

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.

RESULTS:

In HTA, both *norm-based ethics* and *value-based ethics* are mobilized. This duality is fundamental since it proposes two different ethical evaluations: the first is based on the conformity to a norm, whereas the second rests on the actualization of values. The disciplinary foundation generates diversity as philosophy, sociology and theology propose different justifications for ethical evaluation. At the operational level, ethical evaluation's characteristics are applied to the case at stake by specific practical reasoning. In a norm-based practical reasoning, one must substantiate the facts that will be correlated to a moral norm for clearly identifying conformity or non-conformity. In value-based practical reasoning, one must identify the impacts of the object of assessment that will be subject to ethical evaluation. Two difficulties arise: how to apply values to facts and prioritize amongst conflicting ethical evaluations of the impacts?

CONCLUSIONS:

Applying these three criteria to ethical approaches in HTA helps understanding their complexity and the difficulty of operationalizing them in HTA tools. The choice of any ethical evaluations is never neutral; it must be justified by a moral point of view. Developing tools for ethics in HTA is operationalizing a specific practical reasoning in ethics.

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OP105 Systematically Reconstructing Trial Context-Role For CLUSTER Searches?

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INTRODUCTION:

Randomized controlled trials (RCTs) of complex interventions are conducted in a context-specific environment. Principal trial reports, with a focus on main results, are unable to document adequately the context for an intervention, for example, word limits. Important context may be included in “sibling studies” (that is, studies conducted alongside the main trial, for example, process evaluations, and qualitative studies (1). This presentation explores (i) to what extent is it possible to use a systematic and parsimonious method to identify sibling studies and (ii) what is the potential value of yield from these studies?

METHODS:

The systematic CLUSTER approach (2) to follow up of index studies (**C**itations, **L**ead authors, **U**npublished materials, **S**cholar, **T**heories, **E**arly examples **R**elated projects) has demonstrated the value of retrieved items in qualitative terms. However, the CLUSTER approach is painstaking and laborious and may be prohibitive within a time-tight Health Technology Assessment (HTA). A streamlined CLUSTER approach, using freely available Publish or Perish Software integrated with Google Scholar and Microsoft Excel, offers an economical way of building up “clusters” of study reports. A case study of a UK National Institute for Health Research (NIHR)-funded HTA on the management of medically unexplained symptoms in primary care, utilizing quantitative and qualitative research studies, is used to examine the practical application of the approach.