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Construction of Alternatives for Stochastic Choice Models: Reflections From Choice Experiments on Diabetic Markets

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According to design theories, alternatives result from a construct; it can be from an analyst or decision makers and stakeholders. The generation of alternatives for the development of an economic model on medical markets was initiated with academic researchers, since medical and economic investigators also advised medical policies, especially at the time of the study on policy options to address shortages of critical drugs and to provide recommendations on controversial drugs in the TZD class. Global pharmaceutical pricing models have been so far driven by big life science companies in interaction with governments; the most common models discussed at a global level come from neo classical economic theory with adjustments of market prices, use of differentiated pricing to take into account adjustment of prices with GNPs differences or reference pricing to adjust access to consumers (e.g. in EU countries); other proposals include peak load pricing such as in Telecommunications. However, changes in international relation policies require now additional alternatives and objectives in a multi-stakeholder world for global health policies, the engagement of powerful non-state players, and the role of social medias into politics. In EWG-MCDA meeting at West Attica (Athens, 2024), it was proposed to use a C-K design framework to expand policy alternatives, using expansion of the concept space, especially for a cost sharing research agenda; after the recent communications at Euro and ADA conferences in July 2024, this paper proposes some advances for the general framework involving the South and North Hemispheres, and addressing common issues on major diseases such as diabetes.

Keywords: global pharmaceuticals pricing, economic modelling, C-K design theory, policy analytics, cost sharing research

Introduction

Global pharmaceutical pricing models have been so far driven by big life science companies in interaction with governments; the most common models discussed at a global level come from neo classical economic theory with adjustments of market prices, use of differentiated pricing to take into account adjustment of prices with GNPs differences or reference pricing to adjust access to consumers (e.g., in EU countries); some other proposals include peak load pricing such as in Telecommunications. However, changes

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in international relation policies require now additional policy alternatives, with multi-objectives in a multi-stakeholders world for global health policies, the engagement of powerful non state players, and the role of social media into politics.

In EWG-MCDA meetings at West Attica (Athens, 2024), it was proposed to use a theory from design, called the C-K design theory. It may help for instance existing value assessment frameworks, to expand policy alternatives, using expansion of the concept space, especially for cost sharing research agenda; After the two recent communications at Euro in Copenhagen and ADA in Helsinki in July 2024, this paper provides some reflections from the past research and discussion during this year, for the general framework involving the South and North Hemispheres and addressing common issues on major diseases such as diabetes. According to design theories, alternatives result from a construct; it can be from an analyst or decision makers and stakeholders. In the case study used for this paper, the focus is on generation of alternatives for medical policy and ways to adjust prices for supply and demand of drugs for the diabetic market, using an approach with random generators for prices (Huttin, 2024). The model is developed with a case on diabetes type II.

The generation of policy alternatives for medical markets is also at the frontier of different research areas including policy sciences, operational research, management and medical economics. The user case on diabetes type II illustrates an interdisciplinary collaboration, with the engagement of various professionals: physicians, clinical pharmacists, computer scientists, applied economist, econometricians, at various stages.

Review of Existing Design Theories and Issues of Health Policy

This section reviews potential contribution of design theories for generation of alternatives for health policies. A first communication at Ispor in 2021 explored how the literature on design theory (e.g. in policy sciences), may contribute to the construction of choice alternatives in choice models at micro and meso level, for incorporation or calibration of economic models at macro level, for adjustments of supply and demand of medical markets. It is timely to use design science for revision of welfare contracts, facing public budgeting crisis.

At this stage, the selected contributions come mainly from the engineering and management or policy literature.

First, the early contribution in the design literature from Keeney (1992; 1994; 1996), emphasized that it is important to "think first about values" before generation of alternatives. This approach was adopted by pharmaco-economists and business managers in pharmaceutical and life science sector, for the design of Value Assessment Frameworks (AVFs), mainly driven by the Outcome industry. This industry is funded to generate evidence on value (e.g. Value for Money; Value based indication for pricing); such values are then discussed among stakeholders and used in negotiations with regulators for access, prices, and reimbursement levels in various health systems.

The following definitions of "Value" received a consensus for the global assessment of health technologies (Garrison, Pauly, Wilkie, & Neumann, 2018):

> "Gross value: what someone would be willing to pay for an economic good or intervention"
> "Net Value: what the consumer would be willing to pay to avoid losing access to the good"
> "Net Value of an action, a program, a treatment or a technology reflect the willingness to pay for the improvement of well-paying minus the opportunity cost of resource to produce that improvement". (pp. 124-125)

Since 2018 report, more Advanced Value Frameworks have been drafted (e.g. for Nice HTA agency by Angelis and Panavos, 2017).

A second important contribution of design sciences is in cognitive and behavioral sciences; Simon (1977) or Simon and ales (1981) introduced the concept of bounded rationality and authors such as Newstead, Thompson, and Handley in 2002, discussed the limitations of memory and cognition in decision processes. In healthcare especially at individual level, the role of reminder systems and decision aids for instance for physicians and patients, have addressed overflow of information, misinformation, or other potential biases from mindsets of professionals and patients. For instance, the pharmaceutical industry especially addressed this issue for a long time to have Rx Brands in the "physicians' evoked set".

A third contribution of design sciences refers to Soft Operational Research (OR), it refers to concepts, design of processes, structuring problems, policy aiding tools (Tsoukias, 1991; Colorni and Tsoukias, 2018; Pluchinotta and ales, 2019). A process perspective is particularly relevant for life science and healthcare, in the current trend towards precision medicine that both industry and healthcare organizations face. Re-design of information systems, possibly with the deployment of AI, also helps restructuring of infrastructures. Architecture of cost sharing choices is the main elements of the system discussed in this paper.

Among design theories, a fourth contribution is the C-K theory, initiated by Hatchuel and Weil (2002), Le Masson, Weil, Hatchuel (2014). This theoretical framework is explored in this paper, since it may bring new solutions in health policy. This powerful tool had main applications for management of innovation, especially in industrial sectors; this may apply to innovative institutional arrangements with inclusion of healthcare start-ups and alternative ways for resource allocations. As digital governance is critical to fasten access to affordable care, IT diffusion in health systems or life science plays a major transformative role. Big Tech companies, however, compete with pharma companies in the Value Chain, and other stakeholders (especially data acquirers and Telecom companies) introduce mobile pricing formulae, as game changers, especially in e health and M Health spaces of medical markets. A few studies exist to show how the emergence of such technologies and innovative services benefit from the C-K framework (e.g. a community of home-based care workers by Vanda, Sivaramalingam, & Kabaso, 2018). So, such local community driven platforms help to speed up experience sharing and learning processes, at local or regional level. Other studies cover the emergence of nanotechnologies or some technologies introduced inside existing hospitals.

Construction of Alternatives: History of the User Case on Diabetes

This section of the paper describes two researchers' experience (Prof. Huttin and Hausman) in a collaborative project for a physician choice model for the US medical market. The generation of alternatives in this case refers to the role of experimental research in a medical policy process; the alternatives represent categories for choice sets among different pharmacotherapies including the no drug case. The project is also a user case for decision tools, with further experiments on a comprehensive selection of drugs, procedures, or medical devices.

The generation of alternatives for the economic model was initiated with academics, since medical investigators advise medical policies, and economists provide different approaches for pricing policies on such markets. In addition, in the development of this economic model, the use of random generators for drug prices was tested on different drug therapy alternatives for diabetic type II.

At the time of the study, the main problem addressed by the medical investigators was the insulin drug shortage in major States of the USA, leading to series of court trials. Various drug policy options to address these shortages of critical drugs were on the table: imports from Canada, rationing, revision of price policies; it also

led the team to provide recommendations for modifications of classifications. A second problem was also the need to reach a consensus for national clinical guidelines on controversial drugs in the TZD class. This required a special investigation of the national dataset on physicians (called the National Ambulatory Medical Care Survey, NAMCS) and extraction of lists of codes used in a representative nationwide sample of medical records on diabetes type II (Huttin and Wong, 2010). The historical perspective provides elements of the research process and the types of interactions between the investigators; it illustrates that the selection of alternatives for the first drug choice set is the result of a complex series of investigators' decisions.

The selection started with the pharmacotherapy's controversy on evidence of effectiveness or not of some new drug class for some of the patients diagnosed with Type II diabetes. This concern from the medical team of investigators, led the economists to extract from the national survey the list of codes for all ingredients associated with the type of drug therapies; The baseline for the dataset, however, was constrained by the administrative rounds of survey and the information provided at the time of the study for the drug list; The consensus guidelines for first line therapy or second line therapy were the basis for extracting the drug list and the relevant drug codes for classification of different drug treatments[1]. The economic predictive model is therefore created with baseline dated with reference points corresponding to the established stage of knowledge in a country such as the USA; as guidelines and listing decisions are also embedded in a political process, and adoption of new codes may challenge existing clinical pathways, it is not automatically a representation of the state of advances of sciences and not automatically similar in all countries at the same time[2] (e.g. . studies by Huttin and Kornitzer, 2004, and Huttin & Endepresearch group, 2005, on comparison of objective and subjective risks for hypertension, blood pressures thresholds evolved over time and were adopted at different paces in different countries).

Context of the Research Protocol

The approach is disease oriented, therefore it relies on predictive econometrics to represent association and/or causal inference between dependent variables on patterns of utilization of medical services such as medicines, tests, physician services, kits, and supplies related to this disease and series of clinical and socio-economic predictors as independent variables. Such a disease approach is not automatically agreed at macro level and only a few countries such as USA, Germany, or Korea have decided to use disease level for their national accounting systems (e.g. for episode of disease treatment measurements, additional statistics to forecast Burden of Diseases (US) or Cost of illnesses (Canada, Australia, the Netherlands), for ad hoc or satellite health accounts, (some EU countries)). Such a disease approach is not automatically agreed at macro level and only a few countries such as USA, Germany, or Korea for instance have decided to use disease level also, either in their national bureau of economic analysis or bureau of labor statistics, in addition to their national accounting systems, for instance to introduce episode of disease treatment measurements. Such additional statistics help with forecasting Burden of Diseases (e.g. in the USA) or Cost of illness studies (e.g. countries for disease OECD projects at OECD). Even if disease approaches raise controversies among macroeconomists, medical international policies circles still use them, especially for international clinical consensus guidelines and their updates.

[1] the original study on diabetic type II selected as a base for initiating this project relies on the extractions of list of codes for diseases and treatment of the disease imputed in existing administrative survey, regularly updated by national statistical agencies; it therefore depends on the regular or not data collection for such surveys.

[2] in the US medical school, research on finding appropriate scores to better predict utilization of services is an important area: for instance propensity scores in major chronic conditions (Schneeweiss, 2007; Wang, 2021).

The predictive disease modeling process was therefore initiated with this disease approach and the main objective to find the best predictors and their measurements to understand and possibly forecast the demand for such medical services. The knowledge creation with this approach allows the centers of excellence (medical investigative team) to provide comparative evidence and assess the efficacy of treatments or lack of efficiency in different subpopulations and potential side effects as well as issues of non-compliance and lack of adherence to treatment. Study results usually are published in top medical journal such as the *New England Journal of Medicine* or the major American society journals as advise on advance of medical and pharmacological sciences.

At the time of the economic model, the first documentation used is therefore the relevant medical articles discussing the pharmacological debates between old and new drug or no drug treatments and combinations or not of various pharmacotherapies and medical devices.

Historically, the class of diabetic drug called the TZD class was under scrutiny by the research team of physicians and epidemiologists. Partners HealthCare, especially a team from Brigham and Women Hospital (BWH), was very involved in the controversy, since this is one key role of leading teaching centers of excellence. Results from clinical studies are usually then a reference used on consensus guidelines and published in journals such as the *New England Journal of Medicine*.

Interaction Between Medical Professions and Economists

As an applied economist specialized in pharmaceutical economics and health policies, I had the chance to collaborate with the medical team involved in the controversies on drug choices for diabetic type II treatment. The design of analytical databasing was then driven by questions to answer an investigation on controversial drugs and effects of drug shortages; it was a good reason to engage the top medical investigators in the design of a useful dataset. The first descriptive statistics on the sample extracted from the administrative data set called National Ambulatory Medical care survey showed a very high proportion of non-users of basic oral agents; this was a concern for the medical profession and the pharmacists and the team allocated more time for checking the sample, the list of all ingredients, and forms of medications in all dosages forms. A research computer director from a medical team from Partners Healthcare, Boston, was then involved with Prof. C. Huttin to clean and verify the data sets.

Interaction Between Physicians and Pharmacists

This first interaction leads to raising a second important research question on this market, to understand why so many patients with diabetic type II were not on drugs; it highlighted a controversy between the two professions: doctors more favorable to have aggressive and preventive strategies (lifestyle changes and diet), they argued in favor of a revision of guidelines, setting an additional classification called pre-diabetic stage; on the contrary, pharmacists preferred to have patients on an oral agent such as metformin, when they walked in drugstores (lifestyle change takes time and being on an oral agent is safer, pharmacists' remuneration also depends on drug sales, to a large extent). The increasing prevalence of diabetic population both nationwide and globally (in both North and South Hemispheres) also leads to shortages of main diabetic drugs and has contributed to high prices on this US medical market. The use of cheaper drug imports, especially from Canada, was at that time discussed as a health policy option, to reduce shortages in some US market areas, but could only help at the margin, to supply the big US demand for such drugs. US prices on this diabetic market remained very high, especially in large market segments for patients enrolled in commercial plans.

The analytical dataset designed in collaboration with the medical investigators dealing with medical policy on drug issues, was unique; it became also highly relevant for economic research to address the high price problem. Therefore, a project was then initiated by Prof. Huttin and Prof. Hausman at MIT, for the development of an economic model on physicians' choices; this analytical dataset from Prof. Huttin was reshaped for the purpose of economic choice modeling, with the support of data scientists from IQSS center jointly funded by Harvard and MIT (Huttin and Hausman, 2019).

The motivations of the economic team to embark on model development were quite different from the medical investigative team; the main objective was to address the pricing problem with a new method based on random generators for prices and choice modeling to better capture heterogeneity of demand models for care. At the time Prof. Huttin met Prof. Hausman, he was working with two co-investigators on new specification econometric tests; they believed it was necessary to fill a gap from the generalization of the Hausman-McFadden test at an individual level of choices; this additional test may then be of use especially in some mixed logit modeling cases or to complement classifications used in latent class models.

Further development of this economic model requires more experimental research with comprehensive user cases on devices, procedures, or other drug choice sets, with more and larger samples and comprehensive insurance patient profiles. In addition, more economical ways to generate and extract relevant analytical datasets may be necessary. The first milestone of the physicians' choice model and its preliminary findings have created the necessary steps to also train the economic model and use artificial intelligence techniques to expand the methodologies.

Moreover, the fast genetic revolution also has led to more recent pharmacotherapies and has expanded the use of existing drugs to (repurposing) more indications, or a larger space including some risk factors (companies target the obesity risk factor, some diabetic drugs are now used for severe obesity). This recent expansion of the product space is a good example of how existing knowledge might help the expansion of product innovation (the scope of C-K framework).

Is It Useful to Use the C-K Theory to Design or Re-design Reimbursement Policies in Health Care Financing?

C-K theory has been considered useful mainly to help innovation processes; the new product-market development of diabetic drugs, mentioned above, shows that on the supply side of medical markets, innovation processes for new products and services are a major activity in this intensive R&D sector. Innovation in medicine has been at the forefront of scientific and technological innovation to eradicate diseases, improve clinical therapies, and find appropriate treatments. However, the cost of care and provisions of health services is extremely high, and medicines especially are regularly targeted, especially since precision medicine also leads to niche markets, and extremely high prices in such market segments.

The main contribution of C-K theory for economists (e.g. for more fairness and affordable care to populations) is the concept of creative rationality; This idea helps to move beyond the limitation of existing economic theory of expected utility (in particular, subjective expected utility (Savage, 1954)). It also addresses what Simon originally called bounded rationality, which leads to behavioral economic and judgement research on sources of biases, errors, and limits of cognition. Thaler and Sunstein (2009) also helped to move the findings of such models into policy making, especially in areas of public management (e.g. reforms of pensions). It led to

instruments such as nudges (e.g. for nutrition) but also controversy about the potential misuses of such instruments (e.g. debates on nudges versus boosts by Reijula, Kuorikoski, Ehrig, Katsikopoulos, 2018).

Health policies are of course a major area of this field. My own research aimed to address the sensitive topics of how economic and financial constraints or business pressures, interfere with medical decision making processes. It proposes several methods and approaches to strengthen the demand side of medical markets. The policy area under investigation has been called cost sharing research, which addressed the various forms of reimbursement designs, payment models, and risk sharing between different types of payers (insurers, tax payers, patients, and citizens).

To discuss whether C-K theory can contribute to this field, I first summarize the original scientific fields that helped to develop the cost sensitivity simulators as decision tool (Huttin, Endepusresearch, 2009, 2017).

The first research agenda was rooted in behavioral models and judgment research. Judgment studies have been performed in different fields of sciences including medicine, politics, business, and law. It was especially used for counter detailing techniques, first in education, then introduced to the field of medicine by Avorn and Soumerai in Boston. They were the first to use such techniques to provide competitive marketing information, processed by doctors on different medicines, especially prescription branded products. Clinical judgement studies are widely spread for recommender or reminder systems to provide additional information at the point of care for supporting clinical decision making and for patients, in decision aids, especially in shared-decision making process. Decision rules are computed in IT systems of health care organizations; decision tools are embedded in medical informatic systems of major health care organizations, mainly teaching hospitals, or in primary care organizations, generally included in larger networks for secured environments.

The purpose of the cost sensitivity simulators was to use a similar layer of information than the one used in clinical judgement research (based on psychological cues, such as in Brunswik lens model), but on economic or cost cues. The first technology was to develop alert systems for primary care settings, with prospective information for primary care setting and walking clinics. It was designed for early detection of lack of compliance or patient adherence due to financial restraints not well captured in existing information system or triage systems. Such approach is based on experimental research, with study designs such as “reversed conjoint” designs including socio economics cues to describe patients’ or physicians’ economics and not only product economics (in clinical vignettes). This field of medical economics allowed to investigate especially incoherencies in regulated medical markets due to political and bureaucratic processes (e.g. Huttin, Brunswik society meetings in newsletters, 2013 and 2014).

This approach provided evidence when, how providers of care are cost aware, even after triage, and how it affects the burden of disease and outcomes. The concept of awareness is well implemented in value assessment discussion and engagement of multi-stakeholders in data sharing or negotiation processes. Non-state organizations have taken also forms of leadership for providing evidence on international price comparisons and countervail pricing studies from economists in current institutions. The use of Hierarchical (HB) modeling, was implemented in cost sensitivity studies, using an algorithm for “reversed conjoint design” with explicit and implicit information on cost of care in cost sensitivity simulators for patients and providers (see Figure 1).

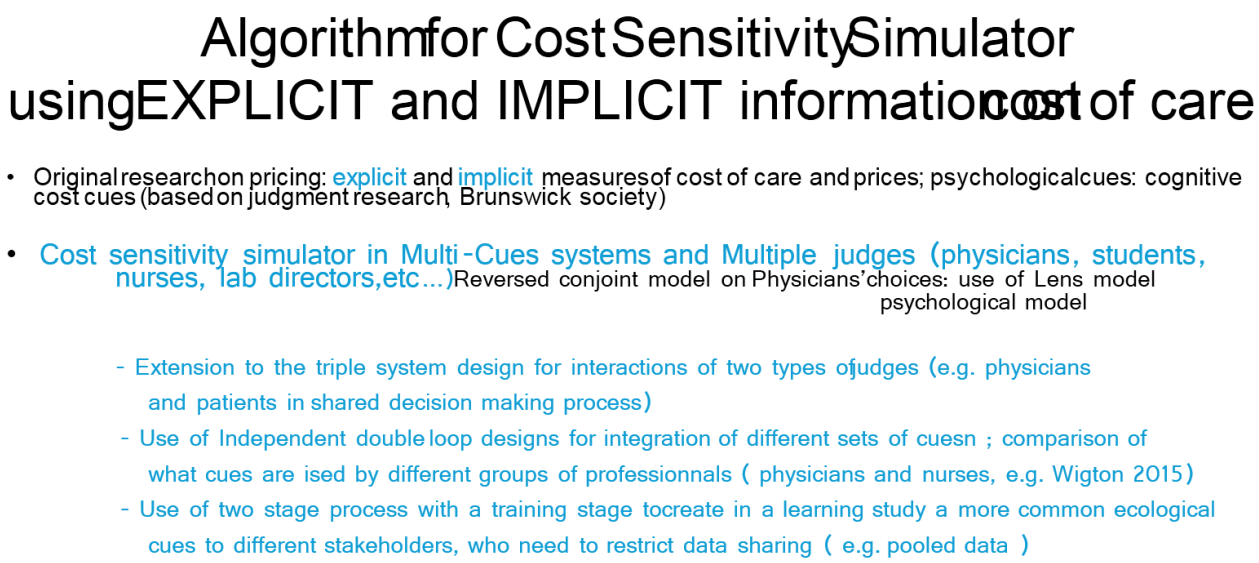

Figure 1. Algorithm for cost sensitivity simulator using EXPLICIT and IMPLICIT information on cost of care.

HB Modeling is also widely diffused on the supply side by top R&D departments for clinical studies (efficacy and toxicity) in multisite clinical trials. If such modeling is implemented as negotiating decision aiding policy tool, it may help the health policy making processes with growing awareness around the challenges of global sustainability (e.g. Reverse Bayesianism models by Karni and Viero, 2013).

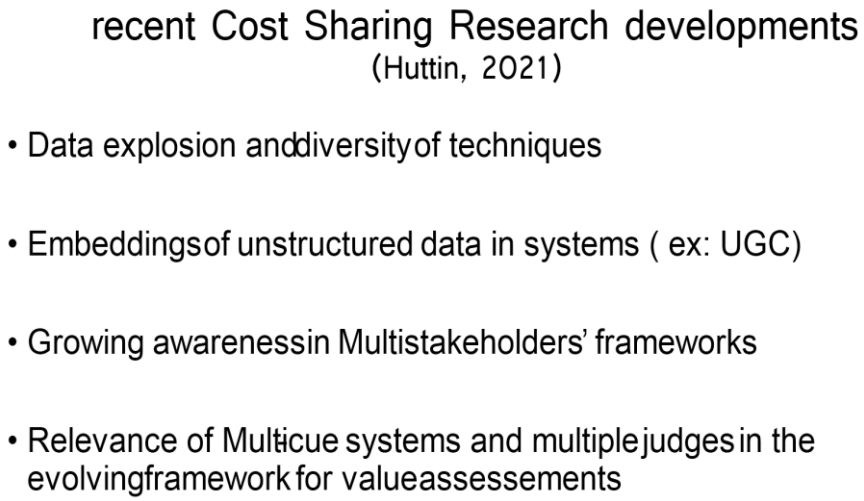

Figure 2. On cost sharing research development milestones (Huttin, 2021).

Technical Note on C-K Theory for Development in the Use of Cost Sensitivity Simulators in Health Systems

In the field of healthcare, especially in Europe, access to medical products and services is part of socialized systems and is largely dependent on public budgeting even if private or mutual funds provide additional contributions especially for coverage of primary care services. Health care expenditures represent a major component of welfare packages and therefore of welfare contracts. The large increase of public debts is not only attributable to resource allocations to health care organizations; however, it may be also a target for reduction of

public debts. When such welfare contracts are debated again, they also raised the problem of social justice or increasing inequalities among population groups and the scope of what the civil society can afford; it may lead to different priority settings between social and health service between preventive versus curative strategies.

Governments facing voters cannot be only captured by economic interests and try to find mechanisms or different institutional arrangements for more fairness in multi-stakeholder value assessment frameworks and affordable access to medical services of good quality. In public management, the concern of large unmet needs, leads to revising incentive mechanism or setting rules-based systems in competitive segments (using for instance mechanism design). However, medical markets have been under global biopharmaceutical or life science companies for a long time; national or regional markets have been dominated by induced supply of medical technologies and the nature of competition on such markets also depends on how economic firms can get highest returns on R&D and profitability for their shareholders, in liberal market economies.

Again, existing economic models for health (e.g. Grossman model) are not currently very useful because of the assumption on longevity that does not lead to sustainable systems. Public investment or foundations also complement private fundings, however emergence of new diseases or pandemics, war risks continue to represent major challenges so additional approaches such as C-K may be useful to expand the innovation path for implementing innovative services, for more realistic welfare contracts and institutional arrangements for the society. Figure 3 summaries preliminary elements for a C-K theory application to the field of cost sharing research, to be discussed for national, regional, or global policy level. Global rulers may decide to adjust prices according to countries' GNPs/capita level, they also need to take into account markets where secondary markets (e.g. with circular models) and donations represent increasing market shares and are not only used to supply domestic demand.

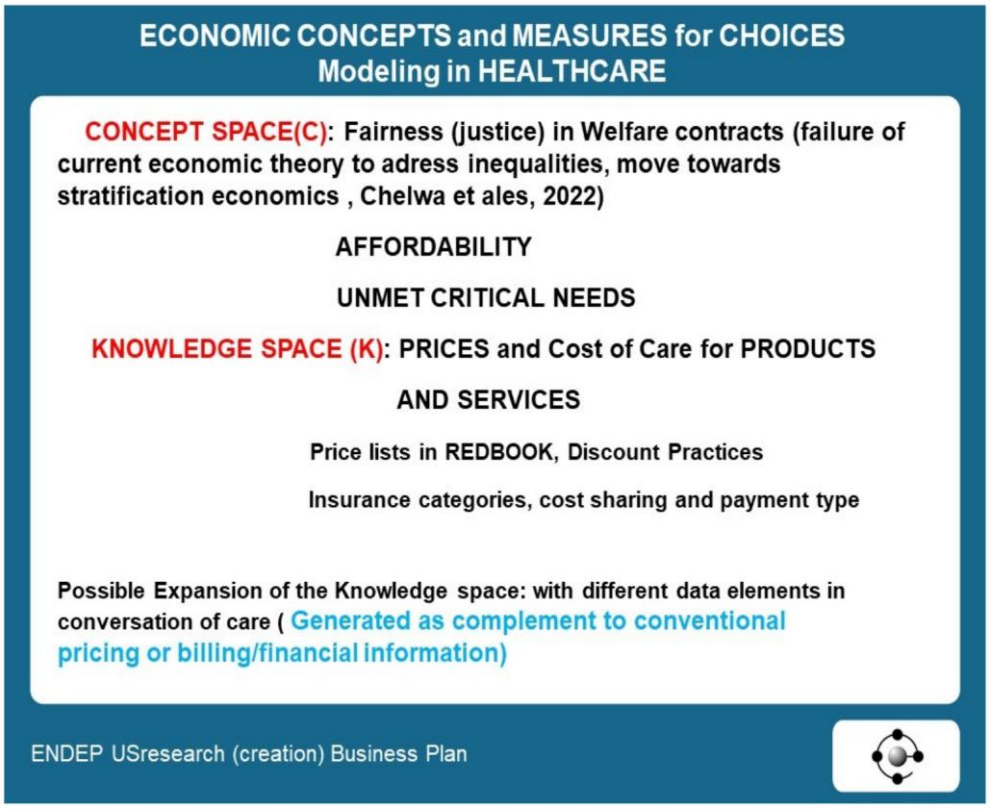

Figure 3. Prof. Huttin's communication in Athens, EWG-MCDA, in April 2024 (Huttin, 2021).

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