

Is the usage of immature survival data surviving HTA decisions?

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BACKGROUND

Context: In health technology assessment (HTA) submissions for oncology, decision-makers are often presented with incomplete survival data on new treatments, making it difficult to evaluate the long-term benefits of the treatment amidst uncertainty and posing challenges to technology adoption decisions [1,2].

Aim: To understand how often National Institute for Health and Care Excellence (NICE) UK informs its decisions for cancer treatments using immature overall survival (OS) data alongside understanding its impact on decision-making.

METHODS

We reviewed the single technology appraisals (STAs) published (January 1, 2021 to December 31, 2022) by the NICE for cancer treatments/oncology indications. This included company submission reports, Evidence Review Group reports, and final HTA guidance documents.

Key words: cancer, carcinoma, melanoma, multiple myeloma, leukemia, and lymphoma

Data extraction parameters:

- Information on the STA (oncology indication, type of molecule)
- Clinical trial characteristics
- Data maturity level for OS
- HTA final recommendation

Data were extracted by one reviewer, and the quality was checked by another reviewer to ensure accuracy. All data were analyzed qualitatively.

The level of OS data maturity was categorized as 'mature', 'partially mature', 'immature', and 'not mentioned/available'.

Over the past two years, approximately 60% of the submissions to NICE have included immature OS data.

The usage of immature OS data highlights the challenges faced by both manufacturers and regulators in balancing the need for timely access to new treatments with the requirement for robust and reliable evidence.

It is crucial to strengthen guidelines around the effective use of immature survival data in HTA submissions to reduce model uncertainty and improve the accuracy of technology adoption decisions.

RESULTS

Studies identified = 68 STAs (NICE publications)

Major oncology indications = non-small-cell lung cancer (n=14); breast cancer (n=10); prostate cancer (n=5) (Fig. 1).

Of these STAs, 59% (n=40) had immature OS data (Fig. 2).

The maturity level of the OS data was not reported in 26% (n=18) of STAs, whereas the information was redacted or not reported in the remaining submissions.

Thirteen percent (n=9) of STAs that had immature survival data, used a single-arm study design, resulting in indirect treatment comparison.

Fifty percent of the STAs (n=34) received positive recommendations, 41% (n=28) were recommended with conditions, and 9% (n=6) were not recommended (Fig. 3).

Compared with 'mature' OS data STAs, the positive recommendations for 'immature' OS data STAs were slightly lower, but conditional recommendations were slightly higher (Fig. 4).

Figure 1. Oncology indications in STAs (N=68)

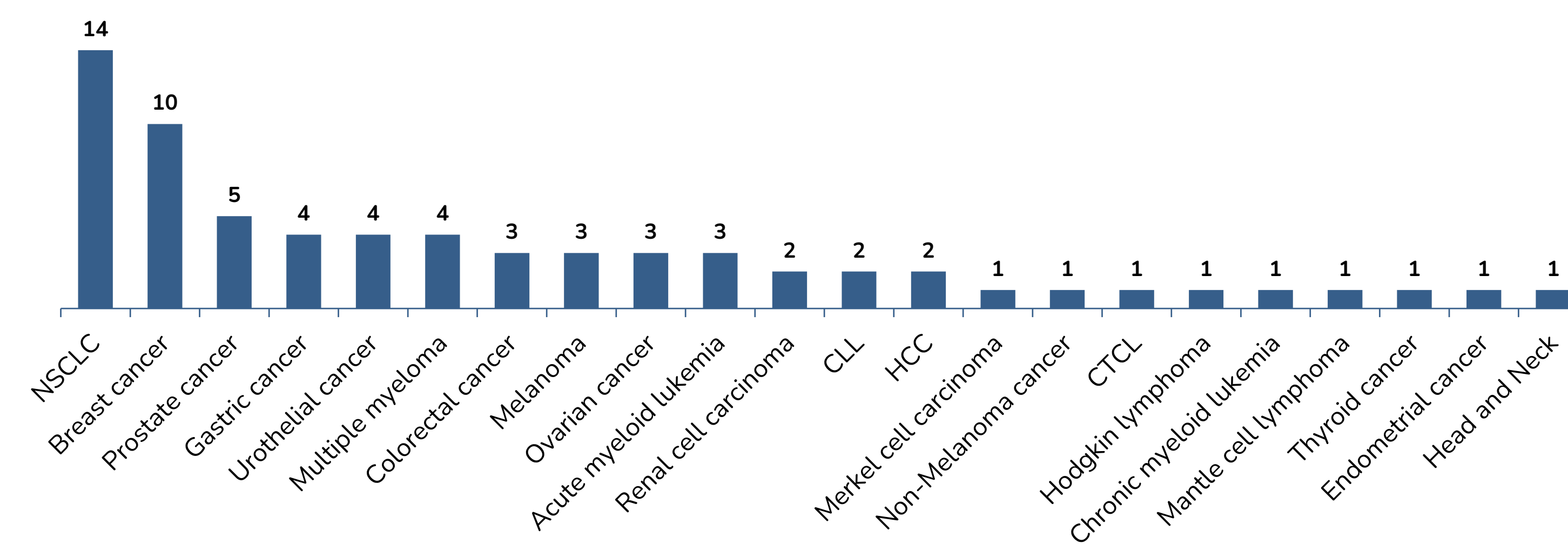


Figure 2. OS data types in STAs (N=68)

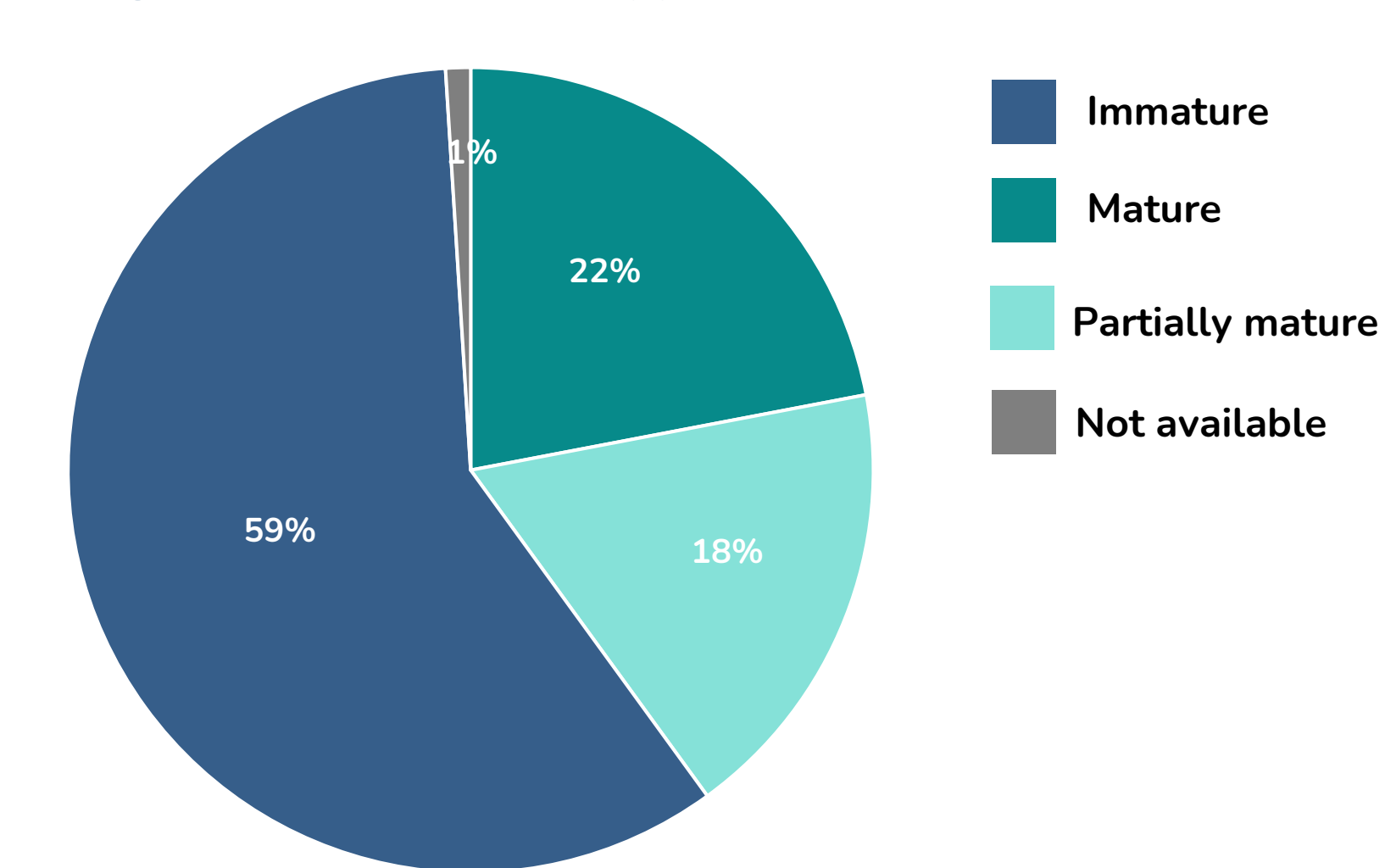


Figure 3. Overview of HTA decisions (N=68)

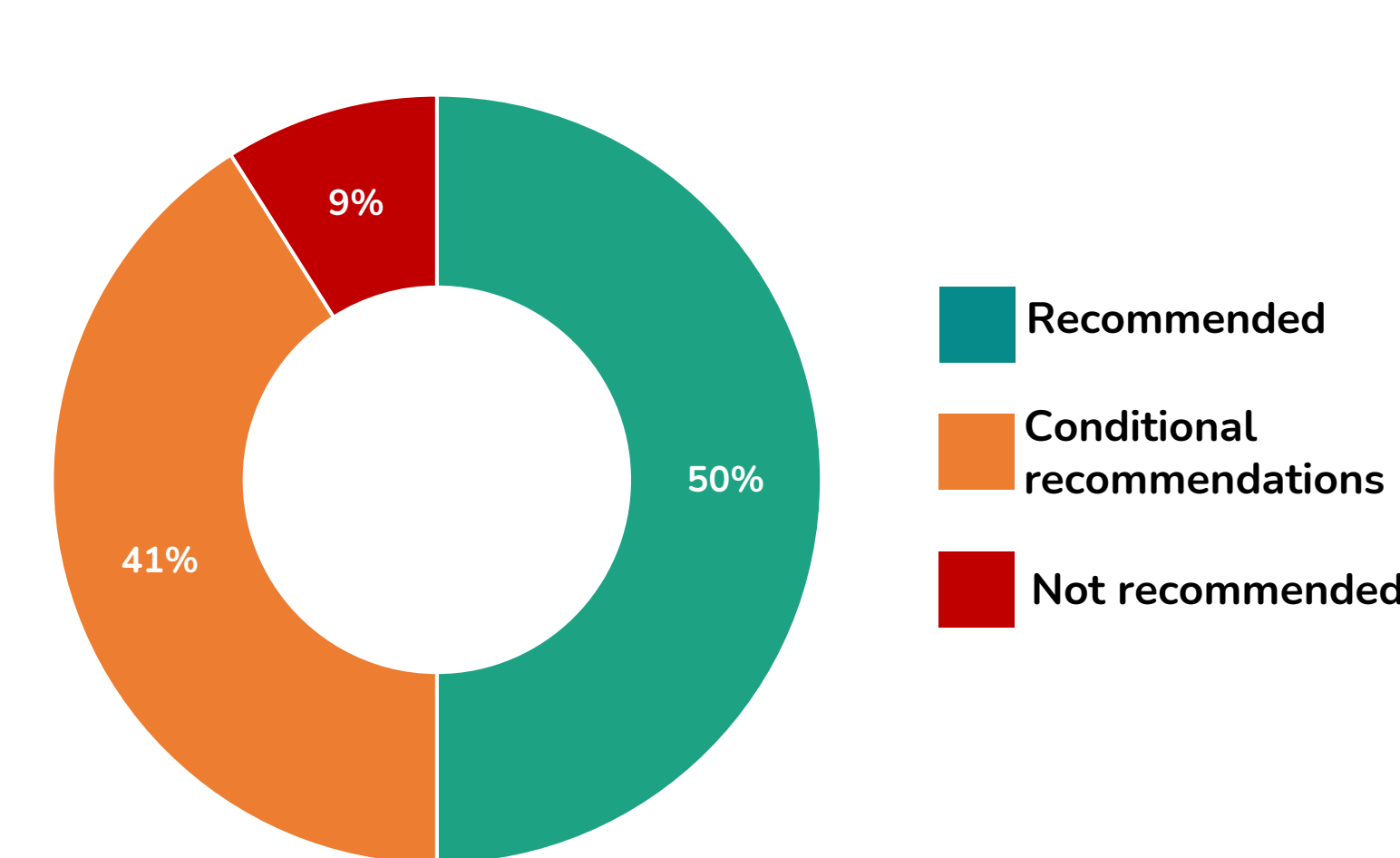
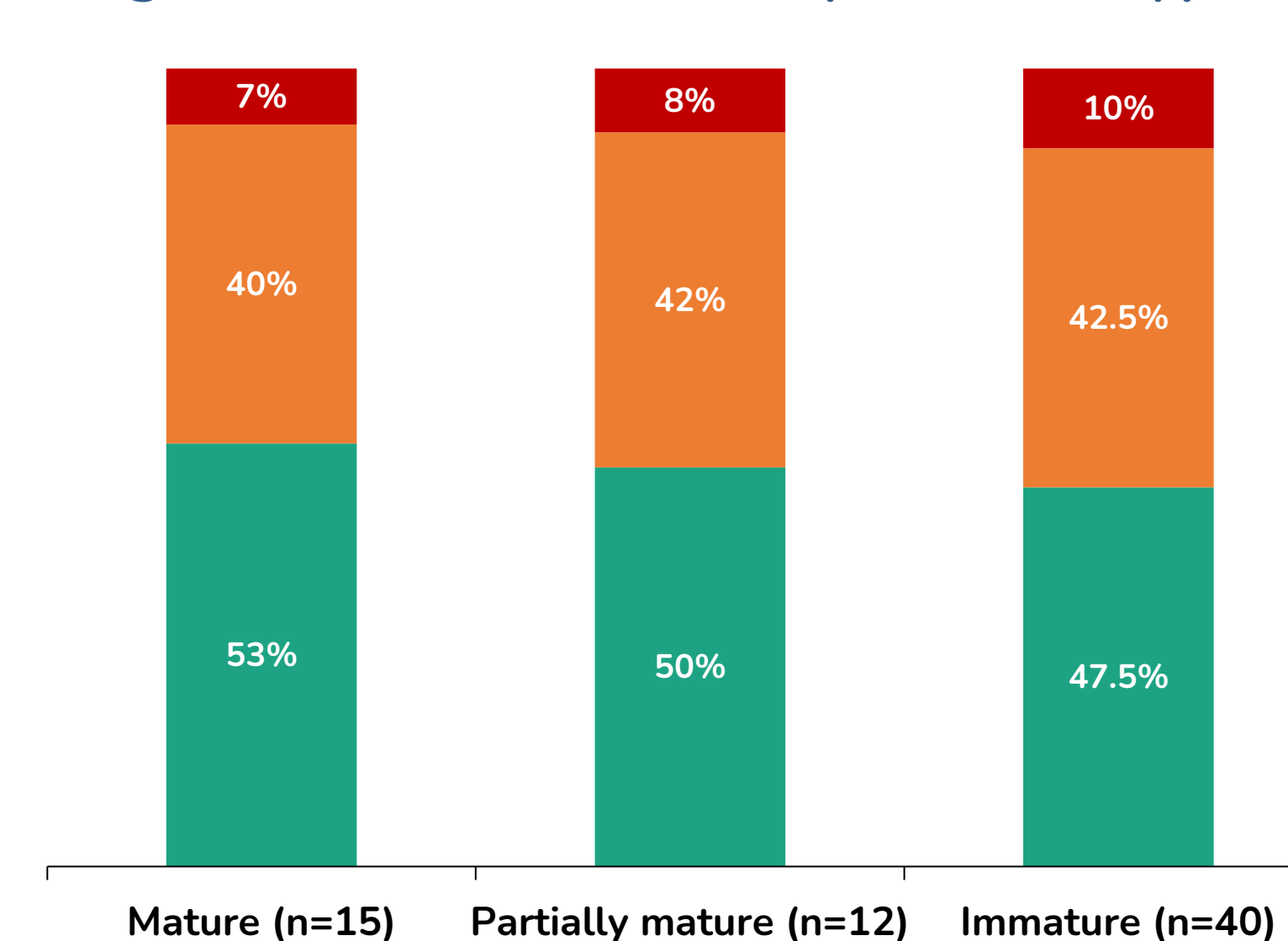


Figure 4. HTA decisions by OS data types



CLL, chronic lymphocytic leukemia; CTCL, cutaneous T-cell lymphoma; HCC, hepatocellular carcinoma; NSCLC, non-small-cell lung cancer; STAs, single technology appraisals.

References:

1. Tai TA, Latimer NR, Benedict A, et al. Value Health 2021; 24(4): 505-512.
2. Dyer M, Wagner P, Wiinberg L, et al. Value Health 2021; 24(Suppl 1): S44.

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