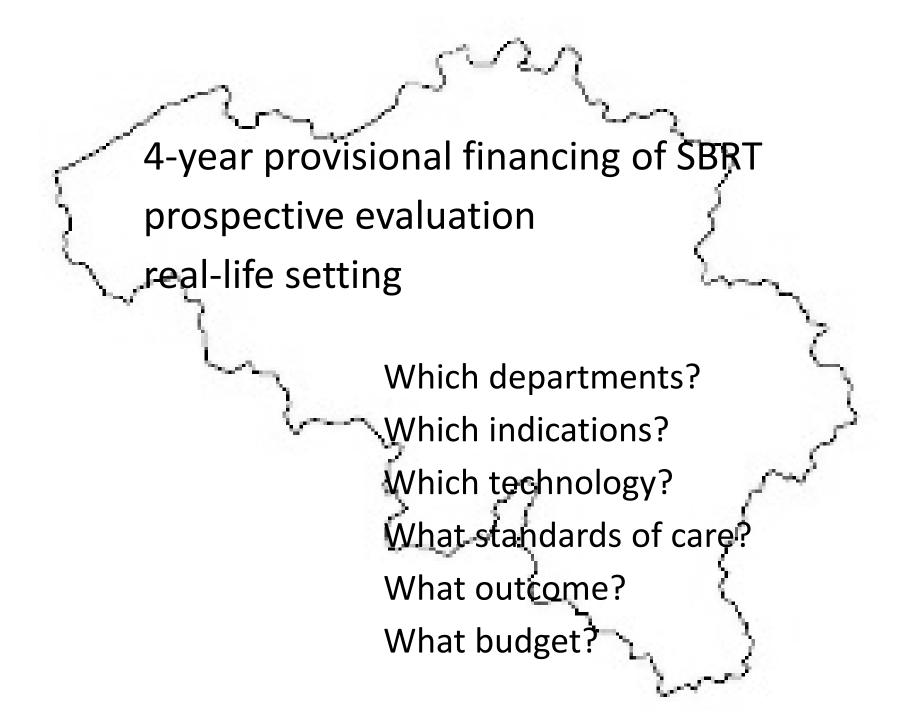




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the sky is not the limit cost-effectiveness is not enough budget impact is equally relevant many unsolved issues focus on evidence and value provisional reimbursement models