



Ένωση
Ασθενών
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HTA implementation in Greece: Patients' Association perspective

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Προτάσεις προς άμεση υιοθέτηση για την επιτάχυνση του έργου των Επιτροπών

- Άρση του όρου περί οριζόντιας τριετούς επαναξιολόγησης των προϊόντων
- Πρόβλεψη ταχείας διαδικασίας ΗΤΑ για μεταβολές που δεν επιφέρουν δημοσιονομική επιβάρυνση και δεν σχετίζονται με την τεχνολογία και την ένδειξη του προϊόντος
- Απλοποίηση της διαδικασίας σύμφωνα με την οποία η Επιτροπή Αξιολόγησης παραπέμπει τα γενόσημα στην Επιτροπή Διαπραγμάτευσης



Τήρηση των χρονοδιαγραμμάτων που ορίζει ο νόμος

- Συμμόρφωση με την Ευρωπαϊκή Οδηγία περί ανώτατου ορίου 180 ημερών από την έγκριση του EMA
- Αποφυγή της ταλαιπωρίας για τον ασθενή για τη διαδικασία μέσω ΣΗΠ



Επαρκής στελέχωση και διοικητική υποστήριξη των Επιτροπών

- Πλήρης στελέχωση και υποστήριξη των διαδικασιών αξιολόγησης τεχνολογίας υγείας με εξειδικευμένο επιστημονικό και διοικητικό προσωπικό
- Αξιοποίηση εξωτερικών αξιολογητών, καθώς και η επανεξέταση των κριτηρίων σύγκρισης συμφερόντων



Διαφάνεια των διαδικασιών

- Διασφάλιση της λογοδοσίας και της διαφάνειας στην πληροφόρηση με τη δημοσιοποίηση όλων των χρονοδιαγραμμάτων κατάθεσης και πορείας της αξιολόγησης.
- Κοινοποίηση των αποτελεσμάτων της διαδικασίας αξιολόγησης για λόγους διαφάνειας και όχι μόνο της τελικής απόφασης.



Διαφάνεια των διαδικασιών



Εγχειρίδιο αξιολόγησης



Horizon scanning



Συμφωνίες Επιμερισμού Κινδύνου



Συχνότητα δημοσίευσης θετικής λίστας



Επίσπευση της ίδρυσης και λειτουργίας ενός ανεξάρτητου οργανισμού ΗΤΑ

- Στελέχωση με εξειδικευμένο επιστημονικό και διοικητικό προσωπικό.
- Δυνατότητα απασχόλησης κατά περίπτωση με την κατάλληλη νομική δέσμευση του απασχολούμενου προσώπου ή φορέα εξωτερικών εμπειρογνομώνων στη διαδικασία.
- Οργανωτική διάρθρωση με τη συμπερίληψη Διοικητικού και Επιστημονικού Συμβουλίου και διευθύνσεων στα πεδία της Κλινικής Αξιολόγησης, της Κοινωνικοοικονομικής Αξιολόγησης και Αποτίμησης, της Τεκμηριωμένης Φροντίδας και της Οικονομικής Διαχείρισης και Διοικητικής Υποστήριξης



“Η αξιολόγηση τεχνολογιών υγείας είναι η γέφυρα μεταξύ επιστήμης και πολιτικών υγείας.”

Facey, Karen. (2011). *Patient involvement in HTA: What added value?*. *Pharmaceutical Policy and Law*. 13. 245-251. 10.3233/PPL-2011-0329.

Patient involvement in HTA: What added value?

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HTA is an interdisciplinary assessment of evidence and knowledge about the intended and unintended effects of using a health technology. Patients with rare diseases have valuable knowledge about the illness in the real-life setting, but too often their views are seen as anecdotal or biased. So, more needs to be done to elicit patients' perspectives to add value to HTA through effective participation of patients throughout the HTA process and collection of evidence about patients' perspectives through robust qualitative research.

Traditionally HTA has been a broad assessment to move evidence into practice, but in recent years a more limited view of clinical and cost effectiveness has been the focus. For HTAs in rare diseases, this is not enough. Consideration of ethical, organizational and social issues are vital and here patients' perspectives could be particularly valuable to bring a real-life understanding of the potential impact of the health technology.

As countries around the world put more emphasis on creating clear plans to manage rare diseases, we need to ensure that all stakeholders work together to ensure that HTAs are being used flexibly to ensure that there is equity of access to therapies for rare diseases that provide real added value.

Keywords: Patient participation, technology assessment, qualitative research, rare diseases

1. Background

Health Technology Assessment International (HTAi) is a scientific and professional society for all those who produce, use, or encounter HTA. Its mission is to support and promote the development, communication, understanding and use of HTA. It acts as a forum for collaboration amongst all stakeholders; sharing information and expertise amongst members across the world.

The HTAi Interest Group on Patient/Citizen Involvement in HTA focuses on promoting effective patient involvement in HTA. It recognises the need to support patients to be involved in the HTA process and so has developed an HTA glossary for patients [1], which is reproduced in this monograph. The Interest Group has had a paper published outlining best practice [2] in 'patient involvement' in HTA and aims to share best practice via its website.

The Interest Group believes that 'involvement' is not just about ensuring the participation of patients in the HTA process, but it's also essential to obtain patients' perspectives in a manner that can be effectively integrated into the largely evidence-based HTA process (as 'evidence'). These elements of effective participation of patients in the HTA process and contribution of evidence are considered here in the context of HTA for rare disease therapies.



“Η συμμετοχή των ασθενών στο HTA είναι απαραίτητη για την ανάπτυξη μιας δίκαιης, διαβουλευτικής και εν τέλει αποτελεσματικής διαδικασίας.”

K. Facey, A. Boivin, J. Gracia et al., Patients’ perspectives in HTA: a route to robust evidence and fair deliberation, *Int J Tech Ass in Health Care* 26 (2010), 334–340.

Patients’ perspectives in health technology assessment: A route to robust evidence and fair deliberation

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HTAi Interest Group on Patient/Citizen Involvement in HTA

on behalf of the HTAi Interest Group on Patient/Citizen Involvement in HTA

There is increasing emphasis on providing patient-focused health care and ensuring patient involvement in the design of health services. As health technology assessment (HTA) is meant to be a multidisciplinary, wide-ranging policy analysis that informs decision making, it would be expected that patients’ views should be incorporated into the assessment. However, HTA is still driven by collection of quantitative evidence to determine the clinical and cost effectiveness of a health technology. Patients’ perspectives about their illness and the technology are rarely included, perhaps because they are seen as anecdotal, biased views. There are two distinct but complementary ways in which HTA can be strengthened by: (i) gathering robust evidence about the patients’ perspectives, and (ii) ensuring effective engagement of patients in the HTA process from scoping,

We thank Chris Henhall for challenging us to clarify whether we were talking about involvement processes or questions, we realized we are passionate about both and needed to explain that more clearly to the HTA community. HTAi Interest Group on Patient/Citizen Involvement in HTA who provided helpful comments on this manuscript: Gonzalez, Janet Hillier, Lesley Holdsworth, Anne Lee, Karen Richter, Cecé Smith and Janet Wake.



”Η «συμμετοχή εμπειρογνομόνων ασθενών» παρέχει προστιθέμενη αξία σε όλες τις φάσεις του έργου της αξιολόγησης, μέσω της βιωματικής γνώσης, με στόχο τη βελτίωση της συνάφειας, της ποιότητας και της εγκυρότητας της διαδικασίας έρευνας.”

Health Equality Europe, Understanding Health Technology Assessment, 2008
www.htai.org/fileadmin/HTAi
Files/ISG/PatientInvolvement/EffectiveInvolvement/HEEGuideToHTAforPatientsEnglsh.pdf Accessed 18 March 2021.

The screenshot shows the PubMed interface. At the top, there is the NIH logo and the text 'National Library of Medicine National Center for Biotechnology Information'. Below this is the 'PubMed.gov' logo and a search bar with the text 'Search PubMed'. To the right of the search bar is a 'Search' button and a 'User Guide' link. Below the search bar are buttons for 'Save', 'Email', 'Send to', and 'Display options'. The main content area displays the article title 'European League Against Rheumatism recommendations for the inclusion of patient representatives in scientific projects' in bold. Below the title is the author list: 'M P T de Wit¹, S E Berlo, G J Aanerud, D Aletaha, J W Bijlsma, L Croucher, J A P Da Silva, B Glüsing, L Gossec, S Hewlett, M Jongkees, D Magnusson, M Scholte-Voshaar, P Richards, C Ziegler, T A Abma'. Below the author list are the affiliations, PMID (21257615), and DOI (10.1136/ard.2010.135129). The abstract section is titled 'Abstract' and contains the following text: 'Objective: To develop recommendations to enable successful inclusion of the patient perspective in European League Against Rheumatism (EULAR)-funded scientific research projects. Methods: The EULAR standardised operational procedures for guideline development were followed. A systematic literature review was presented during a first task force meeting, including 3 rheumatologists, 1 rheumatologist/epidemiologist, 2 allied health professionals, 2 representatives of arthritis research organisations and 7 patient representatives, resulting in 38 statements. A Delphi method was carried out to reduce and refine the statements and agree on a set of eight. Next, a survey among a wider group of experts, professionals and patient representatives (n=42), was completed. Feedback from this wider group was discussed at the second meeting and integrated in the final wording of the recommendations. Subsequently, the level of agreement of the group of experts (n=81) was re-evaluated. Results: The project resulted in a definition of patient research partner and agreement on a set of eight recommendations for their involvement in research projects. These recommendations provide practical guidance for organising patient participation, capturing (1) the role of patient research partners, (2) phase of involvement, (3) the recommended number, (4) recruitment, (5) selection, (6) support, (7) training and (8) acknowledgement. Conclusion: Collaboration between patients and professionals in research is relatively new, and no effectiveness studies are not yet available. Nevertheless, it is possible to define recommendations for the inclusion of patients in research following a solid expert opinion consensus process.'



“Οι προσδοκίες του ασθενούς σαφώς δεν είναι αρκετές για την εποικοδομητική συμμετοχή του στο ΗΤΑ, ωστόσο υπάρχουν μεθοδολογικά εργαλεία για την επίτευξη ισχυρής τεκμηρίωσης που σχετίζεται με την εμπειρία του ως προς την πάθηση ή την τεχνολογία.”

Health Equality Europe, Understanding Health Technology Assessment, 2008
www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/EffectiveInvolvement/HEEGuideToHTAforPatientsEnglsh.pdf Accessed 18 March 2021.



Understanding Health Technology Assessment (HTA)



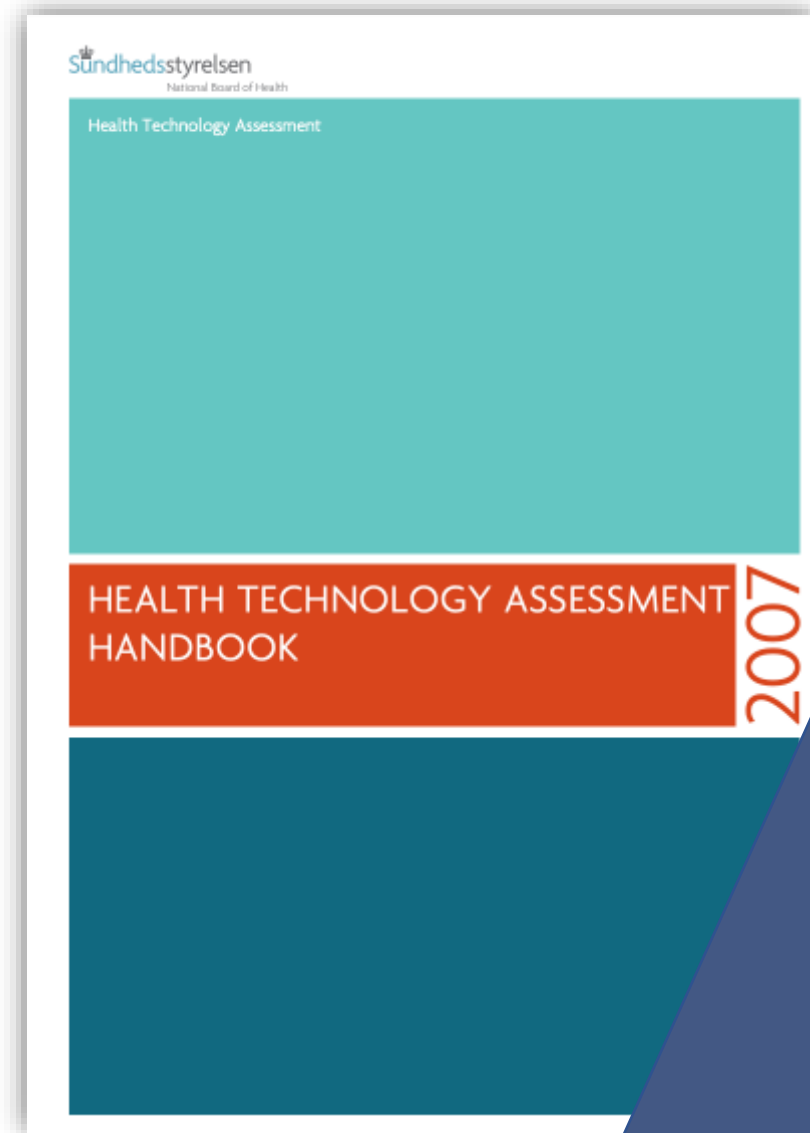
This guide describes how patients and the public can get involved in decisions about what healthcare should be available. It can also be used to help raise awareness of patient needs.

July 2008



“Για την επικοινωνιακή συμμετοχή των ασθενών στις διαδικασίες HTA μπορεί να αξιοποιηθεί μια σειρά μεθόδων ποιοτικής έρευνας, όπως οι ατομικές συνεντεύξεις και οι ομάδες εστίασης.”

F.B. Kristensen and H. Sigmund, Health Technology Assessment Handbook. Copenhagen: Danish Centre for Health Technology Assessment, National board of health, 2007.





“Τα ευρήματα από τη συμμετοχή των ασθενών θα πρέπει να αξιολογούνται κριτικά, όπως κάθε άλλη απόδειξη που αξιολογείται στο πλαίσιο του ΗΤΑ.”

K. Malterud, Qualitative research: standards, challenges and guidelines, Lancet 358 (2001), 483– 488.

The screenshot shows the PubMed interface for the article "Qualitative research: standards, challenges, and guidelines" by K. Malterud. The page includes the NIH logo, a search bar, and various action buttons like "Cite", "Favorites", and "Share". The abstract text is visible, discussing qualitative research methods and their application in medicine. The page also lists similar articles and provides publication details such as the journal name (Lancet), volume (358), issue (9280), and page numbers (483-488).

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> Lancet. 2001 Aug 11;358(9280):483-8. doi: 10.1016/S0140-6736(01)05627-6.

Qualitative research: standards, challenges, and guidelines

K Malterud¹

Affiliations + expand
PMID: 11513933 DOI: 10.1016/S0140-6736(01)05627-6

Abstract

Qualitative research methods could help us to improve our understanding of medicine. Rather than thinking of qualitative and quantitative strategies as incompatible, they should be seen as complementary. Although procedures for textual interpretation differ from those of statistical analysis, because of the different type of data used and questions to be answered, the underlying principles are much the same. In this article I propose relevance, validity, and reflexivity as overall standards for qualitative inquiry. I will discuss the specific challenges in relation to reflexivity, transferability, and shared assumptions of interpretation, which are met by medical researchers who do this type of research, and I will propose guidelines for qualitative inquiry.

Similar articles

[Qualitative methods in medical research—preconditions, potentials and limitations].
Malterud K.
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“Ο ασθενής ως σύμβουλος για την αξιολόγηση του φορτίου της ασθένειας, της εμπειρίας ζωής, των ανεκπλήρωτων αναγκών και της τεχνολογίας.”

K. Lampe, M. Makel¹ and M.V. Garrido, The HTA Core Model: A novel method for producing and reporting health technology assessments, IJTAHC 24 (2009) S2, 9–20.

The screenshot shows the PubMed interface for the article "The HTA core model: a novel method for producing and reporting health technology assessments". The page includes the National Library of Medicine logo, a search bar, and various action buttons like "Save", "Email", and "Send to". The article title is prominently displayed, followed by the authors' names and affiliations. The abstract section is visible, detailing the study's objectives, methods, results, and conclusions. The page also features social media sharing options and a "Full Text Links" section.

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> Int J Technol Assess Health Care. 2009 Dec;25 Suppl 2:9-20.
doi: 10.1017/S0266462309990638.

The HTA core model: a novel method for producing and reporting health technology assessments

Kristian Lampe¹, Marjukka Makela, Marcial Velasco Garrido, Heidi Anttila, Iiona Autli-Ramö, Nicholas J Hicks, Björn Hofmann, Juha Koivisto, Regina Kunz, Pia Kärki, Antti Malmivara, Kersti Meesaar, Päivi Reiman-Mättönen, Inger Norderhaug, Iris Pasternack, Alberto Ruano-Ravina, Pirjo Räsänen, Ulla Saalesti-Koskinen, Samuli Saarni, Laura Wallin, Finn Barlum Kristensen, European network for Health Technology Assessment (EUnet-HTA)

Affiliations + expand
PMID: 20030886 DOI: 10.1017/S0266462309990638

Abstract

Objectives: The aim of this study was to develop and test a generic framework to enable international collaboration for producing and sharing results of health technology assessments (HTAs).

Methods: Ten international teams constructed the HTA Core Model, dividing information contained in a comprehensive HTA into standardized pieces, the assessment elements. Each element contains a generic issue that is translated into practical research questions while performing an assessment. Elements were described in detail in element cards. Two pilot assessments, designated as Core HTAs were also produced. The Model and Core HTAs were both validated. Guidance on the use of the HTA Core Model was compiled into a Handbook.

Results: The HTA Core Model considers health technologies through nine domains. Two applications of the Model were developed, one for medical and surgical interventions and another for diagnostic technologies. Two Core HTAs were produced in parallel with developing the model, providing the first real-life testing of the Model and input for further development. The results of formal validation and public feedback were primarily positive. Development needs were also identified and considered. An online Handbook is available.

Conclusions: The HTA Core Model is a novel approach to HTA. It enables effective international production and sharing of HTA results in a structured format. The face validity of the Model was confirmed during the project, but further testing and refining are needed to ensure o



Συμμετοχή των εκπροσώπων των ασθενών στις διαδικασίες HTA

- Πληρέστερη κατανόηση των επιπτώσεων της τεχνολογίας στο πλαίσιο της πραγματικής ζωής (π.χ. εμπόδια συμμόρφωσης με την τρέχουσα θεραπεία, παρενέργειες, ικανότητα ασθενών να συμμετέχουν στο κόστος κ.λπ.)
- Υψηλότερη αξιοπιστία και συνάφεια των αποφάσεων (π.χ. ποια θεραπεία και φροντίδα πρέπει να είναι διαθέσιμη)
- Μεγαλύτερη ακρίβεια στη μέτρηση των αναγκών και προτιμήσεων των ασθενών
- Αυξημένη διαφάνεια και λογοδοσία στη λήψη αποφάσεων Κόστος υγείας που βασίζεται στον ασθενή και στην εμπειρία του



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