

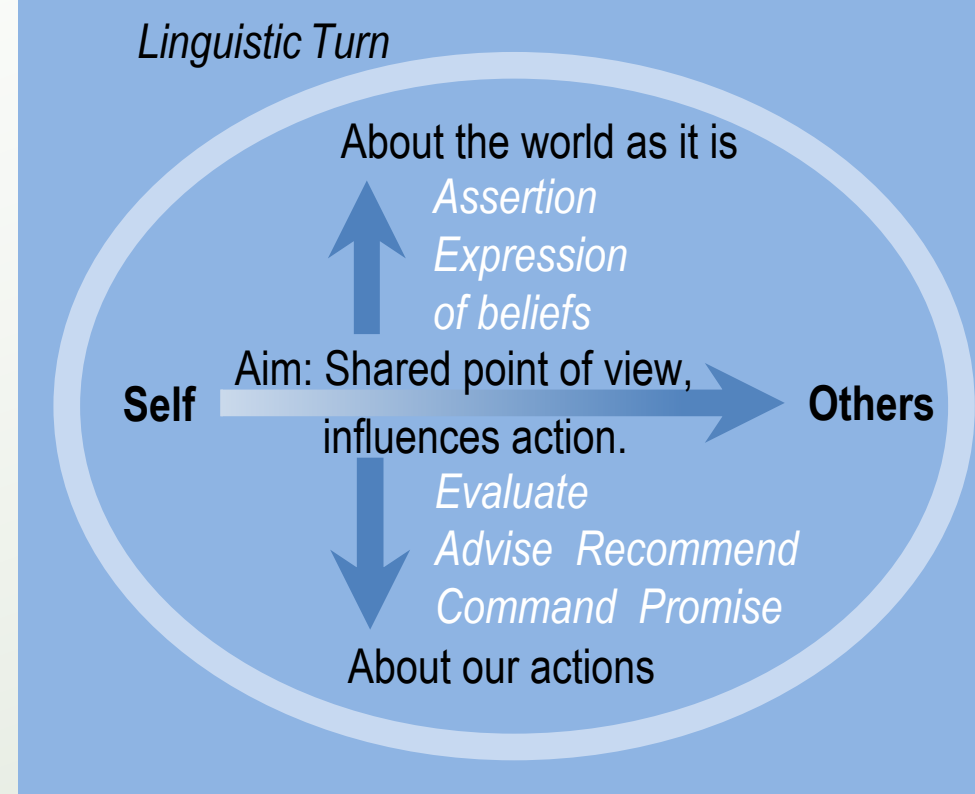
## 1. Introduction

- The value-ladenness of the HTA process has been widely recognized in the HTA literature, and this for different reasons:
  - i) the ultimate goal of the process is to improve health care (1,2,3),
  - ii) all decisional steps in the HTA process are grounded on value judgments (3,4,5,6a,7),
  - iii) value judgments in ethical analysis are known to be useful for decision makers and promote transparency of their decisions (8,9).
- According to some authors, value-ladenness can only be found in the appraisal of a technology, not its assessment which rests solely on facts, whereas its appraisal is rather intertwined with values (10,11).
- The elicitation of implicit value judgments in HTA has been suggested by some authors as a way to clarify the role of ethics in HTA (1,3,6b,12). But for others, what is meant by value and how it can be used in HTA is not clear (6a,9,12). In order to clarify the distinction between facts/values, as well as that of corresponding factual judgments/value judgments, an analysis of their conceptual basis is needed to appreciate how they diverge on certain aspects and converge on others.

## 2. Method

- The distinction between value judgments and factual judgments was debated in the field of philosophy in the early nineteenth century. The distinction was at the core of the Philosophy of Language where the distinction between scientific assertions about facts was considered objective, whereas value judgments on what is right or wrong, or on what is good or bad, were considered subjective. The *Principia Mathematica* by Whitehead and Russell (1967) and the *Principia Ethica* by Moore (1903) both illustrate this commonly held approach. The Speech-Act approach introduced by Austin in his 'How to Do Things with Words' (1962), further developed by John Searle in 1969, and incorporated in the field of Philosophy of Communication by Habermas (1981) and Jacques (1979); reframed these distinctions with the following distinct operations: assertion, evaluation and prescription.
- As shown in **Figure 1**, the approach proposed by the Speech-Act theory changes the knowledge point of view implied in the fact/value dichotomy (or factual judgment/value judgment) to a communicational point of view. This suggests that speech is never neutral because it is always oriented towards having an effect on the others who are listening. **Table 1** clarifies the conceptual differences between the three speech-acts, namely: assertion, evaluation and prescription.

**Figure 1: Speech Act Theory Approach.**



## 3. Results

- Efficacy, safety and cost-effectiveness studies are evaluations that are similar to ethical analyses because they all are statements of an ascription (i.e. attributing a quality to a given object).
- The distinction between these evaluations rests on the choice of criteria such as clinical effectiveness, efficacy, toxicity level, QALY measurement etc., specifying the type of evaluation.
- In clinical effectiveness or in safety studies, the scientific rigor rests on the choice of a procedure to apply the chosen criteria to a given object or to its impacts. A critical analysis of a systematic review of the literature is a procedure based on evidence.
- Evaluations differ from assertions because they do not describe a state of affairs, as the object to be evaluated is always more or less effective (or more or less safe).
- An ethical analysis ascribing "good" to a given object, or its impacts is also an ascription. However, no settled specific procedure exists for the former, which contrasts with effectiveness, safety and cost analysis.
- An ethical evaluation ascribing 'good' to an object (axiology) is different from ethical prescription (morals) ascribing right or wrong to an action. Nevertheless, the prescription of actions is necessarily based on a prior ethical evaluation of "good".

**Table 1: Differences between Assertion, Evaluation and Prescription, in the Field of HTA.**

Assertion (Factual Judgment)	Evaluation (Value Judgment)	Prescription (Moral Judgment)
States the properties of a given object (affirmation)	Attributes a quality to a given object (ascription)	States whether an action is right or wrong
Based on properties of a given object that can be verified	Based on a choice of criteria	Based on a moral criteria of right or wrong
Identified by a standard procedure	Applied by a specific procedure to the object or the impacts of the object	Applied by a specific procedure to the object or impacts of the object
True or false	To some degree (more or less)	True or false
Aspirin is Acetyl Salicylic Acid (ASA) Aspirin is 2-acetoxybenzoic acid The chemical formula of Aspirin is C <sub>9</sub> H <sub>8</sub> O <sub>4</sub>	Aspirin is effective Aspirin is safe Aspirin is cost/effective Aspirin is a good treatment	The health care system ought to provide Aspirin to those in need.

## 4. Discussion

- Analyses of effectiveness, safety and cost-effectiveness are value-laden since they are essentially evaluative. In order to make these evaluations explicit both of the following justifications must be spelled out clearly: i) the choice of the criteria and ii) the procedure to apply such criteria to an object (or its impacts).
- The distinction between assessment and appraisal must be nuanced. The purpose of assessments is to guide actions by influencing decision-making since they are evaluations. Advises, warnings, recommendations and prescriptions are based on evaluations. The importance of evidence-weighting in the assessment presupposes that the best decision must be based solely on evidence. The appraisal of evidence nurtures implicit or explicit recommendations.

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## ACKNOWLEDGMENTS

This study is currently being funded by the Canadian Institutes of Health Research (CIHR grant #142187)