

EUnetHTA – Patient Input Template for REAs

Health Technology Assessment (HTA) on <health intervention> for <condition>; Project ID: <PTJAxx // OTJA/CAxx>.

- final 30-09-2019 -

1. Overview of this form

This form includes prompts or suggestions to draw out the unique knowledge and perspectives of patients that are most likely to inform HTA. This will help in the assessment of the value of a health technology. This form is intended to help patient groups present the range of experiences and views of patients with the disease/condition for which the health intervention is being assessed.

The first two pages of this survey contain text that includes background information necessary to understand the purpose of this form and the type of information that is most helpful to us.

Please note that the original document “Patient Group Submission Template for HTA of Health Interventions” was developed by HTAi, and has been further modified and adapted to the needs of EUnetHTA WP4 patient organisations’ input specifically related to EUnetHTA JA3 Rapid REAs.

What do we mean by "patient" and "carer/care-giver"?

In all parts of this form the term “patient” refers to anyone living with, or who has lived with, or who has a high risk of the condition for which the health intervention is indicated. “Carer/care-giver” refers to anyone who assists a patient in an informal or unpaid capacity such as a family member or friend. It does not include those paid to give care such as doctors or nurses.

What information do we value from patient groups?

We recognise that patients and those who support them have unique knowledge about what it is like to live with a specific disease or medical condition. We believe patient groups can help us understand patients’ unique perspectives by collecting and presenting patients’ and carers/care-givers’ views and experiences by engaging with a wide range of patients. They can describe advantages and disadvantages of health interventions based on patients’ experiences and what patients value from a new intervention.

2. How to complete this form.

In the main sections of this form you are asked to describe the:

- Challenges patients face in living with the condition being studied;
- Experiences of using current therapies;

- Expectations from a new medicine / a new health intervention and, if applicable, experiences of using the new medicine / health intervention which we plan to assess (i.e. <name of therapy / health intervention>)

Each question has a series of prompts in a box that are intended to assist you in providing the information that will be helpful to HTA reviewers and committees in understanding the impact of the condition and its treatment and/or diagnosis. Please address any of the prompts that your group feels are important and describe any other relevant issues that are not captured in the list of prompts.

What type of information is most helpful?

Please provide clear facts, information and summaries of experiences that give a concise, accurate and balanced overview of a range of patients' and care-givers/carers' perspectives/views. Describe experiences at different stages of the condition, with a particular focus on symptoms – their impact and how well they are currently managed with existing treatments. State the source of your information (e.g. web survey, helpline analysis, social networking, focus group, patients' records, one-to-one conversations with those who have experience of an intervention, patient stories, research studies, etc.) and provide clear references where they are available.

For any of the sections in the form where there are groups that should have special consideration, please indicate the specific needs/issues of that group (e.g. children, women/men, ethnic groups, those living in a particular location, those with other disabilities, disease sub-types).

What about scientific papers?

There is no need to send us published scientific papers as we already have access.

Need help with completing the form?

If you require help in understanding HTA related terms, please refer to the HTA glossary (<http://www.htaglossary.net/homepage>) or the EUnetHTA assessment FAQ (<https://www.eunethta.eu/services/submission-guidelines/submissions-faq/>).

If you have any questions when completing this form, please contact <Name and e-mail of project lead>

Many thanks for your valuable input.

3. Information about your patient organisation and this submission.

Name of patient organisation:

Health condition(s) represented by your organisation:

How many members does your organisation have?

How is your organisation funded?

Please provide any direct or indirect links with, or funding from medical industry, and specifically with manufacturers relevant to the technology under assessment during the last 3 years. In addition, please state the percentage of funding by industry in total (if none, please write NONE):

Key contact name:

Role in organisation:

Email:

Phone:

European participants only, please.

Postal address:

Website of your organisation:

Type of group (tick all that apply).

Registered charity

Fellowship

Informal self-help group

Unincorporated organisation

Other

Please state _____

Membership of your group (tick all that apply).

International

National

Regional

Local

Other

Please specify _____

Purpose of group (tick all that apply).

Advocacy

Education

Campaigning

Service

Research

Other

Please specify _____

Describe your membership (number and type of members, region that your group represents, demographics etc.).

What is the source of the information about patients' and carers/care-givers' experiences and needs that are presented in this submission? How did you gather information about the experiences of patients and carers to include in your submission?

Issues to consider in your response:

- Source – such as individual patient stories, review of patient group helpline queries, surveys, social media, one to one discussions with patients, focus groups, interviews, documentation of clinic visits, published or unpublished research
- Strength – how many patients and methods for each source
- Breadth – how representative are your findings compared with the views of the many patients that might be using this health intervention – did you approach patients that are seldom heard?

Are you willing for this submission to be shared on the EUnetHTA website after removal of any financial information and personal information that could identify patients?

Yes

No

The assessment team may wish to include the summary of your input (see section 8: “Summary and key messages”) in their assessment report. Do you agree?

Yes

No

4. Impact of condition – patients with <condition>.

How does <condition> affect patients' quality of life?

Issues to consider in your response:

- Aspects of the condition that are most challenging (e.g. symptoms, loss of ability to work, loss of confidence to go out, inability to drive, social exclusion).
- Emotional and psychological impacts such as fear, anxiety, uncertainty, stigma, embarrassment
- Activities that patients find difficult or are unable to do.
- Aspects of the condition that are the most important to control (e.g. symptoms that limit social interaction or ability to work such as difficulty breathing, pain, fatigue, incontinence, anxiety).
- Support required for daily living (physical or emotional).
- Types of patients that are most affected by the condition (e.g. men/women, children, ethnic groups).
- Challenges in managing this condition when patients also have other medical conditions.
- What patients would most like to see from a new treatment (e.g. halting of disease progression, improvement in a particular symptom).

How does <condition> affect carers/unpaid care-givers?

Issues to consider in your response:

- Challenges faced by family and friends who support a patient to manage the condition.
- Impact of the condition on family life
- Pressures on carers/care-givers' daily life (e.g. emotional/psychological effects, fatigue, stress, depression, physical challenges).

5. Experience with currently available therapies / health interventions.

How well are patients managing <condition> with currently available therapies / health interventions? (Currently available therapies / health interventions may include any form of medical intervention such as medicines, rehabilitation, counselling, hospital interventions etc. If no specific therapy is available, that should be stated.)

Issues to consider in your response:

- Main therapies / health interventions currently used by patients for this condition and how they are given (tablet, injection, physiotherapy, hospital check-ups, etc, at home, in hospital; dose and frequency, ease of access).
- Extent to which current therapies / health interventions control or reduce the most challenging aspects of the condition (e.g. reduction in symptoms; ability to dress, work, go to school, socialise; improve breathing, swallowing, walking).
- The most important benefits of current therapies / health interventions.
- The burden of therapies / health interventions on daily life (e.g. impact at different stages of disease, interruption to work, stigma, clinic visits to receive infused medicines, need for weekly blood tests or describe a typical episode of therapy over a week or period of treatment; difficulty in using the interventions, challenges in recovering after treatment, need for rehabilitation, special clinic visits for treatments and examinations).
- Side effects from the therapies / health interventions that are difficult to tolerate.
- Concerns about long-term use of current therapies / health intervention.
- If the current therapy is a medicine, what are the challenges in taking it as prescribed, or how is dosing modified according to prescription (e.g. dividing doses to avoid side effects or missing due to schedule).

6. Experiences with new medicine / health intervention being assessed (<name of medicine / health intervention>).

For those WITH experience using the new medicine / health intervention, what difference did it make to their lives?

Issues to consider in your response:

- Advantages and disadvantages of the new medicine / health intervention compared with current therapies / health interventions.
- The most important benefits of the new medicine / health intervention.
- Reasons patients do or don't like the therapy / health intervention being assessed compared with other therapies / health interventions.
- The burden of the new therapy / health intervention on daily life (e.g. impact at different stages of disease, interruption to work, stigma, ease of use, clinic visits to receive infused medicines, special clinical visits for treatments and examinations, need for weekly blood tests, need for recalibration).
- Symptoms that have changed and impact on daily life and quality of life such as less pain, less fatigue, improved continence, less nausea, increased mobility, less time linked to assistive device (e.g. oxygen, dialysis, etc)
- Unwanted outcomes (e.g. side effects) from the new therapy / health intervention that are difficult to tolerate and those that patients are willing to tolerate.
- Limitations of the new therapy / health intervention.
- Concerns about long-term use of the new therapy / health intervention.
- Impact of the new therapy / health intervention on carers/care-givers.
- If the new therapy is a medicine, what are the challenges in taking it as prescribed, or how is dosing modified according to prescription (e.g. dividing doses to avoid side effects or missing due to schedule).

For those WITHOUT experience using the new medicine/ health intervention, what are the expectations of it?

Issues to consider in your response:

- Perceived advantages and disadvantages of the new medicine / health intervention.
- Level of improvement patients would like to see.
- The level of side effects that patients would tolerate for a given benefit.
- Aspects of patients' needs or expectations that are hoped the new medicine / health intervention will address (explaining specific issues for particular stages of disease; e.g. improved daily life, ability to work, improved mobility, greater symptom control, easier use, less side effects).
- Impact of the new therapy / health intervention on carers/care-givers.

7. Additional Information.

Please include any additional information you believe would be helpful to the EUnetHTA Joint Assessment Team (e.g. ethical or social issues).

8. Summary and key messages.

In no more than ten statements, please summarize your submission and list the most important points.

For example:

- The biggest challenges of living with <condition> are...
- Current therapies / health interventions are inadequate because...
- The main expectations from patients regarding a new therapy / health intervention are ...