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Using needs-based frameworks for evaluating new technologies: An application to genetic tests



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ABSTRACT

Given the multitude of newly available genetic tests in the face of limited healthcare budgets, the European Society of Human Genetics assessed how genetic services can be prioritized fairly. Using (health) benefit maximizing frameworks for this purpose has been criticized on the grounds that rather than maximization, fairness requires meeting claims (e.g. based on medical need) equitably. This study develops a prioritization score for genetic tests to facilitate equitable allocation based on need-based claims.

It includes attributes representing health need associated with hereditary conditions (severity and progression), a genetic service's suitability to alleviate need (evidence of benefit and likelihood of positive result) and costs to meet the needs. A case study for measuring the attributes is provided and a suggestion is made how need-based claims can be quantified in a priority function. Attribute weights can be informed by data from discrete-choice experiments.

Further work is needed to measure the attributes across the multitude of genetic tests and to determine appropriate weights. The priority score is most likely to be considered acceptable if developed within a decision process which meets criteria of procedural fairness and if the priority score is interpreted as "strength of recommendation" rather than a fixed cut-off value.

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1. Introduction

A rapidly expanding number of new genetic tests is available and used in health care for personalized

prognosis, prevention and care [1]. Using new tests consumes additional resources for genetic services despite the fact that already now, it is not economically feasible to conduct all desirable genetic tests at the expense of existing public health care budgets [2,3]. Therefore, decisions need to be made about which tests are the most important to provide. This is usually referred to as "prioritization", i.e. placing genetic tests into a rank order based on their perceived importance [4].

"Genetic test" is understood here as the application of a laboratory test or assay (the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect alterations related to a heritable disorder or to

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specific reactions to medical treatments) to a defined clinical context [5]. The prioritization thus does not relate solely to tests but to groups of patients in specific clinical situation described as the test attributes below.

The increasing financial pressures on public budgets for genetics services as well as the concern for harmonized high quality provision of essential genetics services across Europe lead the European Society for Human Genetics (ESHG) in collaboration with the EU-funded project EuroGentest [6] to address ways of prioritizing genetic tests in an ethically and economically sensible manner [7]. The aim was to work towards a prioritization framework which is acceptable to the ESHG members as well as the major stakeholders affected by genetics services such as clinicians and patients.

The question as to which criteria should guide the prioritization of public health care resources is a topic of long-standing discussion in the ethical and economic literatures. Therefore, the project also included an assessment of prioritization criteria acceptable for genetic tests. Even if most economic frameworks are based on welfarist maximization of individual benefit or on extra-welfarist maximization of health outcomes, neither of these is likely to be widely accepted by decision makers and stakeholders of genetic services [5].

One prominent alternative to benefit maximization is to base coverage decisions on claims according to medical need, rather than on health benefits [8,9]. Medical need is a key criterion all health care systems relate to in their decision processes [10]. Need-based allocation is also promoted by the World Health Organization (WHO) in the concepts of horizontal (health care to all individuals with the same medical need) and vertical (preferential health care for those with greatest need) equity [11]. Needs are fundamentally different from desires or preferences which are the only source of value in welfarism [12]: an individual might desire something without needing it, and vice versa. Furthermore, while unsatisfied preferences do not necessarily harm individuals, unmet needs necessarily do so [13].

However, “need” is an ethical concept without consented definition [14]. It therefore requires further specification regarding its dimensions relevant for decision making. These dimensions depend on the decision context [11]. This study develops a need-based prioritization framework in the context of decisions about using public budgets for genetic services accountably. It can serve as a theoretical basis for an evidence-based priority ranking of genetic tests, based on standardized information sources about priority-relevant attributes of genetic tests such as the Clinical Utility Gene Cards [15] and weights for these attributes established by discrete choice experiments [16,17].

2. Methods

Currently, no needs-based framework for prioritizing genetic tests in the face of scarce resources is available in the literature. To develop such a framework, this study uses literature searches described elsewhere [5] and

discussions during a consensus process on prioritizing genetic tests [18].

A set of attributes was developed, based on the following theoretical considerations: first, the attributes should be associated with relevant measures of medical need for genetic tests or its alleviation which was the normative basis of this framework; second, the attributes should be mutually independent to the largest possible extent; and third, the attributes should be susceptible to measurement with available data sources to facilitate the establishment of a score representing the strength of need-based claims and further analysis such as discrete-choice analysis to establish potential weights for the different attributes. To assess its feasibility, the framework was applied to the case study of genetic testing for hereditary hemochromatosis.

3. A needs-based framework for allocating health care resources to genetic tests

Health or health care need is a key criterion for decision making under health care resource constraints. While the basic need for physical health is universal, the goods and health care services required to satisfy the need may vary [19]. Furthermore, health can be affected differently in different medical areas. Therefore, to develop a prioritization framework addressing the dimensions of health and health care need which are of specific relevance for the prioritization of genetic services, the terms of health or health care need require further specification. Unlike a welfarist approach, not all attributes of genetic tests which play a role in satisfying the patients’ preferences for genetic tests are relevant for this specification. Instead, only the attributes objectively relevant to physical health are relevant [19].

There is a special feature of genetic tests which can easily blur the lines between welfarist and need-based approaches to prioritization in genetic testing: frequently, genetic tests are performed only for the purpose of providing information to facilitate patient empowerment [20,21], rather than for improving health. This study starts by assuming that the information as such is always considered beneficial because otherwise, the test would not have been requested. Any health benefits are additional to these knowledge based benefits. This excludes tests for multifactorial conditions where clinical impact and patient benefit are unclear and misleading information may be detrimental for patients so that the ESHG has recently made a recommendation against their use [22]. It also assumes that the test results cannot be obtained by less costly means. Furthermore, it excludes prenatal and preconceptive tests as well as screening tests which involves specific issues in the evaluation which have been discussed elsewhere [23–26]. Furthermore, the study assumes that the test results cannot be obtained by less costly means. Also, it excludes prenatal and preconceptive tests as well as screening tests which involve specific issues in the evaluation which have been discussed elsewhere [23–26].

3.1. Health-related need

“Need” can be defined as the gap between an actual state of an individual and a normal individual state as,

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