Gaceta Sanitaria 40 (2026) 102591

Study protocol

Patient and public involvement in health technology assessments: study protocol for a cross-sectional analysis

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ARTICLE INFO

Article history:
Received 6 February 2026
Accepted 9 February 2026
Available online 21 April 2026

Keywords:
Citizen science
Health technology assessment
Meta-research
Patient and public involvement
Transparency

ABSTRACT

Objective: Patient and public involvement (PPI) is an essential component of Health Technology Assessment (HTA), as it enhances the relevance and transparency of evaluation processes. Nevertheless, the scope of such involvement varies considerably across contexts, and empirical evidence on current practices within the National Health System remains limited. This study will examine the extent to which HTA reports incorporate PPI and how these practices are performed and described.
Method: We will conduct a cross-sectional meta-research study of HTA reports produced by the Spanish Network of HTA Agencies (RedETS) between 2020 and 2026. Eligible reports will be identified through public repositories (https://redets.sanidad.gob.es/). A random sample of 150 reports will be selected. General and methodological characteristics, and PPI reporting practices will be extracted (by at least three researchers) from each HTA report using a standardised data extraction form. Descriptive analyses will be carried out to synthesise PPI reporting practices.
Study registration: Open Science Framework (https://osf.io/k6e3q/).

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Participación de pacientes y ciudadanos en las evaluaciones de tecnologías sanitarias: protocolo de estudio para un análisis transversal

Palabras clave:
Ciencia ciudadana
Evaluación de tecnologías sanitarias
Metainvestigación
Participación de pacientes y ciudadanos
Transparencia

RESUMEN

Objetivo: La participación de pacientes y ciudadanos es un componente clave de la evaluación de tecnologías sanitarias (ETS), al mejorar la relevancia y la transparencia. El alcance de la participación varía considerablemente según el contexto, y la evidencia empírica sobre las prácticas actuales en el Sistema Nacional de Salud es limitada. El estudio examinará hasta qué punto los informes de ETS incorporan la participación de pacientes y ciudadanos, y cómo se realizan y describen estas prácticas.

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https://doi.org/10.1016/j.gaceta.2026.102591
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Método: Se realizará un estudio transversal de metainvestigación de los informes de ETS elaborados por la Red Española de Agencias de Evaluación de Tecnologías Sanitarias (RedETS) entre 2020 y 2026. Los informes se identificarán en repositorios públicos (https://redets.sanidad.gob.es/). Se seleccionará una muestra aleatoria de 150 informes. Las características generales y metodológicas de los informes, así como las prácticas de participación, se extraerán (al menos por tres investigadores) utilizando un formulario estandarizado. Se realizarán análisis descriptivos para resumir las prácticas de participación.
Registro del estudio: Open Science Framework (https://osf.io/k6e3q/).
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Introduction

Health technology assessment (HTA) informs evidence-based decision-making by systematically evaluating the effectiveness, safety, and cost-effectiveness of health technologies, promoting efficient and equitable use of healthcare resources.[1] Patient and public involvement (PPI) is increasingly recognised as an essential component of HTA, improving the quality, relevance, transparency, trust, and legitimacy of evaluation processes.[2,3] By incorporating patient perspectives and experiences, PPI enhances social accountability, supports inclusive decision-making, identifies unmet needs and equity concerns, and aligns evaluations with patient community preferences as well as broader public health priorities.[4–7]

Countries such as the United Kingdom and Canada have a long-standing tradition of PPI in HTA.[8–14] Agencies like the National Institute for Health and Care Excellence (NICE)[8–11] and the Canada's Drug Agency (formerly, Canadian Agency for Drugs and Technologies in Health [CADTH])[12,13] actively involve patients and the public in scoping, prioritisation, and report development, demonstrating the benefits of structured, methodologically robust involvement.[14] In Spain, HTA is coordinated through the Spanish Network of HTA Agencies (RedETS) —composed of seven regional HTA agencies/units and one national agency, under the coordination of the Ministry of Health— promoting methodological rigor and harmonisation across regional and national bodies.[15] According to the network's website (https://redets.sanidad.gob.es/, accessed on February 4, 2026), 68 HTA reports were published in 2025 alongside other outputs —including clinical practice guidelines and methodological documents— that supported evidence-informed policy and practice. Early initiatives,[15–17] including a framework[16] and a decision-making flowchart for PPI in HTA,[17] have guided involvement across assessment phases, but practical implementation and reporting remain largely unknown. Surveys of HTA researchers[18] highlighted challenges in clarifying roles, integrating input, systematically documenting PPI, and providing training for both patients/public and researchers to support meaningful involvement, and avoid tokenism.

Despite growing recognition of its importance,[2,7,18] there is limited empirical evidence on how PPI is incorporated into HTA reports produced in the Spanish National Health System. The planned study will investigate the extent to which HTA reports incorporate PPI and the way these practices are reported. Specifically, the study will address the following research questions:

- To what extent is PPI reported in HTA reports produced within the Spanish National Health System?
- How are PPI practices described, and what methodological patterns or gaps can be identified across HTA reports?

Method

This protocol outlines a cross-sectional meta-research study of HTA reports from the Spanish RedETS[15] and is registered in the Open Science Framework (https://osf.io/k6e3q/). Although not a systematic review, the protocol is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P)[19] statement for items applying to meta-research studies (Table S1 in Supplementary Material).

Eligibility criteria

All HTA reports produced by the RedETS between 2020 and 2026 will be eligible for inclusion if they are published in official, publicly accessible formats (e.g., full reports, technical documents). HTA reports are technical documents that systematically evaluate health technologies —including pharmaceuticals and vaccines, medical devices, and medical or surgical procedures— using structured evidence synthesis approaches (e.g., systematic reviews or overviews of systematic reviews of the scientific literature) to assess efficacy, effectiveness, and/or safety. They may also include a contextualization and assessment of the technology's impact on the healthcare system, considering legal, ethical, economic (cost-effectiveness), social, or organizational aspects. In addition, HTA protocols, as well as HTA reports on the monitoring and utilisation of health technologies, will also be eligible. No restrictions will be applied regarding therapeutic area, type of technology assessed, or language. Reports will presumably be published in Spanish but may also be available in English or any of the official regional languages of Spain (e.g., Basque, Catalan, or Galician). The year 2020 was selected to provide a contemporary sample and because it coincided with the publication of the final version of key elements of the RedETS framework for PPI, including a decision-making flowchart for PPI in HTA.[17] Documents that do not constitute official HTA reports —reports under development, meeting summaries, or internal communications that are not publicly available— will be excluded.

Data sources and searches

In September 2026, a comprehensive search will be conducted in the official RedETS public repository (https://redets.sanidad.gob.es/). From this search, a complete list of all eligible reports will be compiled, including full bibliographic references and relevant metadata (e.g., title, agency producing the report, publication year, list of authors and their affiliations). From this master list, a random sample of 150 reports will be selected for detailed analysis, ensuring proportional representation across the study period by including 25 reports from each year (e.g., 25 reports from 2020, and each subsequent year in our sample). Randomisation will be performed using a computerised random sequence generator (https://www.random.org/sequences/). We will not perform a formal sample size calculation, as our objective is to describe multiple indicators that are all considered equally important.

Screening and selection

At least three researchers will independently screen all report titles, with a workload-sharing approach to ensure each title is

reviewed by two researchers. Full-text PDF will be retrieved for reports that meet the eligibility criteria or for which eligibility is uncertain. A full-text screening form will first be pilot-tested on 10 reports. Subsequently, at least three researchers will independently screen all potentially eligible full texts, with any discrepancies resolved through discussion among the research team.

Data collection

Data from each eligible report will be extracted using a standardised data extraction form by at least three researchers, with a workload-sharing approach to ensure data from each report is extracted by two researchers. All data extractors will independently pilot-test the form on 10 reports to ensure consistency in the interpretation of data items. Any discrepancies will be resolved through discussion or adjudication by a senior researcher, if necessary. Full-text reports will be examined to capture information on general and methodological characteristics and PPI reporting practices. The selection and wording of variables related to general and methodological characteristics, and PPI reporting practices will be guided by recommendations from relevant literature on PPI, research reporting, transparency, reproducibility and impact.[20–36] The data extraction form will include the following information:

- General and methodological characteristics:

– Title of the report.
– Publication year.
– Agency or unit responsible for producing the report.
– Number and sex/gender of authors.
– Number and sex/gender of reviewers (e.g., non-authors who provided feedback on draft reports).
– Name and focus of the health technologies being assessed, which may include: screening (e.g., early detection in asymptomatic populations), diagnosis (e.g., identification of diseases or causes of health problems), treatment or prevention (e.g., interventions to cure, manage, or prevent disease), rehabilitation (e.g., restoration or improvement of function and quality of life), and other areas (such as organizational aspects of care or health information technologies).
– Type of health technology (e.g., pharmacological, non-pharmacological, both).
– Age group of the population being assessed, defined as newborns infants (0-27 days), infants/toddlers (28 days-23 months), children (2-11 years), adolescents (12-17 years), adults (>18 years), mixed population (e.g., newborn/infants/children/adolescents/adults), or not reported.
– Type of condition addressed (International Statistical Classification of Diseases and Related Health Problems, 11th Revision category).
– Type of evidence synthesis (e.g., systematic review, scoping review, rapid review, overview of reviews, other).
– Protocol mentioned (yes/no). If applicable, protocol was publicly available (yes/no).
– Number of included studies.
– Number of included participants in the studies (reported or able to be calculated).
– Update of a previous HTA report (yes/no).
– Meta-analysis performed (yes/no). If applicable, number of studies included in the largest meta-analysis in each HTA report that included meta-analysis.
– Indirect comparison performed (yes/no), and if applicable, the method used (e.g., adjusted indirect comparison/Bucher method, matching adjusted indirect comparison, simulated treatment comparison, mixed comparison, network meta-analysis).[27]
– Harms were considered (yes/no).
– Health economic evaluations (e.g., costs) were considered (yes/no).
– Health inequities were considered (yes/no), for example, defined as the inclusion of factors from the PROGRESS-Plus framework,[28] which stands for place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status, social capital, or other characteristics such as age, disability and sexual orientation.
– Patient reported outcome measures and/or experiences were considered (yes/no) (note: considered means that either data for the outcomes/experiences were reported or the authors planned to collect data for the outcome/experience if such data were reported in the included studies).[17,29]
– Present assessments of certainty (or confidence) in the body of evidence in a summary of findings table or text (yes/no).

- PPI reporting practices:

– Patient/public partner included as part of the authorship team (yes/no).
– Patient/public partner included as part of the reviewers section, but not an author (e.g., yes, with individual name; yes, anonymously or as a group; no).
– Patient/public partner included in acknowledgements section (e.g., yes, with individual name; yes, anonymously or as a group; no).
– If applicable, number and sex/gender of patient/public partners.
– If applicable, involvement of patient/public partners by age group adolescents, adults, others (yes; no; not specified; and number).
– If applicable, patient/public partner affiliation (e.g., patient organisation, research advisory group, university/research institute, other).
– If applicable, patient/public author position (e.g., first, middle, last).
– Citation and/or mention of a guideline for conduct or reporting PPI (e.g., citation/no mention, citation/mention without reporting checklist, citation/mention with reporting checklist in appendices). If applicable, which guideline or document (e.g., RedETS decision-making flowchart,[17] GRIPP2,[20,21] other).
– Citation and/or mention of any additional guidelines for conduct or reporting (e.g., Cochrane Handbook,[28] HTA Core Model,[30] PRISMA for systematic reviews,[31] PRISMA for network meta-analysis,[32] PRIOR for overview of reviews,[33] CHEERS for health economic evaluations,[34] CONSORT for randomised trials,[35] and SPIRIT for protocols of randomised trials[36]).
– If available, levels or nature of involvement (according to the classification by the International Association for Public Participation[37]): information (e.g., patients/public were informed about the assessment, without actively contributing), consultation (e.g., patients/public were asked opinions, views, feedback or advice, while final decisions remained with the HTA team), involvement (e.g., patients/public were actively involved in specific tasks or stages of the HTA report such as: 1) scoping/problem definition, outcomes identification, and protocol development/revision; 2) evidence gathering and/or assessment; and 3) revision of the HTA report), collaboration/partnership (e.g., patients/public collaborated with the HTA team across multiple stages, sharing decision-making responsibilities), or empowerment/co-production (e.g., patients/public led or co-led the HTA process, including the identification of unmet medical needs, formulation of assessment questions [PICOS: patient, intervention, comparator, outcomes, study design], protocol development/revision, evidence gathering and assessment, drafting/revision of the HTA report, and dissemination of results).

- If available, PPI activity/process: who are the involved PPI contributors (e.g., patients, caregivers, families, members of patient organizations, community/citizen member, other, not specified), number of PPI contributors (e.g., 1, 2-4, >5), methods to collect PPI input (e.g., discussions, surveys, individual or group interviews, focus groups, Delphi techniques, citizen assemblies/panels, workshops and meetings, feasibility studies, or other methods), stages at which PPI contributors were involved (such as design, assessment process, drafting the report including authorship and/or dissemination of results, reviewing the report, acknowledgement of PPI contributors).[23,24]
- Any reported impact of PPI in HTA (yes/no). If applicable, specify the impact domain:[38] impact on HTA result or recommendation (e.g., improves data interpretation, increases awareness of patient unmet needs, new data consideration, change HTA recommendation or appeal decision direction due to patient input), impact on HTA body (e.g., HTA staff awareness of PPI importance, increases culture of PPI at the organizational level, HTA process improvement) and impact on patients and the public (e.g., satisfaction, co-construction, increases culture of PPI, increases patients/public knowledge and understanding of HTA, increases acceptance of HTA recommendation).
- Any evaluation of the quality of the PPI from a patient perspective (yes/no). If applicable, the assessment tool used (e.g., Patient Engagement In Research Scale [PEIRS],[39] Public and Patient Engagement Evaluation Tool [PPEET][40]).
- Included a plain language summary of HTA for a lay audience (yes/no). If applicable, degree of PPI in drafting the summary (e.g., written by patient/public partner, only revised, not specified).[41]
- Any compensation to patient/public partners (e.g., financial, non-financial, not specified).

Data analysis

We will analyse a comprehensive set of quantitative variables. Categorical variables will be summarised as frequencies and percentages with 95% confidence intervals, and continuous variables as medians with interquartile ranges. PPI reporting practices will be stratified by publication year, health technology focus (e.g., screening, diagnosis, treatment, prevention), age group of the patient population being assessed (e.g., paediatric vs adults), and the agency or unit responsible for the HTA report (e.g., Agency for Health Quality and Assessment of Catalonia, the Basque Office for Health Technology Assessment, Institute of Health Carlos III, Andalusian Health Technology Assessment Area, the Evaluation Unit of the Canary Islands Health Service, Galician Agency for Health Knowledge Management, the Aragon Health Sciences Institute, and the Healthcare Technologies Evaluation Unit of Madrid). Analyses will be performed using Stata 19 or later (StataCorp LP, College Station, TX, USA).

Patient and public involvement

Although this protocol reports no results, the description of the planned methods were guided by the GRIPP2-SF checklist[20,21] (Table S2 in the Supplementary Material). Two patient representatives (CC and BNE) contributed to the study design and will advise on PPI, the interpretation of findings, and dissemination. Collaboration will continue through formal and informal meetings, discussions, phone calls, and email. A plain language summary for this study protocol was prepared (Table S3 in the Supplementary Material). Patient representatives are members of the team and co-authors of this study protocol.

Discussion

This paper presents a protocol for a cross-sectional meta-research study assessing the extent and characteristics of PPI in contemporary HTA reports produced within the Spanish National Health System. To our knowledge, this will be the first study to systematically examine PPI across a representative sample of HTA reports from the RedETS.[15] By analysing a stratified random sample of reports published between 2020 and 2026, we aim to provide quantitative evidence on the scope and reporting of PPI, without restrictions by clinical area, technology type, or assessment purpose. This will allow us to describe current practices, identify patterns and gaps, and explore consistency in documenting patient and public contributions throughout the assessment process.

Findings are expected to be relevant to HTA researchers, agencies, policymakers, funding bodies, patient organisations, and other interest holders. This study may also inform standards and examples of good reporting practices for future HTA development. Potential limitations include reliance on publicly available reports and, therefore, may not capture informal or undocumented PPI activities; exclusion of certain regulatory reports (e.g., therapeutic positioning reports by the Spanish Medicines and Healthcare Products Agency), and focus on reporting practices rather than PPI impact.

Finally, a Spanish-language version of this study protocol was also developed (Table S4 in the Supplementary Material). Results of this study will be disseminated via peer-reviewed articles, conferences, communications with interest holders, lay summaries, infographics, and social media. All underlying data will be openly available in a public repository, and any protocol amendments will be transparently reported in final publications.

Editor in charge

Salvador Peiró.

Authorship contributions

All authors contributed to conceptualizing and designing the study. F. Catalá-López drafted the first version of the manuscript. E. Ganuza, C. Colin, R. Perna, B. Hutton, B. Nafria Escalera, A. Alonso-Arroyo, L. Tejedor-Romero, M. Turrini, D. Sandonís-Camarero, R. Lucas-Domínguez, M. Ridao, A.C. Tricco, S. Staniszewska and D. Moher commented for important intellectual content and made revisions. All authors read and approved the final version of the manuscript. F. Catalá-López accepts full responsibility for the finished manuscript and controlled the decision to publish.

Funding

The Spanish National Research Council (CSIC) through the project: *Involvement of Patients and the Public (IPP) in health and social care research: a proposal for a meta-research project* (PIE-202510E106). IPP-CSIC Seed-Corn Project 2025 – MaX-CSIC Plan (Framework for Self-Assessment and Evaluation of Scientific and Social Excellence-CSIC). A.C. Tricco is funded by a Tier 1 Canada Research Chair in Knowledge Synthesis for Knowledge Users, Canadian Institutes of Health Research (CIHR). A. Alonso-Arroyo and R. Lucas-Domínguez are funded by the Generalitat Valenciana (CIPROM/2024/058). The funders were not involved in the design or decision to submit the protocol for publication, nor will they be involved in any aspect of the study conduct. The views expressed in this manuscript are those of the authors and may not be understood or quoted as being made on behalf of, or reflecting the position of, the funder(s) or any institution.

Conflicts of interest

None.

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Acknowledgements

We thank Phelan-McDermid Syndrome Association for their valuable contributions to this initiative and for their involvement and support in this project.

Appendix. Supplementary material

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.1016/j.gaceta.2026.102591.

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