



# Reviewing and updating NICE's methods and processes

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# What is the difference between methods and process?

## Methods

Way in which evidence is collected and considered in forming guidance

### Examples:

the principles that are adopted  
the ways in which different types of evidence are used  
the considerations that go into making recommendations

## Process

Steps that are taken at different stages of assessment

### Examples:

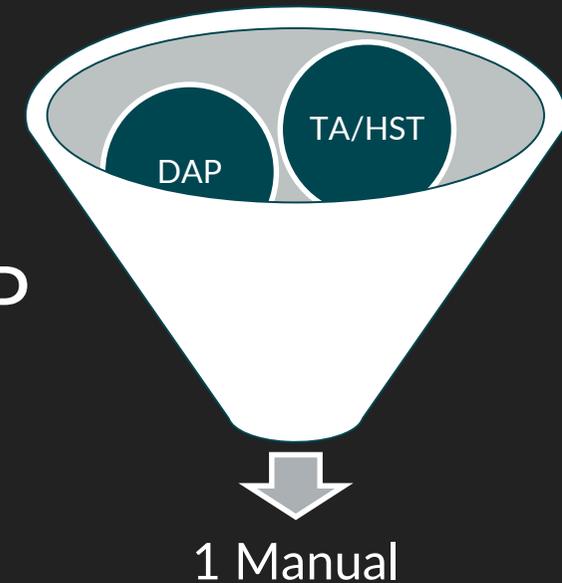
which documents are submitted or produced and when  
how individuals and organisations are involved  
the timings of each step

# Why do we need to review?

- Changing landscape and needs of our system partners
  - introduction of the new process (technical engagement), cancer drugs funds, highly specialised technologies means methods have evolved)
- Multiple guides, addendum and supporting documents – it's confusing, complex and not easily accessible
- NICE committed to review process and methods in 2019 Voluntary Scheme
- Changing nature of the technologies we see
- Lessons learnt from past appraisals

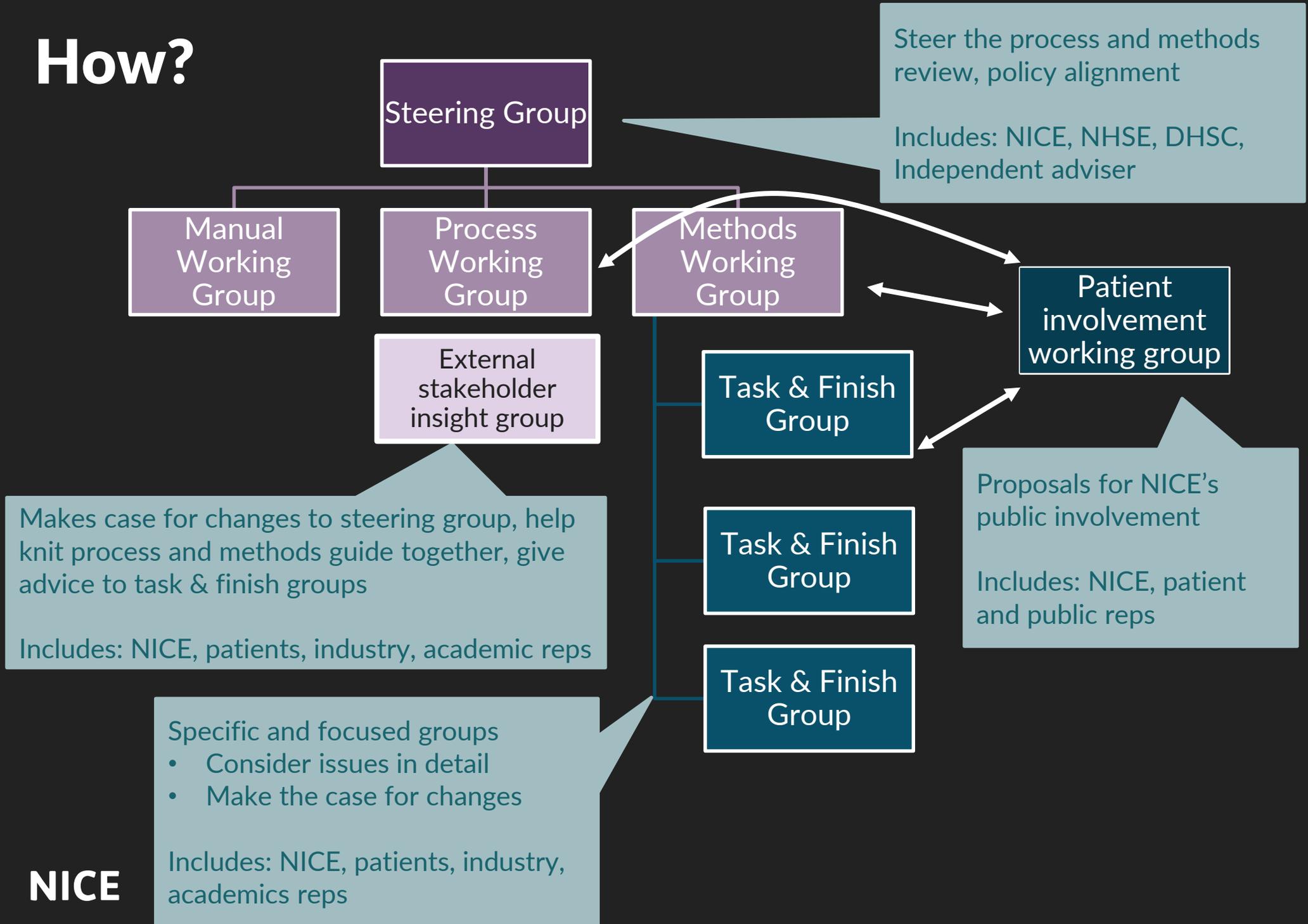
We want to align methods and process for Health Technology Assessment for all innovative technologies

- 4 programmes: TA, HST, MTEP, DAP
- includes drugs, devices, diagnostics
- have common principles
- retain methodological and process differences where there is a clear rationale



This is evolution, not revolution

# How?



# Process areas for review

Scheduling / planning

Stakeholders

Evidence submission  
(company, patient,  
professional,  
commissioner, other)

Independent critique

Technical  
engagement /  
Committee  
preparation

Committee meetings  
(1st, 2nd and so on)

Draft (and draft final)  
guidance  
consultation

Appeal and resolution

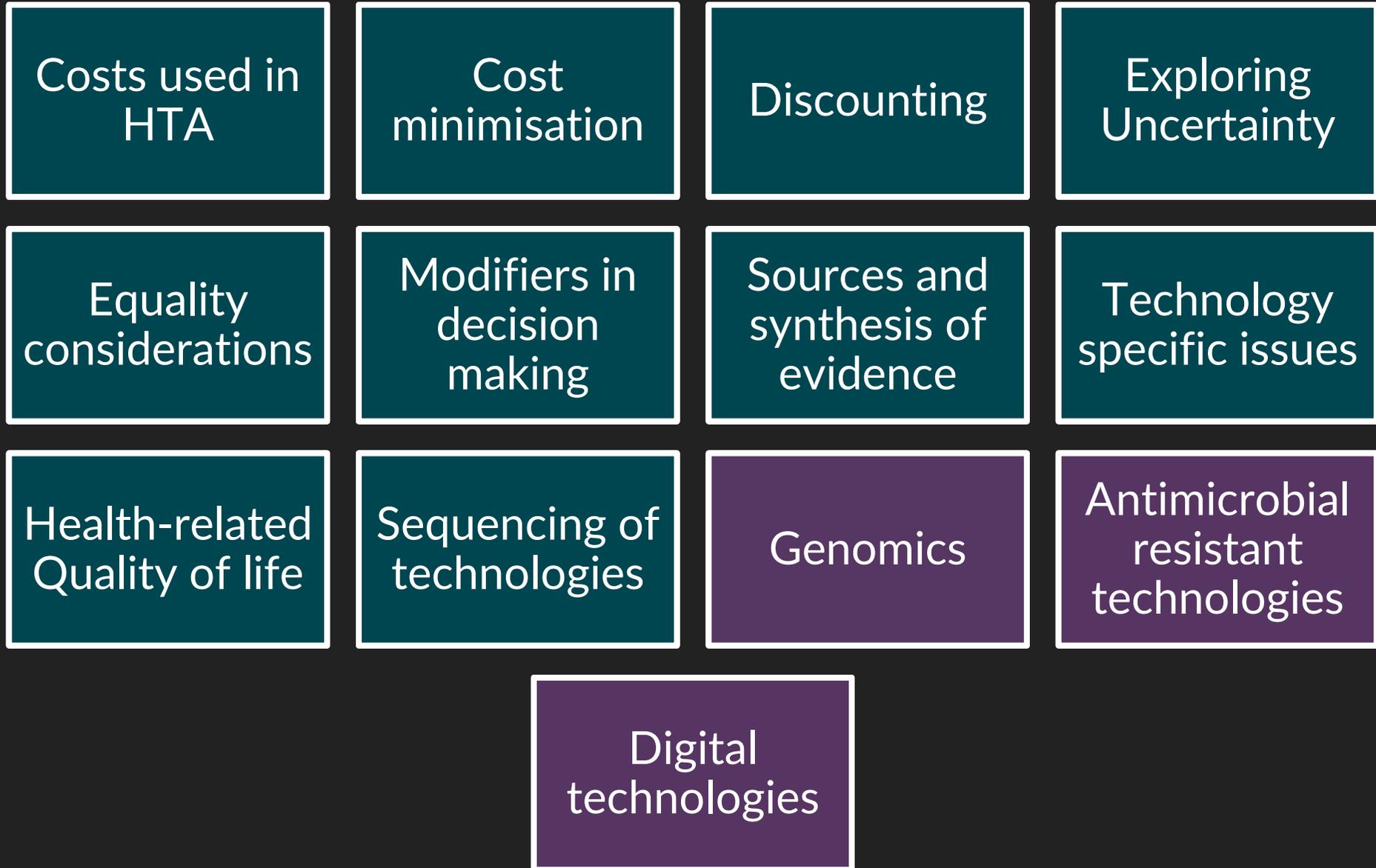
Review  
Consideration /  
Surveillance

Peri- and post-  
publication -  
publishing, comms,  
adoption, RIA

Budget Impact Test

Impact of TA/HST  
charging

# Methods areas for review



# A flavour for what might be looked at..

Topic	What we will be reviewing
Modifiers considered in decision making	<ul style="list-style-type: none"><li>• General framework</li><li>• Unmet need</li><li>• Curative potential</li><li>• Burden of illness and severity</li><li>• Innovative nature of the technology</li><li>• Policy priorities</li><li>• Well being</li><li>• Experience of care &amp; organisational efficiency</li></ul>
Types of evidence (synthesis and sources)	<ul style="list-style-type: none"><li>• Randomised and non-randomised evidence</li><li>• 'Real world' evidence</li><li>• Qualitative evidence, patient evidence, and elicitation</li><li>• Generalisability and bias associated with evidence</li><li>• How to combine this information</li></ul>
Health related quality of life	<ul style="list-style-type: none"><li>• Use of EQ-5D and valuation set</li><li>• Quality of life for children, carers and for people with rare disease</li></ul>

# Methods working group and task and finish groups

- Will assess the case for changing the methods
- Multi stakeholder
  - Includes 3 patient organisation members
    - including overlap with the patient involvement working group
    - Includes task and finish groups which will include additional patient members
- First meetings October 2019 onwards

# Methods task and finish groups

## Costs used in HTA

- Prostate cancer UK

## Cost minimisation

- MTAC committee lay member

## Equality considerations

- TBC
- TBC
- TBC

# Methods task and finish groups

## Exploring uncertainty

- Breast Cancer Now
- Alzheimer's Research UK
- Genetic Alliance UK

## Health related quality of life

- Muscular Dystrophy UK
- Alzheimer's Research UK
- Prostate Cancer UK

## Sources and synthesis of evidence

- Genetic Alliance UK
- Head of Policy, MS Society
- Sarcoma UK

# Methods task and finish groups

## Modifiers considered in decision making

- Cystic Fibrosis Trust
- Myeloma UK
- MS Society

## Technology specific issues

- Number of places TBC

# Stakeholder Insight Group (virtual)

## Role

- To provide key insight on processes
- To test and provide real time feedback on potential new process proposals
- To develop solutions that work for both NICE and stakeholders

## Membership

Committee members, industry, patient/carer groups, professional groups, academic groups, DHSC, NHS England – open to all stakeholders who have been or are involved in guidance production

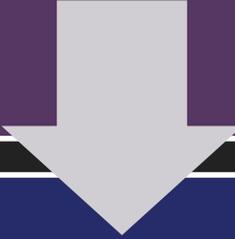
## How

Initial launch workshop (places limited) and follow up via webinars and email (places unlimited)

## NICE

# Patient involvement

Aim: to co-design realistic proposal options for changes to NICE's public involvement in NICE's medicines and non-medicines guidance (technology appraisals, highly specialised technologies, diagnostics, and medical technologies)



Proposal options will be fed into the wider methods and process development for consideration and development



Viable options will form part of the public consultation on the new methods and processes

# Involving patient groups

Work to date on ‘improving meaningful patient and public involvement in NICE’s health technology assessment guidance’

## Working group

- Working group set up
- Members of patient groups and patient experts
- NICE staff

## Workshop

- Patient workshop held on 24 January
- 22 patient organisations and patient experts participated

## Early engagement survey

- Open for 4 weeks
- Responses from 52 organisations

# Working group – how they were selected



# The early engagement survey



Open from 22 July to 12 August 2019

Sent to 15 patient umbrella groups

Promoted via Twitter

Sent direct to a further 600+ patient groups

# Early engagement survey – results 1

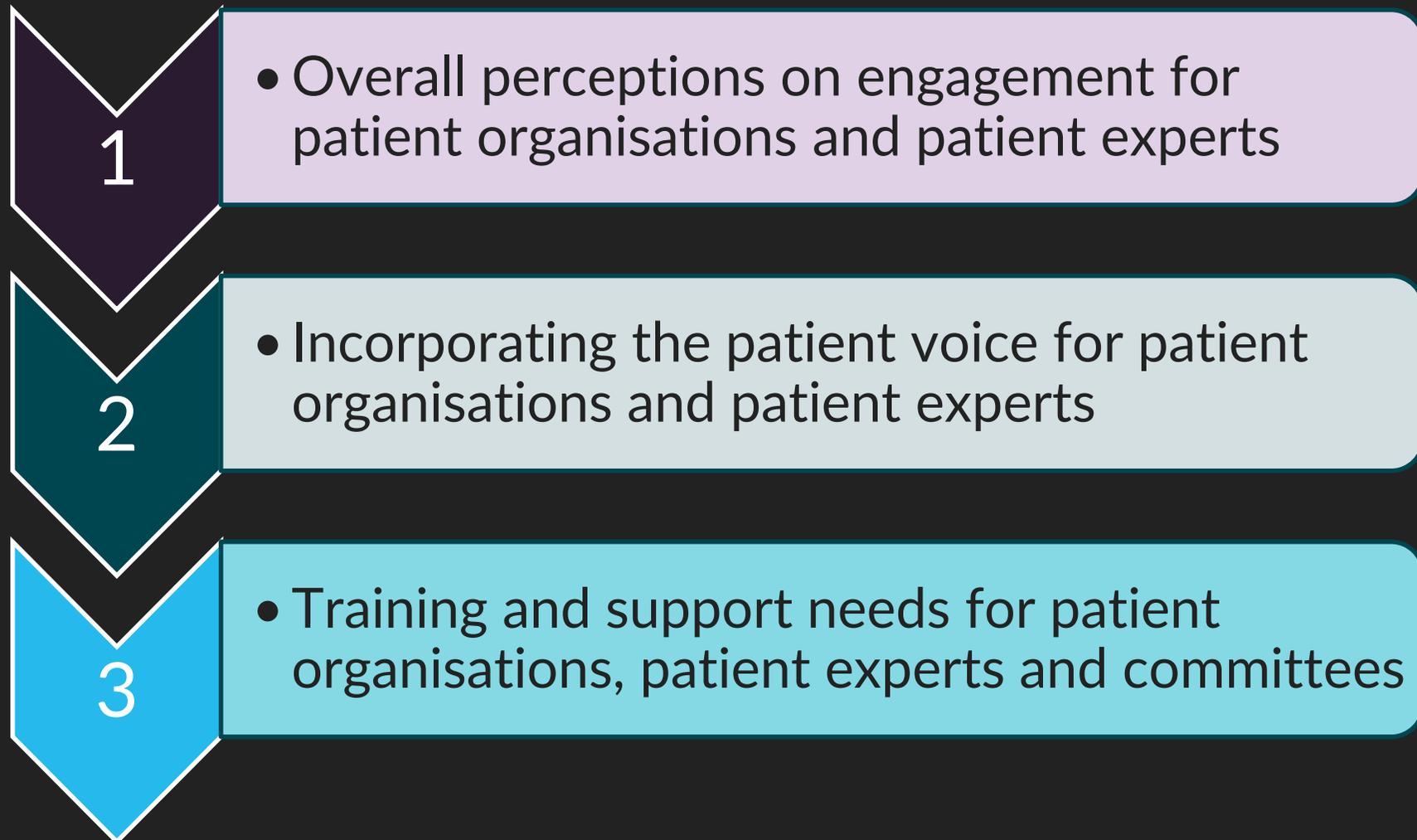
52 patient organisations completed to the survey.

They had experience of participating in a range of programmes:

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

# Early engagement survey – results 2

## 3 themes:



# Early engagement survey – results; theme 1

## Overall perceptions on engagement

The confidence rates of respondents in NICE processes.

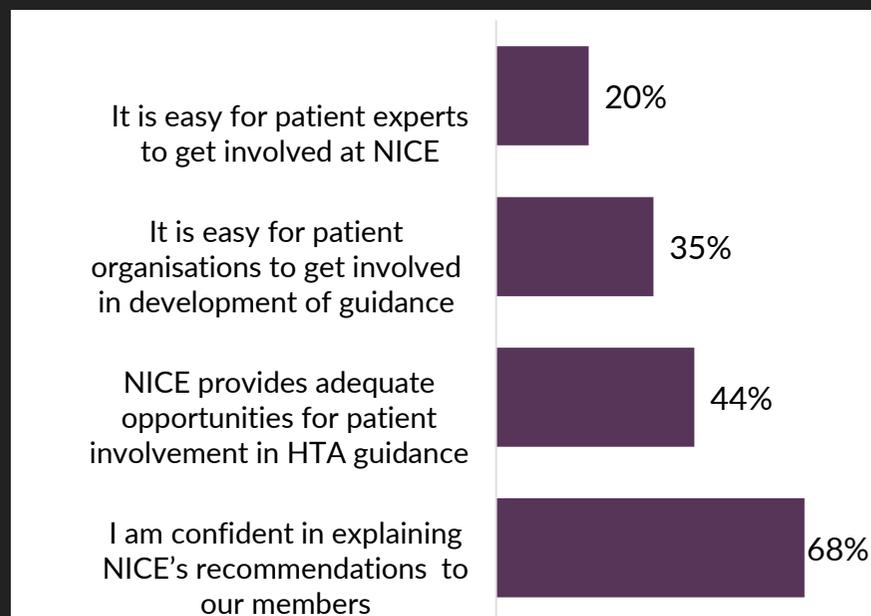


*“Regarding the collection or usage of data, we are confident in our ability to do this; the issue for us lies more in knowing what is useful to NICE. We would like more information about the type of data to collect and what topics/issues these should address.”*

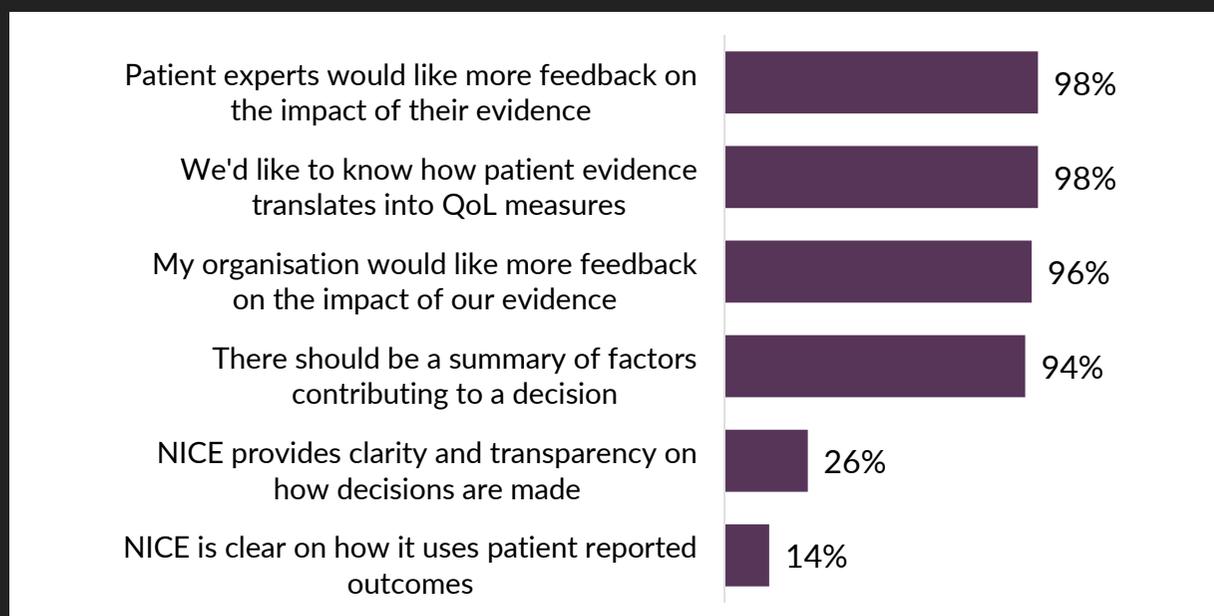
# Early engagement survey – results; theme 1

## Overall perceptions on engagement

### Ease and opportunities for involvement



### Feedback, clarity and transparency



*“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.”*

*“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.”*

# Early engagement survey – results; theme 1

## Overall perceptions on engagement

Key areas include:

- Explanation of processes, including more on appeals and technical engagement.
- Explore additional ways of including patients
- Clarity and consistency on stakeholder involvement
- Consultation document to be clearer on what patients can add
- Explain what is out of NICE's remit
- How to communicate what is needed to fill gaps in evidence
- Provide feedback on patient participation including how it helped inform the decision.

# Early engagement survey – results; theme 2

## Incorporating the patient voice

### Committee culture



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

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

# Early engagement survey – results; theme 2

## Incorporating the patient voice

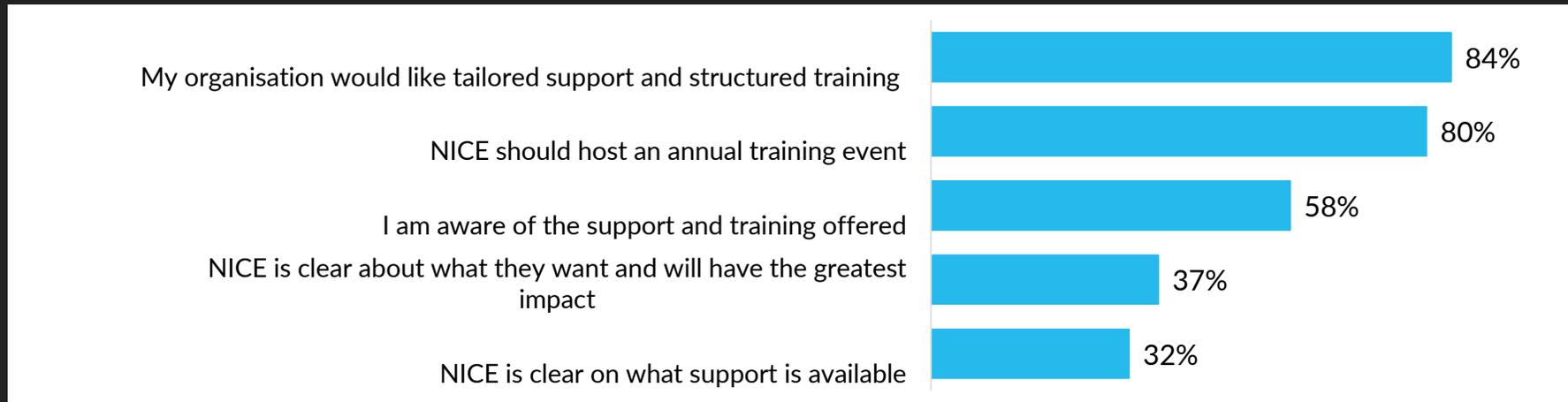
Key areas include:

- How and when patient voice included in the committee
- Additional ways to include patients
- Help with technical engagement
- Support with navigating committee documents
- Better communications and updates
- Update the guide for committees

# Early engagement survey – results; theme 3

## Support and training

### Support and training

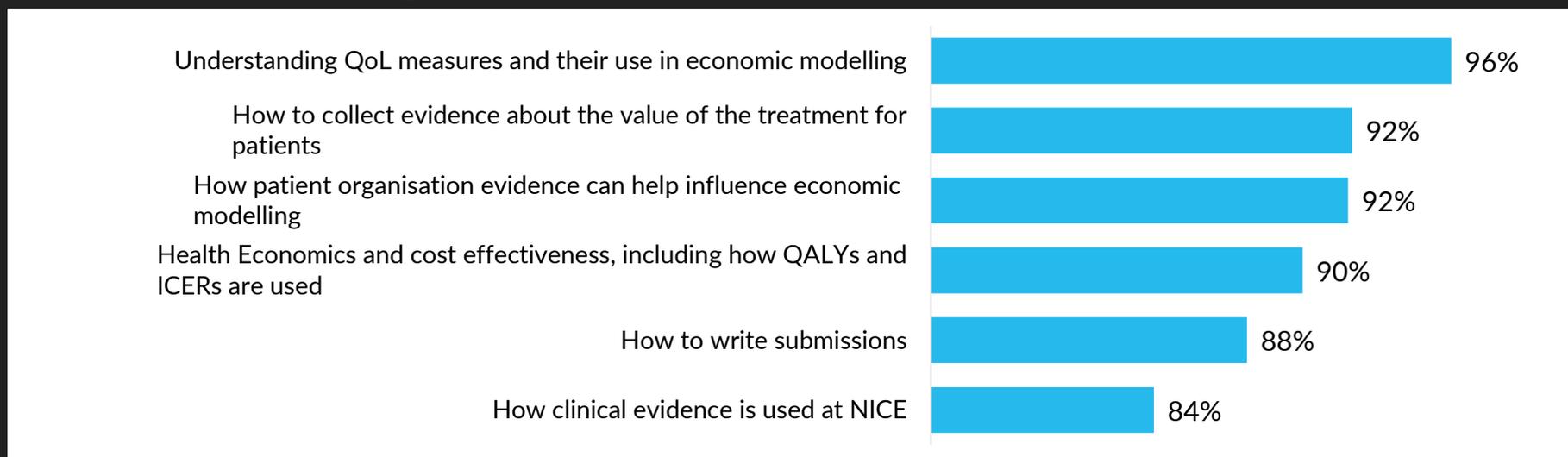


*“As much online, accessible guidance (webinars, for example) is appreciated as smaller organisations do not always have the resources to send staff to training.”*

# Early engagement survey – results; theme 3

## Support and training

### Support and training for patient ORGANISATIONS



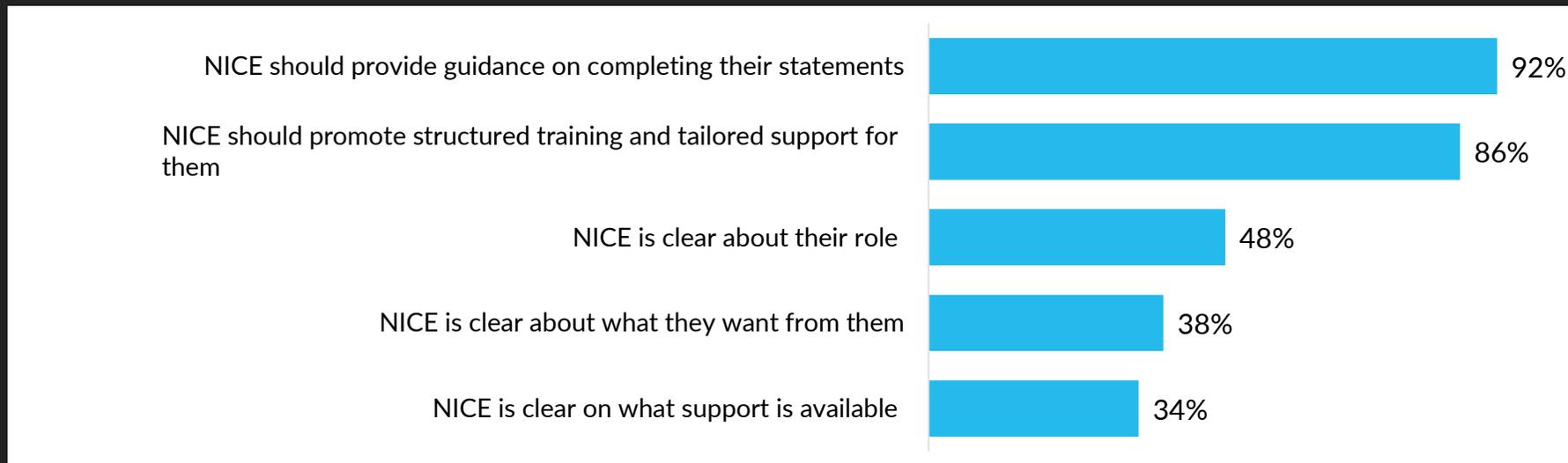
*“Although we understand the cost-effectiveness elements in basic terms, it would be useful to have a refresher to help us better understand the context and enable us to estimate for ourselves whether a treatment might be on the boundary between clinically/cost effective or not.”*

*“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.”*

# Early engagement survey – results; theme 3

## Support and training

### Support and training for patient EXPERTS



# Early engagement survey – results; theme 3

## Support and training

Key areas include:

- Training around economic modelling and how patient groups can interact with this
- Explanation of how the committee reached its decision.
- More support on submissions for groups and individuals
- Case studies and examples of previous submissions

# Early engagement survey – next steps



# What next?

When	Activity
Nov 19 – Dec 20	Stakeholder Insight Group (process only) <ul style="list-style-type: none"><li>• Workshop and virtual group</li></ul>
Now – summer 2020	Methods working group(s) and review started <ul style="list-style-type: none"><li>• Webinars</li><li>• Patient specific webinar 21 Nov</li></ul>
Summer 2020	Engagement and consultation on proposed changes
December 2020 – March 2021	Implement updates of methods and processes

# Keep up to date with NICE's webpage and bulletin

## Changes we're making to health technology evaluation

### On this page:

[What changes are we making?](#)

[Get involved](#)

[Who else is involved?](#)

[Timeline](#)

[Why we're making these changes](#)

[Improvements we hope to see](#)

[Highly specialised technologies criteria review](#)

### What changes are we making?

The [Voluntary Scheme for Branded Medicines Pricing and Access](#) (2019 VS), agreed by government and the ABPI in November 2018, commits NICE to scoping and initiating a review of its methods for both [technology appraisals](#) (TAs) and [highly specialised technologies](#) (HSTs), including a review of the process of guidance production for HST.

We are taking this opportunity to extend this exercise to include the methods and processes of the [Medical Technologies Evaluation Programme](#) and the [Diagnostics Assessment Programme](#) as well, aligning them where appropriate.

### Get involved

#### Consultation: summer 2020

There will be a 6 week public consultation for the proposed updates to our methods and processes in summer 2020. Before the consultation we'll carry out an informal engagement period with stakeholders. During this time we'll ask for targeted feedback on elements of the review.

<https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation>

Questions?



[methodsandprocess@nice.org.uk](mailto:methodsandprocess@nice.org.uk)

For questions about the methods and process review.