

assessments based on “significant unmet need” do not appear to provide consistent or equitable guidelines for addressing the issues specific to rare diseases.

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OP101 Do We Need To Extend Health Technology Assessment To Health Enhancement Assessment?

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INTRODUCTION:

Several health technologies used for therapy can also be used for health enhancement. Drugs stimulating cognitive abilities are but one example. Health Technology Assessment (HTA) has not been developed for assessing enhancements. This raises the question of how HTA should address the blurred distinction between therapy and enhancement. Should we (i) carve out a distinction between therapy and enhancement and limit HTA to therapy, (ii) use HTA for both therapy and enhancement (with some modifications), or (iii)

should we develop a separate health enhancement assessment (HEA)?

METHODS:

A literature search of the medical, philosophical, and bioethical literature was conducted for debates, arguments, and suggested solutions to the issue of therapy versus enhancement.

RESULTS:

The same improvement in health may be therapeutic in one patient, but an enhancement in another. Moreover, both therapy and enhancement share the same goal: increased health and wellbeing. A wide range of arguments try to establish a difference between therapy and enhancement. They refer to naturalness, rehabilitation, normality, species-typical functioning/potential, disease, sustainability, and responsibility. On closer scrutiny few of these arguments do the job in bolstering the therapy-enhancement distinction. We already use a wide range of means to extend human abilities. Moreover, the therapy-enhancement distinction raises a wide range of ethical issues that are relevant for the assessment of a number of emerging health technologies.

CONCLUSIONS:

Existing HTA methodology can address a wide range of non-therapeutic health enhancements. However, a series of broader issues related to the goal of health care and responsibility for altering human evolution may not be addressed within traditional HTA frameworks. Specific HEAs may therefore be helpful.

OP103 CONITEC's Rapid Reports As Technical Support In The Litigation

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INTRODUCTION:

The Unified Health System (SUS) is based on the principle of health as a citizen's right and the state's duty, which must be guaranteed based on public policies. Although there are several legislations, lists of medicines and clinical guidelines, Brazilians who have been prescribed expensive technologies that are not part of the essential drug lists ask judges to issue court orders obliging public health managers to purchase these drugs or to provide elective medical procedures immediately. Due to the health technical inexperience from judges, prosecutors and public lawyers, a partnership has arisen for the National Committee for Health Technology Incorporation (CONITEC) to provide technical assistance to help their decision-making process. Thus the purpose of this study is to describe CONITEC's experiences in communicating with stakeholders in this process.

METHODS:

A case study method was used and information about the rapid reports developed by CONITEC's Executive Secretariat in response to the applicants in the period of 2012 to 2016, was retrieved from CONITEC database.

RESULTS:

Rapid reports (2,773) about health technologies incorporation such as medicines, procedures or medical devices were produced by CONITEC during this period. Most requests covering topics as treatments for diabetes, arterial hypertension, osteoporosis, oncology and epilepsy; diseases for which there are several treatment options in SUS. The data analysis indicated that CONITEC contributed to the evidence based decision-making. On one hand, the Prosecutor's Office has been increasingly requesting information before starting lawsuits and Judiciary Power has increasingly used evidence-based technical information before deciding on the concession of injunctions; on the other hand, from 2012 to 2016 the number of requests decreased for information to State defense in lawsuits that has been already established.

CONCLUSIONS:

There is a growing interest in technical knowledge for fair decision making that respects the current organization of the evidence-based health system.

OP104 Health Technology Assessment's Ethical Evaluation: Understanding The Diversity Of Approaches

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INTRODUCTION:

The main difficulties encountered in the integration of ethics in Health Technology Assessment (HTA) were identified in our systematic review. In the process of analyzing these difficulties we then addressed the question of the diversity of ethical approaches (1) and the difficulties in their operationalization (2,3).

METHODS:

Nine ethical approaches were identified: principlism, casuistry, coherence analysis, wide reflexive equilibrium, axiology, socratic approach, triangular method, constructive technology assessment and social shaping of technology. Three criteria were used to clarify the nature of each of these approaches:

1. The characteristics of the ethical evaluation
2. The disciplinary foundation of the ethical evaluation
3. The operational process of the ethical evaluation in HTA analysis.