



Clinical decision-making process and distributive justice: The mediating role of economic analysis. Empirical evidence from Italy

Anna Arcari MSc¹ | Mario Picozzi PhD² | Anna Pistoni PhD¹ |
Davide Battisti PhD³ | Silvia Ceruti PhD⁴

¹Department of Economics, Insubria University, Varese, Italy

²Department of Biotechnology and Life Science, Insubria University, Varese, Italy

³Department of Law, University of Bergamo, Bergamo, Italy

⁴Department of Biotechnology and Life Science, Research Center for Clinical Ethic, Insubria University, Varese, Italy

Correspondence

Anna Pistoni, Department of Economics, Insubria University, V. Monte Generoso, 71, 21100 Varese, Italy.
Email: anna.pistoni@uninsubria.it

Abstract

Background: The COVID-19 pandemic has not only tested the resilience of public health systems but also underscored the criticality of allocative choices on health resources. These choices, however, are not confined to health emergencies but are integral to public health decisions, which inherently grapple with limited resources. In this context, physicians play a pivotal role as the architects of clinical actions in various scenarios. Therefore, doctors are called upon to make their decisions by considering not only the criteria of clinical appropriateness but also the ethical aspects linked, in particular, to the principle of justice. Indeed, the assessment of the effectiveness of a treatment for a particular patient must be balanced against criteria of equity and justice for the whole. To be fully applied, the principle of justice presupposes the use of economic evaluation techniques designed to drive the organisation decisions by effectiveness and efficiency.

Methods: The present paper aims to empirically analyse whether and to what extent economic evaluation is known and used by doctors in healthcare decision-making and, therefore, what the most widespread approaches are used in such processes. In particular, this paper intends to present the results of an empirical study on a sample of doctors registered with the Order of Physicians in Lombardy (Italy), one of the areas most affected by the COVID-19 pandemic.

Results: The research reveals a particular awareness of the criticality of allocation issues accompanied by a lack of knowledge of the economic evaluation techniques or, more broadly, by an almost total disuse of financial criteria. The main reasons are doctors' need for more knowledge of these tools and insufficient availability of economic information at the country system level.

Conclusion: In the conclusion, we propose some suggestions to facilitate the transition to more current decision-making models consistent with the characteristics of more advanced national healthcare contexts.

KEYWORDS

evaluation, health economics, medical education, public health

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1 | INTRODUCTION

Healthcare rationing refers to allocating scarce healthcare resources and implies using different approaches to providing healthcare services and, in general, patient care. While it is certainly not a new topic of discussion, the COVID-19 pandemic has rekindled the attention of the scientific community and the general public on this topic, and it has regained the focus of many concerns, especially in the field of health economics.¹

As is well known, the pandemic has severely challenged many healthcare systems. Especially during its “first wave,” in mid-2020, hospitals and healthcare professionals around the world had to deal with an unprecedented emergency that, in some areas, has become a real humanitarian crisis with health, social, and economic implications.^{2,3}

More specifically, the pandemic has clearly shown—how allocative choices must always be made, even when it comes to healthcare resources and even when they concern the allocation of life-saving treatments.^{4,5} It was emphasised that in severe resource constraints, it is necessary to consider the needs of individual patients and the community using access/limitation criteria.³

However, the pandemic has only brought to the forefront a long-debated topic and, in a way, has further emphasised the importance of investigating the issue of scarcity of healthcare resources and access to care⁶ from theoretical⁷ and empirical perspectives.

The problem of allocating scarce healthcare resources is also complicated in everyday clinical practice by factors such as the constant aging of the population and the implementation of increasingly effective but expensive therapies.

In particular, the aging population significantly compounds the challenge of allocating healthcare resources as it is directly related to the prevalence of chronic diseases, multimorbidity, disability, and frailty.^{8,9} The elderly generally require more medical care, extended hospital stays, and complex medical treatment, translating into higher healthcare costs. The demographic change of recent decades means that an increasing amount of healthcare resources must be devoted to managing age-related conditions, thus intensifying the competition for limited resources.

Moreover, as anticipated, developing advanced drugs, medical devices, and treatment protocols while improving patient outcomes often strains healthcare budgets as cutting-edge therapies cost considerably.

In this context, in which the needs of individual patients conflict—at least in some cases—with broader societal needs, considerations based primarily on the principle of justice should play a significant role [PA1].¹⁰ Nevertheless, such a dimension is often disregarded or underestimated in the clinical setting, particularly by those who personally have to make choices of this kind.

From a patient-centred care perspective, the doctor-patient relationship is usually considered strictly dual,¹¹ with little room for justice considerations.^{12–15} Moreover, clinicians are traditionally not much trained to deal with allocative problems, and consequently, medical decision-making is primarily based on clinical appropriateness, i.e., the assessment of the safety and efficacy of a treatment or

procedure for a given patient, conducted based on the clinical information gathered. Adopting the principle of distributive justice finds one of its prerequisites in using techniques and tools of economic analysis, which are usually taken as a reference when allocating scarce resources.³ Of course, allocation decisions can be made according to different ethical criteria based on different approaches to justice issues. For instance, *Utilitarianism*, in some of its forms, would allocate healthcare resources in such a way as to maximise the years of life saved with the highest possible quality to maximise the aggregate well-being. The *fair equality of opportunity* approach proposed by John Rawls¹⁶ and integrated considering healthcare issues by Norman Daniels^{17,18} recognises instead that illness may significantly affect actual opportunities to participate successfully in social competition. Rational decision-makers in the original Rawlsian position would be interested in having a “decent minimum of health care”, encompassing at least some elements of preventive, therapeutic, and rehabilitative medical services. Finally, *Prioritarianism* claims that the choice to make is the one that benefits those who have lower overall well-being; prioritising those who are worst-off would have more importance than maximising aggregate well-being or promoting equity per se.¹⁹ But regardless of the approach we decided to follow, there is a strong interest not to waste resources to have more of them available to be allocated.^b In this line, Daniels and Sabin argue that inefficiency somewhat interferes with meeting healthcare needs since fewer needs will be met regardless of the resources available for healthcare if they are inefficiently and ineffectively used.²⁰ This means that every approach for allocating healthcare resources is interested in benefiting as many people as possible. In other words, any of them would prefer scenario A, in which a given amount of resources X are used to cure 10 patients effectively, compared to scenario B, in which the same amount X is used to cure five patients effectively: the more resources we have, the less tragic decision, which however is inevitable, is necessary. Some are more sympathetic to using economic evaluations (e.g., Utilitarianism). However, from this, it does not follow that those who embrace different distributive principles prefer to avoid making unavoidable allocative choices in an efficient system with a precise evaluation of the costs and consequences of alternative actions.

In general, the adoption of economic evaluation methods to allocate healthcare care resources occurs in different contexts and at different levels.^{24–28} It is indeed acknowledged to be crucial at a macro level, i.e., through choices/plans imposed at the national/regional level, as well as at the meso level, i.e., by the individual

^aThe techniques of economic analysis in health care are grouped under an articulated set of labels, such as *cost-effectiveness analysis*, *cost-benefit analysis*, and *cost-utility analysis*. As the authors who have studied and, in some cases, criticised them have pointed out,²¹ these methods differ in terms of their technicalities, their application complexity and their significance. Upstream, they are all due to difficulty finding the information necessary for their use, especially at the ‘micro’ level. While much has been written about economic evaluation techniques in healthcare (Drummond, 1997-2005-2015; 22,23), little is known about their actual use by healthcare decision-makers, hence the need to shed light on this particular aspect of the subject of our research.

^bOf course, following all the approaches above, this stance is valid if we argue that healthcare is a right or a vital interest that should be protected somehow by the State or those who allocate healthcare resources.



healthcare institutions (hospitals, etc.); on the contrary, the adoption of these methods at the micro level, i.e., supporting individual physicians' decisions needs to be more straightforward and less investigated.

At this micro-level, which is the focus of this paper, by a patient-centred approach, the decisions that physicians make are mainly driven by clinical criteria and do not include economic evaluations, which are often described as forms of 'bedside rationing,' i.e., «the withholding by a physician of a medically beneficial service because of that service's cost to someone other than the patient»²⁹ (p. 74).

Nevertheless, such decisions have an undeniable economic and social impact that individual doctors should consider. An individual patient-centred clinical decision generates an "opportunity cost," i.e., the lost benefit to the rest of the community induced by that choice.³⁰⁻³² Given the scarcity of resources that characterises healthcare systems, whatever approach is chosen, appropriate tools should be adopted to measure the effects, including economic ones, of the allocative choices. Consequently, the economic evaluation, i.e., the comparative analysis of alternative actions in terms of "expenditure" for the health system and the community,³³ is a fundamental—though not definitive—tool for appropriately allocating healthcare resources.³⁴⁻³⁶

Starting from these premises, our contribution aims to investigate the role of economic evaluations in the decision-making process by physicians and to determine whether and to what extent physicians are familiar with and use economic analysis methods in the decision-making process. Although, as mentioned, a stream of literature has already analysed the topic,³⁷ providing valuable findings on the use—and barriers to use—economic evaluation tools in healthcare,^{38,39} we believe that further empirical work is needed, primarily related to the Italian context, as the mentioned surveys do not cover it.

More specifically, with this contribution, we tried to answer the following research questions:

1. What is the current level of knowledge and degree of integration of economic evaluation tools among physicians in their clinical decision-making processes?
2. What key factors prevent physicians from using economic evaluation tools in clinical decision-making?
3. What interventions could facilitate or stimulate consideration of resource allocation issues in health care during health crises (as was the COVID-19 pandemic) and in routine clinical practice by introducing economic evaluation criteria into clinical decision-making?

These research questions guided our investigation and are directly aligned with the following objectives:

1. To provide empirical evidence on the awareness and use of economic evaluation tools meant to improve the allocation of healthcare resources by physicians;

2. To identify factors that may hinder the use of economic evaluation tools in clinical decision-making;
3. To identify feasible measures that may ease the consideration of resource allocation problems in healthcare by introducing economic evaluation criteria in clinical decision-making.

To this end, we present the results of an empirical study on a sample of physicians registered with the Medical Association in the provinces of Lombardy (Italy), one of the regions most affected by the COVID-19 pandemic in Europe. Although, as mentioned, the problem of resource allocation is undoubtedly not exclusively related to the COVID-19 pandemic, during the pandemic, the scarcity of resources (i.e., beds in intensive and sub-intensive care units) emerged theatrically, rekindling the attention on the issue and stimulating reflection from both an ethical and a health economics point of view.

2 | MATERIALS AND METHODS

This study was designed and conducted by a group of researchers from different disciplinary fields (economics, medicine, philosophy, and law); therefore, it can be defined as a multidisciplinary contribution regarding the research questions formulated and the interpretation and discussion of the results.

2.1 | Study design and setting

The study was conducted through an online questionnaire administered via the Google Form platform to doctors registered with the Order of Physicians of the Lombardy provinces (Bergamo, Brescia, Como, Cremona, Lecco, Lodi, Mantua, Milan, Monza Brianza, Pavia, Sondrio and Varese). As a preliminary step, all the Lombardy provincial secretariats were approached by telephone to inform them of the project; formal authorisation to administer the questionnaire was then requested by sending a letter presenting the research project to the presidents of the provincial sections. All the local representative bodies approved the project and offered their support in disseminating the questionnaire among members by sending an email with a link to the form. The questionnaire was open for responses from Lombardy's physicians from 1st May 2022 to 11th January 2023.

2.2 | Questionnaire and survey procedure

The authors of this contribution designed the questionnaire: All authors contributed equally to its implementation.

The questionnaire was designed using different survey methods: closed-ended questions, open-ended questions, and a rating scale (Likert scale) to assess physicians' opinions, attitudes, or behaviour quantitatively. The language of the survey was Italian.

The first draft of the questionnaire was presented to a small group of subjects with the same characteristics as the population to whom it would be administered (physicians from Lombardy) to determine whether the text was sufficiently clear and complete. Feedback from this group was used to draft the final version of the questionnaire.

The questionnaire was divided into five sections, preceded by a short introduction in which the purpose of the study was described and some definitions provided. In particular, the introduction clarified that (a) health economics deals with the study of how individual health professionals, organisations, and society make choices in allocating resources, which are by definition scarce, to meet the population's health needs; (b) economic evaluation can be defined as «the comparative analysis of alternative courses of action in terms of both costs and consequences»,²⁸ and in health care, it is based on the ability to measure resources, intermediate products, diagnostic-therapeutic pathways and patient outcomes; (c) the costs to be referred to are usually categorised as follows: present versus future; tangible versus intangible; direct versus indirect.

The first section of the questionnaire was dedicated to collecting the respondents' demographics, particularly their primary education, post-graduate education, and work experience.

The subsequent four sections of the questionnaire aimed to investigate: (a) the degree of knowledge of the economic analysis and evaluation techniques proposed by health economics; (b) the degree of use of these techniques; (c) the difficulties in their implementation/use; (d) the factors that hinder/encourage their implementation in clinical decisions.

Completing the questionnaire online implicitly gave consent to participate in the survey. The survey was conducted according to

Italian law on protecting personal data, and all participants consented to use the information provided anonymously for the present study. Since no identifiable data was collected, the study did not require ethical approval.

3 | RESULTS

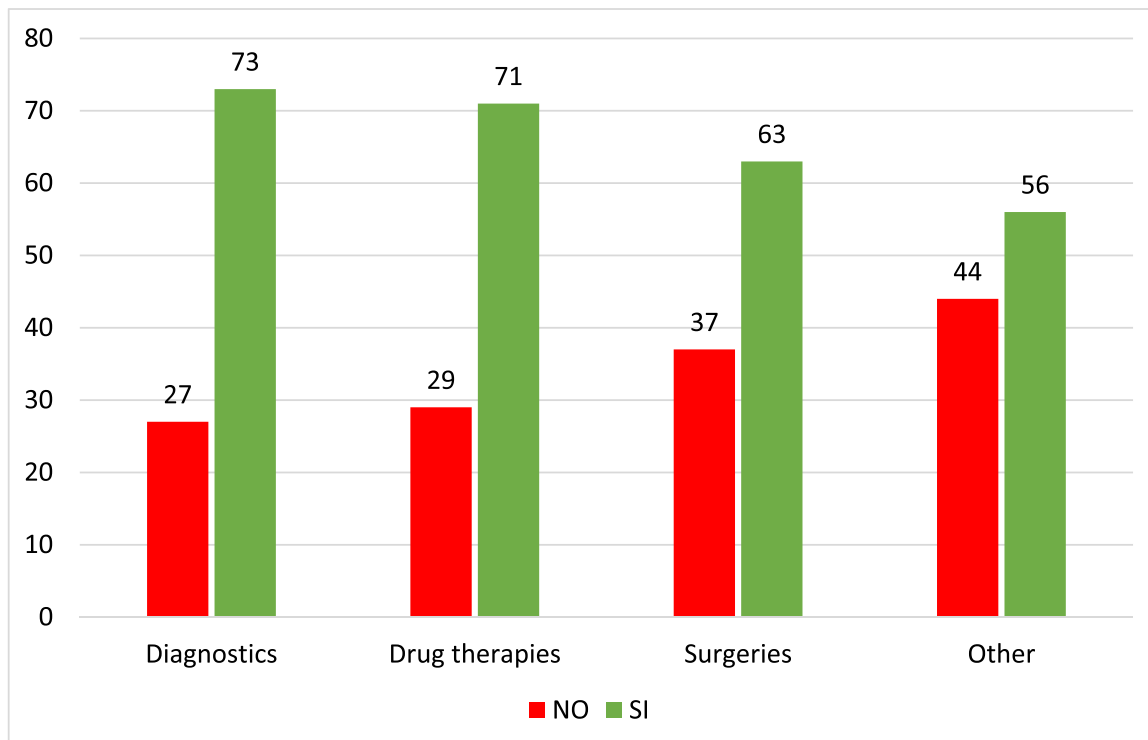
One hundred valid submissions were collected, 98% from medical doctors and 2% from dentists. A total of 22% of the respondents were born before 1955, 62% between 1955 and 1975, and 16% after 1975.

For the most part, the sample analysed considers the use of economic analysis techniques in decision-making essential (see Graph 1), especially regarding the diagnostic and therapeutic-pharmacological spheres. The percentage of agreement in such cases is, in fact, over 70%. The graph below shows respondents' detailed answers.

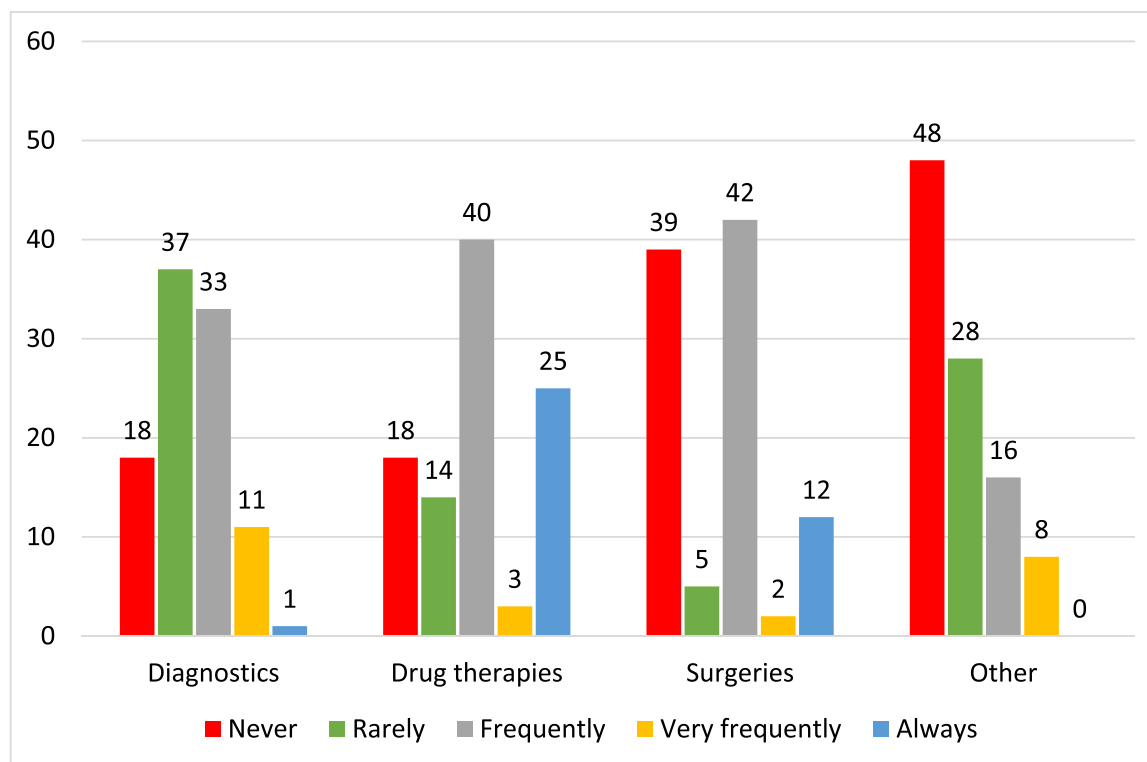
These data demonstrate, therefore, a significant awareness of the usefulness of economic analyses in clinical decision-making, which needs to be followed by the effective use of these techniques (see Graph 2).

Graph 2 shows that economic analyses are used to evaluate drug therapies and surgical interventions, while much more limited use is in prescription diagnostic analyses.

Two context factors that may facilitate or hinder the use of economic analysis techniques were considered in the questionnaire: On the one hand, the degree of knowledge of these techniques and, on the other hand, the availability of adequate economic information.



GRAPH 1 The use of economic analysis techniques in decision-making.



GRAPH 2 The economic analyses in clinical decision-making usefulness.

A total of 88% of the respondents consider business competencies relevant in the exercise of their profession. However, as many as 62% have never attended courses on these topics, while the remainder of the respondents only occasionally.

Concerning the availability of economic information, it must be stressed that the Italian health system, organised under the Ministry of Health and administered on a decentralised regional basis, does not have and does not impose guidelines to be followed in clinical decisions regarding economic considerations. However, according to the respondents, the level of knowledge, and therefore, of use of this type of information, could be higher, except for the DRG^c, which is known by 81% of respondents.

Although well known, the database needs more use. 60% of respondents say they never or rarely use it, while only 27% use it regularly, mainly to obtain information on hospital service charges. The other databases are considered non-immediately usable or reliable. In 65% of the cases, they are considered difficult to consult.

Other information that supports decision-making processes comes from website searches (38%), scientific journals (27%), ministerial circulars (25%), medical opinions (27%), and information from pharmaceutical companies (9%).

The set of these findings is completed by the declared difficulty on the part of the physicians (99% of the respondents) in resorting to the economic analysis techniques proposed by economists (CMA; CEA; CUA; CBA), motivated by the conviction that they are *considered not particularly effective* (58%).

It was also highlighted that, for the decision-making areas taken into consideration (diagnostics, drug therapies, surgery), respondents felt the presence of economic constraints (level of expenditure) and volume constraints (number of services) that limited, in about 20% of the cases observed, their decision-making autonomy as doctors, without, however, markedly undermining their professional ethics (which was reported only by about 6% of respondents).

Completing the picture of the *factors hindering* the dissemination of economic evaluation methods/approaches in the clinical sphere are *ethical reasons* that introduce the subject of this research: when and whether to move from therapeutic practices informed by the sole *"criterion of clinical appropriateness"*, which bring maximum benefit to the individual patient. In 74% of cases, the criterion of clinical appropriateness is considered more important than the economic factor in clinical decisions.

The *criterion of clinical appropriateness* to practices is balanced by *"criteria of allocative justice,"* suggested by the presence of scarce resources (hence the importance of economic evaluations) to ensure a fair distribution of benefits, risks, and costs within the community.

Finally, among the factors facilitating economic analysis techniques are evaluation standards shared by the relevant scientific community, followed by university and post-graduate training on

^cThe DRG system (Diagnosis Related Group) is a health policy tool that indicates the system of hospital remuneration for treatment activities introduced in Italy in 1995. In other words, it is a fee schedule divided into different types of admissions that define the amount of hospital reimbursements after patients are discharge.

economic issues, whose importance has long been documented in the international literature.^{40–42}

4 | DISCUSSION

The empirical analysis reported above showed us a shallow knowledge and use of economic techniques in clinical decisional processes.

Based on the data presented in the previous paragraph, we identified some stereotypical behaviours regarding the degree of knowledge of economic evaluation logic and its use. Firstly, responses were aggregated by age group, identifying three clusters:

- Cluster 1 includes those born after 1975;
- Cluster 2 includes those born between 1955 and 1975;
- Cluster 3 includes those born before 1955.

The clustering was done to verify the respondent's age (data from the questionnaire), which is assumed to condition the physician's decision-making paradigm.

The age bands were defined considering that the respondents' age follows a Gaussian distribution, with the highest numerosity in the middle band (birth between 55 and 75: 54 respondents). A total of 22% of the respondents were born before 1955, 62% between 1955 and 1975, and 16% after 1975.

The identified clusters were placed within two figures (see Figures 1 and 2) showing on the axes, respectively, the degree of use of economic evaluation techniques and the respondents' approach to clinical decisions and the degree of knowledge of economic evaluation techniques and the respondents' approach to clinical decisions.

Figure 1 returns a representation of the investigated phenomenon, which can be considered a determinant of the decisional approach adopted by physicians. This approach combines the decision-making criterion with the degree of knowledge of economic analysis and evaluation techniques. The high or low knowledge of economic analysis tools could be a relevant driver of decisional behaviour.

The most populated quadrant combines poor knowledge of economic issues with the decision-making criterion based on clinical appropriateness. Most of the clusters in the older age sample fall into this quadrant.

Regarding numerosity, the quadrant that combines the criterion of distributive justice with little knowledge of economic logic is the second most represented. All the clusters in the sample, including those at a lower age, fall into this quadrant.

A modest part of the sample, mainly middle-aged individuals, claims a high knowledge of economic logic and bases decisions on clinical appropriateness. Finally, a tiny part of the respondents, mainly middle-aged individuals, claim to know economic logic and to be inspired by the principles of distributive justice in decision-making.

Figure 2, combining the decisional approach and the use of economic analysis techniques and mechanisms, permits the identify four stereotypes of behaviour, which can be defined as follows:

- *Traditionalists*: exclusively adopt the criterion based on clinical appropriateness in their decision-making processes and, therefore, do not use, or only minimally, economic evaluations. As can be seen from the figure in this quadrant falls the majority of the sample of respondents, with a decided preponderance of those we have defined as "seniors" and "mature," i.e., those aged 47 and older,
- *Idealists*: This model includes those who base their decision-making processes on the criterion of distributive justice but do not use, or only minimally, economic assessments. It is the second largest group in terms of numerosity and is primarily made up of respondents in the middle (mature) age group;
- *Innovators*: adopt the criterion of distributive justice in their decision-making processes and consistently use economic evaluations. A small group of respondents, represented by the mature age group, falls in this quadrant;
- *Pragmatists*: those who base their decision-making processes on the clinical appropriateness criterion, mediated by economic evaluations, fall into this model. This group is also sparsely represented and consists of middle-aged people.

5 | LIMITATIONS

Although this study provided many insights into using economic evaluation tools in the medical field, it also has some limitations.

First, we conducted our study exclusively in Lombardy, one of the Italian regions whose healthcare system was most severely tested during the pandemic.^{3,43} Due to the Italian Region's autonomy in terms of health policy, conducting the same survey in another Italian region could lead to different results.

Second, the number of actual respondents ($n = 100$) represents a meager percentage of the investigated population, represented by all Lombardy physicians (56,769 in 2021). However, surveys like ours have been conducted on samples with absolute numbers close to 100 units.⁴⁴ Moreover, the composition of our sample of respondents, in terms of distribution by age brackets and professional profiles, allowed us to collect data in all the areas considered significant for our survey.

Finally, the survey conducted with the questionnaire filled in online could have been verified with in-person interviews to gather further elements of evaluation and more.

Recognising these limitations is applicable to delimit the boundary of significance of our results and the related conclusions and to orient future research.

6 | CONCLUSIONS

We have set our research on the assumption that the allocative issue is now "an integral part of the medical profession" (see WMA). More specifically, physicians must keep in mind three factors in their decisions: the *clinical assessment* of the individual patient, the *principles of distributive justice*, and the *economic implications* for the health

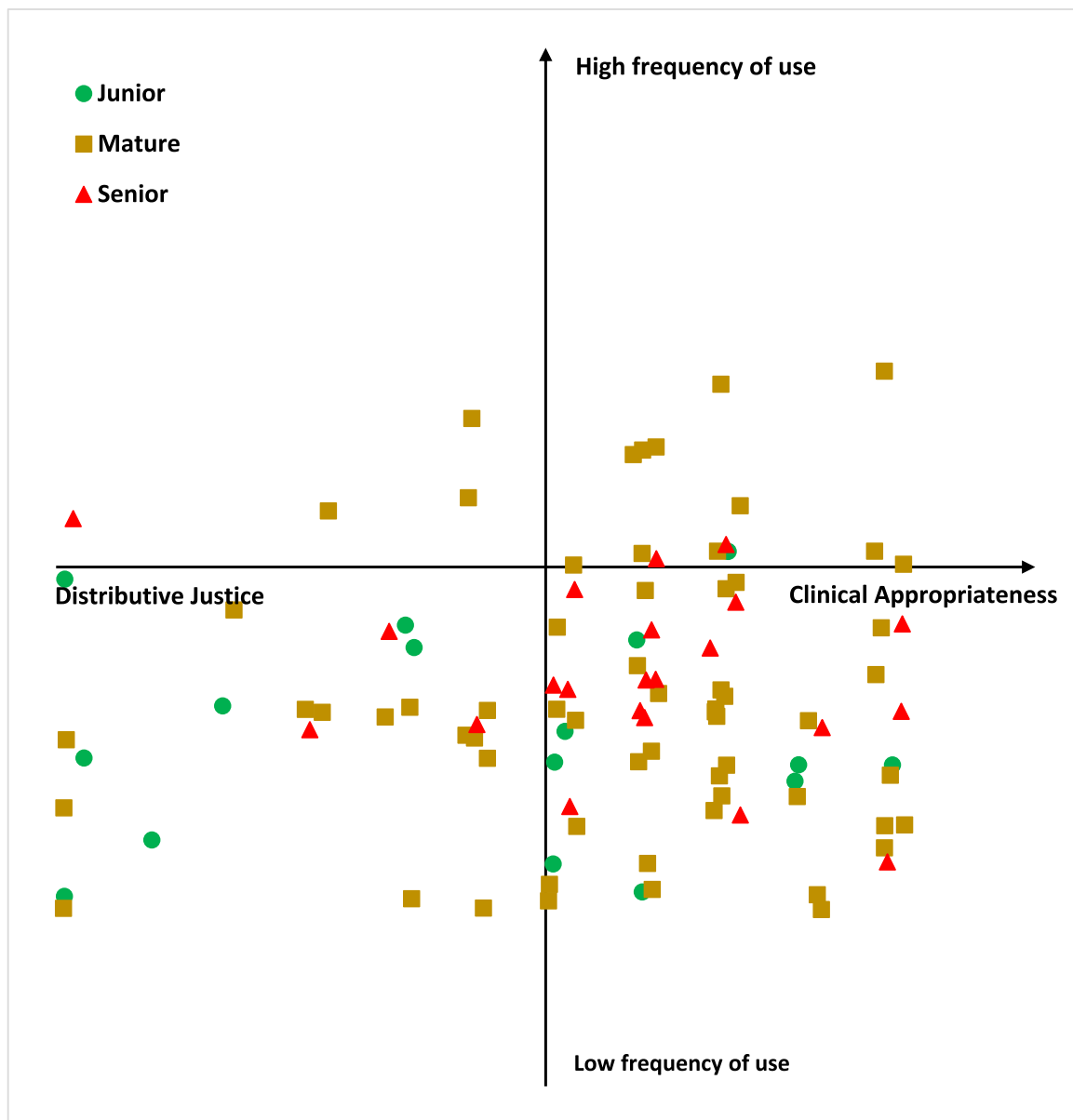


FIGURE 1 The relationship between knowledge and use of economic evaluation techniques.

care system to limit the risk of poorly efficient and effective resource use to the detriment of the individual and the community as a whole.

Despite the limitations highlighted, our survey has provided sufficient material to make valuable suggestions for managing the transition to an allocative culture and practice attentive to the three dimensions mentioned above.

The physicians interviewed brought to light some critical issues. In particular, they have:

- acknowledged the importance of making clinical decisions with an awareness of the economic resources committed by their decisions,
- admitted a widespread lack of knowledge of economic evaluation techniques,

- lamented a lack of immediate applicability or usefulness to the economic analysis techniques available to date, which are better suited to support decisions at the macro or meso level,
- denounced the problematic availability of data needed to set up economic assessments,
- stated the lack of shared guidelines to guide individual care decisions.⁴⁵

These results show that, although to a minority extent, physicians are aware of the “instrumental” role that economic information might play in their daily choices, without necessarily conflicting with, but rather reinforcing, the ethical-deontological profile of their behaviour. Whatever resources are available for health care, waste is inevitably generated if used inefficiently and ineffectively. Thus,

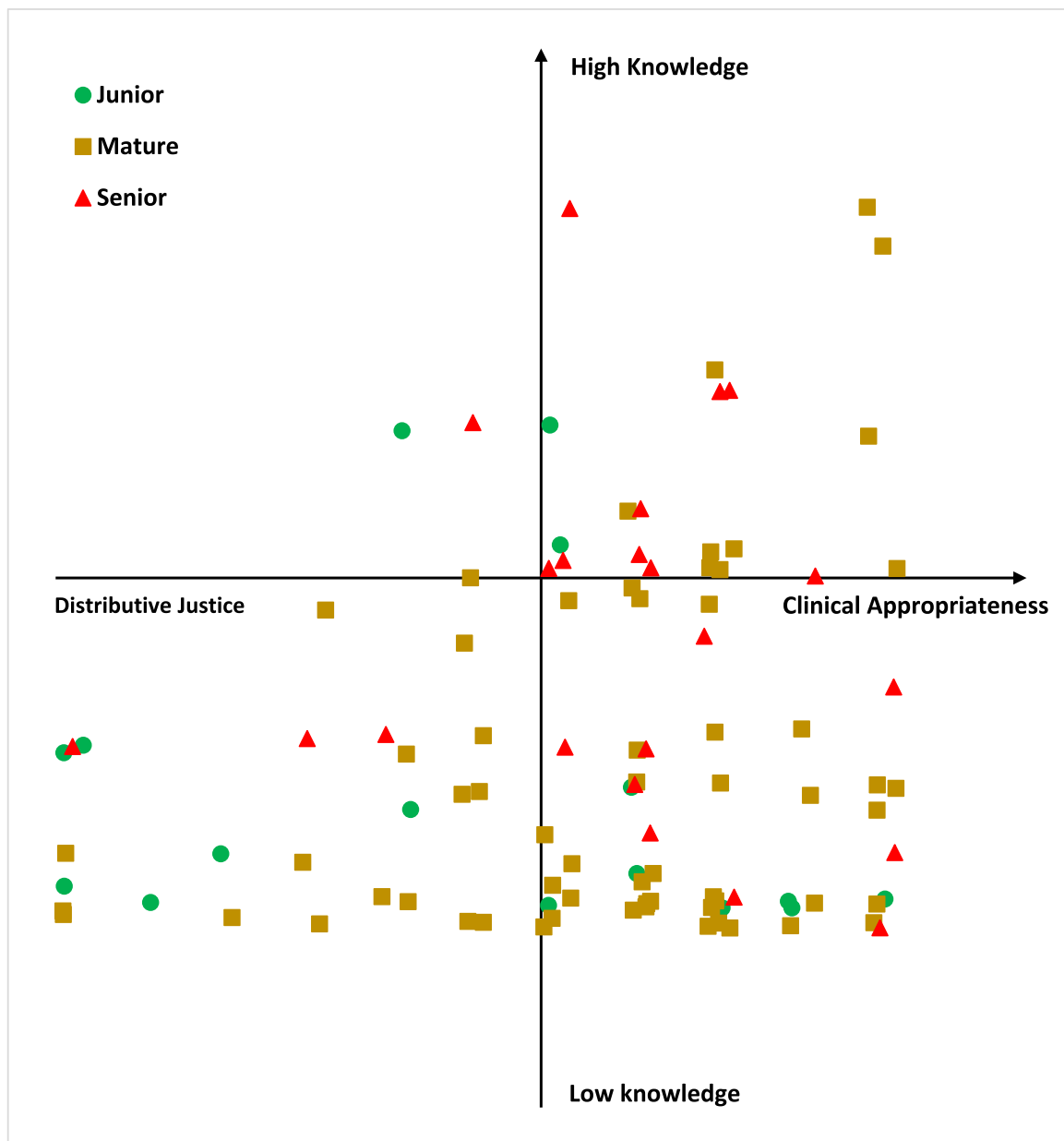


FIGURE 2 The relationship between the economic evaluation techniques knowledge and the decisional approach.

collective needs will never be adequately met,²⁰ and the risk of under-treatment becomes a reality. Conversely, any attempt to reduce waste also automatically reduces the risk of under-treatment. This means that approaches using economic information for the optimal allocation of healthcare resources are not aimed at containing healthcare expenditure tout court but rather at finding allocation criteria that, in the light of the scarcity of resources, ensure care for as many people as possible, certainly not to benefit some at the expense of others. This highlights the moral importance of the relationship between the benefit of the individual patient and the community's interest within clinical practice, taking into account the scarcity of resources allocated to health care relative to the needs of citizens.^{46,47} Therefore, assessing the economic implications is

essential, not only to measure the efficiency of the allocative process but, more importantly, to ensure a "fair distribution" of them. Limiting the uncontrolled use of resources qualifies ethical behaviour, and careful decisions on speculation—not measurable in the absence of economic evaluations—cannot but benefit the entire community and the individuals that make it up.

We conclude, therefore, with some suggestions to be addressed to key players in the healthcare system and beyond. The first suggestion is to bridge the gap between recognising the importance of economic evaluations and knowledge of the techniques that support them. Enriching current medical and surgical curricula with "health economics" courses aimed at providing some basic knowledge of economics no longer seems to be postponable, as well the need to introduce a culture



of managerialism, economic rationality, and results orientation into the public health sector.⁴⁸ The fact that some techniques of economic analysis are not immediately applicable or recognised as valid by primary care physicians refers to the problem back to health economists. These researchers are often distant and misaligned from the needs of these potential users, who do not have to make systemic decisions but, more concretely, would like to understand how many resources they commit when deciding on a treatment or surgery. Mathematically and statistically sophisticated models clash against the need for simple and immediately usable algorithms since the goal is not to seek the absolute optimum but to limit the uncontrolled use of resources. The next consideration concerns the problematic availability of the data needed to feed economic evaluation models and the absence of guidelines issued by the system. Some European countries, particularly in Northern Europe, have invested resources in creating databases where health professionals can find economically helpful information to support clinical decisions.⁴⁹ In Italy, databases are very scarce, and even the most user-friendly ones, such as DRGs, must be adequately used. Added to this is that our healthcare providers operate in a system lacking “guidelines” to guide them in making the “best” decisions. Again, other countries, such as Great Britain, have invested in establishing national guidelines that physicians consider very useful.⁵⁰ Hence then, the invitation addressed to all stakeholders to move in the suggested direction while being aware that the availability of economic data and the usability of appropriate models is a necessary but not sufficient condition to promote the cultural change that must start from the full acceptance, by physicians, that allocative issues are an integral part of their profession.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Anna Arcari  <http://orcid.org/0000-0003-1144-6166>

Anna Pistoni  <http://orcid.org/0000-0002-4346-5188>

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