

PATIENT AND CITIZEN INVOLVEMENT IN HTA INTEREST GROUP

Our vision: Patient and citizen perspectives improve HTA

TERMS OF REFERENCE

**Content approved by the HTAi PCIG Steering Committee on 11 June 2021
For ratification at the Annual Business Meeting on 29 June 2021**

1.0 Purpose

The Interest Group considers “involvement” to be a wide-ranging term that encompasses:

- patient and citizen participation in HTA processes
- research to provide evidence about patients’ and citizens’ perspectives, preferences and experiences to input to HTA.

The Interest Group’s High-Level Aims are to:

- Promote and develop robust methodologies to incorporate patients’ and citizens’ perspectives into HTAs and share best practice in patient and citizen participation in the HTA process
- Strengthen HTA by systematic incorporation of patient and citizen perspectives
- Support countries with limited experience of HTA to elicit and incorporate patients’ and citizens’ perspectives.

The specific aims of the Interest Group are to:

- Promote ways in which patients’ needs, perspectives and preferences can be incorporated into HTAs via submissions of information from patients that will make a difference to decision makers, while enabling effective patient participation in HTA processes (based on core values and standards of relevance, fairness, equity, legitimacy and capacity building)
- Promote and develop methods to elicit patient views to inform HTA decision making
- Determine and develop methods to elicit citizen and societal values to inform all aspects of HTA
- Promote the synthesis of patients’ and citizens’ perspectives on technologies being assessed and the overall societal impact of health technologies
- Promote and develop methods to measure the impact of patient and citizen involvement in HTA.

2.0 Establishment

The HTAi Interest Group for Patient and Citizen Involvement in HTA (‘the Interest Group’) was established in 2005. The Interest Group functions according to the HTAi Policy on Interest Sub Groups.

3.0 Responsibilities

3.1 Forum and catalyst for change

The Interest Group provides HTAi members with a forum to engage in discussion, exchange ideas on initiatives, and to share good practices and develop new tools to support and promote patient and citizen involvement activities in HTA.

3.2 Leadership

To work with champions and thought leaders in all HTA stakeholder groups and from a diversity of perspectives, experiences, needs and locations to:

- challenge the HTA community to move forward in its thinking about patient and citizen involvement
- form synergistic partnerships to work with others toward mutual goals that are aligned with the aims of the Interest Group

3.3 Research

The Interest Group and its members publish papers on methodologies to support its aims.

3.4 Impact

Evaluate the value of patient and citizen involvement in HTA through established or new methodologies.

3.5 Education and training

Identify, promote and develop education and training tools that encourage and support patient and citizen involvement in HTA.

3.6 Resources and tools

Support HTA agencies in adopting and/or developing processes and tools for patient and citizen involvement.

3.7 Funding

Secure the financial resource to enable the Interest Group's work to be carried out in an efficient manner, and in a way that the Interest Group can support others through research funding and attendance at key scientific and network meetings.

3.8 Planning

Develop and deliver evidence-based activity plans from any Project Sub-Committee that support the Interest Group's aims.

4.0 Accountability

4.1 Project Sub-Committees

The individual project sub-committees delivering the Interest Group's work are accountable to the Interest Group Steering Committee (SC).

5.0 Interest Group Composition

5.1 Membership

Any HTAi member can become a member of the Interest Group. Individuals who are not members of HTAi (particularly patients/citizen organisation members) can become a member by prior approval of the Interest Group Chair and the HTAi Secretariat/Managing Director. This to be supported by a written justification.

5.2 Structure

The Interest Group has an overall Steering Committee (SC). The SC may establish up to eight Project Sub-Committees at any one time. Each Project Sub-Committee shall have a lead and up to 12 members. Members of Project Sub-Committees must be members of the Interest Group.

5.3 Steering Committee

5.3.1. The Steering Committee (SC) is responsible for governance, strategy and for providing oversight of the plans and deliverables of any Project Sub-Committee. The SC additionally:

- Develops the overarching strategy for the Interest Group
- Develops and implements the Interest Group external communications
- Assesses collaboration opportunities with other organisations working in the field
- Approves funding requests and reports to the HTAi Board
- Organises sessions for the HTAi annual meeting
- Organises face to face meetings
- Agrees on projects to be delivered by the Interest Group
- Approves outputs from Interest Group Project Sub-Committees such as publications and materials, unless SC approves an alternative approach by prior agreement due to the nature of the work, such as for consortia projects.¹
- Approves membership and the project plan of any Project Sub-Committees (see Appendix 4 for Project Template).

5.3.2. The SC comprises:

A minimum of ten members of the Interest Group representing a balanced contribution from the stakeholder communities (see Appendix 1) within the Interest Group.

Specifically, the SC comprises, at least:

- An elected Chair – responsible for convening and chairing SC meetings, liaison with HTAi, key contact with the HTAi Board, and any external representation on behalf of the Interest Group
- An elected Vice-Chair – responsible for internal coordination of the Interest Group, filling in for the Chair. Chair and Vice-Chair may agree on a different distribution of tasks among themselves
- An elected Financial Secretary – responsible for financial issues such as raising funds and managing budgets for meetings
- At least two patients or patient advocates/representatives
- A Project Co-Ordinator (PCO) – responsible for coordinating any projects and Project Sub-Committees established by the SC.
- The outgoing Chair.

5.3.3. Other members can be co-opted. The SC can co-opt up to three additional members to the SC to encourage diversity and fill gaps in skills, geographies, and stakeholder representation as identified by the SC. Co-opted members shall serve for a period of one year at which time the full SC members will decide collectively if a renewal is required.

6.0 Terms of Office

6.1. Steering Committee membership

Any member of the Interest Group who wishes to become a member of the SC will be asked to demonstrate how they are active in the field of patient and citizen involvement. Preference will be given to those members who have actively participated in the Interest Group. New SC members will be approved by the SC.

6.2. Term of membership

Members of the SC are asked to commit to a three-year period of office, with a possible

¹ This does not apply to journal manuscripts which are the property of the authors. However, authors should advise the SC via the Chair or Project Coordinator when manuscripts resulting from a PCIG project are being prepared. Authors are requested to share the abstract with PCIG SC for information and ensure any funding (e.g., HTAi grants for open access) are reported in the paper.

renewal period of one more term. Members may serve beyond two terms if this is deemed critical to the work of the Interest Group.

6.3. Meeting attendance

All SC members are expected to attend as many SC meetings as possible, and to inform the Secretariat if they are unable to. In this instance, an e-mail response regarding the agenda items may be submitted 48 hours in advance of the meeting when unable to attend. If a SC member attends less than half the scheduled meetings in any 12-month period, consideration will be given to their other commitments and their ability to support the work of the SC.

6.4. Officers of the Steering Committee

6.4.1. Appointment

Any member of the SC may be nominated for a position of office; by him or herself or another member with the candidate's approval. If there is one nomination, the SC will be asked to approve the nomination. If there is more than one nomination for a position, voting will be organised through the HTAi Secretariat to ensure confidentiality. The person receiving the highest number of votes by the SC will be selected. This process will take place in April to allow the appointment to be made at the May SC meeting and to be ratified at the Annual Business Meeting in the summer of that year.

6.4.2. Vice Chair

A permanent Vice-Chair is appointed for three years with a term that is to run concurrently for two years with the Chair. After the Chair's first three-year term, the SC has the option of:

- Appointing the Chair to run for a second three-year term
- Appointing the Vice Chair to become the new Chair if the Vice Chair expresses an interest in the role
- Appointing a new Chair. The outgoing Chair will revert to a normal member of the SC.

If the Vice Chair decides not to take on the role of Chair, after the Vice Chair's first three-year term the SC has the option of:

- Appointing the Vice Chair to run for a second three-year term
- Appointing a new Vice Chair. The outgoing Vice Chair will revert to a normal member of the SC.

6.4.3. Two terms

Chair and Vice-Chair must stand down after two terms in office.

6.5. Executive (Technical Officer) to the Steering Committee

6.5.1. An appointed Technical Officer will support the SC. The Technical Officer will be appointed by HTAi with inputs from the PCIG SC members. The duration of this position will be in line with HTAi guidelines for TOs: the position will be held for two years with a possible one-year extension.

6.5.2. Technical Officer role

The role of an appointed Technical Officer will be as stipulated in the HTAi Technical Officer position guidelines as follows. TOs will work closely with the Interest Group Chairs, Interest Group Executive Teams and/or Interest Group SC and working groups within the Interest Group to support specific tasks of the Interest Group. These tasks will vary depending on the needs of each Interest Group, and may include:

- environmental scans for articles, conferences, events, trainings of interest, etc.;
- maintaining Interest Group member contact lists;
- scheduling meetings and taking minutes;
- data collection from members;
- drafting communications and HTAi newsletter materials, maintaining website, etc.; and
- other tasks as directed by Interest Group Chair(s), Executive Team or SC.

6.6. Project Coordinator

The Project Coordinator is responsible for coordinating any projects and Project Sub-Committees established by the SC. The Project Coordinator will ensure that project templates (see Appendix 4) are complete for each project and made available to the SC. The Project Coordinator will schedule presentations and updates by Project Sub-Committees to the SC.

6.7. Advisor to the Steering Committee

If it is considered appropriate, the SC can appoint individuals who have contributed to the founding and/or continued impact of the Interest Group in an advisory role to the SC.

7.0 Responsibilities of Steering Committee Members

Members of the SC are expected to:

- Familiarize themselves with the Interest Group Terms of Reference.
- Attend each regularly scheduled SC meeting.
- Come to meetings prepared to engage in respectful, meaningful discussion and provide considered, constructive and thoughtful feedback and commentary, express opinions and ask questions to enable the SC to exercise its best judgment in decision making and advising the Project Sub-Committees.
- Act in the best interests of the HTAi in accordance with the Society's Mission, Vision, Values, and Strategic Plan, including focusing on membership and partnership recruitment; knowledge sharing, and financial stability and good governance.

8.0 Quorum

A SC meeting quorum is five.

9.0 Interest Group Operations

The Interest Group will undertake the majority of its work virtually by email and teleconference.

9.1. Annual General Meeting

The Interest Group will hold its Annual General Meeting at the HTAi Annual Meeting, usually in June. This meeting will be funded by and organised with the HTAi Secretariat. All members will be informed of the agenda at least one week in advance. Notes of this annual meeting of the Interest Group will be made available to all members of the Interest Group showing the actions planned for the forthcoming year.

9.2. General Business

Business between Annual Meetings will be undertaken with the whole Interest Group electronically, using the facilities available to Interest Groups on the HTAi website (list serves, document files, etc) and by email.

9.3. Annual Face-to-Face Meeting

The SC and members of Project Sub-Committees will meet face-to-face once a year, usually in October, for strategic planning, activity development, best practice sharing and planning for the next HTAi Annual Meeting.

9.4. Steering Committee Meetings

9.4.1. The SC will meet at up to eight times a year. Meetings will be organised a year in advance, in January. Half the meetings of the SC will be dedicated to governance of the Interest Group, with the other half being to review any projects of approved Project Sub-Committees. Different arrangements can be agreed upon need and circumstances.

9.4.2. Teleconferences will be organised by the Technical Officer, Secretary or delegate from the Interest Group Executive, who will provide a freephone dial-in number/online platform access details. The Technical Officer or Secretary will also issue the agenda and papers for the SC, minute the meeting and publish those minutes on the website.

9.4.3. Project Sub-Committees will provide quarterly progress reports to the Project Coordinator for SC meetings, which the Technical Officer will forward to the Secretariat for publication on the website after the SC meeting.

9.4.4. The Interest Group Technical Officer or Secretary or delegate will work with the HTAi Secretariat to organise materials on the Interest Group web pages and coordinate input to HTAi Bulletins.

9.4.5. In the instance where a third party agrees to assist the Interest Group with secretarial duties these will be agreed upon by the Chair, Vice-Chair and Secretary. Together with the third party they will form part of the Interest Group Executive.

9.5. All Meetings

The Interest Group Executive will liaise prior to all meetings to support the timely development and delivery of relevant meeting materials. All meeting materials will be circulated five days before the meeting is scheduled.

9.6. Funding

The Interest Group will be able to request funding for work from HTAi (in the region of USD 20,000/year to cover the work of all Interest Groups). The Interest Group may apply to other organisations to support specific short-term costs (such as workshops, travel costs, etc). Any funding for specific activities, such as workshops or projects, must be provided in an unrestricted manner, i.e. the funder shall have no influence in the organisation; which will remain the responsibility of the SC. All such funding needs to be supported by signed documentation that is retained by the Secretary/Technical Officer.

9.7. Secretarial Support

The Technical Officer provides administrative support and facilitation, including:

- Setting up meetings
- Preparing agendas
- Taking minutes
- Collecting pre-reads and distributing them in advance SC meetings

Organisational support for the project sub-committees is provided by the Project Coordinator as defined in section 6.6.

9.8. Remuneration of the Committee Members

Interest Group members shall receive no remuneration for their service on the SC. However, when specific SC members are part of funded projects in which members of the interest group are paid for their contribution, these SC members can receive remuneration for their work on the project.

9.9. Declaration of interests and conflict of interest management

Declarations and conflicts of interest are managed according to the HTAi Conflict of Interest Policy and Procedure.

9.9.1. All SC members and project sub-committee members will complete a Declaration of Interest upon appointment and update it in January of each year. These declarations will be retained by the Technical Officer in the *Members' Register of Interests* that will be available on request from the Technical Officer (or Secretary) who is responsible for the management of Declaration of Interest forms and for ensuring that the Member's Register of Interests is current.

9.9.2. The Interest Group Member shall promptly declare any conflict of interest and ask that such declaration be recorded in the minutes.

9.9.3. The Interest Group Member shall refrain from all discussion of, and voting on, the matter giving rise to the conflict of interest.

9.9.4. The Interest Group Member shall excuse himself/herself from the portion of the meeting where the matter giving rise to the conflict of interest is being discussed.

9.9.5. The Interest Group Member shall return to the meeting after the matter giving rise to the conflict of interest has been discussed and/or voted on.

9.10. Confidentiality

While the Interest Group aims to be open and transparent, from time-to-time confidentiality will be required. Interest Group members shall respect confidential discussions and documents. Some Interest Group meetings, such as the annual face-to-face meeting and PCIG Exchange, will be held in accordance with the Chatham House Rule. When meetings are held according to the Chatham House Rule, the rule will be clearly stated and participants will be reminded of its implications.

10.0 Review

Review of these Terms of Reference (ToR) shall take place every two years or as directed by the SC. Significant changes to the ToR shall be ratified by members during the Interest Group Annual Business Meeting. On occasion, minor changes that do not affect the structure, membership or composition of the Interest Group may be communicated to the membership via the listserv and ratified by the SC between AGMs. The SC will determine by unanimous vote if a change meets the above criteria is minor.

Approved date: June 2021

Review date: Mar 2023

HTAi is a multi-stakeholder organization. The Interest Group's statement on partnership is presented in Appendix 1. PCIG values for patient involvement in HTA can be found in Appendix 2. PCIG values for patient involvement in HTA – public participation standards can be found in Appendix 3. The template for project sub-committee proposals is in Appendix 4.

Appendix 1

Working Together in Equal Partnership

The HTAi Interest Group for Patient and Citizen Involvement in HTA (The Interest Group) sets out to 'work together in equal partnership'.

Our members are made up of patients and citizens or members of the public, clinicians, researchers including statisticians and economists, employees of industry, and HTA agencies. All members are considered equal, and their input and feedback is equally respected. We are all committed to overall improvement in HTA processes and the availability of equitable quality health care to improve health outcomes.

The members of the Steering Committee and its Project Sub-Committees volunteer their time, expertise, and energy, with paid assistance coming from the HTAi Secretariat.

Some of our members undertake projects that are funded by industry, or they 'are industry'. When this work is relevant to the Interest Group it is carried out with full scientific rigour and conscientiousness in the delivery of products that 'our community' can use. No one corporate organisation is favoured over another.

We as individuals find our own way to the HTAi Annual Conferences. The HTAi Secretariat is able to award a number of 'patient travel grants' each year. Some of the funding for these is from industry and they are awarded at 'arm's length' by an independent assessment committee.

Our Vision is that: Patient and citizen perspectives improve HTA

APPENDIX 2

PCIG Values for Patient Involvement in HTA

The PCIG has developed the PCIG Values as principles to be upheld in the involvement of patients in HTA processes (2014). This is a process that involves confidential materials, Pharmaceutical Company Codes of Practice, and protection of competitive edge. The Values and Quality Standards are becoming widely accepted internationally.

	RELEVANCE	FAIRNESS	EQUITY	LEGITIMACY	CAPACITY BUILDING
GOAL FOR HTA PROCESSES	Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.	Patients have the same rights to contribute as other stakeholders and have access to processes that enable effective engagement.	Patient involvement contributes to equity by seeking to understand the diverse needs of patients with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly.	Patient involvement facilitates those affected by the HTA recommendations or decisions to participate; contributing to the transparency, accountability and credibility of the decision-making process.	Patient involvement processes address barriers to involving patients and build capacity for patients and HTA organizations to work together.
QUALITY STANDARDS FOR PATIENT INVOLVEMENT	<p>A strategy outlines the processes and responsibilities for those in HTA to effectively involve patients.</p> <p>These are regularly reflected on and reviewed.</p>	<p>HTA organizations designate appropriate resources to ensure and support effective patient involvement.</p> <p>A staff member is tasked with providing support; patient perspectives and experiences are documented; and the influence on HTA conclusions and decisions reported.</p>	<p>HTA participants receive training about appropriate involvement of patients and consideration of patient perspectives throughout the HTA process.</p> <p>Patients and patient organizations are given the opportunity to participate in training to empower them so they can best contribute.</p>	<p>Proactive communication strategies are used to effectively reach, inform and enable a wide range of patients to participate fully in each HTA.</p> <p>Clear timelines are established for each HTA with advance notice of deadlines to ensure appropriate input from a wide range of patients.</p>	<p>Feedback is given to patient organizations who have contributed to an HTA, to share what contributions were most helpful and provide suggestions to assist the future involvement.</p>

APPENDIX 3

PCIG Values for Patient Involvement in HTA

The PCIG has developed the PCIG values as principles to be upheld in the involvement of patients in HTA processes (2014). These are expressed in terms of the IAP2 Public Participation Standards (Section 7) in relation to patients.

	RELEVANCE	FAIRNESS	EQUITY	LEGITIMACY	CAPACITY BUILDING
GOAL FOR HTA PROCESSES	Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.	Patients have the same rights to contribute as other stakeholders and have access to processes that enable effective engagement.	Patient involvement contributes to equity by seeking to understand the diverse needs of patients with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly.	Patient involvement facilitates those affected by the HTA recommendations or decisions to participate; contributing to the transparency, accountability and credibility of the decision-making process.	Patient involvement processes address barriers to involving patients and build capacity for patients and HTA organizations to work together.
	INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
GOAL FOR PATIENT EMPOWERMENT	You clearly understand your role in HTA, and its purpose	You are encouraged and supported in a fair and equitable way to provide relevant patient input	You receive relevant training so that you can integrate a number of perspectives and present your perspectives well. You are given the opportunity to utilize your knowledge and experience of the disease and its treatment to best inform HTA	You receive the right information and can build your capacity to provide effective input. Feedback is provided in a transparent, accountable way	You are able to form effective working relationships with the people involved in HTA processes. Impact is documented and gaps in knowledge identified and addressed

APPENDIX 4 Project Sub-Committee template

HTAI PCIG

PROJECT NAME:

Short Title: (max 15 letters)

Date

Project Summary

i Summarize the project in not more than 60 words. This summary will be uploaded to the PCIG website.

•

Project Aims and Description

i Describe the aims of the project

- Why is it needed
- What will it achieve
- Which audience it is designed for
- A general description of the project (no more than 2 paragraphs)
- (OPTIONAL) Special considerations – for example, listing skills that will be needed to complete this project (e.g. need involvement of team members experienced with preference studies, ...)

Project team

i Describe those involved

- Project lead
- Team members

Deliverables and Dissemination

i List the final deliverable, its format and how it will be disseminated

- Deliverable 1: (e.g.: A word document)
- Deliverable 2:
- Dissemination route (e.g.: HTAi PCIG resources pages, E-bulletin, peer reviewed journal, conference plenary...)

High-Level Timeline/Schedule



Outline the ball-park timeline for the project to be completed

- *E.g. Project kick-off Q1 2019,*
- *E.g. Draft deliverables sent for consultation Q3 2019*
- *E.g. Final deliverables sent for dissemination via X and Y channels in Q4 2019*