VP103 Health Technology Assessment Of Genetic Tests For Cystic Fibrosis Carrier Screening In Italy

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INTRODUCTION:

Cystic Fibrosis (CF) is a genetic disorder caused by mutations in CFTR gene. In Italy, reported prevalence is approximately .70 *per* 10,000 inhabitants (1). The practice and recommendations for Cystic Fibrosis carrier screening are very heterogeneous in Europe. A proposal of a carrier genetic test in the general population raises many questions. Health Technology Assessment (HTA) could offer a sound methodological basis for this evaluation. The aim of this work was to summarize the available evidence, using the HTA approach, on the genetic tests for Cystic Fibrosis carrier screening.

METHODS:

A systematic literature search was used to find the best available international and national evidence on genetics test for CF carrier screening. In this report, we specifically addressed the health problem of disease, description and technical characteristics of tests – its analytic and clinical validity, and clinical utility. Economic evaluation of different scenarios was synthesized from the literature. Ethical, organizational, and social aspects of CF and genetic screening were also considered.

RESULTS:

Several screening strategies have been evaluated in the literature and screening options can be characterized by different timing, model and place of screening (2). The reported cost of a screening test ranged from EUR25 to EUR212 (3). Estimated life time cost of care for CF patients ranged from EUR291,048 to EUR1,105,452. Ethical analysis emphasized that the use of these tests is an advantage in terms of the acquisition of knowledge and of responsible management of choices, but at the same time raises many ethical questions. Social considerations reported among patients and their families an overall positive attitude toward population CF carrier screening.

CONCLUSIONS:

The advances in the molecular genetics technology have made CF carrier testing reliable and affordable. The multidisciplinary approach of this HTA provided an evidence-based evaluation of genetic tests and offers a firm scientific background for the decision-makers to consider the implementation of a screening for Cystic Fibrosis carriers into the Italian health care system.

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VP107 Pharmaceutical Industry's Experiences with the German Health Technology Assessment Scientific Advice

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INTRODUCTION:

The early benefit assessment of drugs was introduced in Germany with the 'Act to Reorganize the Pharmaceuticals' Market in the SHI' (AMNOG) in 2011. Before submitting the manufacturer's dossier, optional scientific advice is offered by the Federal Joint Committee (G-BA). The objective was to elicit manufacturers experience with the scientific advice offered by the Federal Joint Committee.

METHODS:

To prepare the survey, several manufacturers were interviewed on their experience with the scientific advice offered by the Federal Joint Committee. Subsequently, a questionnaire was developed to collect information for this purpose, comprising eight items on different topics aimed at understanding the perceived quality of the scientific advice provided.

RESULTS:

The qualitative part comprised seven manufacturers who had received between one and ten advisories before the end of 2012. With regard to the quantitative elicitation part, a total of sixty-one completed questionnaires from nineteen manufacturers were included until the beginning of 2015 (corresponding to almost 25 percent of the overall implemented scientific advice). Fourteen cases were about so called "early" scientific advice in terms of relating to evidence before commencing phase-III trials, forty-four cases concerned "late" scientific advice (pivotal trials were just conducted or already terminated), another two concerned repeated scientific advice and finally, four referred to miscellaneous contents (multiple answers possible). Both, the preceding qualitative and the following quantitative part of the elicitation, highlighted points about the process as well as the content shortcomings from an industry's point of view: inconsistencies, lacking expertise with conducting clinical trials, partially incomplete answers and a low readiness to engage in dialogue were criticized. On the other hand, the majority of respondents showed a positive attitude concerning unambiguousness, completeness, traceability, atmosphere and the protocol of the advice. Over the course of time, propositions on study design, agreement with the determined appropriate comparative therapy and subgroup definitions improved significantly.

CONCLUSIONS:

A more active involvement of further stakeholders and the incorporation of procedural elements from other health are systems with longer experience could improve the scientific advice provided.

VP108 Environmental Sustainability In Hospitals Health Technology Assessment - A Survey

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INTRODUCTION:

In the age of limited resources, hospital managers confront the need to strictly balance resource allocation at their disposal between drugs, wages, purchases and operation costs. This entails an endless search for creative pathways to efficiently merge the trends to preserve the environment.

A "green" hospital is an entity that is planned, built and operated so as to minimize the 'ecological footprint': for example, saving energy by utilizing natural light; recycling water, paper or waste; and using insulation and soundproofing (1).

'Evidence-based environmental design', a new approach to advanced building techniques, is gaining momentum worldwide. It synergizes with additional trends: promoting quality, improving potential utility, raising the accountability of hospital workers and involving the public and patients in overcoming health system dilemmas.

The aim was to analyze the standpoints of professionals in health and architecture regarding environmental accountability, in comparison to public opinion, and

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