Improving meaningful public involvement in NICE medicines and technologies guidance

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# Introduction

This report has been compiled by the Centre for Health Technology Evaluation (CHTE) 2020 9c working group, which was established to help influence the future of patient and public involvement in CHTE programmes, and to ensure that vision is co-designed with the patients, carers and organisations we work with. The working group consisted of NICE representatives and patient organisations (David Chandler, Psoriasis and Psoriatic Arthritis Alliance; Holly Heath, Breast Cancer Now; Julie Fear, Arrhythmia Alliance; Mark Zwanziger, NET Patient Foundation; Shelagh McKinlay, Myeloma UK; and Tom Billins, Genetic Alliance UK).

# Background

1. NICE is undertaking a wide-ranging review of our [methods and process for health technology evaluation](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation). In November 2018 we set up a specific workstream to consider the public involvement aspects of this review, aiming to co-design realistic proposals for changes to public involvement in NICE’s medicines and non-medicines guidance (technology appraisals, highly specialised technologies, diagnostics, medical technologies and interventional procedures guidance).
2. To achieve this, the Public Involvement Programme (PIP) set up a working group. The aim of the working group was to:

* Identify improvements needed in the current approach using anecdotal evidence, direct and indirect feedback.
* Identify event invitees and audience for a targeted consultation.
* Work with stakeholders and internal colleagues to identify proposals for improvements.

1. These proposals would then be:

* Consulted on, with a targeted audience.
* Used for the wider methods and processes review for consideration and development.
* Finalised, and form part of the formal public consultation on the new methods and processes.

# Methodology

1. External organisations were invited to join the working group, selected for their experience working with NICE. The working group consisted of NICE staff (Public Involvement Programme representatives and the Associate Directors of relevant guidance types) and 6 patient members, comprising of individuals who have experience with NICE processes. This includes representation from:

* A Patients Involved in NICE (PIN) executive
* A patient organisation which was not a member of PIN
* Patient experts who have contributed to NICE’s medicines and non-medicines guidance
* Organisations with experience of providing patient commentary to NICE’s medicines and non-medicines guidance.
* A lay member involved with NICE’s medicines and non-medicines guidance.

1. Figure 1 shows the representation of the working group. The patient members on the working group were representatives from:

* Arrhythmia Alliance
* Breast Cancer Now, and member of The Charity Medicines Access Coalition
* Genetic Alliance UK and member of the Patients Involved in NICE executive group
* Myeloma UK
* NET Patient Foundation
* Psoriasis and Psoriatic Arthritis Alliance**Figure 1: representation on the working group**

1. The first working group meeting took place on the 11 January 2019, helping to shape the agenda and the invite list for a stakeholder event on the 24January 2019. Invitees were selected based on the following criteria:

* Spread of experience of participating in Diagnostics, Medical Technologies, Technology Appraisals, Highly Specialised Technologies and Interventional Procedures
* People and organisations who have participated in one or more medicines and non-medicines guidance before (i.e. not new to their role or to NICE)
* Mixture of longer experience and less experience
* Including members of Patients Involved in NICE (PIN) without making membership of PIN a requirement.
* Spread across disease areas, including rare diseases, trying to avoid disproportionate representation in any area.
* A mixture of patient organisation representatives and those experienced patient experts

1. The event was facilitated by Karen Facey, an academic expert in patient involvement in health technology assessment. The event’s aim was for participants to:

* Consider issues with current involvement processes and methodologies
* Understand the limits and parameters of the broader technology appraisals / highly specialised technologies / medical technologies / diagnostics processes
* Co-design proposals for improved ways of working, which were reviewed by the working group, and subjected to a targeted consultation in Q4 2018/19.

1. Twenty-two patient organisations with expertise across a spread of health areas attended the stakeholder event, all of whom had in-depth experience of participating in NICE health technologies guidance.
2. A report was drafted by Karen Facey, finalised by the working group and shared with all the event participants. The report drew out the following key themes from the event:

* Information collection and synthesis
* How patient evidence fits into modelling and health economics
* Understanding committee decision making and patient impact
* Understanding outcome and having feedback on patient impact
* Templates, tools and resources
* Training and support for patient organisations
* Training and support on submissions
* Training and support for patient experts
* Committee culture
* Committee chairing

1. Following the report, the working group prioritised themes to shape an online survey for patient groups. These priorities were then translated into questions for the ‘early engagement survey’.
2. The working group identified and agreed umbrella patient organisations for the survey and updates to be sent to. The umbrella groups identified were:

* Access to Cancer Medicines Coalition
* Arthritis and Musculoskeletal Alliance (ARMA)
* Blood Cancer Alliance
* Cancer 52
* CMAC (Charity Medicines Access Coalition)
* Dermatology Council for England (DCE)
* Findacure
* Genetic Alliance UK
* LSD collaborative
* Metabolic support UK
* National Voices
* Neurological Alliance
* PIN (Patients Involved in NICE)
* Richmond Group
* Specialised Healthcare Alliance

1. Between the stakeholder event and engagement survey, PIP presented and participated in question and answer (Q&A) sessions with external networks to provide updates. These included:

* April 2019 – presentation and Q&A for The Association of the British Pharmaceutical Industry Patient Organisation Forum
* May 2019 – email to umbrella groups
* June 2019 – email to umbrella groups
* June 2019 – presentation and Q&A for the Access to Cancer Medicines Coalition
* June 2019 – presentation and Q&A for Patients Involved in NICE (PIN)
* June 2019 – Q&A for Cancer 52

1. The umbrella organisations, along with the participants from the January event, were then emailed the survey in July and encouraged to circulate to their member organisations. They were sent a link to the online survey and a Word version of the survey. Attached to the email was a summary of the work, the reasons for doing it, and how patient groups were involved.
2. The survey was also promoted on the PIP twitter account, informing patient organisations of the work and encouraging them to participate.
3. Following constructive feedback on twitter, the survey was then emailed to all relevant patient organisations on the NICE database.
4. The PIP team monitored response rates and sent reminders and regular tweets to encourage participation.
5. After the survey had closed, PIP worked with the NICE Audience Insight team to analyse the results and present the data for the working group.
6. The working group met on the 5 September 2019 to review the data and identify key themes. Recommendations and proposals were developed by the working group and agreed on the 21st October.
7. The stages of patient group involvement in NICE’s methods and process review were:

* 11 January- working group meeting to agree the purpose of project, review feedback, and shape the stakeholder agenda and invitee list.
* 24 January- stakeholder event with 22 patient groups. Participants identified priorities and solutions for NICE by reviewing feedback from Cancer 52 and Genetic alliance, reports and charters, and international examples.
* 5 March- working group meeting to finalise the stakeholder event report and identify patient umbrella groups to communicate with.
* 22 March- stakeholder event report sent to all participants
* 29 April- working group meeting to discuss the themes and priorities from the stakeholder event report to help plan the early engagement and communication.
* 26 June- working group meeting to finalise early engagement, communications, and questions.
* Summer 2019- early engagement with patient stakeholders through online engagement for all patient groups who participate with NICE and umbrella groups.
* 5 September- working group meeting to go through results of the early engagement and shape priorities and proposals for methods and process groups
* 15 November 2019- final report send to the CHTE 2020 the methods working group.

# Results

1. 52 patient organisations completed to the survey, with experience of participating in a range of programmes:

* Technology Appraisals (N=36)
* Highly Specialised Technologies (N=14)
* Medical Technologies (N=12)
* Diagnostics (N=9)

1. The key findings of the survey were:

* Whilst most organisations were confident in their ability to feed into NICE processes, some questioned whether NICE provided adequate opportunities for public and patient involvement. Only small numbers thought it was easy for patient organisations and patient experts to get involved with NICE.
* There was a perceived lack of feedback from NICE to enable organisations and patient experts to identify which parts of their evidence were most helpful and inform future submissions. Greater transparency would help organisations be more effective, and increase confidence that committees are valuing patient evidence.
* Most would welcome greater support, advice and training from NICE. In particular, on what evidence will have the greatest impact, specifically when it comes to QALYs and ICERs.
* There was some interest in greater documentation and sharing of information through the consultation process.
* There was a perceived lack of clarity on the role of patient experts and what is needed from them, so additional guidance, training and support for patient experts from NICE would be welcomed.
* The vast majority were interested in exploring new ways for incorporating the patient voice in NICE processes - so long as this does not supersede involvement in later stages too.
* Generally, organisations didn't feel the committee culture or chairing was consistent, or that it sufficiently values or supports patient expert participation - therefore further committee training (beyond the inductions) is probably needed. A charter or standards for committee culture would be welcomed.

1. The results have been separated into 3 themes:

* Theme 1: Overall perceptions on engagement for patient organisations and patient experts
* Theme 2: Incorporating the patient voice for patient organisations and patient experts
* Theme 3: training and support needs for patient organisations, patient experts and committees

1. A summary of the data can be found in appendix 1.

## Theme 1: Overall perceptions on engagement

**Figure 2: the confidence rates of respondents in NICE processes.**

1. Most organisations felt relatively confident in their interactions with NICE, having been involved with technology appraisals in a variety of ways over time.
2. Specifically, finding and supporting patient experts and responding to consultations was a key area of expertise, but one that many acknowledged could still be improved upon.
3. Involvement at scoping stages was also something organisations felt comfortable supporting with, though it can be inconsistent and time intensive.
4. Whilst relatively confident in gathering evidence and writing submissions, some felt less sure of whether what they are doing is useful to NICE or being listened to.

“Regarding the collection or usage of data, we are confident in our ability to do this; the issue for us lies more in knowing what is useful to NICE. We would like more information about the type of data to collect and what topics/issues these should address.”

**Comment from survey respondent**

1. Lower confidence was particularly apparent for appeals and technical engagements. Some had yet to participate in these, however others highlighted that the complex technical processes can be a barrier to participation in technical engagements.

### Recommendation 1: NICE to ensure different processes and involvement opportunities are explained, prioritising the appeal and technical engagement processes.

1. Many factors were identified which influenced a patient organisation or patient expert’s ability to participate fully, in particular:

* Size and resources of the organisation
* Level of technical expertise
* Previous experience in NICE processes.

1. Individuals and smaller charities often have to balance NICE commitments with other work, caring commitments or ‘coping as patients’. This means they don’t always have the time and resources to fully participate.
2. Capacity restraints arose with larger organisations too – as with numerous guidance developments in progress at any one time, it can be hard for organisations to prioritise between these and other work.

“Although we find it easy as a well-resourced charity, that has been involved over many years, we know that other charities are not aware of how to sign up as a stakeholder, let alone any detail on the steps of the process and when they should be commenting or participating.”

**Comment from survey respondent**

### Recommendation 2: NICE to review programme process charts and key timeline diagrams to ensure clarity of involvement opportunities for patient organisations.

1. For some technology appraisals, the size of the patient population was identified as being limiting factor in nominating patient experts or submitting evidence. This was identified as something that could become a more significant problem as companies explore products for increasingly rare conditions. Some feel this may have implications for the suitability of the QALY.
2. Similarly, for technology appraisals for late stage cancers, respondents identified that survival benefits are often in the order of months not years, meaning patient experts might not be alive at the time of the committee meeting.
3. The need to physically attend meetings was identified as a barrier, as it prohibits involvement from less mobile patient groups. Patient organisations suggested video conferencing should be explored, and would welcome written submissions for all guidance types.

### Recommendation 3: NICE to explore additional ways to present patient information.

1. Some respondents highlighted a lack of consistency in engagement with patient organisations, for example the list of key stakeholders to consult with can miss key patient organisations.

### Recommendation 4: NICE to review stakeholder engagement processes throughout all programmes to ensure accurate stakeholder identification and involvement is consistent

1. Figure 3 shows the percentage of respondents who agreed with statements around ease and opportunities of involvement.

**Figure 3**

1. Whilst relatively confident in their roles in relation to NICE, very few patient organisations saw involvement (by themselves or patient experts) with NICE as easy, beyond a relatively superficial level.
2. The complexities of the decision-making process, by their nature, meant that involvement can be very demanding and time consuming.
3. Similarly, whilst there are lots of opportunities for the public and patient organisations to get involved in developing guidance, many raised concerns around whether their voices were being heard at key decision-making stages. Essentially, if there aren’t mechanics in place to consider patient evidence then the opportunity isn’t adequate.
4. Following the same theme, patient organisations felt NICE was transparent on a relatively superficial level. There are open meetings and public documentation, but organisations felt it lacked a level of detail that would enable them to truly understand decision making.

### Recommendation 5: NICE to review if the final appraisal document meets audience’s needs in explaining how the final draft decision was reached.

### Recommendation 6: NICE to ensure policy positions explain which decisions are out of NICE’s control.

1. Figure 4 shows the percentage of respondents who agreed with statements around feedback, clarity and transparency.

**Figure 4**

1. There was a perceived lack of feedback and transparency from NICE to enable organisations and patient experts to identify which parts of their evidence was most helpful to inform future submissions. This was particularly true when drugs which have not been approved have ‘stock phrases’ like there ‘was not enough evidence at this time’, which was not deemed to be sufficiently clear. More transparency on the gaps in information and how decisions were reached would be welcome here.
2. It was felt that greater transparency around this would not only enable organisations to be more effective in responding to consultations, but also increase confidence that committees are valuing patient evidence. Something that isn't always clear currently.

“Although we recognise this is not always easy to quantify, a fuller explanation of how the patient perspective was considered in the committee discussion and whether certain details were particularly helpful, would give us valuable feedback.”

**Comment from survey respondent**

“NICE should give detailed feedback and transparency on the impact of patient organisation submissions on the committee’s decisions. This is vital to understand how to approach future NICE appraisals and understand the impact of our advocacy work.”

**Comment from survey respondent**

### Recommendation 7: NICE to explore how to communicate gaps in evidence and the information required.

### Recommendation 8: NICE to explore including patient specific questions during (ACD type) consultations where the initial draft recommendation is negative.

### Recommendation 9: NICE to explore mechanisms to provide feedback to patient organisations following a submission or testimony, explaining how their information influenced the decision.

## Theme 2: Incorporating the patient voice for patient organisations and patient experts

1. Figure 5 shows the percentage of respondents who agreed with statements around the committee culture.**Figure 5**
2. Generally, organisations didn't feel the committee culture or chairing is consistent, or that it sufficiently values or supports patient expert participation.
3. Whilst there are examples of good practice, more poignant stories of feeling disregarded or irrelevant were prominent. Specifically, organisations raised concerns about:

* insufficient time being allocated to patient experts

“patients are given “their 5 minutes”, but not really asked to engage.”

**Comment from survey respondent**

* committee members apparently not listening to submissions

“patient experts feel that some committee members do not pay attention to the invited stakeholders (for example, not lifting their eyes from their laptops).”

**Comment from survey respondent**

* discussions held in an insensitive way, given how personal the appraisal is likely to be to patient experts.

### Recommendation 10: NICE to review the committee guide to ensure there are clear standards for all committee members to follow.

1. Whilst most acknowledged they need to work with lay members (84% agree), a few respondents raised concerns over whether the process by which lay members represent patient views was fair.

### Recommendation 11: NICE to explore how and when the patient evidence is presented to the committee

1. The majority of patient organisations were interested in exploring new ways for better incorporating the patient voice in NICE processes, for example through:

* pre-committee meetings for example the Scottish Medicines Consortium’s PACE meetings (92% agree)
* focus groups to gather evidence from patients and clinicians (88% agree)

1. It was felt these should be piloted correctly, with clear guidance on when to use. It was also felt that these new methods do not supersede involvement in scoping workshops and consultations, or later stages of consultation.

### Recommendation 12: NICE to explore other methods to incorporate the patient voice

1. A couple of organisations also highlighted a desire to attend or contribute towards other processes, for example attending the second committee meeting, feeding into decisions over whether to use STA or HST and contributing to committee documents on the condition.
2. Patient organisations felt the process for involving patients and patient experts in technical engagement also needed improvement (82% agree), with some commenting that it’s not clear how the patient voice is incorporated. Others highlighted that the highly technical nature of the engagement, documents and processes acted as a barrier to most patient experts.

### Recommendation 13: NICE to review information explaining the technical engagement process to meet audience need.

1. Despite these barriers, most organisations believed it’s still important for patient experts to play a role, with just 36% agreeing that organisations should be involved instead of patients.
2. Patient organisations didn’t typically feel that they get enough information on what the committee needs at each stage of the process (just 31% agree they do) and nor do they feel patient experts get enough information (just 24% agree the do).
3. Whilst this clearly relates to the earlier point on needing feedback on what information is most useful, it is not exclusively related to this. For example, they would also value support negotiating the committee documents to identify the areas most pertinent to them, and where the patient voice is most needed (particularly if committee documents are shared late).

### Recommendation 14: NICE to review the support available to help navigate and understand committee documents.

1. On the whole organisations were happy with the patient expert and patient organisation submission forms, and feel they strike the right balance without being too broad/generic or too focused (as they appreciate creating bespoke forms each time would be excessively time consuming).
2. There was interest in greater documentation and sharing of information through the consultation process and on the NICE website. Specifically, that:

* NICE should provide an agreed summary of the condition and patient issues (92% agree)
* Following an appraisal information from patient groups on the disease should be kept on the NICE website (90% agree).

1. However, in the comments, this was not raised as a major concern and needed to be balanced against the potentially intense work involved in developing these. Rather than wanting more information, many were seeking streamlined, easier to digest communications and contact.
2. Whilst broadly happy with communications about changes in timelines (58% feel they are adequate), knowing why delays had occurred would aid with further communications.

### Recommendation 15: NICE to ensure stakeholders receive regular informative communications and information.

## Theme 3: training and support needs for patient organisations, patient experts and committees

1. Figure 6 shows the percentage of respondents who agreed with statements around support and training.

**Figure 6:**

1. Patient organisations felt structured, tailored, support across the process would be particularly welcome, as it would allow people to access the training they need, when they need it. Ideally this would be:

* layered, to enable basic introductions for newcomers and more detailed support for experts
* specific and focussed, so can target gaps in understanding (given time constraints)
* clearly communicated and promoted; as it’s not always clear what support is available
* remotely accessible with a combination of e-learning, webinars and user guides .

“As much online, accessible guidance (webinars, for example) is appreciated as smaller organisations do not always have the resources to send staff to training.”

**Comment from survey respondent**

1. There was interest in a broader annual training event, as an opportunity to refresh on processes and encourage peer support and collaboration. However, concerns around practicalities and content were voiced.

### Recommendation 16: NICE to review the information and support offered to patient organisations

1. Figure 7 shows the percentage of respondents who agreed with statements around specific training and support for patient organisations.

**Figure 7:**

1. Patient organisations would like more support and clarity on what to include in submissions and what will have the greatest impact.
2. Case studies, or best practice examples, would be particularly useful here, ideally supported with commentary from committee members or chair explaining why it was useful.
3. Specific gaps in knowledge were identified around economic modelling, with over 90% of respondents wanting to see additional guidance, training and support on understanding NICE processes. In particular, more on quality of life (QoL), quality-adjusted life-years (QALYs) and incremental cost-effectiveness ratios (ICERs)

“Although we understand the cost-effectiveness elements in basic terms, it would be useful to have a refresher to help us better understand the context and enable us to estimate for ourselves whether a treatment might be on the boundary between clinically/cost effective or not.”

**Comment from survey respondent**

“It took me a lot of studying and searching the internet to understand QALY's and ICERs. Some training or at least an explanatory pdf would have been very welcome.”

**Comment from survey respondent**

### Recommendation 17: NICE to review information and support tools, explaining how committees reached their decision.

1. Figure 8 shows the percentage of respondents who agreed with statements around support and training for patient experts.

**Figure 8:**

1. Organisations didn't think NICE is clear on the role of the patient experts or what it needs from them. Many felt it is not clear to what extent patient experts can influence decisions.
2. This appears to be rooted in some confusion over whether they are individual expertsin the process or if they need to represent the views of the whole patient community. With implications for whether it’s the patient expert that needs training, or the committee and chair that need training on how to value and involve them.

### Recommendation 18: NICE to review the information provided on the role of patient experts.

1. Many noted that patient experts were often overwhelmed by the amount of reading and technical language involved. Plain English summaries, and guidance on areas/questions that are most relevant to patient experts, would be welcomed.
2. Most would also like to see additional guidance, training and support for patient experts from NICE. With a few suggestions that NICE should offer emotional support and counselling for patient experts where needed given the significant emotional burden they face.

# Proposals to meet recommendations and next steps

1. Table 1 has been developed by the working group, using feedback from the early engagement survey and the stakeholder event to develop proposals to meet the 18 recommendations within this report.
2. The CHTE 2020 programme team are asked to:
   1. consider the report and review the recommendations and proposals.
   2. agree the relevant workstream each recommendation should be sent to.
   3. agree what information will be shared with participants and the public. This could be publishing the full report on the CHTE 2020 NICE webpages or producing summary information (N.B. as the participants were anonymous, NICE should publish this information in the public domain).
3. Workstreams are asked to consider the recommendations and include relevant proposals in their workplan.

### Table 1: Proposals to meet recommendations

|  |  |
| --- | --- |
| Recommendation | Proposal to meet recommendation |
| Recommendation 1:  NICE to ensure different processes and involvement opportunities are explained, prioritising the appeal and technical engagement processes. | Update current guides and factsheets to ensure stakeholders understand how they can participate in CHTE related topics. The review will include:   * + - Including links to existing process timelines from relevant CHTE web pages     - Development of appeal and technical engagement guides     - Ensure PIP web pages are linked from relevant CHTE web pages     - Update internal templates with relevant web page links and PIP contact details     - Review communication process by PIP to patient group stakeholders following notification of CHTE topics     - Explore the use of social media to promote CHTE topics     - Promote guides and key contacts to patient organisations     - Develop appeal and technical engagement patient process guides     - Promote all guides to patient organisations     - Add links to these guides and fact sheets in CHTE templates, letters, and on each programme’s webpages.     - Review process of following up invitation to participate (ITP) and expert invites. ITP is the initial communication from NICE starting a new guidance topic.     - Explore the use of social media to promote the ITP stage, linking to relevant NICE web pages. |
| Recommendation 2:  NICE to review programme process charts and key timeline diagrams to ensure clarity of involvement opportunities for patient organisations. | * + - Publish all programme process charts, and diagrammatic timelines, with the key patient involvement opportunities clearly marked.     - Included links to these within PIP support resources and webpages.     - Include links to these within key guidance topic emails.     - Develop statements for the website to explain the reasons guidance could get delayed. Include links to these statements in communications to stakeholders with clear signposting to the relevant team (e.g. the PIP team and the developer team). |
| Recommendation 3:  NICE to explore additional ways to present patient information. | * + - Explore the use of written submissions in all guidance types     - Explore video conferencing to present patient information, especially for topics with reduced mobility patient groups.     - HST’s currently accept nominations from pharma companies, but these are usually routed via a patient group. CHTE to consider stopping this.     - Engage with patient organisations to ask for their suggestions to engage end-of-life patient experts.     - Engage with patient groups to ask for their suggestions to engage hard to reach or find groups. |
| Recommendation 4:  NICE to review stakeholder engagement processes throughout all programmes to ensure accurate stakeholder identification and involvement is consistent. | * + - Review current stakeholder identification processes across guidance stages and different programmes.     - Review the process of asking organisations to become stakeholders for different parts of a technology appraisal (e.g. organisations who participate in medicines scoping are then asked whether they want to participate post scoping, which causes confusion). |
| Recommendation 5:  NICE to review if the appraisal consultation document and final appraisal document meets audience’s needs in explaining how the final draft decision was reached. | * + - NICE to review current documents to ensure they explain a decision in an understandable format or consider a separate patient explanation document.     - NICE to review how to explain how the patient contribution affected the decision making. |
| Recommendation 6:  NICE to ensure policy positions explain which decisions are out of NICE’s control. | * + - Review the policy positions to ensure they adequality communicate which decisions are out of NICE’s control and the reasons for this. This might include Managed Access Agreements (MAAs) and Patient Access Schemes (PASs).     - Promote these policy position during appropriate communication with stakeholders. |
| Recommendation 7:  NICE to explore how to communicate gaps in evidence and the information required. | * + - Review communication with patient organisations to inform them what specific information is required from patient experts and patient organisations at the beginning of, or during, a given guidance topic.     - Review whether it’s possible to include topic specific questions in the patient organisation and expert templates as standard rather than exceptionally. This information may be identifiable during the final scope sign-off.     - Review developing a link between the lay lead and the patent organisation before the committee meeting. This would be managed through PIP.     - Review support documents and information to help organisations understand what information is often required and how to generate it. |
| Recommendation 8:  NICE to explore including patient specific questions during (ACD type) consultations where the initial draft recommendation is negative. | * + - When a technology is not recommended after the first committee meeting, explore whether patient specific questions can be included in the consultation document as standard (which mirrors the positioning of the SMC’s PACE – pre final committee and when the draft recommendation is a no). |
| Recommendation 9:  NICE to explore mechanisms to provide feedback to patient organisations following a submission or testimony, explaining how their information influenced the decision. | * + - Review the benefits of the feedback letter process used in the IP and HST programmes. If appropriate, replicate the practice throughout CHTE. This could involve using the lead team members and specialists. |
| Recommendation 10:  NICE to review the committee guide to ensure there are clear standards for all committee members to follow. | * + - Review the committee guide to ensure there are clear standards committee members must follow. For example, appendix B of the [supporting information for applicants](https://www.nice.org.uk/Media/Default/Get-involved/Join-a-committee/Member/member-interventional-procedures-info.pdf).     - Review the policy on appointments to ensure it covers key aspects.     - Regularly remind committee members of the guide and standards within.     - Provide feedback to committees from patient organisations and experts, using exit survey data and PIP intelligence.     - Develop a committee charter for committee members to sign and review annually (e.g. at away days). This charter should be co-designed with committee members and stakeholders to include values and behaviours expected. This charter can then be measured against during tenure renewals and form part of inductions and training. |
| Recommendation 11:  NICE to explore how and when the patient evidence is presented to the committee. | * + - Explore whether patient slides can be presented at the beginning of committee meetings and scoping workshops (when the latter are held).     - Develop an enhanced role of the lay lead, especially during the technical engagement steps to ensure the lay lead can focus on the correct part of a patient submission. |
| Recommendation 12:  NICE to explore other methods to incorporate the patient voice. | * + - Review methods used by other HTA organisations (e.g. the SMC PACE meeting).     - Evaluate the extra technical engagement step currently being piloted in TA and consider implementing it in all programmes. This extra technical engagement step is a separate conference call with patient organisations, patient experts and the committee lay lead, conducted before the main technical engagement teleconference and first committee meeting.     - Invite patients to the second committee meeting if there is a specific thing that they can add, informing them of what they can add in advance.     - Consider new methods, such as implementing decision explanation documents as used by the Scottish Medicines Consortium. |
| Recommendation 13:  NICE to review information explaining the technical engagement process to meet audience need. | * + - Review current information to ensure it provides clear information explaining the technical engagement process and how the patient voice is incorporated into it.     - Explore including a ‘patient engagement’ step within the technical engagement process (currently TA only).     - Explore including a ‘patient engagement’ step and technical engagement in other CHTE programmes such as HST. |
| Recommendation 14:  NICE to review the support available to help navigate and understand committee documents. | * + - Develop support documents and information to help navigate and understand committee documents, explaining what the sections are and the information within.     - Promote support currently offered by PIP to patient organisations once they register as a stakeholder.     - Explore working with a patient organisation to share their experience of involvement with NICE, linking personal experience with the process guides and helpful resources on the website.     - Provide patient (and other) experts with ‘overview’ committee slides in advance of the committee meeting including the items for discussion so that they can better contribute at the meeting. |
| Recommendation 15:  NICE to ensure stakeholders receive regular informative communications and information. | * + - Review communication practices to inform stakeholders when timelines have altered and provide an explanation where appropriate. This includes on-going communication when delays last longer than originally communicated.     - Use plain language in communications, being considerate of the tone and time when the communication is sent (e.g. not a Friday afternoon). |
| Recommendation 16:  NICE to review the information and support offered to patient organisations | * + - Host webinars and develop e-learning modules.     - Update and promote toolkits and guides. |
| Recommendation 17:  NICE to review information and support tools, explaining how committees reached their decision. | * + - Review information provided to stakeholders around its use of QoL, QALY and ICER.     - Promote information to stakeholders around its use of QoL, QALY and ICER.     - Review decision notes to ensure they explain how committee decisions were made. This includes which specific factors influenced their decision and how the evidence influenced them (e.g. the technology was not cost effective due to X factors after discount fees were applied). This could be similar to consultation comments tables used in guidelines. |
| Recommendation 18:  NICE to review the information provided on the role of patient experts. | * + - Update information provided to patient experts and nominating organisations to explain the role of the patient expert, information about how the committee works, and the available support from PIP and CHTE. This should be done in collaboration with patients and CHTE, with the use of real-life examples.     - Explore translating this information into a webinar as an optional additional resource.     - Ensure the role of the nominating organisation in supporting patient experts, including emotional support, is clear in documentation/resources.     - Review the availability of this information. |

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### Appendix 1: Summary of data

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Very confident | Confident | OK | Not confident | Not confident at all | Not applicable | TOTAL (n) | Very confident/ confident (%) | Not at all/ Not confident (%) |
| Supporting patient experts | 15 | 25 | 7 | 0 | 0 | 3 | 50 | 80% | 0% |
| Finding and nominating patient experts | 17 | 19 | 8 | 3 | 1 | 2 | 50 | 72% | 8% |
| Responding to guidance consultations | 11 | 25 | 10 | 2 | 0 | 2 | 50 | 72% | 4% |
| Participating in scoping consultations | 16 | 19 | 9 | 4 | 1 | 1 | 50 | 70% | 10% |
| Participating in scoping workshops | 12 | 20 | 10 | 4 | 1 | 3 | 50 | 64% | 10% |
| Gathering data for evidence submissions | 9 | 21 | 11 | 6 | 1 | 1 | 49 | 61% | 14% |
| Writing evidence submissions | 11 | 19 | 12 | 4 | 1 | 1 | 48 | 63% | 10% |
| Putting in a NICE appeal/resolution | 2 | 13 | 16 | 5 | 2 | 12 | 50 | 30% | 14% |
| Responding to the technical engagements (TA only) | 3 | 8 | 17 | 10 | 4 | 8 | 50 | 22% | 28% |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| I am confident in being able to explain NICE’s recommendations after they have been published to our members | 7 | 27 | 7 | 9 | 0 | 0 | 50 | 68% | 18% |
| NICE provides adequate opportunities for patient involvement from organisations and experts in health technology appraisal guidance | 1 | 20 | 9 | 14 | 2 | 2 | 48 | 44% | 33% |
| It is easy for the public and patient organisations to get involved in the development of NICE guidance | 1 | 16 | 13 | 17 | 2 | 0 | 49 | 35% | 39% |
| It is easy for individual people with the condition (patient experts) to get involved at NICE | 0 | 10 | 8 | 22 | 8 | 1 | 49 | 20% | 61% |

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|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| My patient organisation would like tailored support and structured training throughout the process to improve participation | 14 | 28 | 6 | 2 | 0 | 0 | 50 | 84% | 4% |
| NICE should host an annual training event for participating patient organisations. | 23 | 17 | 9 | 1 | 0 | 0 | 50 | 80% | 2% |
| I am aware of the support and training offered by NICE to support the involvement of patient organisations | 8 | 21 | 2 | 12 | 6 | 1 | 50 | 58% | 36% |
| NICE is clear about what they want from patient organisations and what will have the greatest impact | 2 | 16 | 7 | 16 | 6 | 2 | 49 | 37% | 45% |
| NICE is clear on what support is available for patient organisations | 4 | 12 | 12 | 11 | 9 | 2 | 50 | 32% | 40% |

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|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| NICE should support patients and organisations to understand the importance of quality of life measures collected in trials, and how these are used in NICE's economic modelling. | 26 | 22 | 1 | 1 | 0 | 0 | 50 | 96% | 2% |
| NICE should provide support and advice to patient organisations about collecting evidence about the value of the treatment for patients | 18 | 28 | 3 | 1 | 0 | 0 | 50 | 92% | 2% |
| My organisation would like training on understanding Health Economics and cost effectiveness, including how Quality Adjusted Life Years (QALYs) and Incremental Cost Effectiveness Ratios (ICERs) are used at NICE. | 30 | 15 | 2 | 3 | 0 | 0 | 50 | 90% | 6% |
| My organisation would like training on how our evidence can help influence the Health Economic modelling. | 31 | 14 | 4 | 0 | 0 | 0 | 49 | 92% | 0% |
| NICE should provide training for patient organisations on writing submissions | 15 | 28 | 6 | 0 | 0 | 0 | 49 | 88% | 0% |
| My organisation would like training on understanding how clinical evidence is used at NICE | 26 | 16 | 3 | 5 | 0 | 0 | 50 | 84% | 10% |
| The patient organisation template is too generic | 4 | 18 | 20 | 3 | 0 | 3 | 48 | 46% | 6% |
| NICE provides adequate support on what to include in submissions | 2 | 14 | 10 | 16 | 3 | 4 | 49 | 33% | 39% |

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|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| NICE should provide guidance for patient experts on completing their statements | 20 | 26 | 3 | 1 | 0 | 0 | 50 | 92% | 2% |
| NICE should promote structured training and tailored support for patient experts | 21 | 22 | 5 | 1 | 1 | 0 | 50 | 86% | 4% |
| NICE is clear about the role of patient experts | 3 | 21 | 8 | 11 | 2 | 5 | 50 | 48% | 26% |
| NICE is clear about what we need from patient experts | 2 | 17 | 7 | 17 | 2 | 5 | 50 | 38% | 38% |
| The patient expert statement template is too generic | 4 | 14 | 22 | 3 | 0 | 7 | 50 | 36% | 6% |
| NICE is clear about what support is available for patient experts | 2 | 15 | 11 | 16 | 2 | 4 | 50 | 34% | 36% |

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|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| NICE should provide an agreed summary of the condition and issues important to patients | 26 | 20 | 2 | 0 | 0 | 2 | 50 | 92% | 0% |
| NICE should have a pre-committee meeting which involves patients, for example the <a href>Scottish Medicines Consortium’s (SMC) Patient and Clinician Engagement (PACE)</a> | 29 | 17 | 3 | 1 | 0 | 0 | 50 | 92% | 2% |
| Once NICE has appraised a disease, the information from patient groups about living with the condition and current treatments should be kept on the NICE website, and updates made in consultation with patient groups | 24 | 21 | 3 | 1 | 0 | 1 | 50 | 90% | 2% |
| In submissions, NICE should ask patient organisations what is different about the new treatment | 19 | 26 | 2 | 1 | 0 | 1 | 49 | 92% | 2% |
| To gather evidence, patient organisations would welcome the option of a focus group, that would include patients and clinicians, to draw out and summarise all the key issues for the condition and the treatment being considered | 29 | 15 | 5 | 0 | 1 | 0 | 50 | 88% | 2% |
| NICE should increase the value of patient evidence and its impact | 37 | 7 | 4 | 0 | 0 | 2 | 50 | 88% | 0% |
| Patient organisations and experts need to work with the committee lay members | 29 | 13 | 6 | 0 | 0 | 2 | 50 | 84% | 0% |
| NICE should improve patient involvement in technical engagement | 21 | 19 | 7 | 0 | 0 | 2 | 49 | 82% | 0% |
| NICE should include patient organisation stakeholders in the technical engagement, but not include individual patient experts | 10 | 8 | 18 | 7 | 3 | 4 | 50 | 36% | 20% |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| Committee chairs need training on the value of patient evidence and how to better include the patient experts in the committee discussions | 19 | 16 | 10 | 0 | 0 | 5 | 50 | 70% | 0% |
| My patient organisation feels that the patient expert participation is valued by the committee chairs | 4 | 14 | 13 | 14 | 2 | 3 | 50 | 36% | 32% |
| NICE has consistency in chairing styles | 5 | 5 | 11 | 12 | 5 | 12 | 50 | 20% | 34% |
|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| NICE should have standards or a charter to help improve committee culture to be more patient inclusive and give greater value to patient evidence | 27 | 16 | 3 | 0 | 0 | 3 | 49 | 88% | 0% |
| NICE should provide ongoing training for committee members beyond their induction | 17 | 23 | 5 | 1 | 0 | 4 | 50 | 80% | 2% |
| NICE ensures that there is consistency of opportunities for patient experts to be involved across all health technology committees | 4 | 7 | 12 | 9 | 0 | 18 | 50 | 22% | 18% |
| The committee culture is supportive to patient experts | 2 | 7 | 13 | 19 | 3 | 6 | 50 | 18% | 44% |
| NICE provides adequate induction training for committees, the NICE technical team and the assessment organisation that embeds patients’ values and equal standing | 1 | 5 | 9 | 10 | 1 | 22 | 48 | 13% | 23% |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| My organisation and patient experts would like to know how their evidence translates into Quality of Life (QoL) measures | 31 | 18 | 0 | 0 | 0 | 1 | 50 | 98% | 0% |
| My organisation and patient experts would like to have a greater understanding of how the calculations around the Quality Adjusted Life Years (QALYs) and Incremental Cost Effectiveness Ratios (ICERs) have been achieved so that we can better target our evidence to help. | 28 | 20 | 1 | 1 | 0 | 0 | 50 | 96% | 2% |
| NICE should provide a summary showing what factors contributed to the decision | 29 | 18 | 0 | 1 | 1 | 1 | 50 | 94% | 4% |
| My organisation receives enough information on what the committee needs from us at each stage of the process | 3 | 12 | 8 | 17 | 2 | 7 | 49 | 31% | 39% |
| NICE provides clarity and transparency on how decisions are made | 5 | 8 | 5 | 22 | 7 | 3 | 50 | 26% | 58% |
| My organisation believes patient experts receive enough information on what the committee needs from them at each stage of the process | 2 | 10 | 8 | 18 | 3 | 8 | 49 | 24% | 43% |
| NICE is clear on how it uses patient reported outcomes | 1 | 6 | 10 | 19 | 6 | 8 | 50 | 14% | 50% |

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|  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | Don't know | TOTAL | Strongly agree/agree (%) | Strongly disagree/disagree (%) |
| Patient experts would like to know what parts of their evidence were helpful to the committee’s decision making and why | 31 | 18 | 1 | 0 | 0 | 0 | 50 | 98% | 0% |
| My organisation would like feedback and transparency on the impact of their submissions on the committee’s decisions | 30 | 18 | 2 | 0 | 0 | 0 | 50 | 96% | 0% |
| NICE keeps my organisation adequately up to date with changes to the timeline | 9 | 20 | 7 | 9 | 2 | 3 | 50 | 58% | 22% |
| NICE should adopt a framework for engagement based on Health Technology Assessment International (HTAi) Values and Standards similar to the <a href>Canadian model at the Canadian Agency for Drugs and Technologies in Health (CADTH) such as fairness, equity, communication, support and feedback</a>. | 6 | 12 | 14 | 0 | 0 | 17 | 49 | 37% | 0% |
| Patients and organisations understand the importance of commercial access schemes (such as <a href>PAS</a>s) | 6 | 7 | 10 | 19 | 5 | 2 | 49 | 27% | 49% |
| My organisation understands the patients' role in commercial access schemes | 4 | 7 | 9 | 21 | 5 | 4 | 50 | 22% | 52% |