Health Technology Assessment international

Key ethical considerations for patient groups collecting and reporting information for HTA submissions

Long guide

Purpose

To complete submissions for health technology assessments (HTAs), patient groups may gather information about patients' and caregivers' experiences of living with a condition, their preferences and unmet needs for treatment. This may involve (but is not limited to) conducting interviews, focus groups and surveys and collecting input using social media. As a result, patient groups need to think about any ethical and legal issues that may arise when engaging with people and using their personal information. This document aims to help your patient group identify and respond to those issues. The guidance is not mandatory and can be adapted to meet your needs.

This 'Long Guide' is intended to supplement the *Key ethical considerations for patient groups collecting and reporting information for HTA submissions: Short guide* and has been written to provide additional detail around some of the concepts.

Background

Many patient groups do not have the time, resources or training to undertake the rigorous, systematic investigations required for academic healthcare research. But most patient groups do have a network of patients and caregivers that they can collect information from to inform their HTA submissions.

Collecting information of relevance to HTAs can touch on sensitive issues and has the potential to impact on personal privacy. This means there are ethical issues that patient groups should consider when undertaking these activities.

When gathering information from patients and caregivers, it is important to protect their personal safety, dignity, rights and well-being. A balance is needed between fairness in providing the opportunity to have a voice in the HTA process and overburdening people with requests for information and feedback. This document provides some guidance on:

- The need for the activity
- Inclusivity
- Informed consent
- Ensuring anonymity and confidentiality
- Data protection and privacy

1. Need for activity	

Is there existing information?	• Do you already have information that can answer the HTA submission questions? Maybe you already hold:
	  ○ past surveys
	  ○ interviews
	  ○ patient stories
	  ○ information from helplines or social media.
	• Do other patient groups have reports and information that is relevant? If you have access to information collected in other countries, for example by partner patient groups, this information can be assessed to see if you still need to get additional information from patients and caregivers in your country.
	• If you can share or access information from others, make sure:
	  ○ sharing is legal
	  ○ the identity of individuals has been removed so that the submission is fully anonymised
	  ○ you never receive or send raw information that identifies particular people taking part.

Is there a gap in the information?	• Have you found a gap in the information already available that needs to be filled? • Are there questions on the submission form that could be answered by seeking further input from your members? • Could you provide clearer, more useful answers if you collected more information? For example, would you be better able to describe the impact of the condition on everyday life? Or might you be able to identify a group that might particularly benefit from a medicine being assessed?
Is this the right way?	• Have you planned and tested the way you will collect the information to make sure it helps to fill that gap? • It is important to balance the amount of information gathered with its practical use. Think about the information you really need to complete the submission. Ensure that your information gathering is tailored to match those needs. • For example, is the way you are gathering patient views the right one for you? Will it give you the information you want? Does it ask about things you don't need to know? Are the questions easy to understand?

2. Inclusivity	
Have you taken steps to reach out to as broad a population as feasible?	• The people providing input should be as representative as possible. Vulnerable groups, such as children, cognitively impaired, homeless, imprisoned or with restricted movements are often not included when collecting information. Steps should be taken to include members of these populations, where possible. If you choose to leave out a group, you should be able to give your reasoning.

3. Informed consent	
Gathering information from patients can be a sensitive area. Volunteers, patient group staff and others who gather this information need to understand that although the activity is important to the patient group in providing useful information to the HTA body, the needs of the patients always come first. This is done by using an informed consent process where the people taking part are specifically told the reasons why they are being asked for information and the ways in which this information will be used, shared and stored. Part of the process is to ensure that the people taking part understand that they are free to refuse to take part or that they can stop giving information at any point. Core components of informed consent are: voluntariness, information provision and decision-making capacity. Before asking someone to take part, you should consider if they are competent to give their consent. If they are competent to consent, consider discussing the following.	
How will the information being collected be used and shared?	• It is important that people understand why they are being asked to give information. If they do not understand this, they cannot be considered to have given informed consent for the gathering of this information. • Be clear about who will see the raw information collected. Who will analyse this information and who will generate the anonymised report on all the insights collected? This may include your patient group preparing the submission and individuals external to the patient group (such as people hired to prepare the submission or perform the analysis in preparation for the submission). • Be clear and use plain language to help those taking part understand exactly why their views and experiences are being sought.
Who is collecting the information?	• Being clear about who is collecting this information is a major part of informed consent. People taking part should know that it is your patient group which is collecting this information.
Do they know they can refuse to take part, stop taking part, or not answer all the questions?	• A key principle of ethics is that the person giving the information has control over how much information they give. They can refuse to take part, stop taking part at any time or choose not to answer all the questions without this being held against them or harming them. It is important to clearly state this. • If the steps you take to remove an individual's identity will also make it impossible to retrieve and remove any one individual's contribution after a certain point, have you told the people taking part that the opportunity to

	withdraw only exists up to that point?

Do they know about conflicts of interest?	• Have you explained what a conflict of interest is to the people taking part? When collecting information, be transparent about any conflicts of interest you, that is the patient group, might have.
	• Conflicts of interest may arise from funding, non-financial support (such as provision of free samples), taking part in a trial sponsored by the company submitting an HTA request, etc. They may involve:
	  ○ the patient group as a whole
	  ○ individuals or organisations performing the analysis of the patient group submission
	  ○ or those preparing the submission.
	• Have you asked the people taking part to declare any conflicts of interest? It is also important to recognise that people giving information may also have conflicts of interest through their affiliations with other organisations or interested parties.

What is involved in taking part?	• Do people taking part know how much time their participation will take, what will be discussed, and that their words or stories could be used in the submission? • For example, will they be interviewed for five minutes or will they take an online survey that will take 15 minutes to complete? What are the topic areas to be discussed? Will their actual words be quoted? • Consider explicitly asking patients for permission to quote their comments because the use of direct quotes is a common way of summarising or presenting information by patient groups. You can emphasise again that their quotes will be anonymised.
Have they been given realistic expectations about the potential benefits of taking party?	• Briefly explain how evidence submitted to HTA bodies is assessed, and where patient group submissions fit alongside all the other evidence that HTA bodies consider. Patient group submissions provide information that may not be found in other sources of information, including published material and input from researchers and clinicians. • It may help to explain that patient group submissions often help to frame the assessment by explaining what matters most to patients and carers. Submissions can help the assessors understand people's experiences of current therapies and patient and caregiver expectations of new technologies. Patients may have had first-hand experience of the medicine being assessed. In these cases, patient group submissions can provide information about first-hand experience with the new treatment. Patient group submissions also help highlight the practical outcomes patients believe are important to them in treating and managing their condition, or any particular people who may benefit from the new treatment.

Do they understand the risks or potential harm of taking part (such as distressing thoughts, sense of stigma)?	• Consider the nature of the risks that may occur when someone takes part in your collection of information. Assess how likely and great each risk is. There may be legal, social, economic, psychological or physical risks such as worsening symptoms from the exertion of taking part or stress from re-living experiences. • What steps have been put in place to limit these risks? Do the people taking part understand them? Adequate understanding of risks and benefits is an important part of informed consent.
How will their identity be concealed for the submission (anonymity)?	• Explain to people taking part how their information will be anonymised. Anonymous information ensures that those reading the final submission will not be able to identify the people who gave the information. • It is good practice to clearly state who will have access to the anonymous information and who will have access to the raw information before it is anonymised. For example, usually the person conducting the interviews will be the only person who knows who provided a particular comment.
Do they belong to a vulnerable population?	• If the person is a member of a potentially vulnerable group (such as children or people suffering from cognitive impairment), it is important to put in place safeguards to ensure that they are able to take part in an informed and safe way. If these vulnerable groups are excluded from this process it will be important to explain clearly why this is the case.
Have they knowingly given consent?	• Have the people taking part knowingly given consent for this information to be collected and used? • It is good practice to check that the person taking part has understood how the information will be collected, used, analysed, stored and possibly included in the HTA report. If the report may be made available publicly, this must also be made clear to those taking part. It is important to explain this in a format and language that is easy for them to understand.
Do they consent to you using their information again?	• Have they given consent that the information you collect for the submission can be used again for other submissions (and that their identity will remain concealed)? • If a patient group would like to use the information for future submissions in the same area, it should let the people taking part know how their information may be re-used and give them the option to opt out of this re-use of their information. Emphasise that anonymity will be retained.
Do you have a process to destroy information given by people who choose to pull out?	• A person taking part may withdraw their consent after providing their information. It is good practice to plan how their information will be removed from the stored information and from the submission. • It is also important to know if the original information they provided can be destroyed (in some countries this is not possible). Having a process in place that clearly outlines the steps that will be taken to remove responses from the submission or to destroy the original information provided will help ensure a consistent response to these withdrawals.

4. Ensuring anonymity and confidentiality	
Because the privacy of medical information is subject to legal protections, it is important to anonymise and maintain confidentiality of the health information provided by patients for the purpose of the HTA submission. Do the people taking part understand the following.	
Do they understand guarantees given about concealing their identity?	• People taking part need to understand the steps taken to make sure their identity is concealed in the submission. How will you make sure individuals hired to help conduct the analysis, assessment groups hired by HTA bodies, etc., cannot recognise any individual from the submission? When making statements that guarantee that patient group submissions will be anonymous, explain how this will be achieved and ensure that the person taking part understands the process that will used to protect their identity.
Do they understand how their information will be stored and kept safe?	• Your group should have a policy for information storage and handling. It is good practice to inform the people taking part exactly how their information will be stored and how it will be protected. This is extremely important when information that has not been anonymised is being recorded and stored.
Has your patient group thought about the following processes.	

Have you got a process to make sure individuals cannot be identified in the submission?	• To make sure those who give information cannot be identified in a submission, it is good practice to have a system that everyone follows to keep this anonymity in place. For example, you may decide:
	  ○ not to use the real names of those taking part
	  ○ to use initials, letters or numbers for people taking part
	  ○ not to collect any identifying information.
	• Making sure that the whole team responsible for collecting the information uses the same process and standards will help ensure a consistent approach. If the submission and final report includes quotes, make sure they are anonymous and cannot be traced back to anyone.

How will you tell people who have taken part about the outcome of the HTA in a way that does not reveal to others that they took part?	• Telling people who have taken part about the process and its outcomes is important, but steps must be taken to make sure that this does not identify those taking part to others. Sending an email to everyone who took part, for example, could reveal the names and contact details of those involved. Instead, use more general forms of communication such as a social media, newsletter, websites, etc.

5. Data protection and privacy	
Does your patient group have a data protection policy you need to follow?	• Some patient groups have their own policies for data protection and retention. When gathering this kind of information, it is worth checking your own group's policies to make sure that they are understood by all those involved in this process. Make sure they are suitable for this particular information gathering exercise.
Does your region/country have a data protection or privacy policy you need to follow?	• Data protection laws vary from country to country and across regions. Before gathering any information, you should check your own country's data protection policies and make sure that you are adhering to them in the course of this work.
Do the people collecting information know that responses must be stored securely and they must not discuss or report responses in a way that identifies a person?	• When a team of staff members, volunteers or third parties are gathering information, it is important that they all follow the same processes for storing the responses securely and for ensuring anonymity, including when discussing the project among themselves. • Having clear guidelines, policies and procedures in place will help make sure everyone protects data and anonymity in the same way.
Is the data you collected and reported locked in a drawer or password protected?	• Notebooks and transcripts of interviews are just one example of the kind of data that can be left exposed. Have a secure (locked) drawer or cabinet in which all these materials are stored when not in use. • Electronic information such as survey responses, Excel sheets or Word documents should be password protected.
Have you backed up the data you collected and reported?	• Ensure that you securely backup all electronic information regularly.

Need more information?

- Links to further information and useful examples can be found on the HTAi website under the Patient and Citizen Interest Group
- Contact the HTAi Patient Involvement and Education Interest Group at info@htiai.org