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Nutrition Economics – Are We Ready For A New Approach? Opportunities To Advance The Science

Tuesday, November 08, 2022 15:00-16:00

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Agenda

Item #	Time	Topic	Presenter(s)
1	15:00	Introductions	Tricia
2	15:05	Nutrition & the Nutrition Economics Special Interest Group: Progress to Date	Tricia
3	15:15	Regulatory issues: health technology assessment and the clinical value of nutritional care	Mark
4	15:25	Need for future research: Improving equity in reimbursement across settings	Tânia
5	15:35	SIG initiatives	Aditi
6	15:41	Summary	Tricia
7	15:45	Discussion – Q&A	All
8	16:00	Adjournment	Tricia

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1

Nutrition Economics Special Interest Group

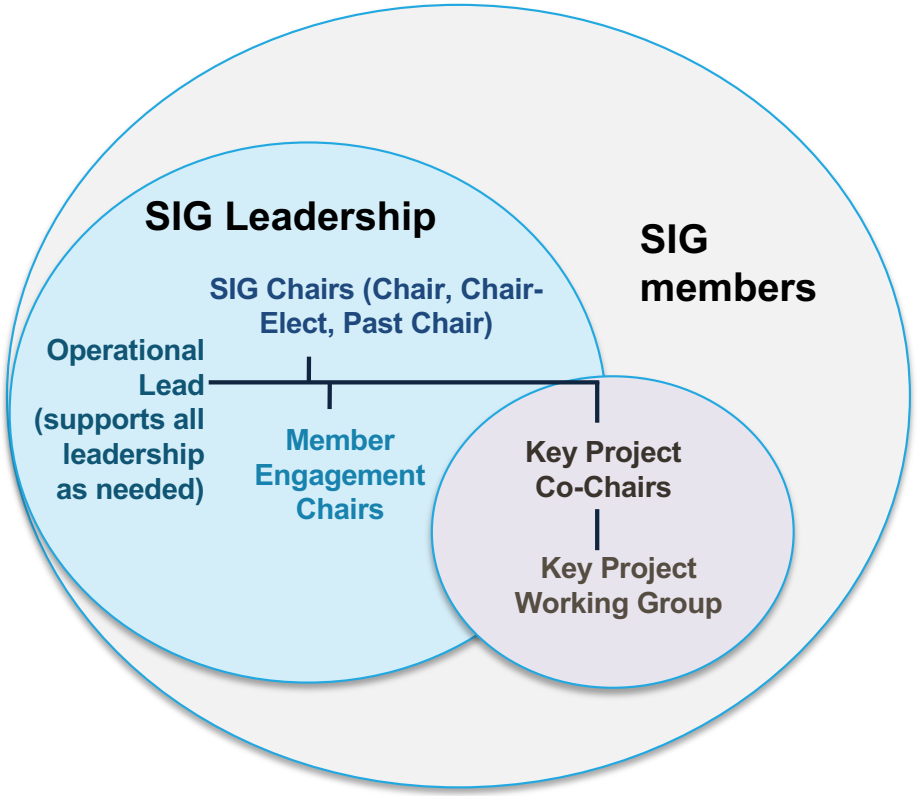
Progress to Date

What is an ISPOR Special Interest Group (SIG)?

A SIG is an organized member group initiated by ISPOR members and intended to:

- **Focus on a specific topic area** to advance the health economic and outcomes research (HEOR) science and the use of HEOR in healthcare decisions
- **Monitor trends and disseminate information** to SIG members or the larger ISPOR community
- **Develop scientific and educational work products**
- More information is available at: https://www.ispor.org/member-groups/special-interest-groups

Structure of an ISPOR SIG



SIG Leadership

- Provide overall direction and leadership
- Identify topics for the SIG to address and platforms for delivery
- Work with the co-chairs to ensure the project timelines are met
- Provide updates to the SIG
- Submit yearly reports to ISPOR
- Recruit new SIG members

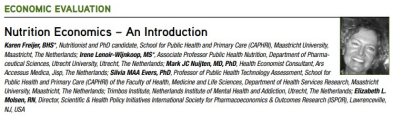
Member Engagement Chairs

- Develop and implement projects that encourage member participation
- Facilitate topic content dissemination
- Monitor and support the SIG community

Nutrition Economics

Intersection of the **nutrition** and **health economics** disciplines to **assess the impact of nutrition** on health and disease and to **illustrate the health and economic aspects** of specific changes in the daily nutrition and nutrition recommendations through the lens of cost effectiveness

Evolution of the SIG's Work


ECONOMIC EVALUATION

Nutrition Economics – An Introduction

Karen Freijer, BHS*, Nutritionist and PhD candidate, School for Public Health and Primary Care (CAPHRI), Maastricht University, Maastricht, The Netherlands; Irene Lenoir-Wijnkoop, MS*, Associate Professor Public Health Nutrition, Department of Pharmaceutical Sciences, Utrecht University, Utrecht, The Netherlands; Mark JC Nuijten, MD, PhD, Health Economist Consultant, Ars Accessus Medica, Jlop, The Netherlands; Silvia MAA Evers, PhD, Professor of Public Health Technology Assessment, School for Public Health and Primary Care (CAPHRI) of the Faculty of Health, Medicine and Life Sciences, Department of Health Services Research, Maastricht University, Maastricht, The Netherlands; Trimbos Institute, Netherlands Institute of Mental Health and Addiction, Utrecht, The Netherlands; Elizabeth L. Molsen, RN, Director, Scientific & Health Policy Initiatives International Society for Pharmacoeconomics & Outcomes Research (ISPOR), Lawrenceville, NJ, USA

2014 Publication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Contents lists available at sciencedirect.com

Journal homepage: www.elsevier.com/locate/jval

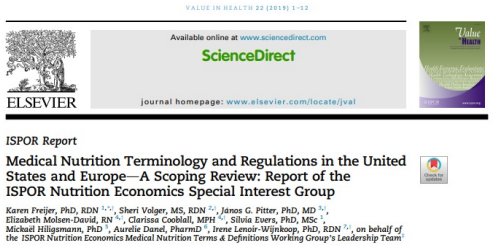
ISPOR Report

Are We Ready for a New Approach to Comparing Coverage and Reimbursement Policies for Medical Nutrition in Key Markets: An ISPOR Special Interest Group Report

Moreno Perugini, MBA, MHE, Tricia J. Johnson, PhD, Tania Maria Beume, MSc, Olivia M. Dong, PhD, John Guerino, MHS, Hao Hu, PhD, Kirk Kerr, PhD, Shannon Kindilien, MA, Mark Nuijten, PhD, MD, Theresa U. Offil, PharmD, Matthew Taylor, PhD, Alvin Wong, MS, Karen Freijer, PhD

2022 Publication

2019 Publication


VALUE IN HEALTH 22 (2019) 1–12

Available online at www.sciencedirect.com

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journal homepage: www.elsevier.com/locate/jval

ISPOR Report

Medical Nutrition Terminology and Regulations in the United States and Europe—A Scoping Review: Report of the ISPOR Nutrition Economics Special Interest Group

Karen Freijer, PhD, RDN [1,*], Sheri Volger, MS, RDN [2], János G. Pitter, PhD, MD [3], Elizabeth Molsen-David, RN [4], Clarissa Cooblall, MPH [4], Silvia Evers, PhD, MSc [1], Mickaël Hiligsmann, PhD [5], Aurélie Danel, PharmD [6], Irene Lenoir-Wijnkoop, PhD, RDN [7], on behalf of the ISPOR Nutrition Economics Medical Nutrition Terms & Definitions Working Group's Leadership Team†

2022 ISPOR Europe

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ISPOR Report

Are We Ready for a New Approach to Comparing Coverage and Reimbursement Policies for Medical Nutrition in Key Markets: An ISPOR Special Interest Group Report

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ABSTRACT

Objectives: Healthcare policy makers should ensure optimal patient access to medical nutrition (MN) as part of the management of nutrition-related disorders and conditions. Questions remain whether current healthcare policies reflect the clinical and economic benefits of MN. The objective of this article is to characterize coverage and reimbursement of MN, defined as food for special medical purposes/medical food for a diverse set of countries, including Australia, Belgium, Brazil, Canada, China, France, Germany, Hong Kong, Italy, Japan, The Netherlands, Singapore, Spain, United Kingdom, and United States.

Methods: Data sources included published literature and online sources. ISPOR's Nutrition Economics Special Interest Group developed a data collection form to guide data extraction that included reimbursement coverage, years that reimbursement policies were established, and presence of a formal health technology assessment (HTA) for MN technologies.

Results: Reimbursement coverage of MN technologies varied across the countries that were reviewed. All but 3 countries limited coverage to specific formulations of products, regardless of demonstrated clinical benefit. The year that reimburse-

Table 1. Coverage of FSMP/MF reimbursement by country across different settings.

Country	Hospital	Outpatient	Community
Australia	Yes	Yes, limited to some disease conditions; might differ across provinces	
Belgium	Yes	Yes, limited to patients discharged from hospital	No
Brazil	Yes	Yes, limited to specific disease conditions and varies by state and municipalities	Yes, limited to some disease conditions
Canada	Yes	Yes, limited to some disease conditions; might differ across provinces	
China	No	No	No
France	Yes	Yes	Yes
Germany	Yes	Yes	Yes
Hong Kong	Yes	Yes, limited to low-income individuals*	No
Italy	Yes	No	Yes; might vary by region
Japan	Yes	Yes, limited to enteral tube feeding	
The Netherlands	Yes	Yes	Yes
Singapore	Yes	Yes, limited to low-income individuals†	Yes, limited to nursing homes
Spain	Yes	Yes	Yes
United Kingdom	Yes, limited to the public system under certain circumstances for malnourished patients		
United States Centers for Medicare & Medicaid Services	Yes, limited‡	Yes, limited‡	Yes, limited‡

Source: Perugini 2022

Table 3. Comparison of HTA for drugs and FSMP/MF by country.

Country	HTA for drugs	HTA for MN
Australia	Y	N
Belgium	Y	N
Brazil	Y	Y*
Canada	Y	N
China	N	N
France	Y	Y
Germany	Y	N
Hong Kong	Y	N
Italy	Y	N
Japan	Y	N
The Netherlands	Y	N
Singapore	Y	N
Spain	Y	N
United Kingdom	Y	N†
United States	N‡	N

FSMP/MF indicates food for special medical purposes/medical food; HTA, health technology assessment; MN, medical nutrition; N, no; NICE, National Institute for Health and Care Excellence; Y, yes.
*Brazilian guidelines for HTA are directed to all health technologies, with the same guidelines for drugs, MN, and other health technologies.
†NICE did not review any MN product with a single technology appraisal but issued a clinical guideline in 2006.[37]
‡No official HTA is in place for drugs; individual insurance plans have assessment procedures, but these are usually not made public.

Table 4. Coverage of FSMP/MF reimbursement by country and specific formulas.

Country	Are complete formulas* reimbursed?	Are noncomplete† formulas reimbursed?	Are enteral tube feeding formulas reimbursed?	Are oral nutritional supplements reimbursed?
Australia	Y (state dependent)	N	Y (only hospital)	Y (only hospital)
Belgium	Y	N	Y	N
Brazil	Y	Rarely	Y	Y (only for specific diseases)
Canada	Y	Y (only geriatric patients)	Y	Y (only geriatric patients)
China	N	N	N	N
France	Y	Y	Y	Y
Germany	Y	Rarely	Y	Y
Hong Kong	Y (specific populations only)			
Italy	N	N	N	N
Japan	Y (specific products)	N	Y (specific products)	N
The Netherlands	Y	Y	Y	Y
Singapore	Y (specific populations only)			
Spain	Y	N	Y	Y
United Kingdom	Y	Y	Y	Y
United States‡	Y	Y	Y	N

FSMP/MF indicates food for special medical purposes/medical food; N, no; Y, yes.
*Complete formulas are nutritionally complete products defined as having a balanced composition of macro- and micronutrients that reflect dietary recommendations. These products can be used as a supplement to the daily diet or as a sole source of nutrients needed.
†Incomplete formulas are nutritionally incomplete and therefore not suitable for the use as a sole source of nutrients. These products contain some specific nutrients in higher amounts, whereas the amount of other nutrients is insufficient or lacking. The incomplete formulas are mostly disease specific ones, modified to meet specific nutritional and metabolic demands.[25]
‡Centers for Medicare & Medicaid Services coverage only. Commercial plans usually refer to Centers for Medicare & Medicaid Services guidance for medical nutrition.

Source: Perugini 2022

Potential themes to further explore from current paper

1) HTA for medical nutrition and the need for more evidence

2) Regional and within-country differences in medical nutrition reimbursement and extent to which this variation creates inequities

3) Payer archetypes and medical nutrition

2

Regulatory Issues

Health Technology Assessment and the Clinical Value of Nutritional Care

Objective

1) To present the value of nutrition from a broad clinical and economic perspective

2) We do not consider the OTC market as the economics of supply and demand determine already the price

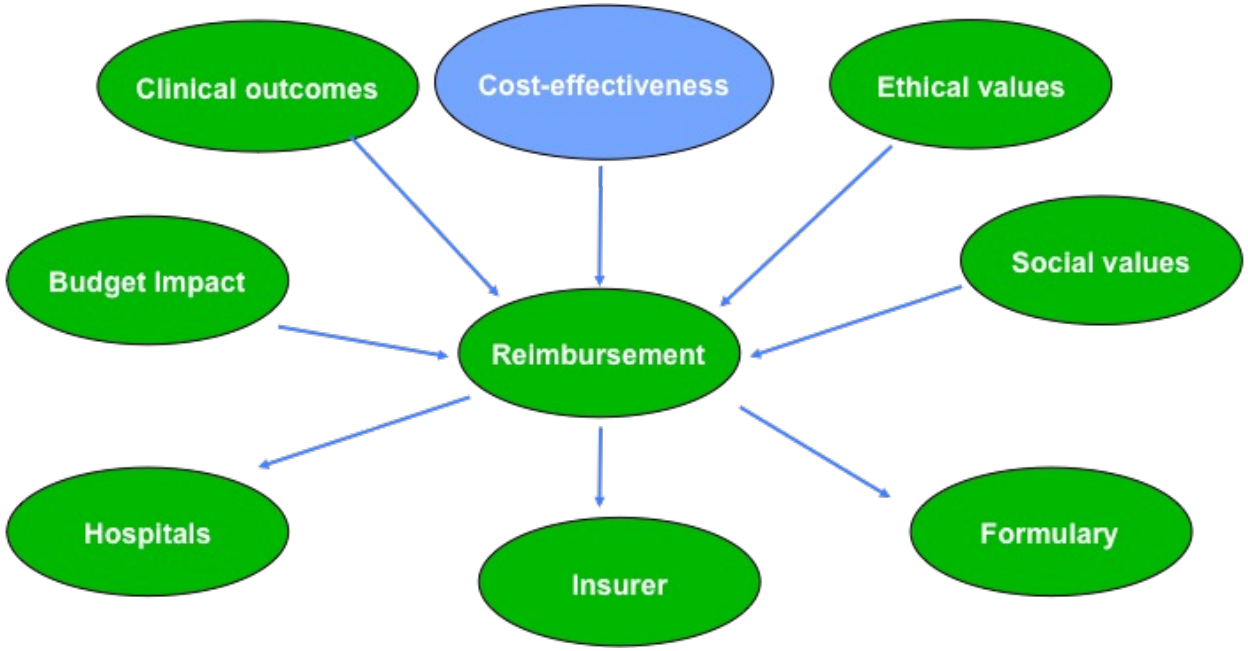
3) Focus on
   - Healthcare market, where normal market mechanisms do not apply
   - Medical nutrition, especially malnutrition

Context - malnutrition

1) 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, prevalence of malnutrition is 3.1%, a prevalence of risk of malnutrition is 26.5%.
2) Malnutrition impairs recovery from disease and injury (including surgery), increasing mortality and complications leading to lower QoL and extra costs.
3) The extra cost of treating a patient with malnutrition is 2 to 3 times higher than for a non-malnourished patient: e.g. LOS – 30% higher.

Context – reimbursement nutritionals

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



- 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: merging of health economics and nutrition disciplines to assess the clinical and health economic impact of nutrition.

Application reimbursement criteria

1) Case: health economic impact of Food for Special Medical Purposes (FSMP) relative to standard care in patients undergoing abdominal surgery in the Netherlands.
2) Based on reduction length of stay (30%).
3) Underestimation excluding:
   - Cost complications
   - Lost QoL
   - Indirect costs due to productivity loss

Safety, Efficacy & Quality

Clinical & Cost effectiveness

'4th Hurdle'

Affordability and impact on services

'5th Hurdle

Application reimbursement criteria

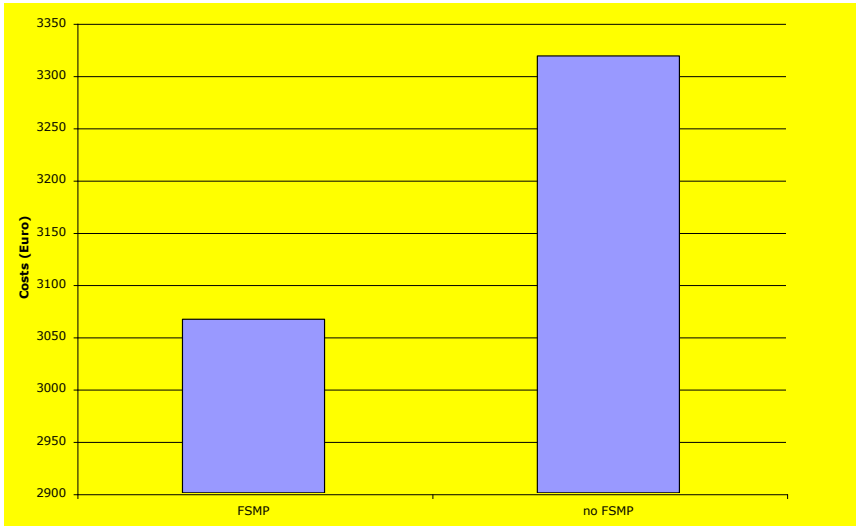
Proven clinical evidence

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

Application reimbursement criteria

Proven favourable budget impact

1) The use of FSMP reduces the costs from € 3,318 to € 3,066, which corresponds with a € 252 (7.6%) cost savings per patient
2) The use of FSMP would lead to an annual cost saving of € 40.4 million.



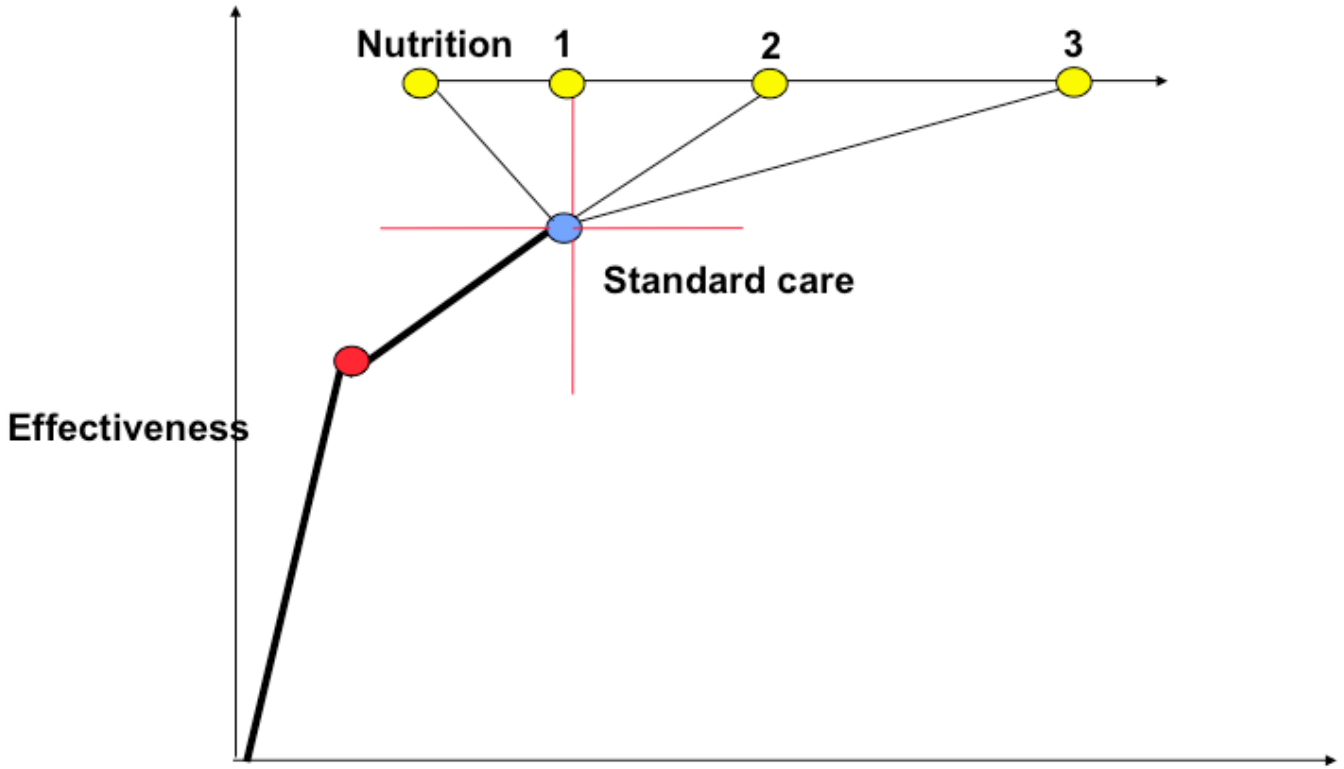
Application reimbursement criteria

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

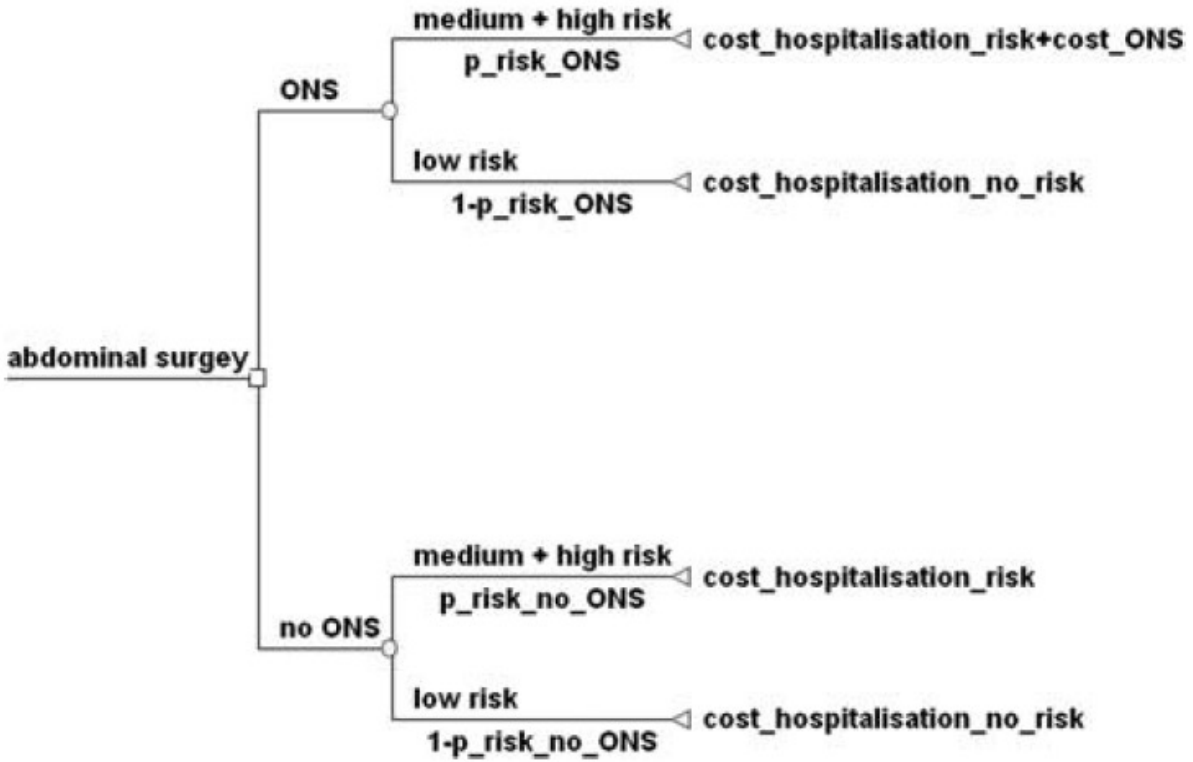
Application reimbursement criteria

Proven cost-effectivenes

Dominant position



Health Economic Model



Conclusion – value of nutrition

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

Conclusion – value of nutrition

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

3

Need for Future Research

Improving Equity in Reimbursement Across Settings

Nutrition Economics and Health Economics

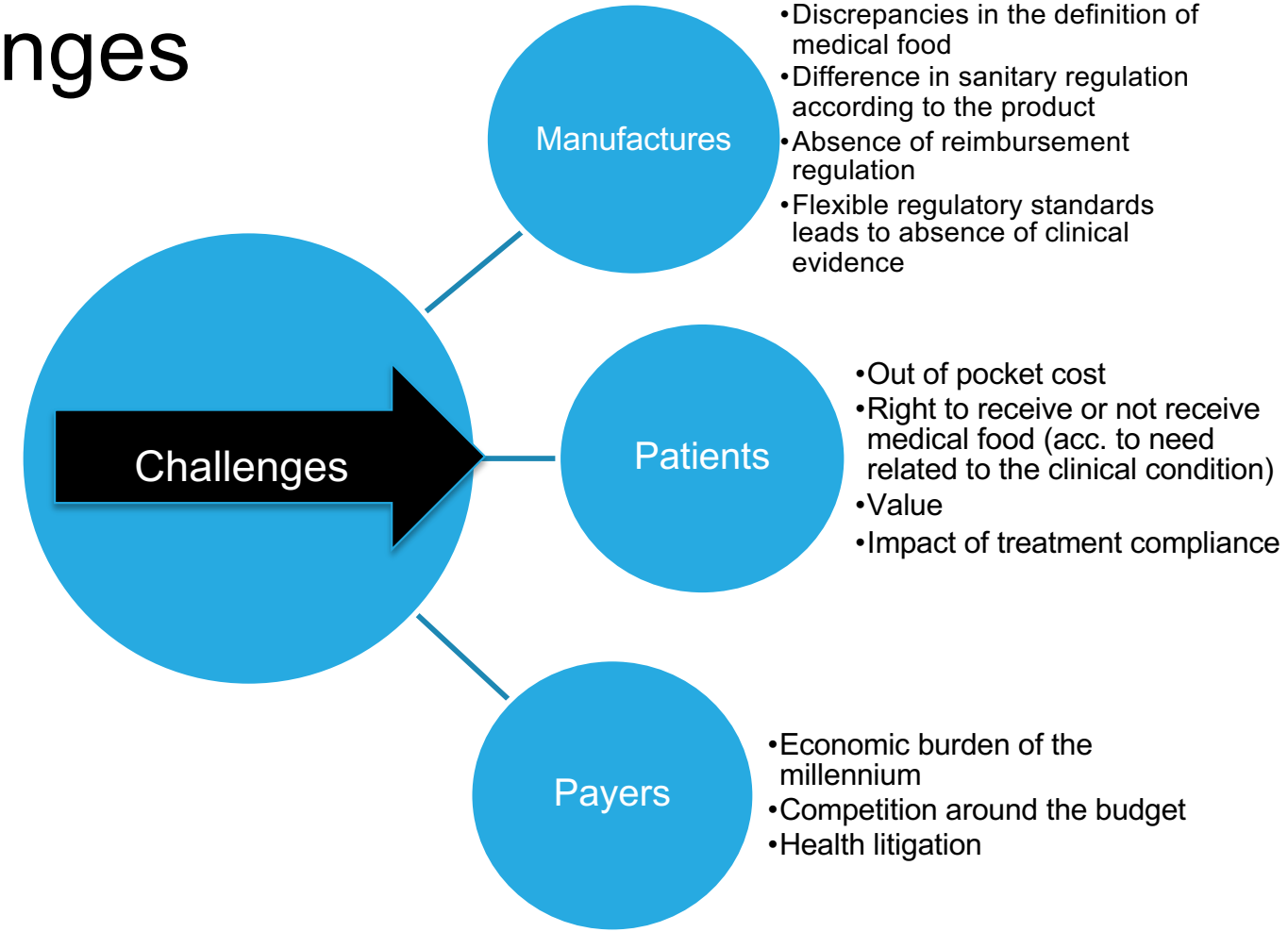
Source: Author adaptation from Alan Willians "plumbing" Diagram, in Maynard et Kanavos, Health Econ. 9: 183-190 (2000).

ISPOR Special Interest Group Nutrition Economics: disparities in economics of nutrition

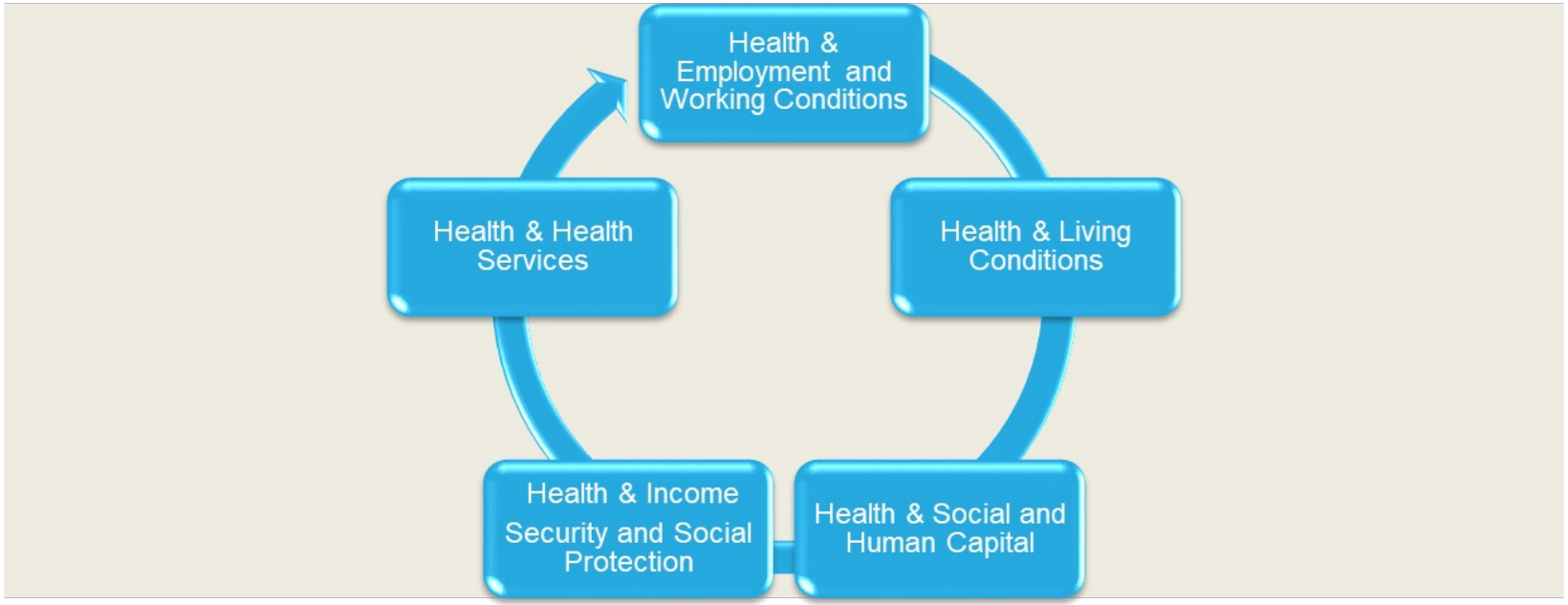
Coverage
Variation in coverage among the healthcare settings: Coverage of medical nutrition is most common in hospital settings.
In fifteen countries, only Spain, Germany, France, and the Netherlands provide coverage for medical nutrition in the three settings.
Less inclusive coverage in outpatient and community settings
Updates of the coverage policies are not regular
Limitation in the use of HTA for decision-making

Reimbursement
Variation in reimbursement between countries: included in the bundled payment or separately.
Eligibility restricts patient access
Variation in reimbursed products: complete formulas, non-complete formulas, enteral tube.
Limitation in the use of HTA: price-based decisions
Reimbursement is also different between administration route: enteral and parenteral nutrition

Challenges


Challenges
Manufactures
•Discrepancies in the definition of medical food
•Difference in sanitary regulation according to the product
•Absence of reimbursement regulation
•Flexible regulatory standards leads to absence of clinical evidence
Patients
•Out of pocket cost
•Right to receive or not receive medical food (acc. to need related to the clinical condition)
•Value
•Impact of treatment compliance
Payers
•Economic burden of the millennium
•Competition around the budget
•Health litigation

Nutrition Economics and the Health Equity Status Report (Initiative)



Source: Author's own adaptation from Healthy, Prosperous lives for all: The European Health Equity Status Report. Copenhagen: WHO Regional Office for Europe; 2019. Licence: CC BY-NC-SA 3.0 IGO.

Improving Equity in Reimbursement across Settings

- Development of multisectoral policies to promote fair access
- Analysis of reimbursement and coverage in different health systems- including all settings
- Development and implementation of HTA and health economics evaluation guidelines for medical food.
- Improvement of the availability of disaggregated data to facilitate analysis of policies and programs
- Comparative Effectiveness Research

SIG Current/ Planned Initiatives

Planned Activities:

- Journal club: 2-3 times every year
  - Planned for January 2023 and September 2023
  - Have an article idea? Email us!
- Webinar: Once a year
  - Have an idea? Email us!
- Project/ Report/ Manuscript: Research paper(s)- Next publication targeted for 2023-24
  - Ongoing: Role of nutrition in older adults: A systematic literature review of health economic evaluation studies
- Participation In ISPOR conferences: Forum or Other Presentation/ Discussions
- Newer Opportunities and Continue Collaboration
  - Expansion of SIG: welcome new members and their ideas
  - Expand on current SIG initiatives – Ideas? Email us!

SIG Tentative/ Future Initiatives- At a glance

Further Research Topics Thought under different activities:

- Targeted literature review on medical nutrition in older adults
- Scoping review: Guidelines about methodology for performing nutrition studies
- Reviewing the top trends. Few examples as below:
  - Nutrition and Economic focused key issues
  - Nutrition is priority/ Nutritional care is a human right
  - Global issues along with regional focus, such as case scenarios from APAC
- Any other highlighting issue if suggested/ requested by ISPOR members

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