

Value of nutritional therapy in health economics

Mark Nuijten | The Netherlands

**VALUE OF NUTRITIONAL THERAPY
IN HEALTH ECONOMICS**

ONCA CONFERENCE COPENHAGEN

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A2M - Minerva

OBJECTIVE

Objective

- To present the value of nutrition from a broad clinical and economic perspective.
- We do not consider the OTC market as the economics of supply and demand determine already the price.



- Focus on:
 - 1) healthcare market, where normal market mechanisms do not apply.
 - 2) medical nutrition, especially malnutrition.

NUTRITION

Context - epidemiology

- **The causes of disease-related malnutrition (DRM) are multifactorial with metabolic stress due to acute or chronic illnesses. The breakdown state of the body increases the daily nutritional needs, in particular for protein.**
- **The prevalence of people at risk of malnutrition is estimated at 20 million adults in the European Union (EU).**
- **Malnutrition is prevalent across all healthcare settings, particularly in patients in hospital, as well as prevalent across all age groups.**
 - **About 1 in 4 (18–34%) adult hospital patients are malnourished or at risk of malnutrition.**
 - **>Among the elderly, a prevalence of malnutrition of 3.1% and a prevalence of risk of malnutrition of 26.5% was made.**

Context - complications

- **Malnutrition has functional consequences in adults and older people:**
 - **Reduced muscle strength and fatigue can lead to falls, reduced ability to selfcare, and poor recovery from chest infection.**
 - **Malnourished hospital patients experience significantly higher complication rates than well-nourished patients (30.6% vs. 11**
 - **and the risk of infection is more than three times greater.**
 - **Significantly higher mortality rates have been found in “at-risk” hospital patients compared with “not-at-risk” patients (12% vs. 1%).**
 - **Poor Quality of Life (QoL) is also reported in malnourished surgical patients, patients with end-stage renal disease undergoing hemodialysis and in general admissions to the acute hospital setting.**

Context - economic impact

- **Malnutrition impairs recovery from disease and injury (including surgery), increasing mortality and complications. The adverse consequences of malnutrition leading to increase of morbidity have an economic impact.**
- **Malnutrition is associated with increased healthcare resource use across all age groups.**
 - **Increase in length of hospital stay, readmissions and GP consultation. Average length of hospital stay may be increased by 30% in malnourished patients.**
 - **Due to increased morbidity and healthcare resource use malnutrition is costly to the individual, to society and to the economy. The extra cost of treating a patient with malnutrition is 2 to 3 times higher than for a non-malnourished patient.**

Context - Reimbursement

Reimbursement - nutritional

- Few authorities produce clear guidelines for clinical efficacy or tolerance trials; no countries produce clear guidelines for health economic data.
- The payers (insurers) are busy to be involved more and more.
- No formal guidance for cost-effectiveness analyses.

NUTRITION- ECONOMICS

Nutrition Economics

Safety, Efficacy & Quality



Clinical & Cost effectiveness



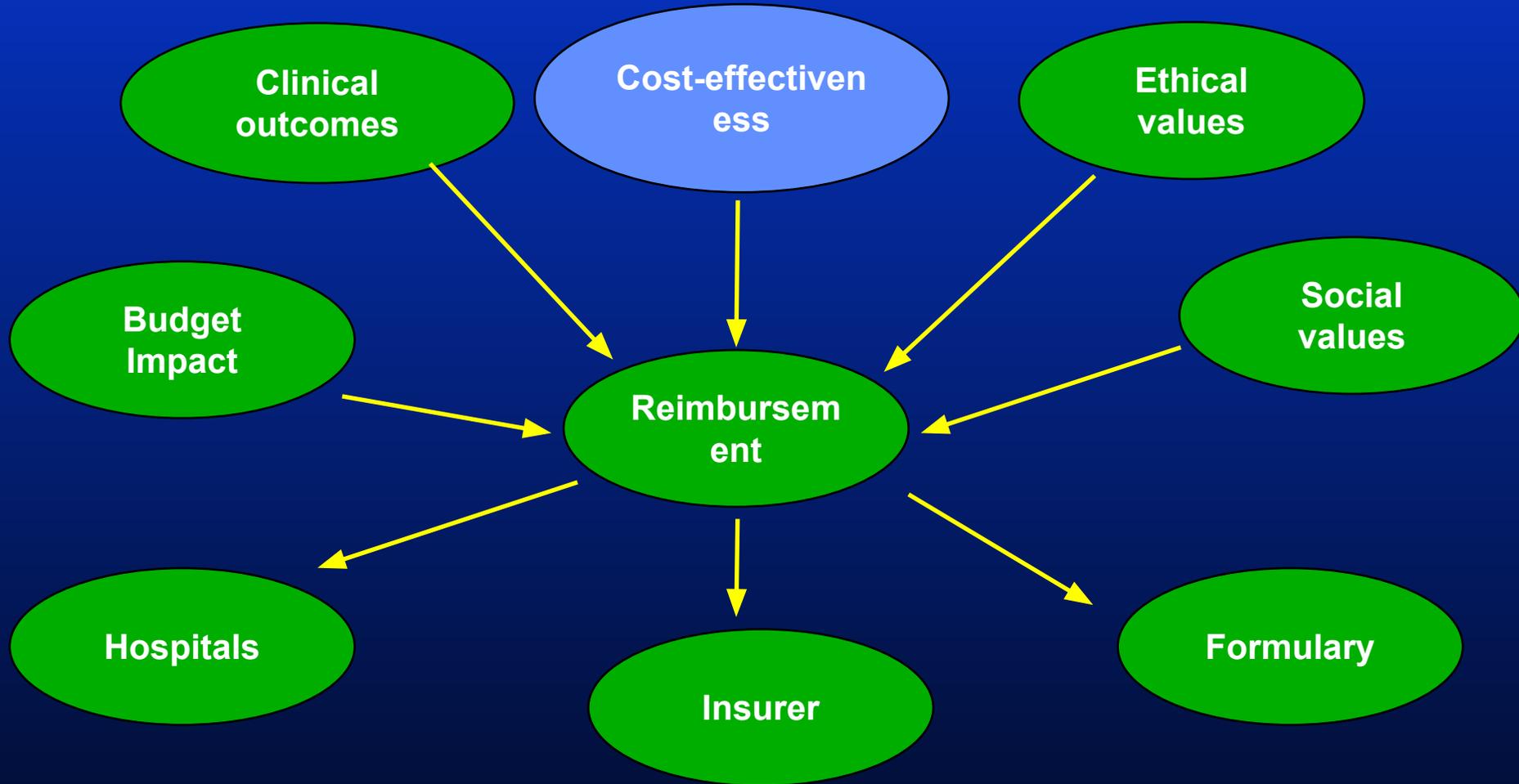
'4th Hurdle'

Affordability and impact on services



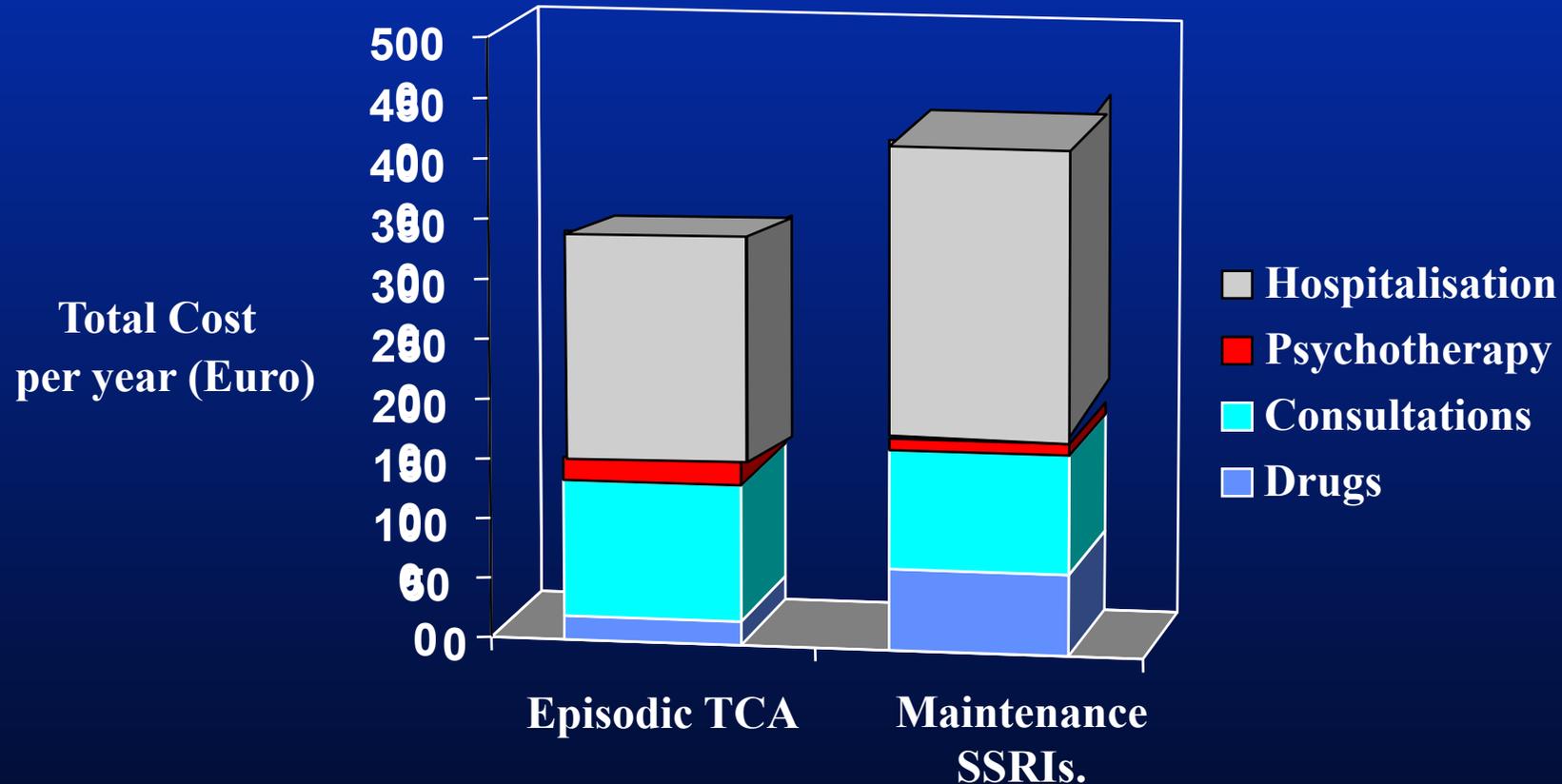
'5th Hurdle'

Nutrition Economics



Nutrition Economics

Maintenance treatment with SSRIs will increase total costs, and NO offset by less consultations, psychotherapy and hospitalisation.
BUT: higher effectiveness and Quality of Life



Nutrition Economics

Utility - QALY

- Survival, but also correction for Quality of Life
 - Final (hard) endpoint between 0 and 1:
 - Dead: 0
 - Perfect health: 1

	Survival	Quality of Life	QALY
Treatment A	8	0.5	4.0
Treatment B	5	0.9	4.5

- Comparison across diseases

Nutrition Economics

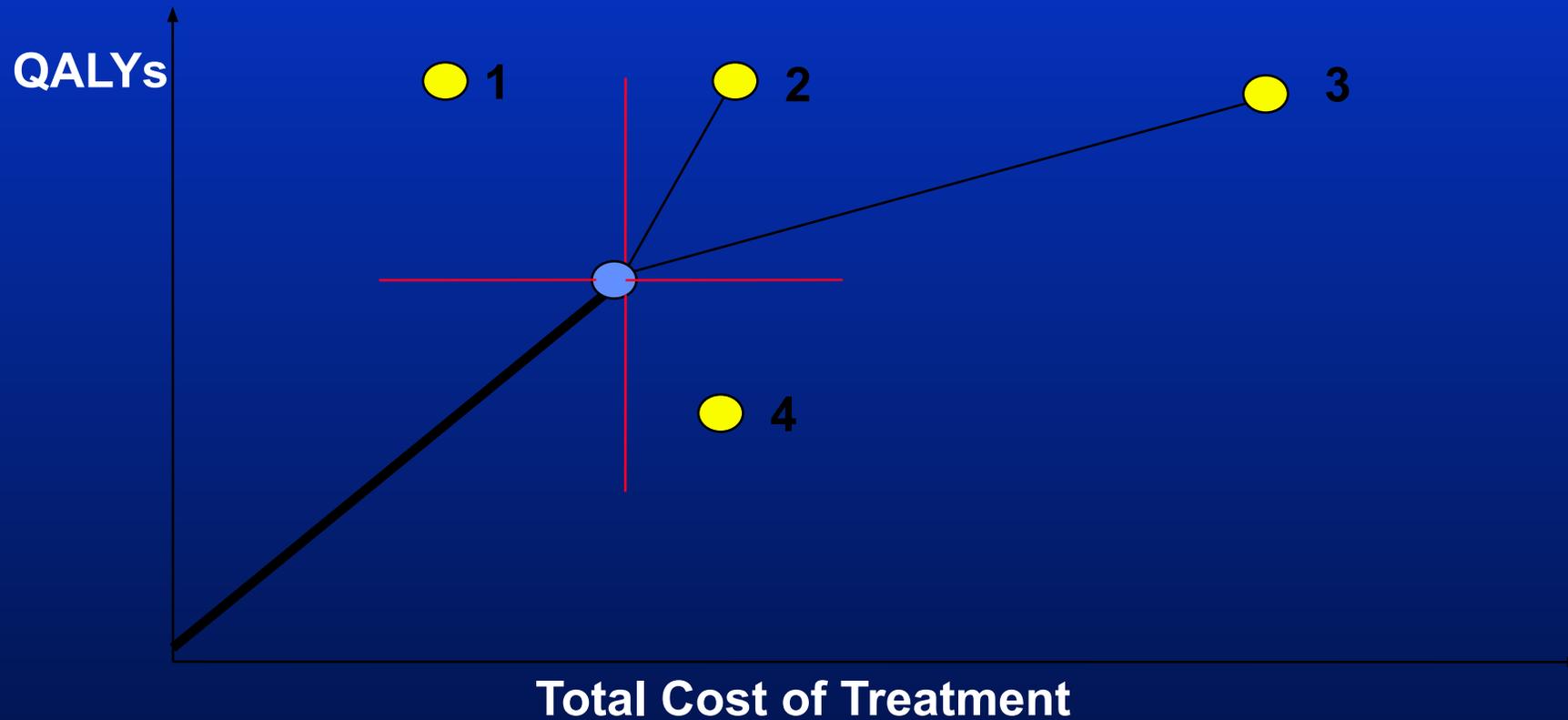
Cost-effectiveness:

- Incremental cost-effectiveness ratio - Cost per QALY

	Survival	Quality of Life	QALY	Total costs	ICER
Treatment A	8	0.5	4.0	1000	
Treatment B	5	0.9	4.5	1500	
Difference			0.5	500	1000

- Interpretation: Extra Euro 1,000 to gain one year in perfect health!

Nutrition Economics



$\frac{\text{Total costs}}{\text{Effectiveness (QALYs)}} < 20.000 \text{ euro}$

Nutrition Economics

Cost-effectiveness ratios

- No explicit threshold in any country
- Proposed levels (per QALY) - \$20,000 Canadian
 - \$50,000 US
 - £10,000 UK
 - E 20,000
- Observed values - £20,000 - £30,000 UK
 - \$22,000 Australian

Nutrition Economics

Nutrition economics: merging of health economics and nutrition disciplines to assess the clinical and economic impact of diet on health, disease treatment and prevention:

- **Nutrition is crucial for its potential impact on health-related quality of life (HRQoL) and economic impact at the societal and individual levels.**
- **Epidemiological and scientific evidence demonstrates clear links between food and health maintenance/disease development.**
- **Morbidity and mortality are directly related to protein and energy malnutrition.**

Nutrition Economics

Nutrition

- **Need of justification of evidence, but also increasingly need for health economic evidence**



- **No specific guidelines for execution of health economic evaluations**
- **Are current guidelines for health economics developed for pharmaceuticals applicable for nutrition or do they need adaptation**

Nutrition Economics

Application to nutritionals

- **Cost-effectiveness analyses can be applied to nutrients, if clinical evidence exists.**
- **There are no fundamental differences in applying health economic concepts to drugs or nutritionals (modelling and costing methodologies).**
- **The availability of clinical evidence for nutritionals is the main constraint for cost-effectiveness studies in nutrition.**
- **Budget impact is important for nutritionals because high prevalent of malnutrition diseases**

Nutrition Economics

Category	Clinical evidence	ICER	Central reimbursement	Payers	OTC
severely ill patients in the hospital	Very high	nutrition dominant	Maybe	No	No
severely ill patients in ambulatory setting	High	< threshold	Yes	Yes	Maybe
medical nutrition for patients or persons at risk in an ambulatory setting	Medium	< or > threshold	No	Yes	Yes
nutrition for the prevention of disease in healthy persons.	Low	>threshold	No	Maybe	Yes

**EVIDENCE
FOR NUTRITION**

Evidence

Specific issues - design

- **Specific end-points required, such effectiveness, well-being, QoL as indicators of toxicity and benefit - not only single outcomes.**
- **Evaluation side-effects: Nutrition is recognized as safe, but novel nutrition products may be of unknown risk.**
- **Compliance: The likely lower adherence than with drugs and, therefore extra effort and design required with nutrition studies (forced compliance).**
- **Dosing: more variance in daily dosing than drugs.**

Evidence

		Drugs	Nutrition	
Audience	Payer	+++	+	
	Health care providers	+++	+	
	Medical community	+++	+	
	Clinical guidelines	+++	+	
	Consumer	+	+++	
	Employers	++	+	
Target	Patients	treatment	+++	+
	At risk population	prevention	++	++
	Population	prevention	+	+++
Outcomes	Hard outcome	+++	+	
	Intermediate	++	+++	
	Short-term	+++	+	
	Long-term	++	+++	
	Effectiveness	+++	++	
	QALY	++	+	
Population		homogeneous	heterogeneous	
Comparator	standard of care	placebo	easy	difficult
		standard of care	active treatment	active treatment
				no treatment
Internal validity		+++	+	
External validity		+	+++	
Time horizon		short and long	long	

Placebo: Should a probiotic yoghurt be compared to a placebo yoghurt?

**ARE REIMBURSEMENT CRITERIA
APPLICABLE TO NUTRITIONALS ?
A CASE STUDY**

Criteria to Nutrition

Criteria

- **Clinical benefit**
 - Efficacy
 - Side - effects
 - Ease of use
- **Cost-effectiveness**
- **Budget Impact**

Criteria to Nutrition

Case Study: background

- **Malnutrition has high prevalence and clinical consequences may be costly. Consequently inappropriate treatment of malnutrition may have a high economic impact.**
- **Nutritional support, including oral nutritional supplements, enteral tube feeding and parenteral nutrition, can be an important part of the management of any patient:**
 - **Reduction complications**
 - **Reduction length of stay**
 - **Cost-effective**
 - **Increase Quality of Life**
 - **Reduction of hospitalisation costs**



Criteria to Nutrition

Case Study: objective

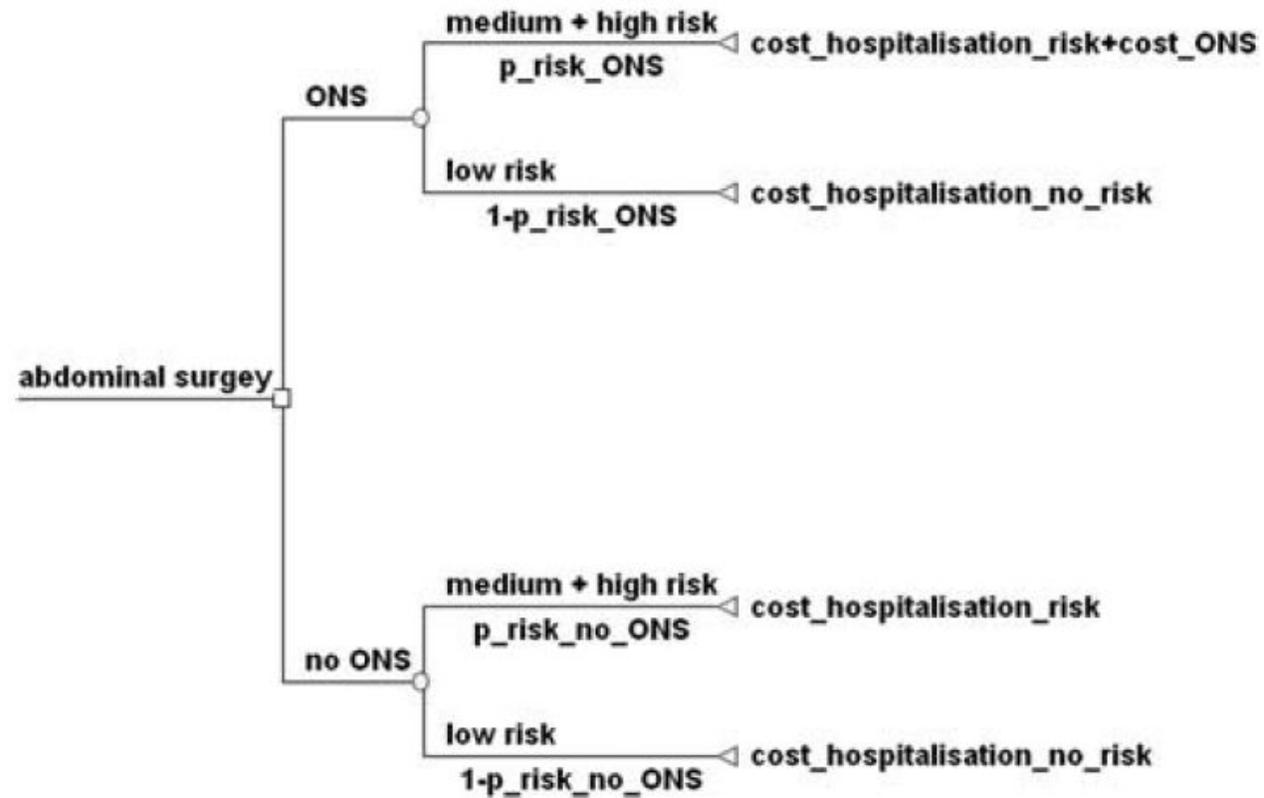
- The primary objective of this study was to assess the health economic impact of Food for Special Medical Purposes (FSMP) relative to standard care in patients undergoing abdominal surgery in the Netherlands

Criteria to Nutrition

Case Study: methods

- **The incremental cost difference was based on the costs associated with the cost of FSMP and hospitalization**
- **The costing methodology is based on a conservative approach:**
 - **The model is based on the assumption that the use of FSMP only has an impact on the length of stay.**
 - **The favourable impact on adverse events by FSMP and therefore the lower costs of adverse events were not included, because of lack of data.**
 - **Indirect costs due to productivity loss were not included**

Criteria to Nutrition



Criteria to Nutrition

Case Study: data for the model

- **The annual number of abdominal surgery procedures is 160,283 in The Netherlands.**
- **Malnourishment: A prevalence of 30% malnourishment derived from the Dutch LPZ report from 2007, which corresponds with international data for surgical patients.**
- **Length of stay: 8 days length of stay was based on an international study, including Dutch centers.**
- **A 30% increase of length stay resulting from malnutrition was derived from the BAPEN report. These data were validated with a Delphi survey with Dutch and British surgeons.**

Criteria to Nutrition

Case Study: data for the model

- **Dosage:** The dosage is two bottles daily per patient, which is used 8.5 days before and after the operation.
- **Costs of Treatment:** The price of standard bottle is € 2.19.
- **The cost of hospitalisation was derived from the Dutch Costing Manual. *Per diem* for academic hospital is € 476 and for general hospital is € 337;**
Distribution: academic hospital 16% and general hospital 84%.
- **The costs were inflated from 2003 to 2008.**

Criteria to Nutrition

Case Study: base case results

- The use of FSMP reduces the costs from € 3,318 to € 3,066, which corresponds with a € 252 (7.6%) cost savings per patient
- The additional costs of FSMP are more than balanced by a reduction of hospitalisation costs. The hospitalisation costs reduce from € 3,318 to € 3,044 per patient, which is 8.3% cost saving and corresponds with 0.72 days reduction in LOS.
- The use of FSMP would lead to an annual cost saving of € 40.4 million based 160,283 abdominal procedures per year.

Criteria to Nutrition

Case Study: conclusion

- **This health economic study showed that the use of FSMP is a very cost-effective treatment in the Netherlands and is dominant over standard care without FSMP: cost savings and higher effectiveness.**

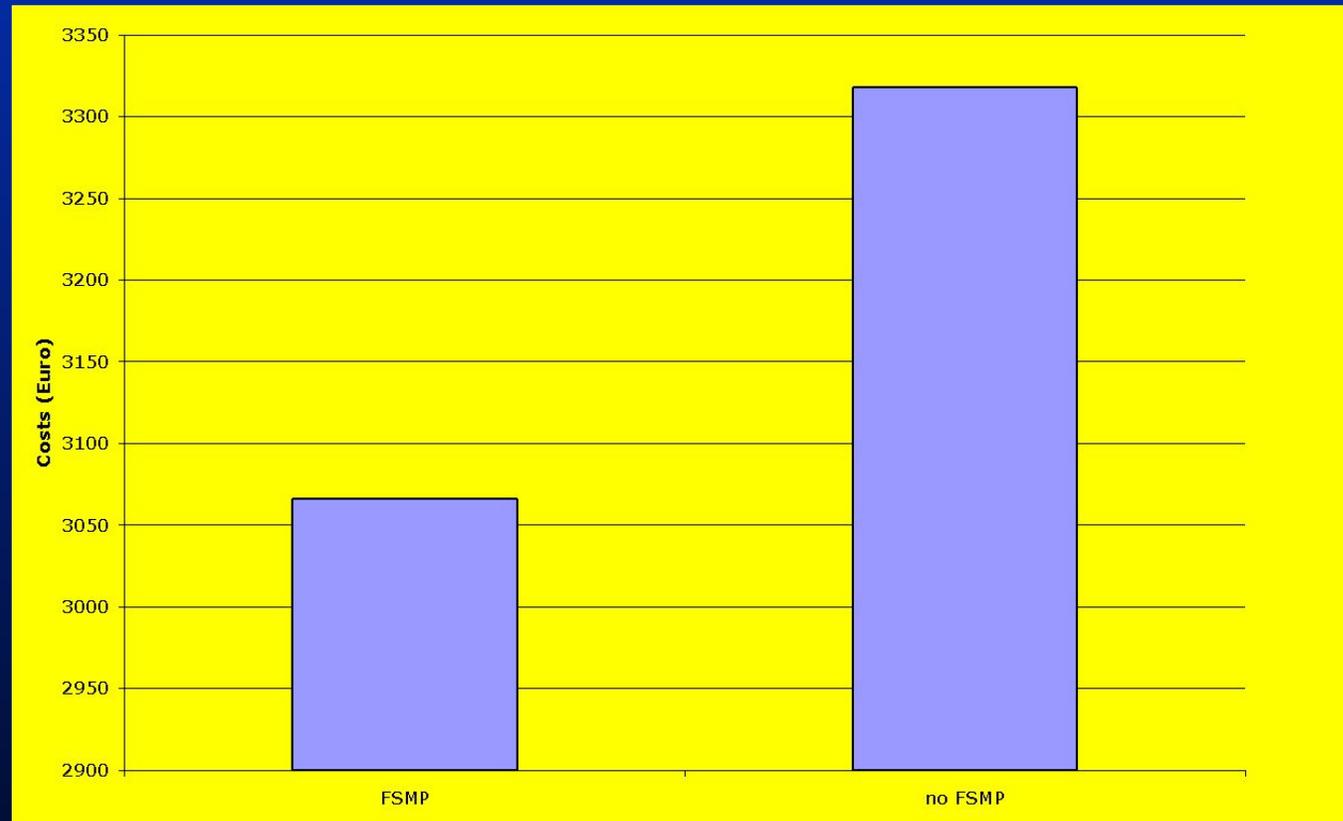
Criteria to Nutrition

Proven efficacy in RCT (p<0.05)

Overview of clinical studies.		
Beattie	intervention	control
ONS in abdominal surgery		
age	54,4	62,4
LOS	18,4	20,6
wound infections	4	7
chest infections	2	6
wound and chest infections	6	13
Keele	intervention	control
elective moderate-major GI surgery		
BMI	23,5	25,1
age	64,7	60
post-operative LOS	10,8	13,2
wound infections	2	7
wound dehiscence	1	2
GI perforations	0	1
subphrenic abcess	0	1
multiple	1	1
complications	4	12
Macfie	intervention	control
elective major GI surgery		
BMI	25	25
age	66	64
post-operative LOS	10	13
septic complications	4	2
other complications	2	1

Criteria to Nutrition

Proven favourable budget impact



Criteria to Nutrition

Application Criteria for Pharmaceuticals

appropriateness pharmaceutical scheme?		
Clinical benefit	efficacy	yes
	safety	yes
	ease of use	
cost-effectiveness		yes
budget impact		yes

VALUE OF NUTRITION

VALUE OF NUTRITION

Conclusion

- This health economic study showed that the use of FSMP is a extremely cost-effective treatment: cost savings and higher effectiveness.
- But drugs are often cost-effective, but not cost saving
ICER of €80,00 / QALY still means there are extra costs.
- Threshold analysis show that price nutrition can be at least 10 times higher and still be cost-effective - ICER < € 80,000/QALY.
- This analysis raises questions on the appropriate pricing of nutrition compared drugs.

VALUE OF NUTRITION

Conclusion

- The price setting does not reflect the clinical value of nutritionals from a health economic perspective.
- Willingness to pay for medical nutrition seems, currently, low compared with pharmaceuticals.
- The current price laws for nutrition are based euro per unit of ingredient, e.g. protein.
- **BUT:** drug prices are not constrained by costs of ingredients and therefore the value determines the price.
- Value is not similar to prices and costs and, therefore, we also do not favour this use of ‘cost plus pricing’ for nutrition.

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