PATIENT PARTICIPATION IN HEALTH TECHNOLOGY ASSESSMENT: A PROPOSAL FOR A METHODOLOGICAL FRAMEWORK BASED ON SATURATION-BASED REGISTRY AND CAUSAL INFERENCE METHOD

HTA288

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Introduction and Objective

The EU HTA Regulation gives patients the opportunity to provide input in every joint clinical assessment (JCA);[1] in Spain, Royal Decree 415/2026 broadens it to the assessment of social aspects.[2] This input is individual and template-based, with no method to turn it into assessment evidence.[3,4] Causal inference has been proposed for European HTA because many cancer drugs are approved on single-arm studies.[5]

The aim of this study is to set down a structured method for introducing patient-based evidence in the HTA action.

Methods

(1) **Review of official documents** from the EU (including the four published JCA reports), the EMA and ICH, and Spain, and of the HTAi standards, performed in October 2026.[1-4,6-8]

(2) **Structured narrative review** in PubMed (11 search strategies, no date limits; checked against the SANRA criteria[9]): title and abstract screening by a language model against predefined criteria, verified by the authors.

Results

18 official documents

1,092 records screened → **41** records included

Causal graphs have been built with patients outside HTA;[10-12] within HTA we found only stakeholder logic models[13] and, in PubMed, no causal graph derived from patient interviews.

The EMA notes limited experience with qualitative patient data;[7] no official document mentions saturation or how to turn patient experience into PICO elements (Figure 1). The four published JCA reports list one or two carers each and record that their input was considered;[6] in France, its impact on the national PICO is not known.[14] For a rare paediatric tumour and an aggressive lung cancer, relative quality-of-life results were not available or not recorded.[6]

Figure 1. Official documents mentioning each concept.

	EU law	HTACG	EC	EMA, ICH	Spain
Interviews	0/2	1/3	3/3	**3/3**	1/3
Qualitative	0/2	1/3	0/3	**3/3**	**1/3**
Registries	1/2	0/3	0/3	2/3	1/3
Saturation	0/2	0/3	0/3	0/3	0/3
Causal	0/2	0/3	0/3	0/3	0/3
PICO	**2/2**	**3/3**	3/3	0/3	**2/3**

Dark: developed in at least one document; light: in passing. Spain: Royal Decree 415/2026 and two RedETS reports. HTAi standards: no mentions. JCA reports are not included in the figure.

A methodological framework is proposed (Figure 2).

Figure 2. Proposed framework: from patient interviews to the assessment scope.

1 Interviews: the full patient journey and what happens.

2 Saturation-based registry: expands until no new themes emerge (sufficiency, not statistical representativeness); each statement retains its quote.

3 Causal graph: arrows linked to quotes are testable causal hypotheses, checked against clinical evidence; an absent arrow assumes no direct relationship.

4 Linking to PICO: subgroups (P), comparators actually available (C) and outcomes, including the harms of alternatives (O).

5 Outcome registry specification: the graph identifies why patients choose or avoid each option. An outcome registry must record these reasons; with trial data on the same outcome, it allows the probability of benefit and the cost of not acting to be bounded per subgroup.[15]

Conclusions

- A **saturation-based registry of patient interviews combined with a causal graph** is proposed to help patients **shape the PICO and review the draft report**[1] and to give **national payers subgroup evidence**.
- It targets settings where quality-of-life evidence is weakest, if the registry exists **before the assessment starts**. It will next be tested against published JCAs.

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ABBREVIATIONS: EC, European Commission; EMA, European Medicines Agency; HTACG, HTA Coordination Group; ICH, International Council for Harmonisation; JCA, joint clinical assessment; PICO, population, intervention, comparator, outcomes; SANRA, Scale for the Assessment of Narrative Review Articles.

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