EXPLORING INTERNATIONAL HTA DECISIONS

The International Impact of National Institute of Health and Care Excellence (NICE) Decisions

OHE
Simon Brassel
Edward Oliver
Nadine Henderson
Phill O'Neill
Martina Garau

SANOFI
Omar Saeed
Ilana Gibbons
Rachel Allen
Richard Hudson
Kinga Malottki
Hannah Wentzel
Nathalie Largeron

Contact
Simon Brassel
sbrassel@ohe.org

ohe.org

Background

The National Institute of Health and Care Excellence (NICE) is perceived as an influential HTA organisation whose decisions and methods may shape the decisions, processes and timings of other HTA agencies.

The empirical evidence on the global influence of NICE is, however, sparse and mixed.

For cancer drugs, a positive recommendation by NICE is associated with a higher probability of reimbursement in Europe [1]. In contrast, others found that on a global level, positive recommendations by NICE may be associated with a higher probability of not being recommended by other countries [2].

Aim

To explore what effect, if any, NICE HTA (Health Technology Assessment) decisions have on the decisions made by other countries' HTA agencies around the world within the field of cancer and orphan drugs.

Data & Methods

We selected 51 Drug Indication Pairs (DIPs) from three Therapeutic Areas (Cancer 59%, Orphans 18% and Cancer Orphans 23%) with a NICE decision published between 2018-2019.

We retrieved information on NICE's HTA process (e.g., timelines, appraisal routes) and outcomes for each DIP. Where available – equivalent information from HTA bodies within Australia, Brazil, Canada, France, Italy, Poland, South Korea, and Sweden was collected, resulting in 408 observations.

The respective databases were searched for related decisions until a cut-off date at the end of Q4 2021.

We coded each country's decision into three outcomes: Positive (including full recommendations and recommendations with restrictions), Negative, and Other (e.g., terminated).

We first compared outcomes and decision speeds.

We then tested for categorical independence between outcomes of NICE and other HTA bodies using either Chi-squared or Fisher's exact test for significance testing. We explored causality by creating dummy variables indicating whether NICE decided before another country's HTA body.

Finally, we tested the effect of negative decisions and terminated NICE appraisals when using un-coded NICE outcomes.

Results 1 – The International **impact** of NICE Decisions is **ambiguous**

Within the full sample , there was no significant relationship between the three decision outcomes categories on an aggregate level (Fisher exact statistic: 0.7).

However, when uncoded NICE decisions outcomes were used and terminated appraisals were included (Table 1), then categorical NICE outcomes significantly related (Chi-squared, p-value: 0.0055) with other countries' decisions. Inspection of the residuals of the Chi-Square Test indicated that

- terminated NICE appraisals and negative NICE decisions have a positive relationship with no HTA being carried out in other countries,
- positive NICE decisions have a positive relationship with positive outcomes in other countries,
- positive NICE decisions with restrictions have a positive relationship with negative outcomes in other countries, while the direction of decision associated with the CDF is ambiguous.

When exploring causality using the coded decision outcome categories, a positive recommendation first issued by NICE had a significant relationship with a negative decision in other countries (Chi-squared, p-value: 0.05), which is counterintuitive. We were unable to examine the relationship for negative decisions as the sample size was too small even when coded outcomes were used.

Within a country subset (Poland, Italy, Korea, Sweden), a favourable decision was more likely when NICE published a favourable decision beforehand. However, the results were insignificant (Fisher exact, p-value: 0.53).

		NICE Outcomes					
		Terminated	Not recommended	Optimised	Optimised - CDF	Recommended	Recommended - CDF
NON-NICE OUTCOME	No HTA	35	20	27	33	51	12
	Negative	6	1	13	13	9	2
	Positive	15	11	32	48	67	10
	Other	0	0	0	2	1	0

Table 1

p-value= 0.005

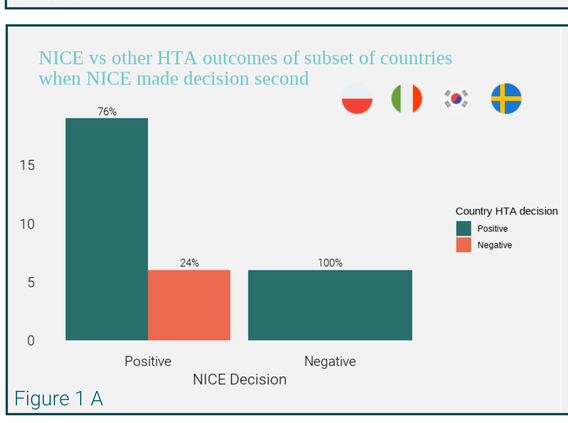


Figure 1 A

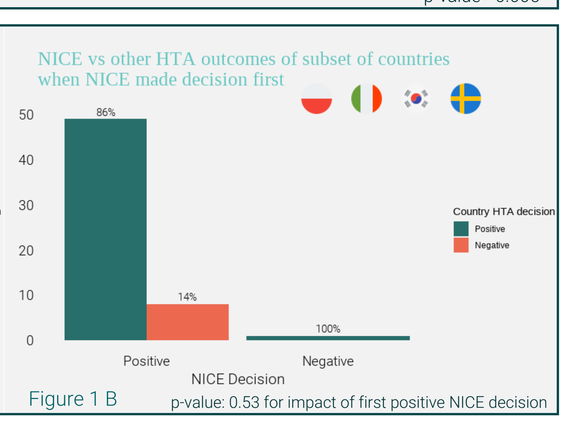


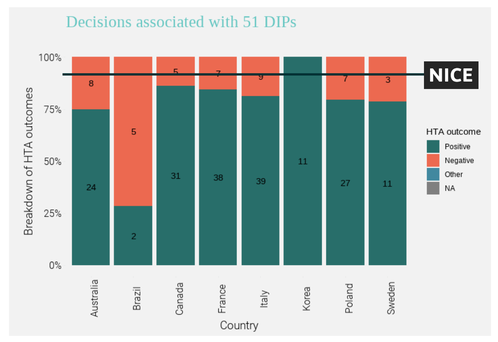
Figure 1 B

p-value: 0.53 for impact of first positive NICE decision

Results 2 – NICE **outcomes** are **often positive** and NICE **timelines** are **relatively fast**

Within each country only a limited number of the 51 DIPs have been assessed reaching from 45 in France to only 7 in Brazil.

90% of NICE's non-terminated decisions were positive and hence, either recommended (36%) or positive with restrictions (54%) within our dataset.



Only Korea's HTA agency had a higher positive recommendation rate (100%).

Brazil's HTA agency had the lowest positive recommendation rate and issued only two recommendations from 7 assessed DIPs.

Limitations

Limitations are related to the small sample size of DIPs, the fact that many countries only appraised a subset of those and the relatively large amount of positive NICE decisions with restrictions (optimised decisions).

Discussion and Conclusion

- A clear causal link between NICE decisions and decisions in other countries using the full set of countries, could not be established. This might be driven by the disproportionate number of positive recommendations with restrictions by NICE which often relate to negative decisions in other countries.
- While insignificant, within a sub-sample of countries, the analyses indicate a positive influence of positive recommendations by NICE on the probability of a positive outcome in another country.
- Overall, NICE decisions lead often to a recommendation (or at least a recommendation with restrictions) and are made relatively fast.
- We plan to explore the international impact of NICE further using qualitative research methods.

References

1. Maynou, Laia, and John Cairns. "What Is Driving HTA Decision-Making? Evidence from Cancer Drug Reimbursement Decisions from 6 European Countries." *Health Policy* 123, no. 2 (February 1, 2019): 130–39.
2. Hernández-Villafuerte, K., M. Garau, and N. Devlin. "Do Nice Decisions Affect Decisions in Other Countries?" *Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research* 17, no. 7 (November 2014): A418.

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