

Legal governance: how does law circumscribe the social role of HTA?

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1. Introduction

- The results of the InternE³LS' systematic review (1) indicates that the difference in the perception of the social role of HTA is one of the **difficulties of integrating ethics in HTA**.
- Three major factors were identified:
 - the difference between appraisal and assessment (2,3),
 - the integration of appraisal in assessments (4),
 - appraisal in local HTA (5),
- Our hypothesis is that a closer study of the dynamics of hard law and soft law could give a more detailed comprehension of the relations between the perception of the social role of HTA and the challenges of integrating ethics.

2. Method – Theoretical framework

- Considering it as a governance model**, the law can be analyzed by the various legal instruments that are elaborated in order to coordinate and provide guidance for the operations of public or private actors in a given society.
- Legal governance can be divided in **three categories**, each of them ranging from a greater to a lesser level of **legal obligatory intensity**:
 - traditional hard law**, ii) **soft law integrated in hard law**, and iii) **soft law**.
- Fully obligatory and constraining, hard law** refers to traditional statutory laws and regulations (i.e.: the HTA agencies' constitutive statutory laws).
- Soft law integrated in hard law** regroups normative instruments that can either be employed as auxiliary means to **complement** regulations (used by legislators) or be invoked to **interpret** hard law norms (used by judges) (e.g.: legal recognition of ethical codes).
- Without being explicitly** recognized in any mean by traditional hard law, **soft law** regroups **non-obligatory and non-constraining** normative instruments aiming to orient the human conduct and behaviours (e.g.: ethical charters, codes of conduct, etc.) (6).
- Depending on the legal category they refer to, normative instruments have in the case of **hard law**, or don't have in the case of **soft law** non recognized by traditional hard law, a normative force that can cause binding effects.

2. Method – Analysis

- Three HTA agencies** were selected for this study, based on geographic and cultural criteria. The "Institut national d'excellence en santé et services sociaux" (**INESSS**) is our regional agency for the province of Québec, Canada (7). Since both the French and English traditions culturally inspire our institutions, the comparison with the "Haute Autorité en Santé" (**HAS**) (France) and National Institute of Care Excellence (**NICE**) (United Kingdom) was undertaken.
- Our analysis of the **legal, administrative and procedural documents** relating to the existence and assessment processes of these three agencies was guided by the following criteria:
 - The social role of the HTA agency: appraisal / assessment
 - The explicit reference to ethics in *hard* and *soft law* (normative strength)
 - The integration of ethics in the agencies' actions and procedures

3. Results

Agency	Social role	Hard Law (Constitutive act)		Soft Law (Agency's documents and/or procedures)	
		Ethics of * HTA	Ethics in * HTA	Integrated in Traditional Hard Law	Non-Recognized by Traditional Hard Law
INESSS	appraisal	Must respect ethical principles of integrity, transparency and equity (<i>INESSS Act</i> , s. 4)	<u>Ethical framework</u> EXPLICITLY REQUIRED by the law. In addition, the Institute determines and publishes an ethical framework setting out the principles that guide its assessment of the results of the scientific evaluation, and gives the reason behind its recommendation. (<i>INESSS Act</i> , s. 6)	NONE	<i>Règles de fonctionnement du comité scientifique:</i> <u>Procedure only:</u> Both scientific committee's members and recommendations must respect and apply INESSS' ethical framework (s. 4, 7)
HAS	assessment	Respect of ethical principles must be taken into consideration (<i>Social Security Code</i> , s. 161-71 (4) a))	<u>Ethical framework</u> NOT MENTIONED	NONE	<i>HAS' Ethical Evaluation Guide:</i> <u>Document:</u> Descriptive ethics of ethical controversies of a technology <u>Procedure:</u> a) Only restricted to important issues b) Report of the controversial arguments on the technology
NICE	appraisal	NONE	<u>Ethical framework</u> NOT MENTIONED NICE must publish its own charter establishing procedures for carrying out its functions (<i>NICE Regulation 2013</i> , s. 14)	<i>NICE Charter:</i> <u>Document:</u> NICE is committed to ensuring that the value judgments made in recommendations and decisions reflect values of society. (s. 19)	<i>Social Value Judgments, 2nd ed.:</i> <u>Document:</u> - Based on social values reflected by Citizen Council - 4 principles of bioethics - Distributive justice, Utilitarian/Egalitarian <u>Procedure:</u> - Incorporated where appropriate in NICE methodology

4. Discussion

- Hard law* contributes to establish a **general mandate** and some **legal legitimacy** for these agencies. In contrast, *soft law*, which is grounded in the HTA agencies' practices, plays a major role in the **legal governance of HTA**.
- Based on these three agencies, our results demonstrate that existing practices seem to **better integrate ethics than constitutive laws** do. In this context, social actors become responsible to define, structure and operationalize the ethical evaluation *in* HTA.
- In addition, the legal framework (*hard law*) through which HTA unfolds **does not clearly support its structural and social role**. Despite existing legal frameworks, the normative legitimacy of HTA is not entirely established, **as it depends on soft law**. Taken altogether, this maintains a persisting conceptual vagueness in HTA governance.

5. Conclusion

- The social role of HTA should be defined either through **modifying existing legislations** (*hard law*) or through **harmonization** of the agencies' internal policies and regulations (*soft law*).
- Such legal initiatives would help clarify the aims of HTA evaluations: assessments (scientific) or appraisal (value-laden), and therefore give a clearer indication on how best to integrate ethics in HTA.

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