Can just three PICOs be feasible for oncology assessments with the Joint EU HTA Framework, whilst considering all 27 member states specificities?

HTA228

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INTRODUCTION

- From 2025, oncology treatments will be the first therapy area to be mandated to be assessed using the Joint EU Health Technology Assessment (HTA) process for clinical evaluation
- Prior to the manufacturer submission, each member state (MS) will define PICOs (Population, Intervention, Comparator, Outcomes) using a survey
- PICOs help specify the assessment framework and will be consolidated by the assessor and co-assessor from the Member State coordination group into as few PICOs as possible1. Though no official upper number of PICOs have been reported, anecdotally it has been assumed to aim for 2-3
- Different MS often have different views on the comparators depending on available products and clinical practice in their market, on the populations they are willing to treat and the types of endpoints that they deem to be relevant; leading to uncertainty over whether PICO's can be condensed to just 2-3

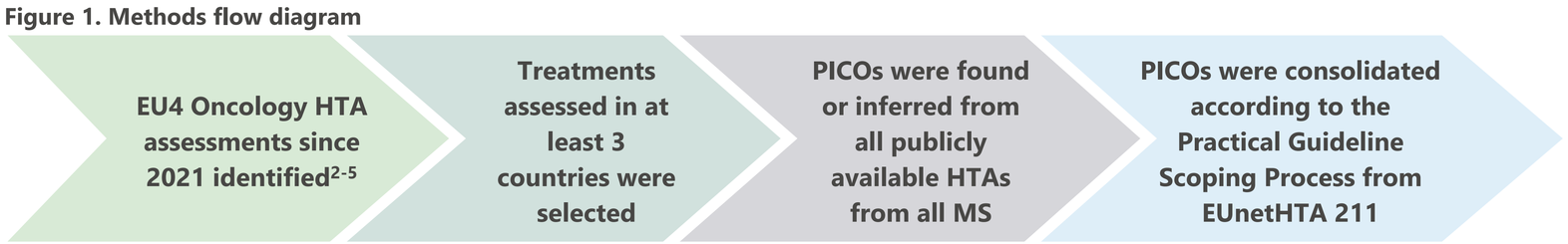
OBJECTIVE

To understand the number of PICOs that may be proposed by EU Member States for inclusion in oncology EU HTA assessments

METHODS

EU4 Oncology HTA assessments since 2021 were identified using HTA agency databases[2-5]. Treatments assessed in at least 3 countries were selected and PICOs were found or inferred from all publicly available HTA assessments from a MS. PICOs were consolidated according to the Practical Guideline Scoping Process from EUnetHTA 21

Figure 1. Methods flow diagram



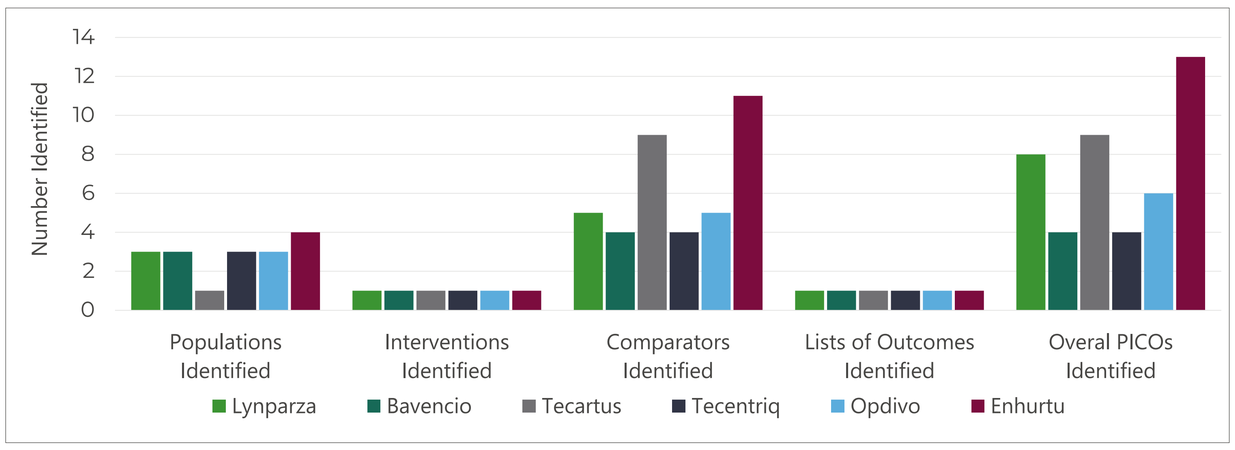
RESULTS

- Six were the oncology treatments assessed in at least 3 of the EU4 countries and for which all publicly available HTAs from all the MS were identified and analysed to extract the PICOs
- All 6 oncology products from 4 EU countries had a higher number of PICOs than what has been estimated

DRUG	THERAPY AREA	EU COUNTRIES WITH PUBLIC HTA	PICOS IDENTIFIED	POPULATIONS IDENTIFIED	INTERVENTIONS IDENTIFIED	COMPARATORS IDENTIFIED	LISTS OF OUTCOMES IDENTIFIED
Bavencio *(avelumab)*	Urotelial carcinoma	DE FR IT ES DK IE	**4**	3	1	4	1
Lynparza *(olaparib with bevacizumab)*	Ovarian cancer	DE FR IT ES DK IE	**8**	3	1	5	1
Tecentriq *(atezolizumab with bevacizumab)*	Hepato-cellular carcinoma	DE FR IT ES DK IE PT	**4**	3	1	4	1
Tecartus *(brexucabtagene autoleucel)*	Mantel cell lymphoma	DE FR IT ES SE FI	**9**	1	1	9	1
Opdivo *(nivolumab)*	Squamous cell carcinoma of the oesophagus	DE FR IT ES SE	**6**	3	1	5	1
Enhertu *(trastuzumab deruxtecan)*	Breast cancer	DE FR ES DK SE NL FI	**13**	4	1	11	1

- The high number of PICOs was due either to subpopulations or differences in the comparator

Figure 2. Comparison of the PICO breakdown across the recently assessed oncology therapies in the EU



CONCLUSION

- None of the investigated treatments were found to have 2-3 PICOs, following consolidation as per the Joint EU HTA guidelines[1]
- Similarly, a recent EUnetHTA PICO exercise found 9 PICOs for Pombliti, where 10 MS were surveyed[6]
- We can speculate that the number of PICOs will grow significantly higher once all EU27 MS PICOs taken into account
- MS-specific heterogeneity in population and treatment practices, exemplified by the number of PICOs, may make the Joint EU HTA's aim to harmonise assessments challenging
- Moreover, if the MS feels the Joint Assessment has not addressed their needs it may lead to duplication due to additional national submissions
- For manufacturers, this means that additional data collection and work on the affiliate level will likely remain necessary
- For patients, this may mean delayed access in countries needing additional data. Germany, typically one of the first markets in Europe for products launches, is also one of the country that will likely require additional data and, because of this, may see it-self being pushed down the launch order

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