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## Background and Objectives

Qualitative research provides important first-hand data drawn from lived experience on the impact condition on patients and their caregivers and possible treatment benefits (Renjith, 2021).

The NICE process for evaluating highly specialised technologies includes discretion for the Evaluation Committee to consider all available clinical evidence presented. Including qualitative evidence related to the experiences of patients, caregivers, and clinicians relating to the condition or the technology under evaluation.

A review of NICE methods demonstrated an increasing recognition of the potential contributions of qualitative evidence generation, although how this data should be handled, distinguished from other data sources, and integrated alongside clinical and cost-effectiveness data is unclear (Booth, 2020). However, it was recommended that mixed methods approaches combining qualitative and quantitative data are considered exemplar data collection methods.

Recommendations suggest exploring integrating quantitative and qualitative evidence in all NICE activities, with further specific guidance on how and when this should feature in technology submissions.

**Objective:** To report the prevalence of qualitative data collection and analysis methods used within NICE appraisals of highly specialized technologies (HST).

## Methods

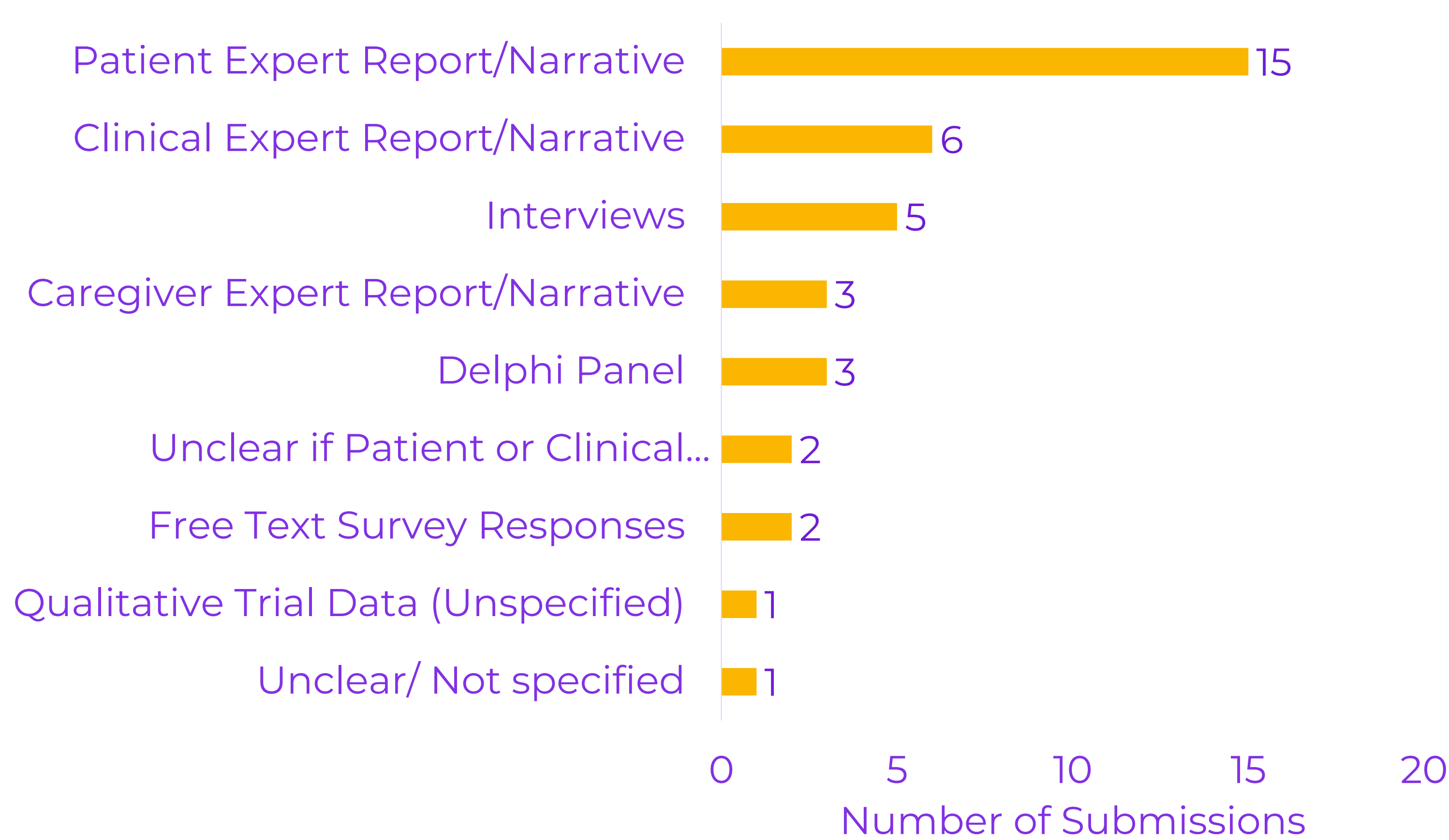
Twenty sets of NICE HST submission guidance documents and supporting committee papers between 2005 and 2020 were examined. Data were extracted on background information and target indication, qualitative data sources, methods, evidence categories, evidence target, evidence type, analysis methods, and resulting discussions or critiques.

## Results

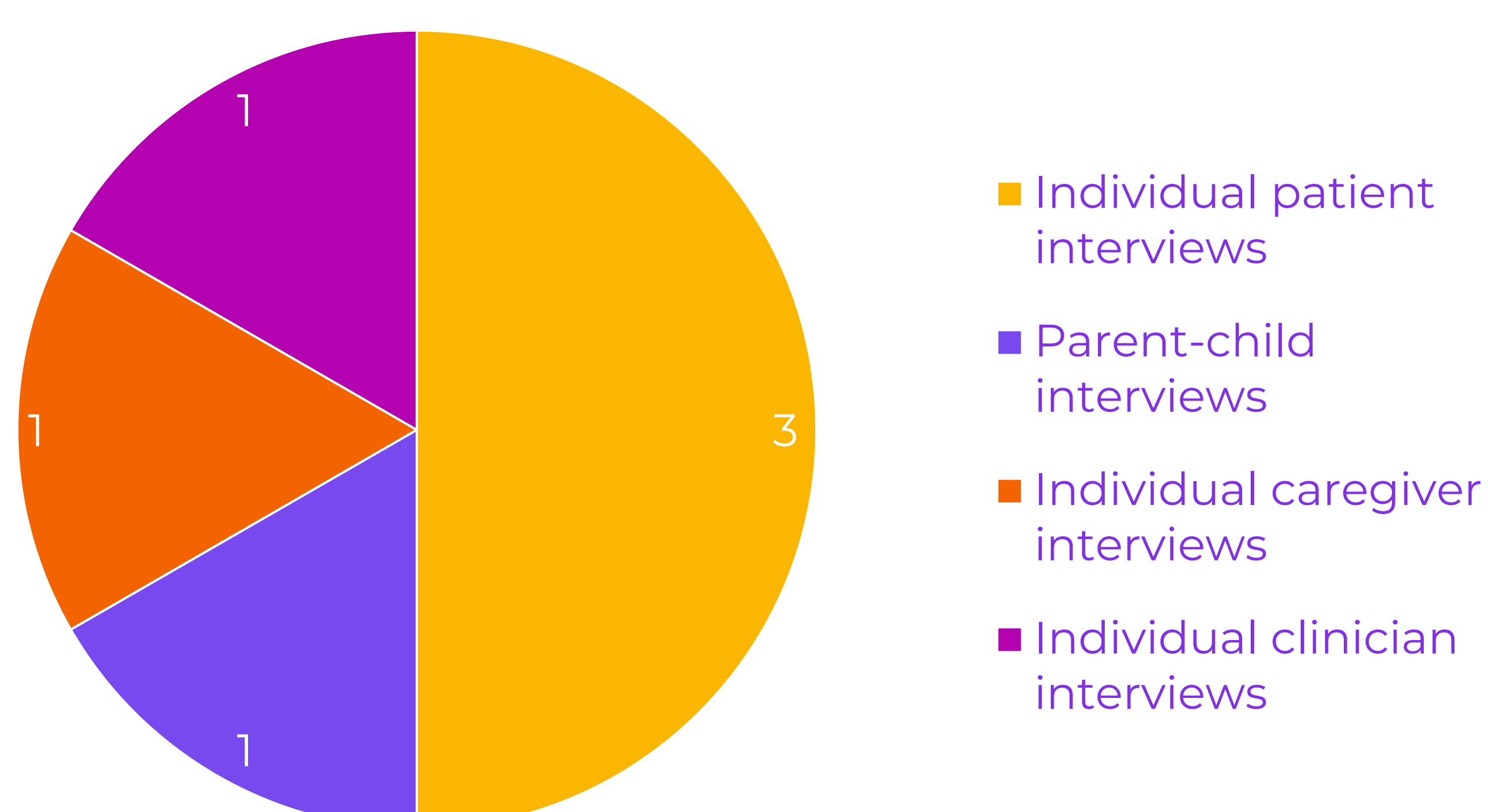
Qualitative evidence contained within submissions predominantly took the form of patient or caregiver expert reports and narratives, as part of a standardized practice within HST reviews. However, only 7 instances of interviews were discussed across 5 submissions, with less evidence presented for free text survey responses (2, n=2) and qualitative trial data (1, n=1).

Together, qualitative evidence was explicitly featured within 18 submissions and 8 of total submissions included evidence that was unclear if either qualitative, quantitative, or mixed methods in nature.

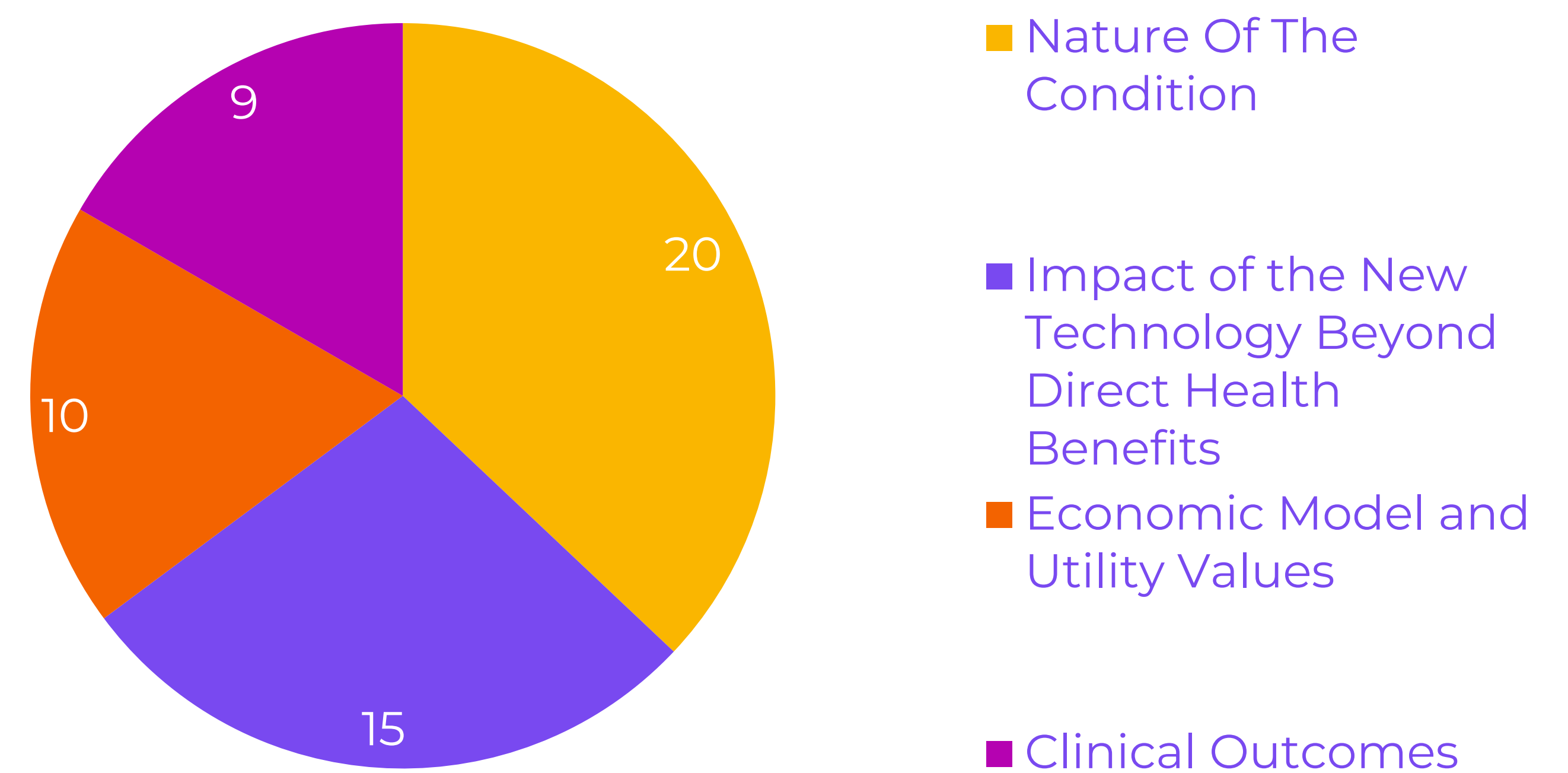
### Data Collection Method / Data Source



### Interview type



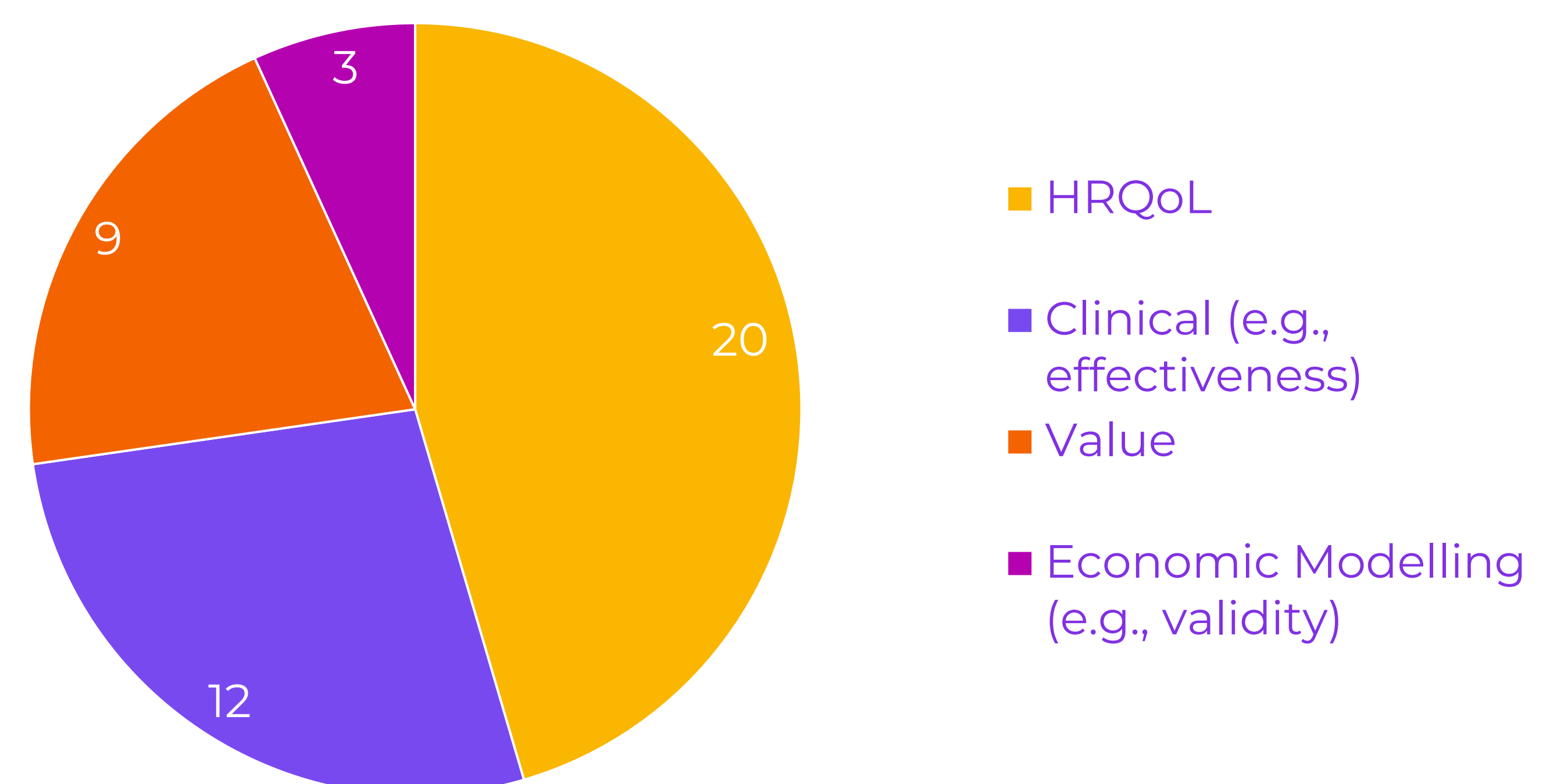
### Evidence Category



All submissions contained such evidence within the submission category 'Nature of the Condition' (N=20) including evidence for disease burden, unmet needs, and management and treatments. This was followed by 15 submissions containing evidence presented in support of the impact of the new technology beyond direct health benefits.

All submissions included at least some qualitative evidence for which the data collection or analysis methods were unclear, although two submissions reported the use of direct quotations.

### Outcome Relevant to Evidence Presented



Most frequently discussed was evidence in support of patient health-related quality of life (HRQoL) impacts (n=20) and caregiver impacts (n=18) followed by value of the technology (n=9) economic model validity (n=4). The final considerations within discussions and guidance document recommendations all took into account conclusions that incorporated the qualitative evidence presented.

## Conclusions

Patient and caregiver expert reports are highly prevalent within NICE HST appraisals, with clinician evidence presented less frequently. However, we acknowledge that formal evidence may not be expected for patient or caregiver narrative reports featured as these are a standardized practice for committee meetings.

Qualitative evidence featured heavily in discussions around HRQoL and the effect conditions can have on patients, families, and caregivers. The predominant source of qualitative evidence is patient and clinician reports/narratives and direct interviews. Such evidence is presented principally in reference to patients, with a high prevalence also for caregivers and possible spillover effects to family.

There was a notable lack of clarity regarding the data collection and analysis methods used to generate qualitative evidence. This limits any transparent critique of evidence presented within discussions and can further limit comparability across technologies. These findings demonstrate support for Booth (2020) who recommends 'future specific guidance on how and when qualitative (and integrated) data should feature as part of submissions', with such guidance asserting transparency of data collection and analysis methods.

## References

- Booth A. (2020). A methodological update on the use of qualitative evidence in technology assessment. Report by the Decision Support Unit.
- NICE. (2017) Interim Process and Methods of the Highly Specialised Technologies Programme. <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf>
- Renjith, V., Yesodharan, R., Noronha, J. A., Ladd, E., & George, A. (2021). Qualitative Methods in Health Care Research. International journal of preventive medicine, 12, 20. [https://doi.org/10.4103/ijpvm.IJPVM\\_321\\_19](https://doi.org/10.4103/ijpvm.IJPVM_321_19)

