How does haemovigilance link with quality management and cost savings?

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Haemovigilance: recurring elements in the definitions

- Organized surveillance
- Collecting and evaluating information
- On serious adverse or unexpected events or reactions in donors or recipients
- Epidemiological follow-up of donors

Content

- Evolution in the sector

- Health economics
  - introduction
  - blood products & QALY
  - blood products & costs considered

- Conclusions & Recommendations

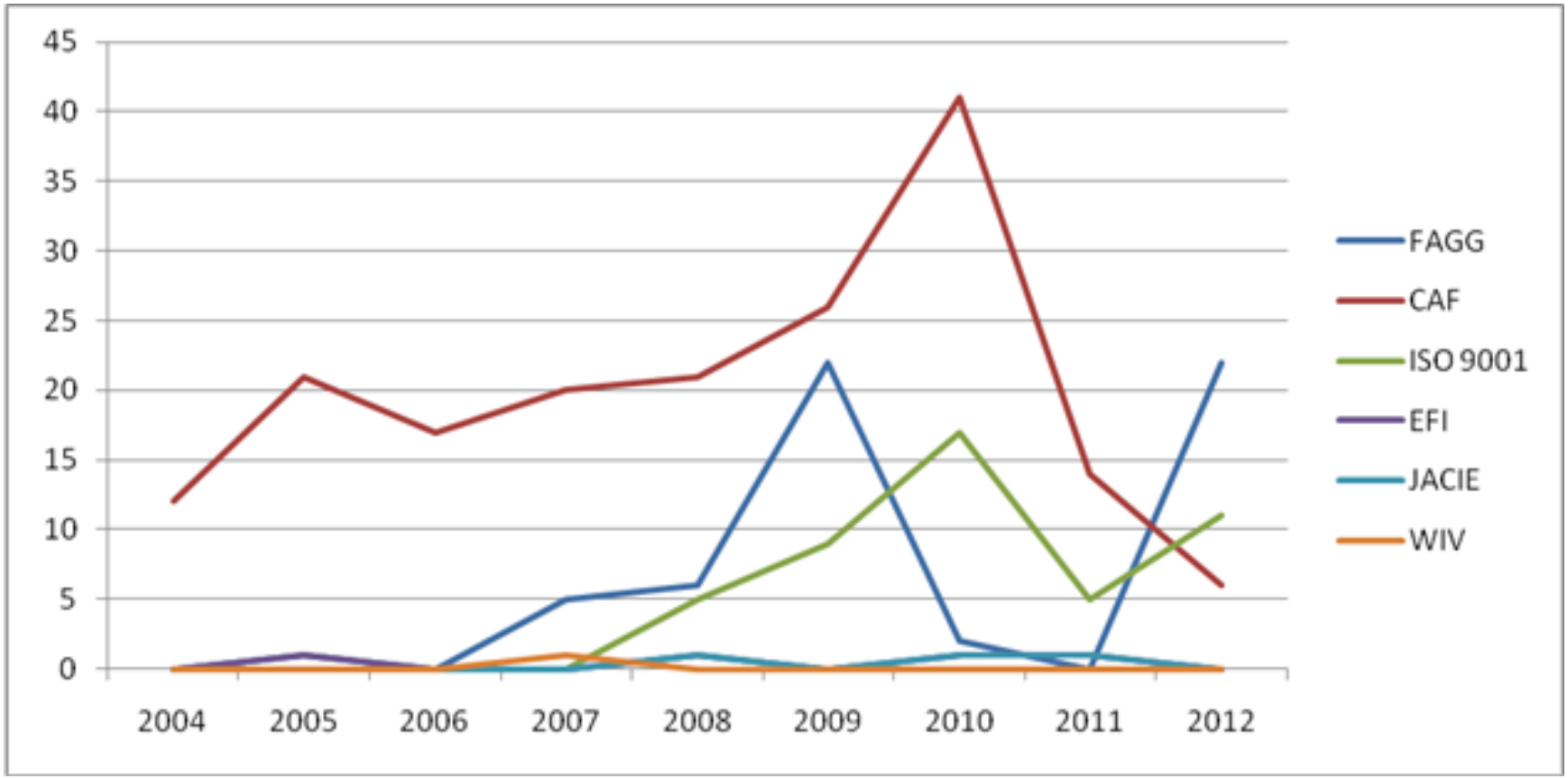
Safety measures ever increase – product

- Lab tests
  - Syfilis (1961)
  - HBsAg (1971)
  - anti-HIV1 As (1985); anti-HIV1,2 As (1992)
  - anti-HCV As (1990)
  - ALT (1994; eliminated 2007)
  - Bacterial testing (1999)
  - NAT HIV1 en HCV (2002)
  - NAT HBV / HIV2 / HIV O (2010)
  - HLA As screening of donors (2010)
- Other measures
  - Viro inactivation plasma (1992)
    - no pooling (2004)
    - Only male donors without transfusion antecedents (2004)
  - Irradiation of blood products (since 20 jaar, in 2009 reimbursed)
  - Universal leukoreduction (2005)
  - Platelets
    - in PAS instead of plasma (2008)
    - Pathogen Reduction Technology (2009)

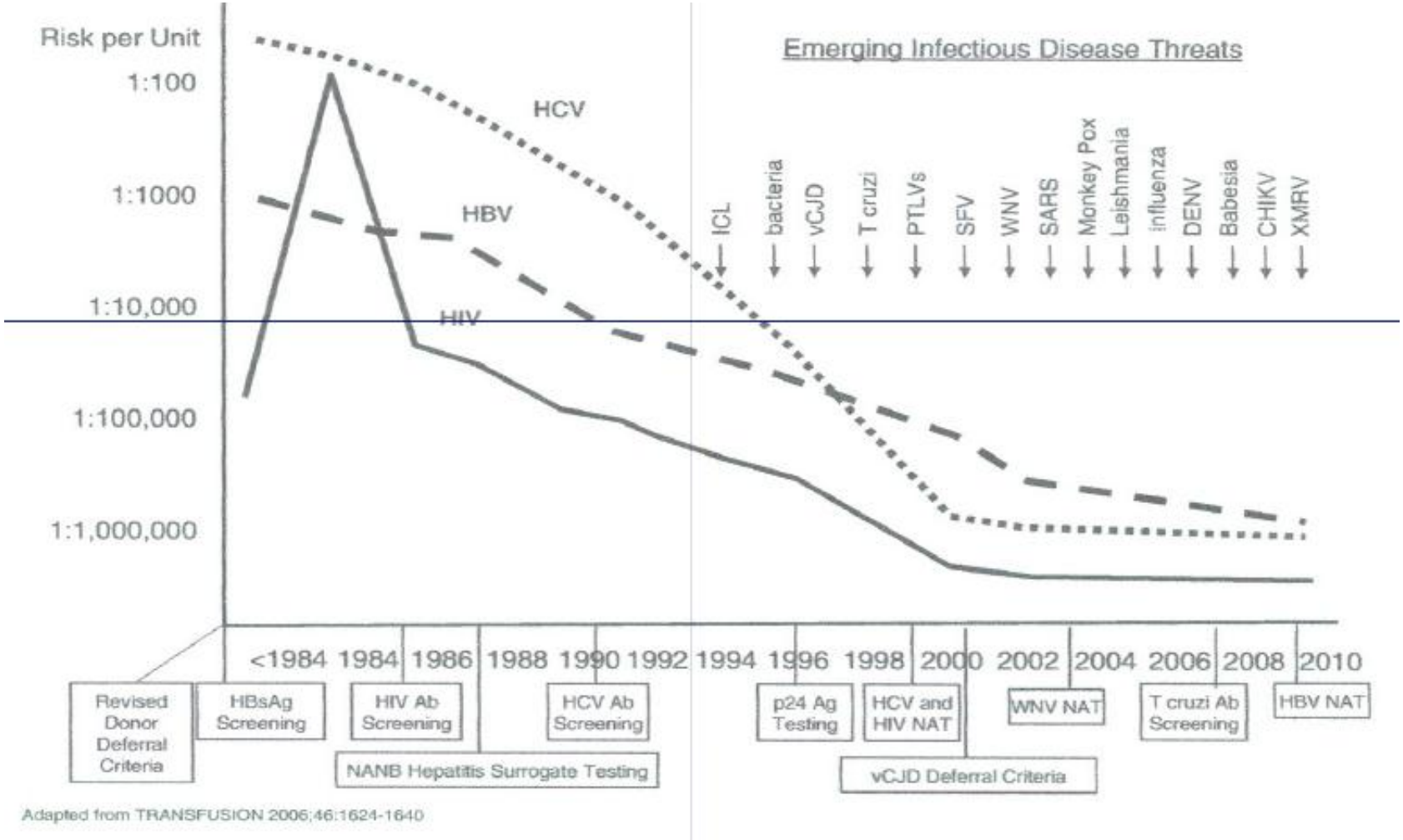
Safety measures ever increase – process

- Donor selection
  - Exclusion criteria
- Quality norms
  - Inspections
- Haemovigilance
  - Formal reporting procedure (by competent authority, 2005)
  - …

Number of inspections ever increases



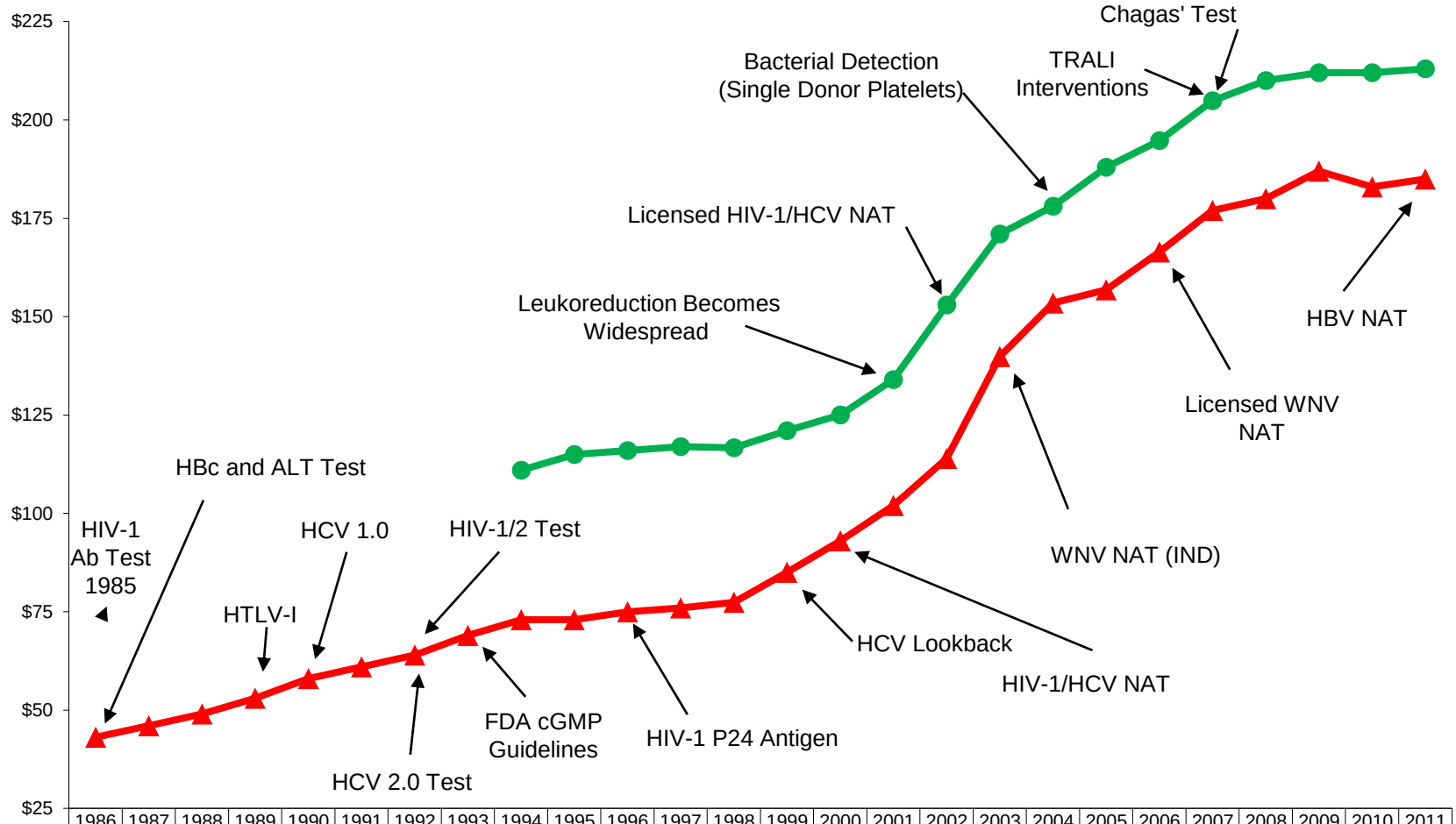
Blood products become ever safer



Adapted from TRANSFUSION 2006;46:1624-1640

But… blood becomes ever more expensive

1986 - 2011



	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
RBCs	43	46	49	53	58	61	64	69	73	73	75	76	77	85	93	102	114	140	154	157	166	177	180	187	183	185
RBCs, LR									$111	115	116	117	117	121	125	134	153	171	178	188	195	205	210	212	212	213

LR = Leukoreduced

Blood "incidents" in Belgium

Process-related	**2007**	**2008**
Serious adverse events	156	145
Serious adverse reactions	153	142
Total	**309**	**287**
Product-related	14	9
in %	**4,5**	**3,1**

source: annual report FAGG

Challenge for blood operators

- Our instinct & tradition is to make blood ever safer
  - The precautionary principle: in the interest of public health, risk management action should be taken in the absence of certainty about risk

- New challenge is to balance this with sustainability
  - The principle of risk based decision making: risk management actions should be proportionate with the level of demonstrated risk

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A “unit” of health effect

- Number of symptomfree days
- Number of days with good life quality
- Number of patients cured
- Number of complications avoided
- Number of years without complication
- Number of years with responder status
- Number of life years gained (LYG)

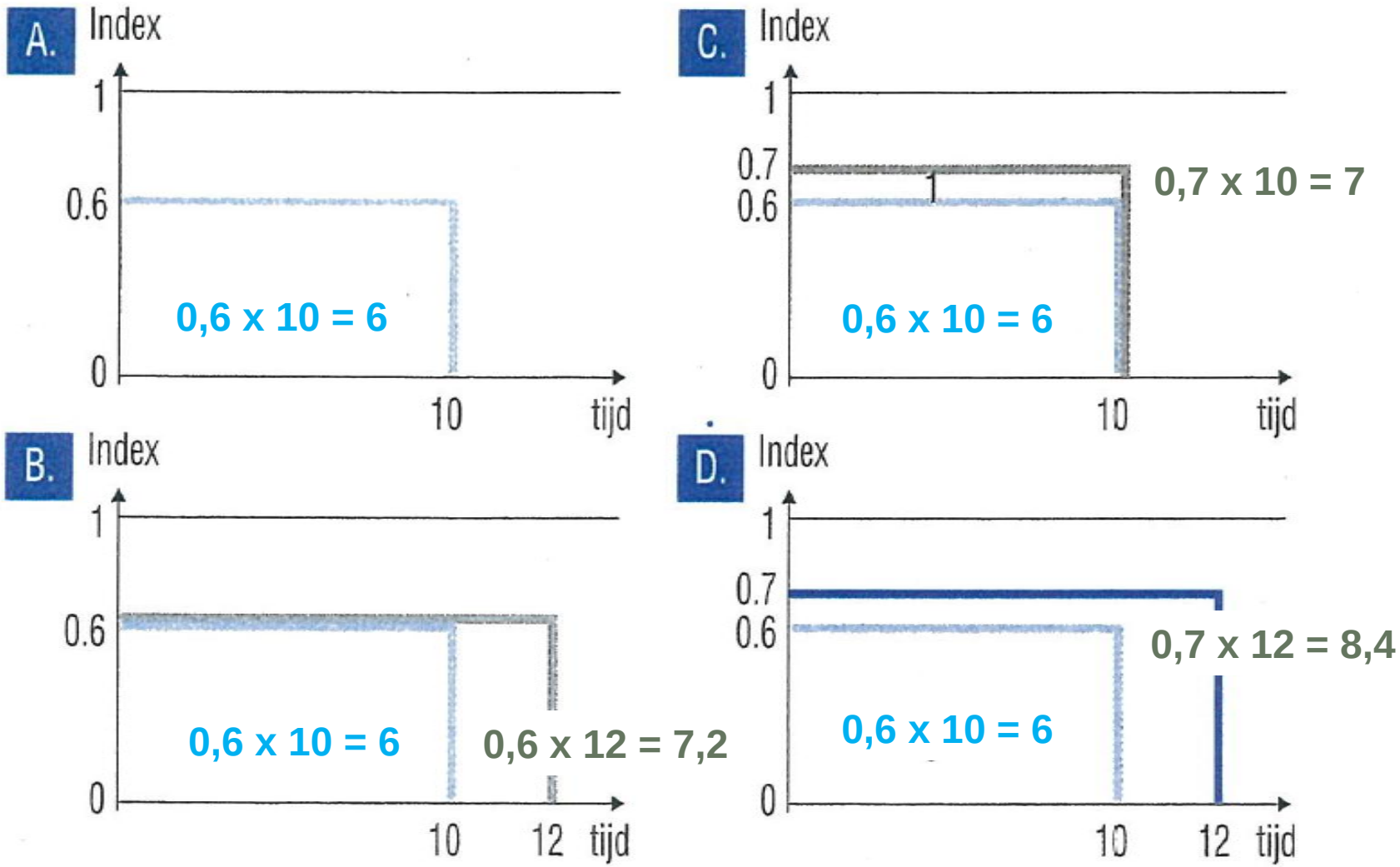
- Disability adjusted life years (DALY) (adjusted for handicap)
- Quality adjusted life years (QALY) (adjusted for quality)

Different Types of Economic Analysis

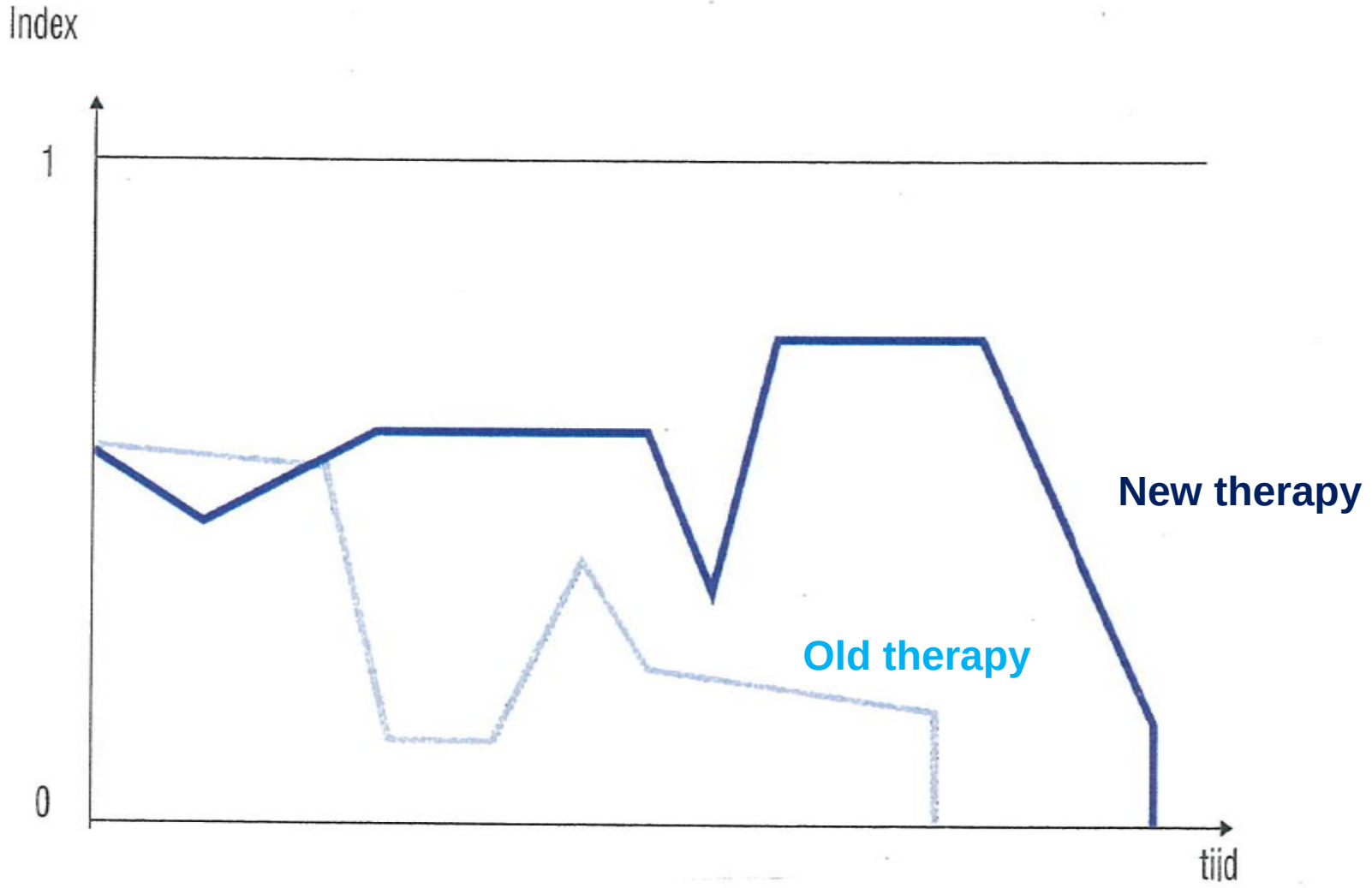
Type of analysis	Objective determines	Technique	Outcome Measure
Cost minimization	which of 2 options with equal benefits has lowest costs	Compares costs between different options thought to be equally effective	
Cost effectiveness	how a given goal is achieved most efficiently	Relates costs to some measures of outcome	Natural units (e.g. LYG, life-years gained (saved) or treatment – specific terms e.g. reduction in LDL level)
Cost utility	the best way of spending given health care budget	Relates cost to healthy years gained	Healthy years (e.g. quality-adjusted life years (QALY), healthy years equivalent)
Cost benefit	how much more or less of societies' resources should be allocated to achieve a defined goal	Compares input and output in monetary units	Benefits converted into monetary terms

Adapted from Drummond MF and Jefferson TO. BMJ 1996;313:275-283 & Ebrahim S, Br Med Bull 2000; 56(2): 557-570

Schematic representation of QALY: the concept



Schematic representation of QALY: real-life



How to measure QALY? the EQ5D questionnaire

Mobility
No problems walking (score 1)
Some problems walking (score 2)
Bedridden (score 3)

Selfcare
No problems washing – getting dressed
Some problems washing – getting dressed
Not capable to wash or dress myself

Daily activities (f.i. work, study, spare time, …)
No problems doing my daily activities
Some problems doing my daily activities
Not capable to do my daily activities

Pain
No pain or other complaints
Moderate pain or other complaints
Severe pain or other complaints

Mood
No anxiety or depression
Moderate anxiety or depression
Severe anxiety or depression

$3^5 = 243$ possibilities

Utilitities corresponding to EQ5D profielen

3^5 = 243 possibilities

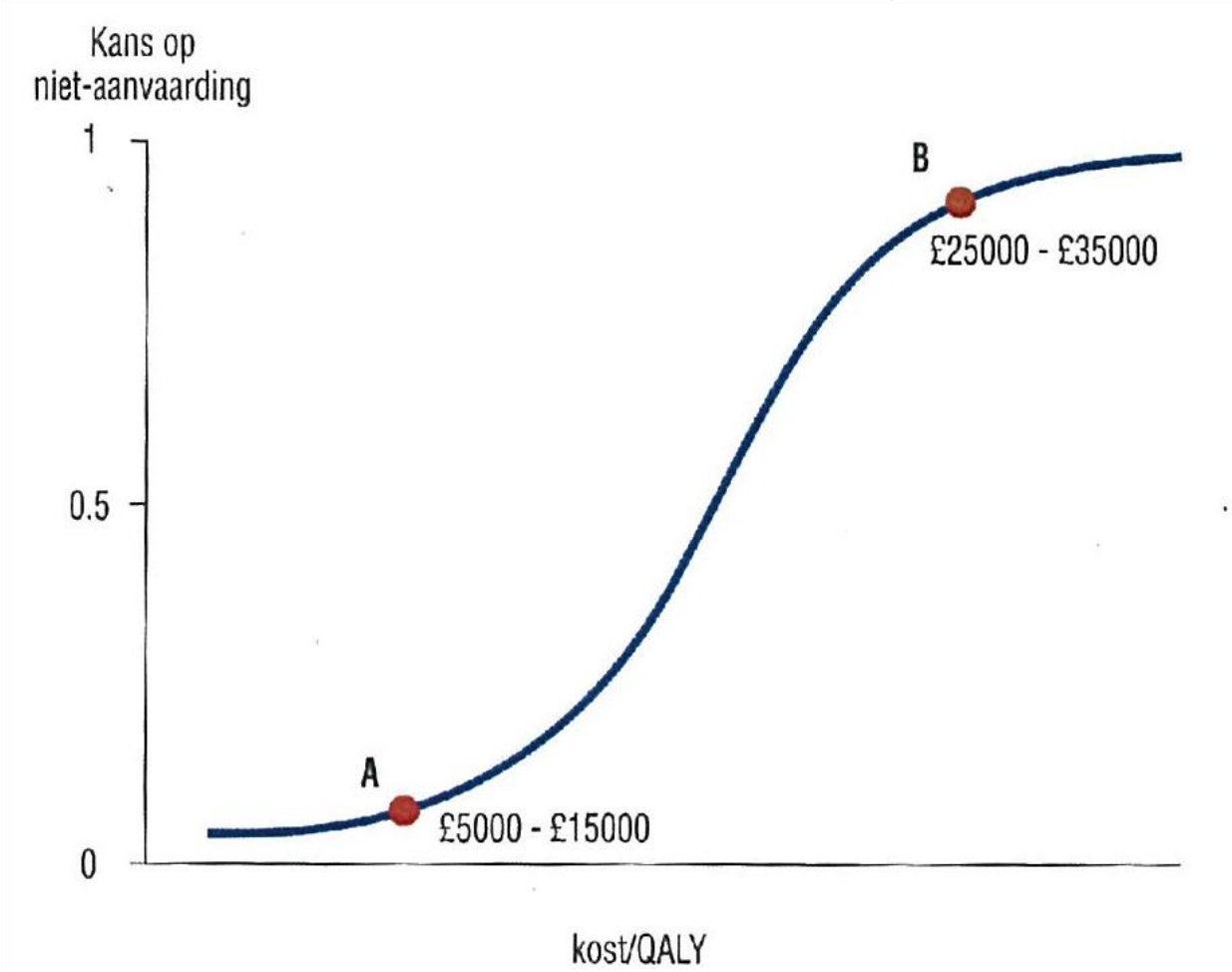
Status	Index
11111	**1.000**
11112	0.7444
11113	0.3847
11121	0.7641
11122	0.6607
11123	0.3010
…..	…..
33321	0.1320
33322	0.0286
33323	- 0.0748
33331	0.0484
33332	- 0.0550
33333	- 0.1584
Death	**0.0000**
In coma	- 0.0163

Limit of willingness to pay per QALY

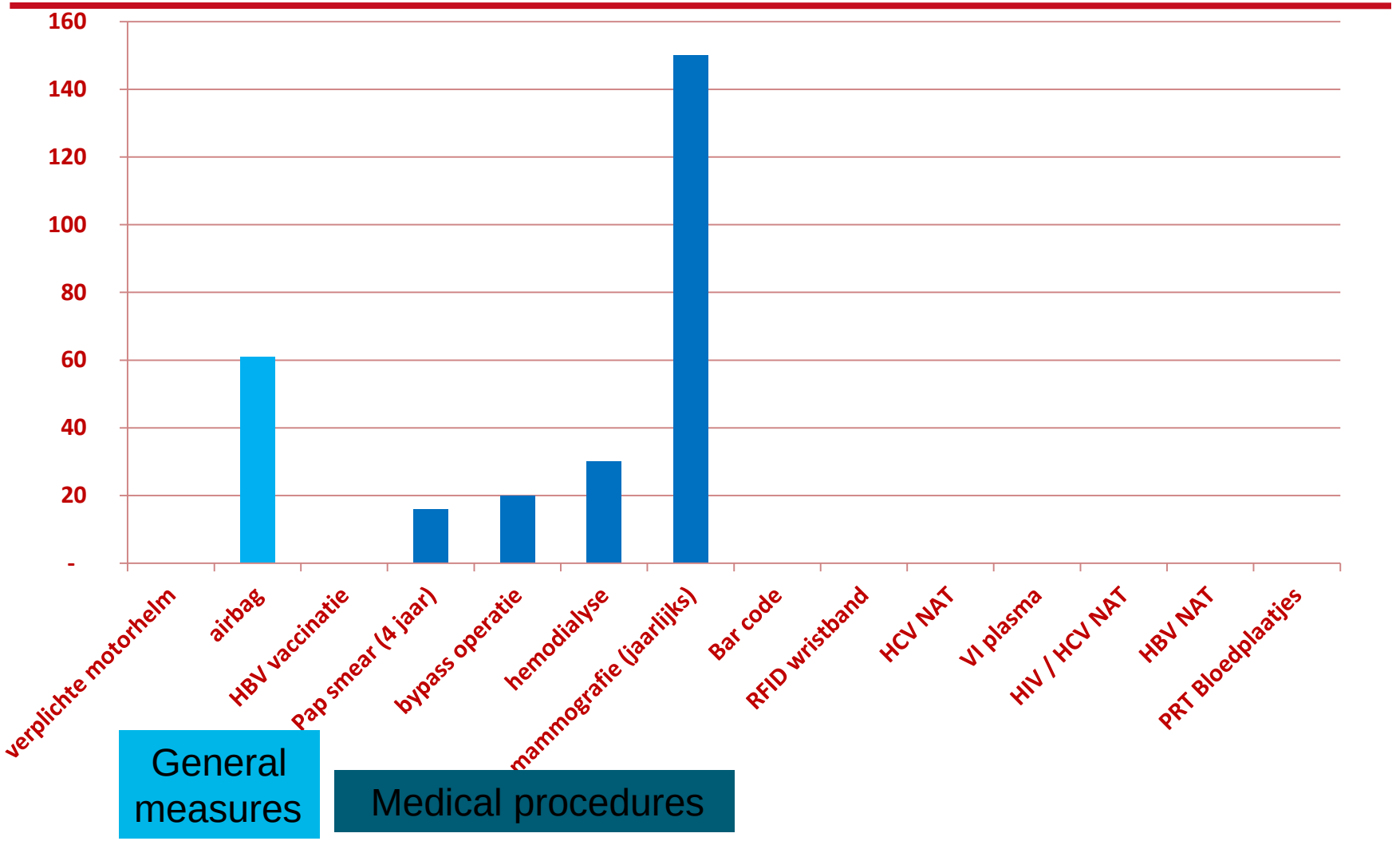
Country	Currency	Limit (local currency)	Limit (Euro)
US	USD	50.000-100.000	36.600-73.200
Sweden	SEK	50.000	54.000
UK	GBP	30.000	44.500
Australia	AUSD	42.000-76.000	26.200-47.400
Canada	CND	20.000-100.000	13.700-68.700
The Netherlands	EURO	20.000	20.000
New Zealand	NZD	20.000	11.200

* Conversion based on exchange rates august 1, 2007

Double barrier of societal willingness to pay per QALY



Cost per QALY (1,000 $)



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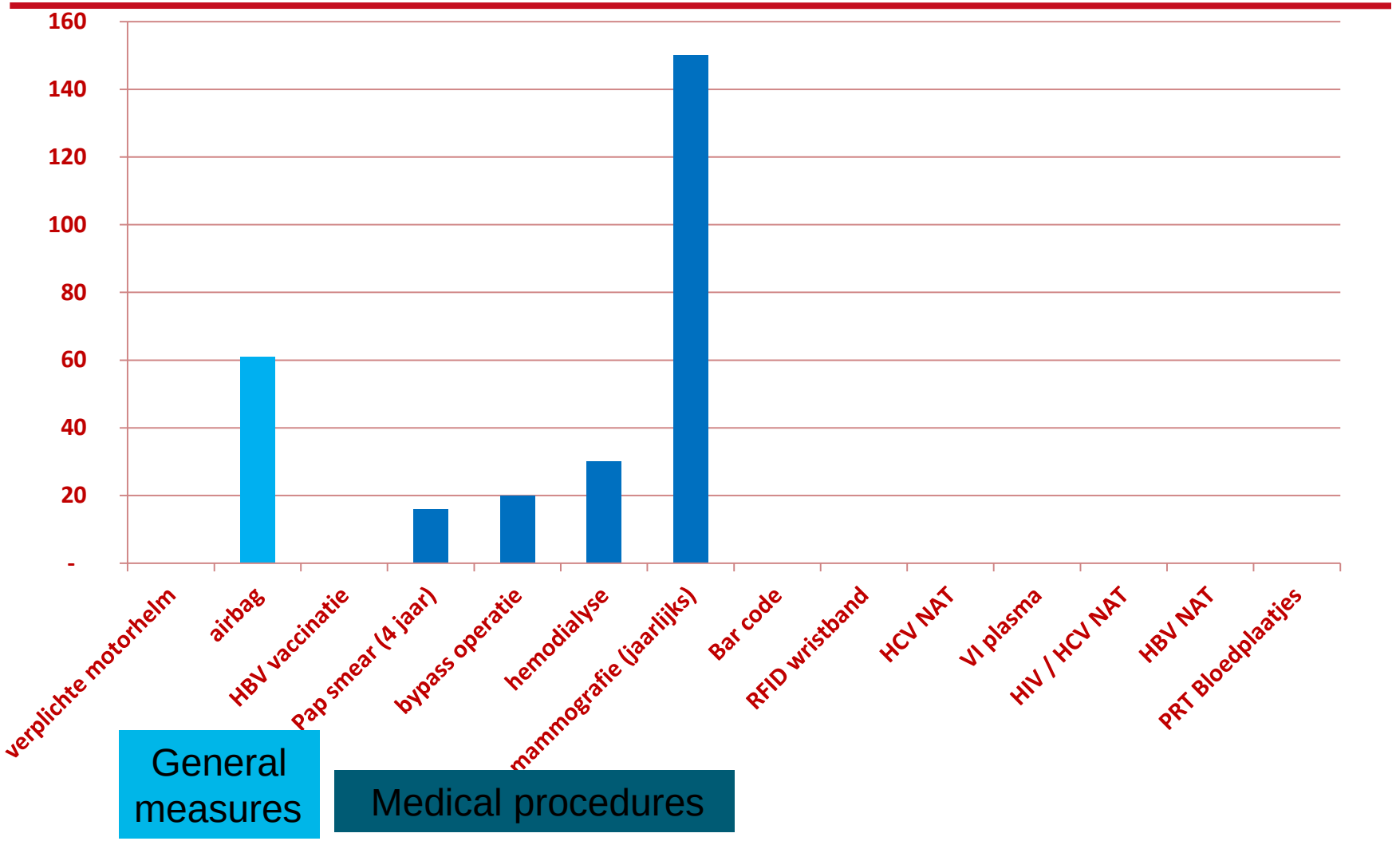

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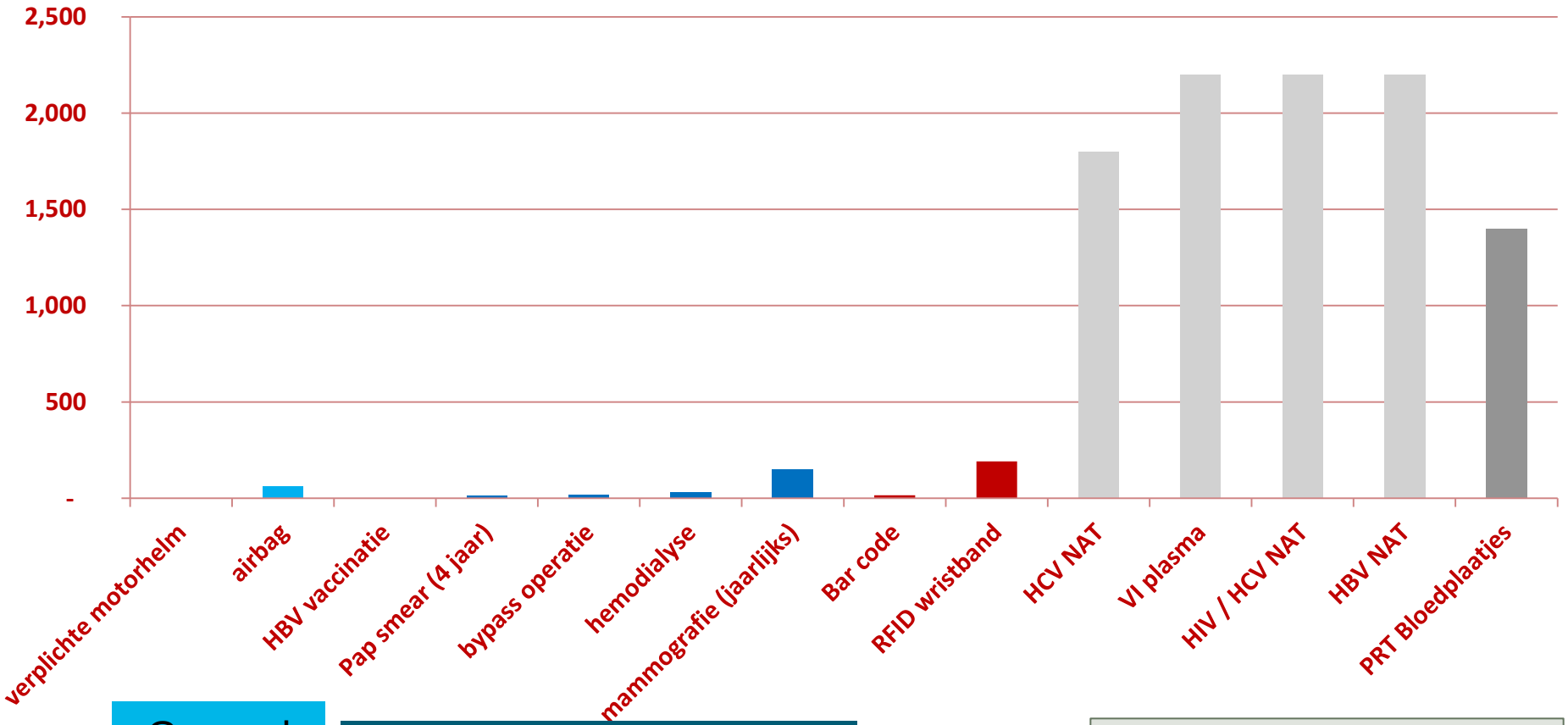


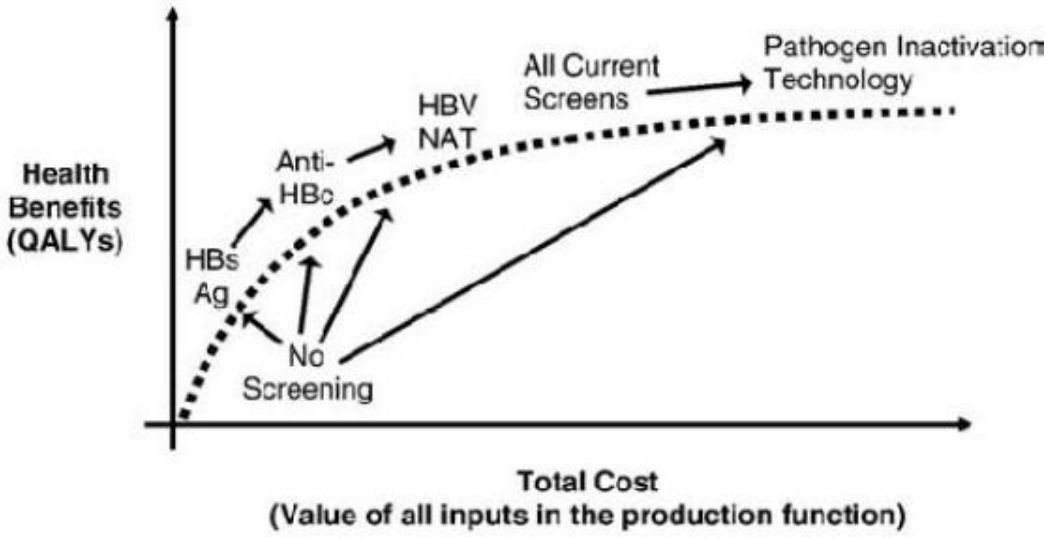
General measures

Medical procedures

Product-related

Incremental increase in cost-effectiveness

- F.i. HIV-tests
  - 1st generation (Ab): $ 3.600/QALY
  - 2nd generation (NAT): > $2 million/QALY
- Cost – result curve



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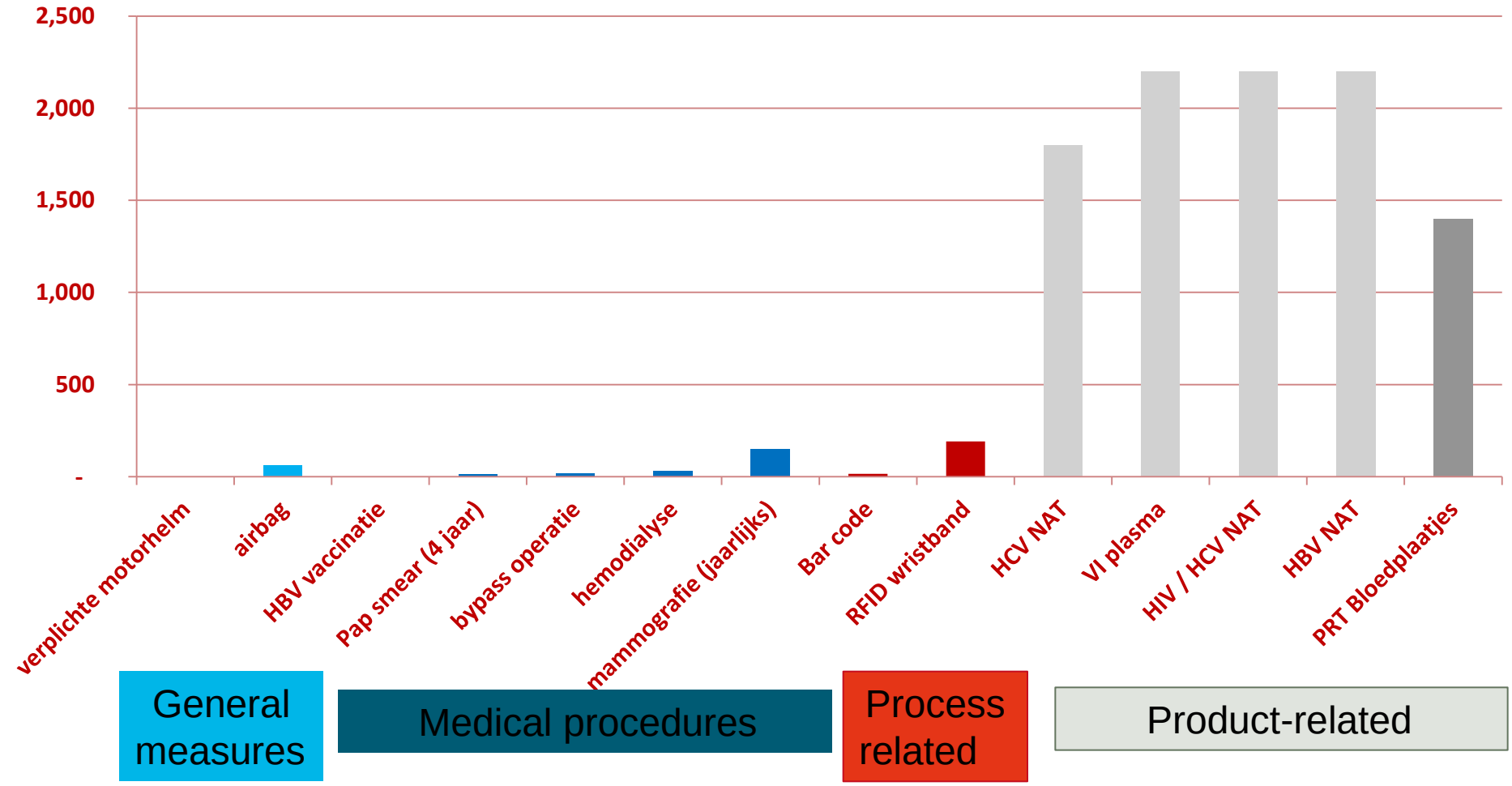

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Perspectives of Economic Analyses and Costs Considered

Perspective	Costs of primary interest

Societal	• All medical and nonmedical costs :
	  ○ Hospitalization
	  ○ Long-term care
	  ○ Home care
	  ○ Social welfare services
	• Productivity losses (indirect costs)
	• Intangible costs

Third party payer	• Charges that pertain to reimbursement of providers • Average, not marginal cost
Health care provider	• Variable costs that influence the expenses of providing health care
Patient	• Costs that affect out-of-pocket payments • Lost wages (indirect costs)
Employer	• All insurable direct costs • Lost wages (indirect costs)

Luce BR, Elixhauser A: Standards for socio-economic evaluation of health care products and services. Springer-Verlag Berlin Heidelberg New York. 1990

Cost of a transfusion: cost types

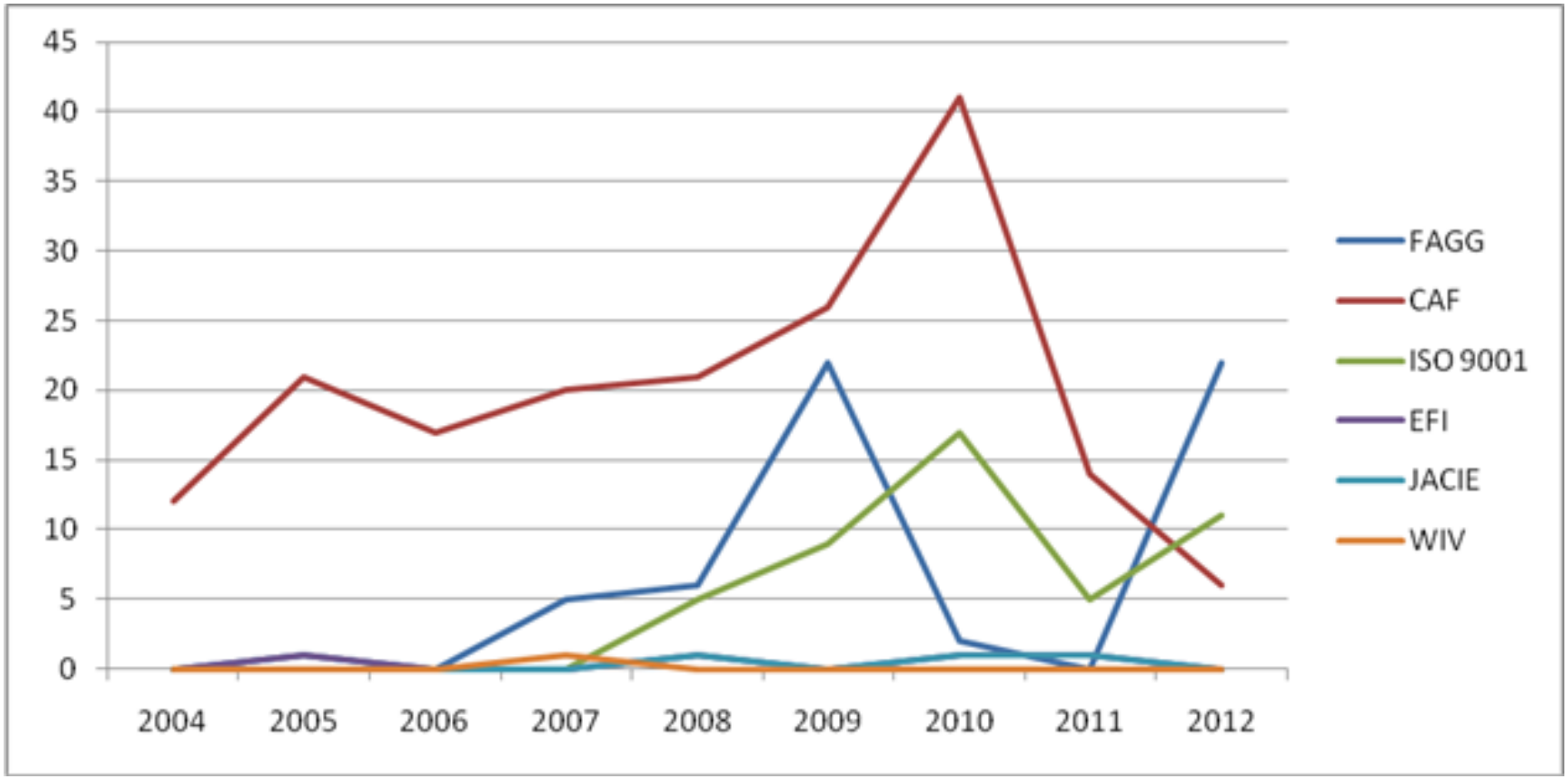
Direct costs	cost of the blood product itself	
Indirect costs	storage, testing, release, costs of administration (working time, disinfection, disposables, …)	€ 407 - € 923 (average € 593)
Costs due to the extra care needed by a transfusion patient	increased length of hospital stay	3 -5 days (on average 2 days)
Costs due to transfusion reactions and inherent risks of a red cell transfusion	Increased for infection, to die	

Shander et al. 2010

Cost of red cell transfusion: the case of Belgium

Transfusion rate (/1000 inwoners)	**50**	***Reduction to 45***
Direct costs (million €/year)	67	*6.7*
Indirect costs (million €/year)	310	*31*
Costs for extra care (million €/year)	228	*22.8*
Costs of transfusion reactions (million €/year)	???	
Total cost (million €/year)	**605**	***60.5***

Cost of inspections?



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Willingness to pay per QALY for our sector is extremely high: contributing factors

- Emotional issue with the broader public
  - Blood has a symbolic value
- Personal career risk for politicians
  - Incidents are often acute and mono-factorial as opposed to most other health intervention incidents
- Lack of good data & clear conclusions
  - Cost models are not widely used and health economics analyses are not applied as they are in the rest of health care.
  - As a result, blood safety interventions and outcomes cannot be compared between jurisdictions nor with other health care measures.

Factors that contribute to slow adaptation of a Health Economics approach

- Outside the sector: willingness to pay is very high

- Inside the sector:
  - Instinct & tradition is to make blood ever safer
  - Every additional (expensive) measure to approach zero-risk allows blood operators to grow revenue without growing output (which is comfortable to manage)

Link between haemovigilance and health economics should be bi-directional

1. In the past, HV has contributed greatly to HE by collecting data to evaluate effectiveness
2. For the future, HE should contribute to HV
    1. HV should expand to include also cost-effectiveness
        1. With a particular focus on process improvements; as these are least studied
    2. HV is in itself (probably) a more cost-effective approach to achieve defined safety levels than many technical improvements
        1. But we need more studies to prove this
        2. Complex to calculate