





Socioeconomic Impact Analysis

Conceptual Framework Development

Update on OECI Consensus Task Force

by Prof. Michael Schlander, MD, PhD, MBA

Presentation to OECI Health Economics Working Group, Valencia, June 15, 2022 on behalf of the Task Force on Socioeconomic Impact Research (Schlander / van Harten / Retèl / et al.)



Task Force Membership

 Netherlands Cancer Institute (NKI-AVL), The Netherlands

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- German Cancer Research Center
 (DKFZ) / Health Economics, Germany

Michael Schlander (*TF Chair*), Karla Hernandez-Villafuerte, Diego Hernandez, Rachel Eckford, Phu Duy Pham, Jasper Ubels



Rationale, Objectives, and Anticipated Outcomes

¬ Rationale:

- Many cancer patients experience financial hardship, not only in the U.S.
 - ¬ Direct medical and non-medical expenditures (incl. co-payments) ...
 - ¬ Indirect costs (net loss of income, even after social transfers) ...
 - Intangible costs (psychological distress, decreased quality of life) ...
 - ... contributing to impaired clinical outcomes (including higher mortality)
- ¬ The "socioeconomic impact" of cancer extends beyond patients
 - ¬ Survivors …
 - ¬ Partners …
 - ¬ Dependents ...
 - ¬ Caregivers ...



Rationale, Objectives, and Anticipated Outcomes

¬ Rationale:

- Need to better understand the extent of the problem, including predictors and moderators of individual vulnerability of patients, such as
 - Individual factors (e.g., personal values, preferences, general perceptions)
 - Environmental and social factors (e.g., psychological and economic support)
 - Characteristics of the respective health and social security system
 - Access to, as well as organization, location, and modality of medical care
- Research to date in Europe has been heterogeneous,
 - characterized by inconsistent use of terminology
 - impaired by a shortage of validated instruments
 - lacked a coherent and comprehensive conceptual framework



Rationale, Objectives, and Anticipated Outcomes

¬ Objectives:

- To fill the gap in standards and guidance for studies exploring the socioeconomic impact of cancer and cancer care on patients and their relatives;
- To reduce or eliminate the risk of wasted research efforts due to redundant, overlapping, and incomparable work owing to unnecessarily heterogeneous use of terms and definitions,

and

 To support and facilitate further research in the field, including a potential platform for future collaborative projects by members of the Task Force.



Anticipated Outcomes of Task Force

Phases 1 & 2

- A European Consensus
 on a comprehensive conceptual framework
- European Recommendations
 for a consistent taxonomy & terminology
 and

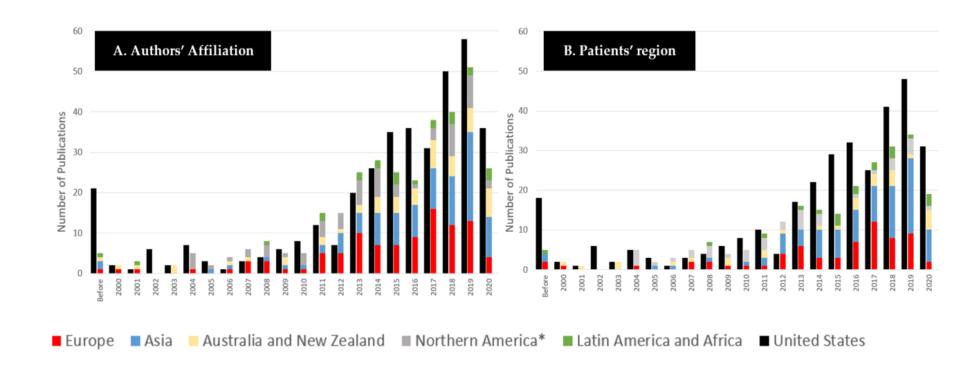
Phase 3

Instrument Development & Validation for measuring the socioeconomic impact of cancer from the perspective of patients and their relatives



Starting Points – Initial Analysis

Origin of "Socioeconomic Impact Literature"



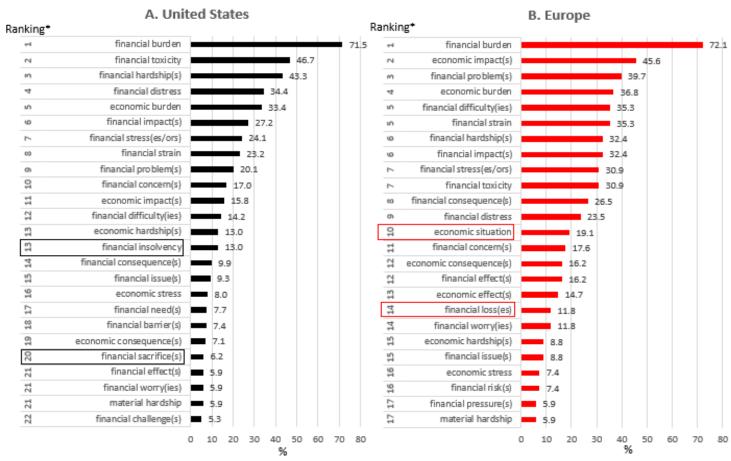
7 / 20 OECI Health Econ. WG Valencia, June 15, 2022 Initial internal analysis at time of project initiation; status March 2021.

*Here, "Northern America" refers to Mexico and Canada; this presentation was chosen to illustrate the dominance of U.S. publications. Source: DKFZ Analysis (Health Economics, K. Hernandez-Villafuerte, R. Eckford, et al., 2021)



Starting Points – Initial Analysis

Definitions used in "Socioeconomic Impact Literature"



^{*}Rankings are based on the number of articles (original articles, literature reviews and abstracts) that mentioned the term at least one time. More than one term can have the same ranking if the number of articles that mentioned the terms is the same. Boxes highlight the terms that only appear among the 25 most frequently used terms in that particular region.

Source: DKFZ Analysis (Health Economics, K. Hernandez-Villafuerte, R. Eckford, et al., 2021)

dkfz.



Starting Points: Initial Analysis ("Financial Toxicity")

The Need for a Broader Definition

"Financial Toxicity" is not a neutral term!

National Cancer Institute (NCI):

Problems a patient has related to the cost of medical care such as not having health insurance or having a lot of costs for medical care not covered by health insurance can cause financial problems and may lead to debt and bankruptcy.

Financial toxicity can also affect a patient's quality of life and access to medical care. For example, a patient may not take a prescription medicine or may avoid going to the doctor to save money.

- 1. reflecting the traditional focus on (presumably "health-related") quality of life
- 2. what about other constructs (and their valuation), capturing the full range of "intangible costs" incurred by patients (such as capabilities / functional status, health perceptions, psychological well-being / distress, social networks, life satisfaction, etc.)

¹https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-hp-pdq

1. adopting the perspective

of patients

2. what about impact of/on relatives (caregivers, dependents, etc.)

- 1. focus on
 "out-of-pocket"
 (oop) costs,
 i.e., direct
 medical &
 non-medical
 costs from the
 perspective
 of patients
- 2. what about [net] income loss, i.e., indirect costs from the perspective of patients
- 3. negative (and positive?) impact on patients and relatives ...
- 4. ... of the disease *per se* and of medical care

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The Need for a Broader Definition: Socioeconomic Impact Analysis

Financial Impact of Cancer on Patients:

Net Impact:

minus social support/transfer payments

[if applied for and received!]

Income Loss (examples)

- Sick Leave
- Reduced Productivity
- Reduced Working Hours
- Unemployment
- Early Retirement

Direct & Indirect Costs

Increased Expenses

(out-of-pocket costs)

- ¬ Co-Payments
- Travel & Accommodation
- Housekeeping
 - Child Care

Intangible Costs & Impact on Relatives

- Subjective Financial Distress
- Psychosocial Impact
- ¬ Quality of Life (…)

Impact on Caregivers
Impact on Dependents

Impact on Partners (...)



Socioeconomic Impact Analysis

Initial Working Hypothesis

Health-Related Outcomes

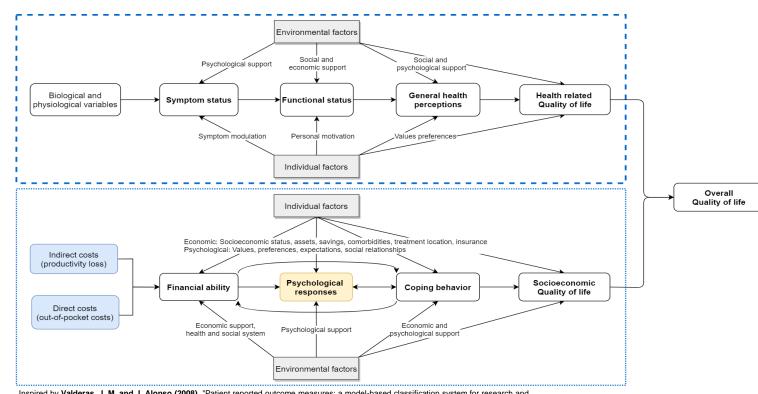
[e.g., Health-Related QoL in the extra-welfarist tradition of health economics]

Socioeconomic Outcomes

[by design largely neglected by most traditional PRO measurement instruments]

Note role of ex ante socioeconomic status as a moderator of outcomes

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Inspired by Valderas, J. M. and J. Alonso (2008). "Patient reported outcome measures: a model-based classification system for research and clinical practice." Quality of Life Research 17(9): 1125-1135.

Further references: Altice, C. K., et al. (2017). "Financial Hardships Experienced by Cancer Survivors: A Systematic Review." Journal of the National Cancer Institute 109(2): djw205.; Benoit Francoeur, R. (2005). "Cumulative financial stress and strain in palliative radiation outpatients: The role of age and disability." Acta Oncologica 44(4): 389-381; Carrap. P. M., et al. (2018). "The financial burden and distress of patients with cancer: Understanding and stepping-up action on the financial toxicity of cancer treatment." CA: A Cancer Journal for Clinicians 68(2): 153-165; Devellis R.F. (2017) Scale development: Theory and application. Fourth Edition. SAGE Publication. USA; Gordon, L. G., et al. (2017). "A Systematic Review of Financial Toxicity Among Cancer Survivors: We Can't Pay the Co-Pay." The Patient - Patient-Centered Outcomes Research 10(3): 295-309; Jones, S. M., et al. (2020). "A theoretical model of financial burden after cancer diagnosis." Future Oncology 16(36): 3095-3105; Santacroce, S. J. and S. M. Kneipp (2019). "A Conceptual Model of Financial Toxicity in Pediatric Oncology." Journal of Pediatric Oncology Nursing 36(1): 6-16; Witte, J., et al. (2019). "Methods for measuring financial toxicity after cancer diagnosis and treatment: a systematic review and its implications." Annals of Oncology 30(7): 1061-1070.





Approach

Theoretical Considerations (TC)

- ¬ Review of relevant health economic (costing) principles
- Review of relevant PRO measurement principles

Review of Prior Empirical Work (Focus on Europe)

- Project inventory (by Task Force members)
- Review and analysis of conceptual frameworks (best-fit synthesis)
- Review of current use of terminology (taxonomy analysis)

Synthesis: OECI Consensus Recommendations

- Lessons for measurement instrument development
- Review and analysis of "financial burden" measurement instruments
- ¬ Integration with SEC Trial insights; instrument development & validation



OECI Task Force on "Socioeconomic Impact Analysis" Iterative Process / Main Topics

¬ Inauguration of Task Force

- Bilateral Meeting NKI / DKFZ, January 29, 2021:
 Discussion of "Socioeconomic Impact of Cancer" and related projects & subjects
- OECI Health Economics Working Group Meeting, March 16, 2021:
 Decision to Establish Task Force (based on proposal by Michael Schlander et al.)

Project Phase I (Analysis & Foundations)

- Meeting M1, May 03, 2021:
 Kick-Off Meeting (Objectives, Process, Principles of Cooperation)
- Meeting M2, July 01, 2021:Work Plan, Research Inventory
- Meeting M3, September 28, 2021:
 Theoretical Underpinnings: Costing Theory (DH), PRO Measurement Principles (JU)
- Meeting M4, December 17, 2021:
 Terminology Review (KHV) and Conceptual Frameworks in the European Context
 (PDP); Draft Themes & Subthemes / Questionnaire on Themes & Subthemes
- Meeting M5, January 24, 2022:
 Follow-up on Questionnaire; Planning of Project Phase II & Work Packages



OECI Task Force on "Socioeconomic Impact Analysis" Iterative Process / Main Topics

Project Phase II (Conceptualization / Framework Development)

- Meeting M6, April 01, 2022:
 Themes and Subthemes (Questionnaire Analysis; Review of Selection & Definitions)
- Meeting M7, April 22, 2022:
 Relationship between Themes and Subthemes (PHP, JU)
- Meeting M8, May 23, 2022:
 Terminology, linked to Themes and Subthemes (KHV)
- Meeting M9, Valencia, June 16, 2022:
 Gap Analysis, Drafting Output & Initiating Writing Process, Communication Planning
- Meeting M10, yet to be scheduled (Q3, 2022):
 Consensus Meeting write-up and review of draft output documents; Q3, 2022
- Subgroup SG 1: Output Planning (several meetings; proposal to TF available)
- ¬ Subgroup SG 2: Costing Standards (several meetings, work in progress)

Project Phase III

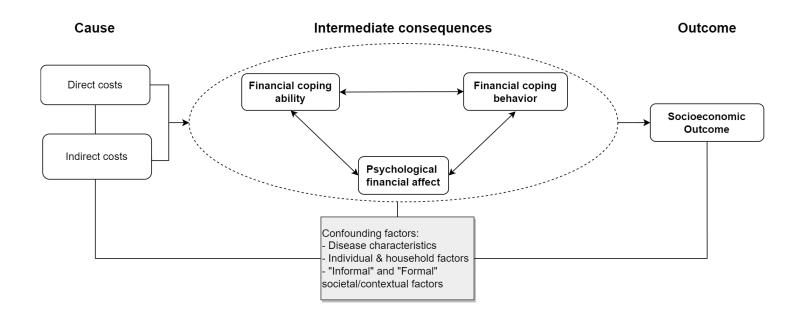
- Measurement Instrument Review & Analysis (PDP et al.)
- ¬ SEC Study Analysis & Reporting (JVC et al.)
- Measurement Instrument Development & Validation



OECI Task Force – Framework Development

Proposed General Framework

Causes and Outcomes



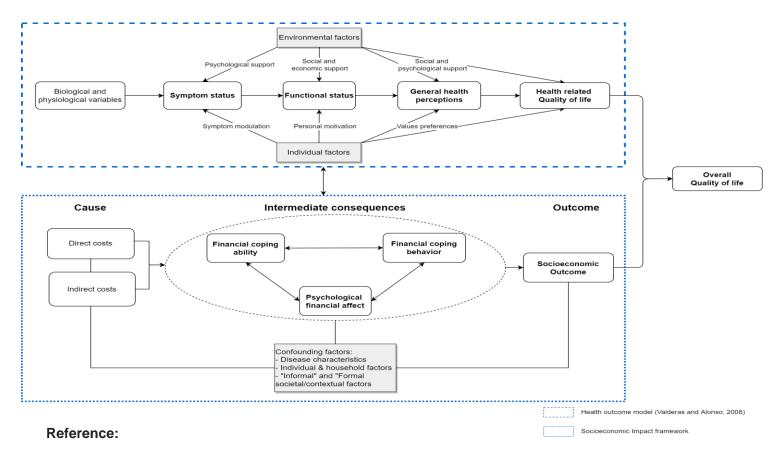
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Finalization => Precise Wording / Check for Double-Counting



OECI Task Force – Framework Development

Integration Framework



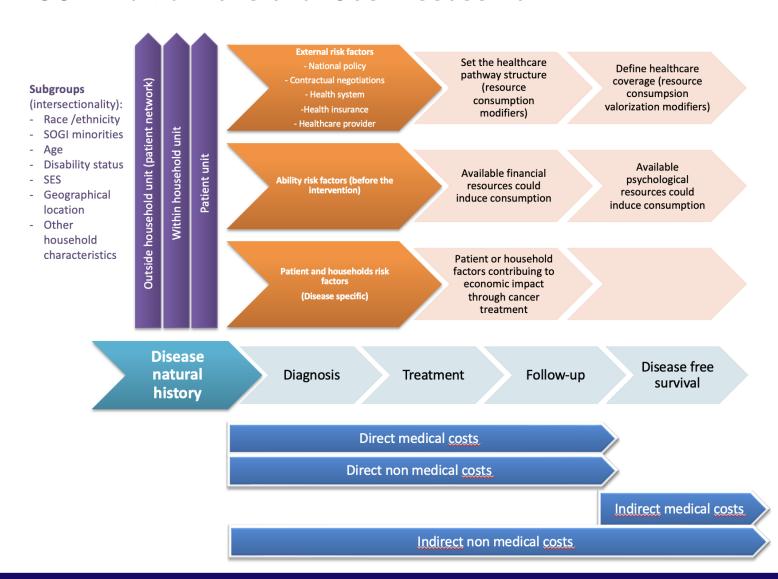
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Valderas JM, Alonso J. Patient reported outcome measures: a model-based classification system for research and clinical practice. Qual Life Res. 2008 Nov; 17 (9): 1125-35. doi: 10.1007/s11136-008-9396-4. Epub 2008 Oct 3. PMID: 18836850.



Socioeconomic Impact Analysis

SG2: Multidimensional Cost Assessment





SG1: Output Planning & Preparation

Publications

Ancillary Publications

European Lit. Review

[DKFZ: K.H.-V. & R.E.]

Rationale

[International Journal of Cancer] **IDKFZ & NKI Teams**

Taxonomy Review

[Lead: K.H.-V. & R.E.]

> Best Fit Framework Synthesis

[Lead: P.D.P. & J.U.]

Costing Standards

[Lead: Camila I.Q.L., Olaya S.L. et al.]

Primary Output

High-Level OECI Policy Paper

[Task Force] [Target Journal t.b.d.]

> Instrument Review

[Lead: P.D.P.]

OECI Consensus Recommendations

[Task Force] [Annals of Oncology t.b.c.]

> SEC Study Findings ...

[Lead: Julie vC.]

Need:

Draft Abstracts

&

Draft Tables of Contents

for each paper planned

SG1: Output Planning & Preparation

ISPOR Europe (Vienna 2022) Breakout Session Proposal

Topics & Leads

[European ISPOR Meeting, Vienna, November 06-09, 2022]

1.	Rationale /	Objectives /	Process / Ke	y Results	MS
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2. European Review, Taxonomy, Themes & Subthemes JU

3. Costing Standards for Socioeconomic Impact Analysis CIQL

4. SEC Trial Results & Outlook VR

5. Discussion with Audience MS/All







