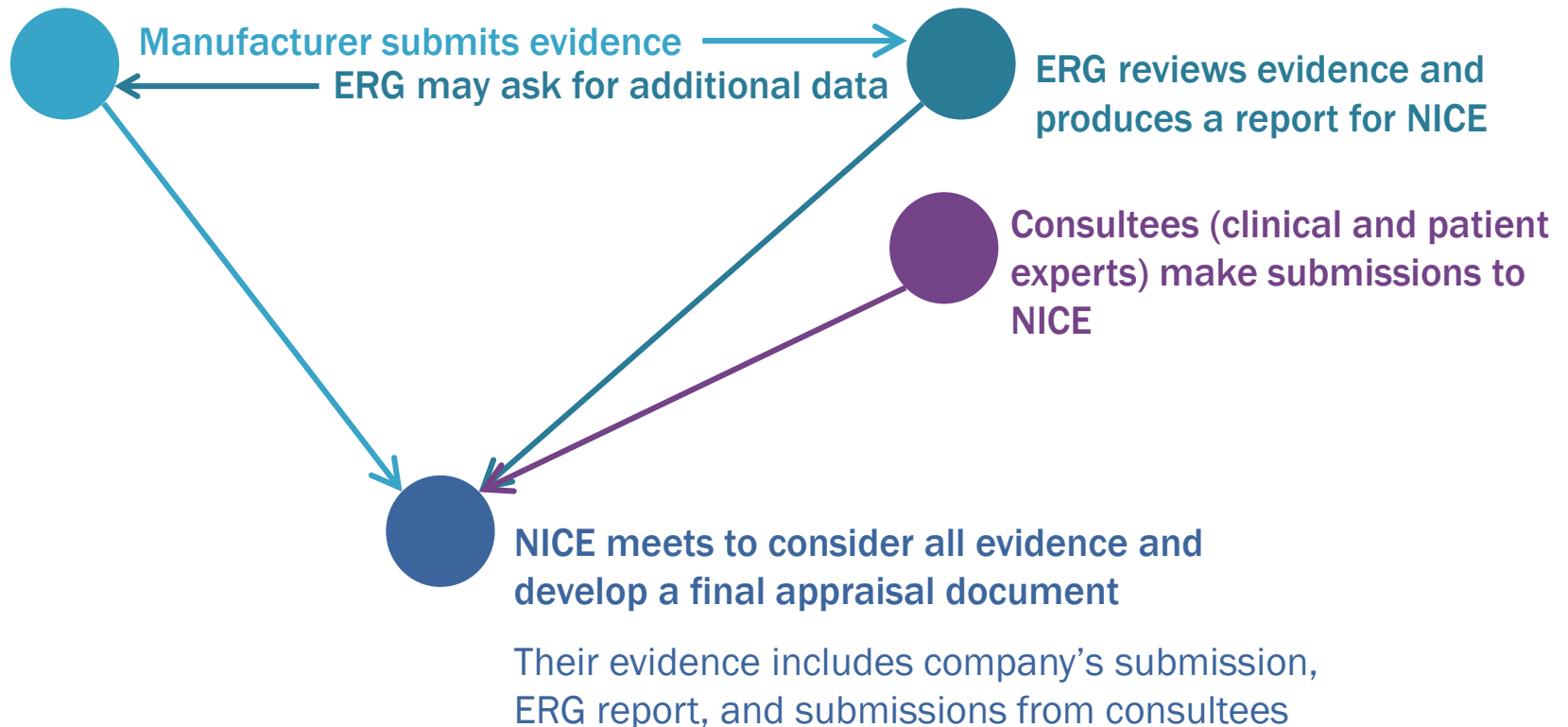


Do Evidence Review Groups Bias NICE Decisions?

Lorraine Versoza,

ISPOR Milan, Monday November 9th, 2015

NICE Single Technology Appraisal (STA) Process



Background

ERGs are independent, academic organizations.

They systematically review the clinical efficacy and cost-effectiveness of products based on manufacturer-submitted dossiers.

Evidence Review Groups (ERGs)

Aberdeen Health Technology Assessment (HTA) Group

BMJ-Technology Assessment Group (BMJ-TAG)

Kleijnen Systematic Reviews

Liverpool Reviews and Implementation Group (LRiG)

Peninsula Technology Assessment Group (PenTAG)

School of Health and Related Research (SchARR)

Southampton Health Technology Assessments Centre (SHTAC)

University of York

Warwick Evidence

West Midlands HTA Collaboration

Objective

This presentation explores how the different ERGs behave:

1. Trends in how ERGs are commissioned by NICE
2. How ERGs are related to NICE's reimbursement decisions
3. How ERGs affect NICE's cost-effectiveness assessments

This evaluation is important from policy and industry perspectives, as it sheds some light on the factors that might influence NICE's technology appraisal process.

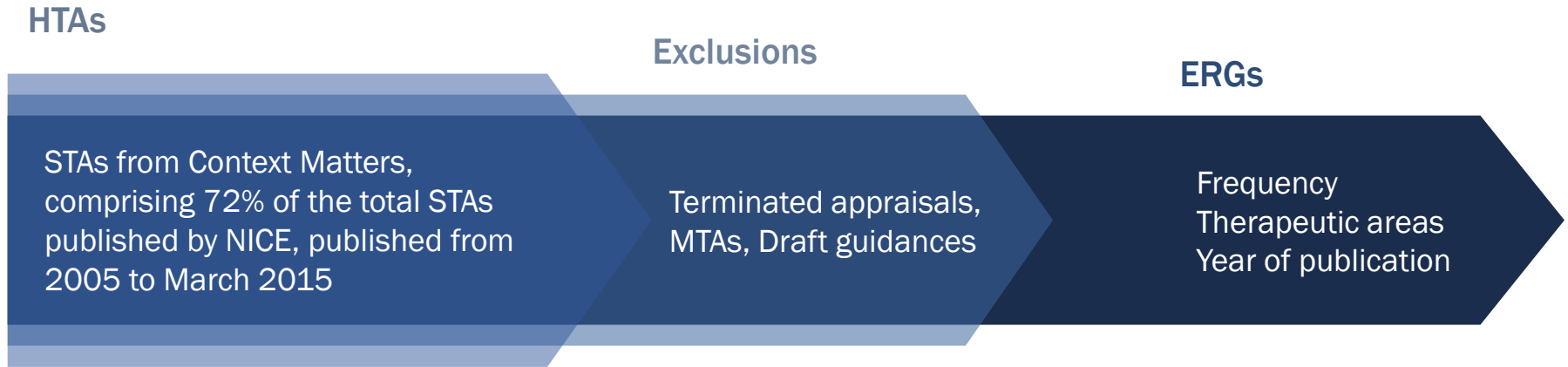
How Do ERGs Behave?

Description of data sample

Context Matters™

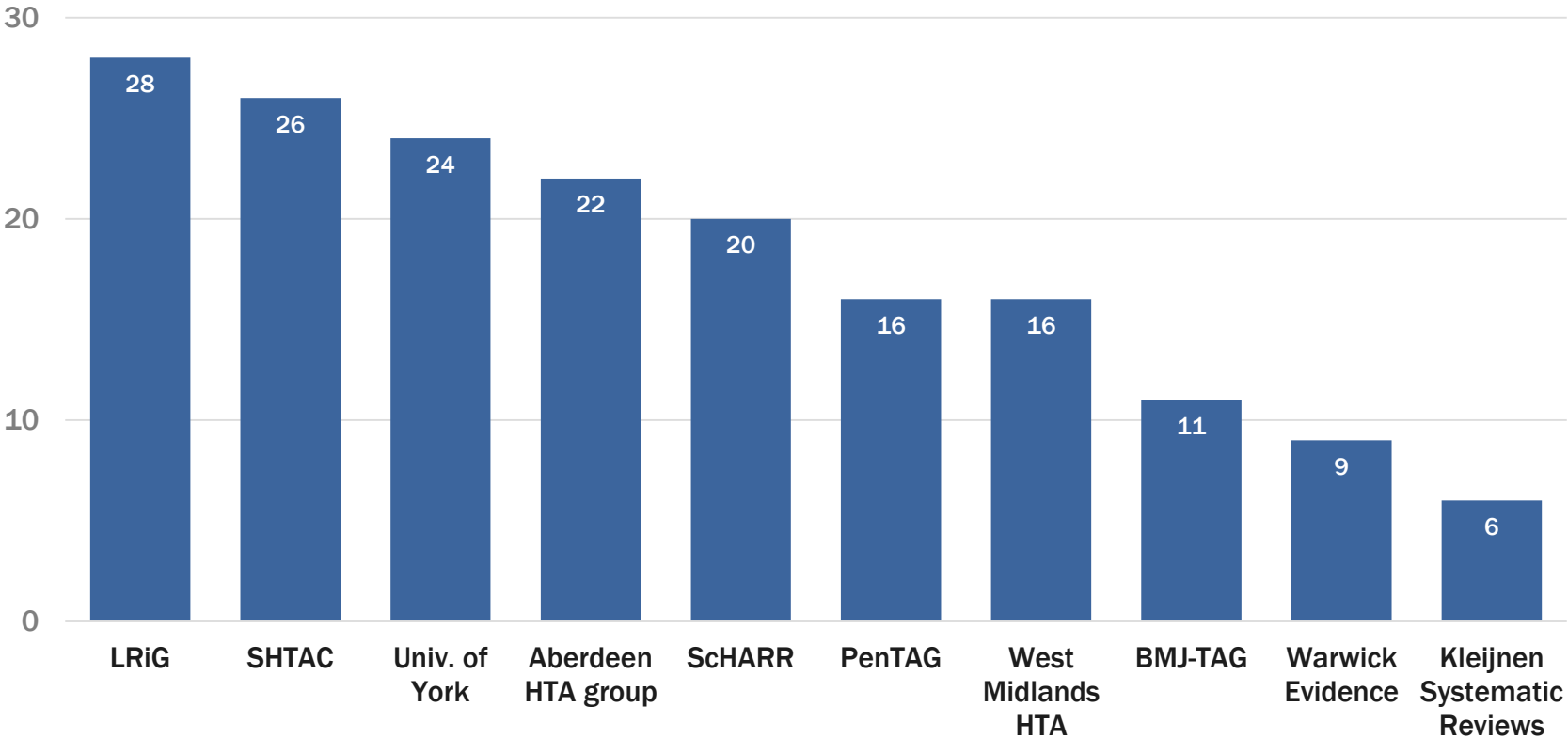
Methods

178 reimbursement events were included in the data set.



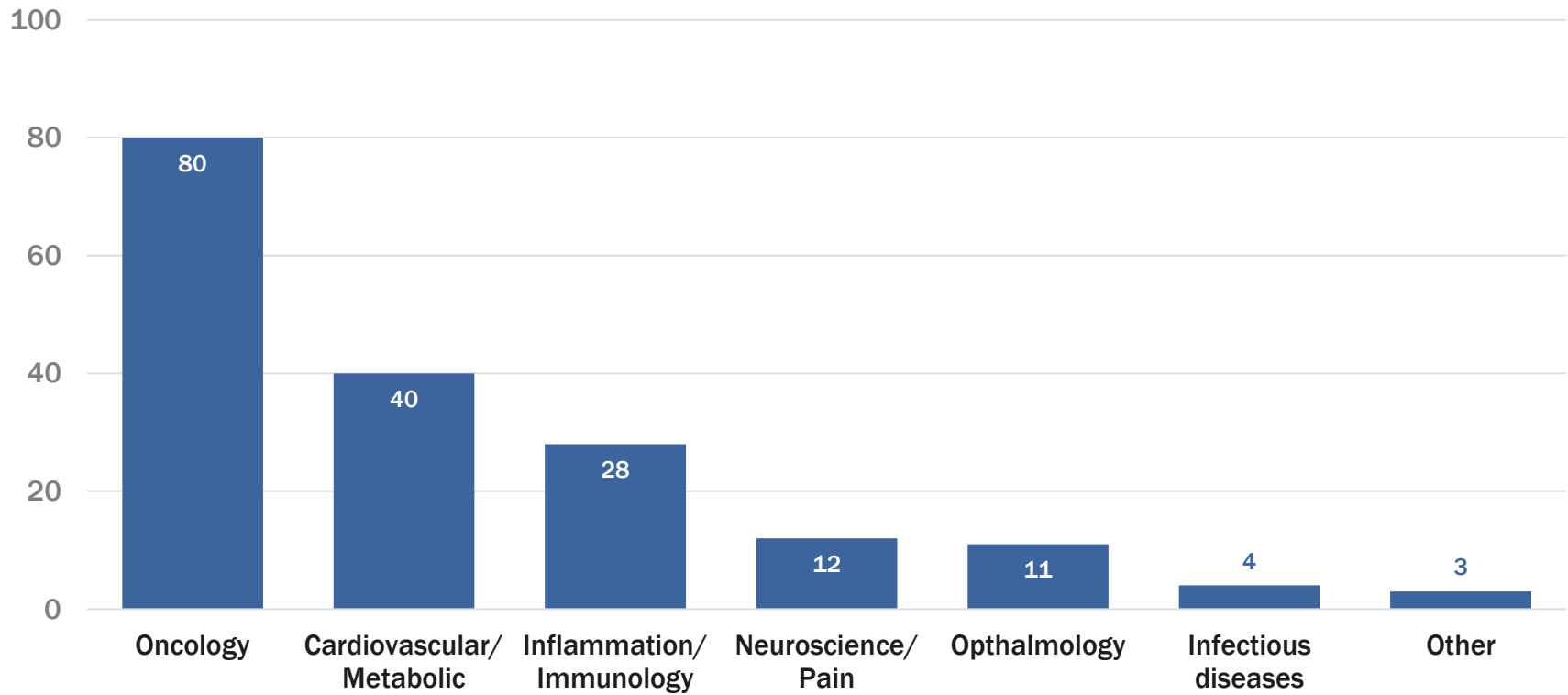
Number of Assessments by ERG

There was an unequal distribution in ERG frequency.



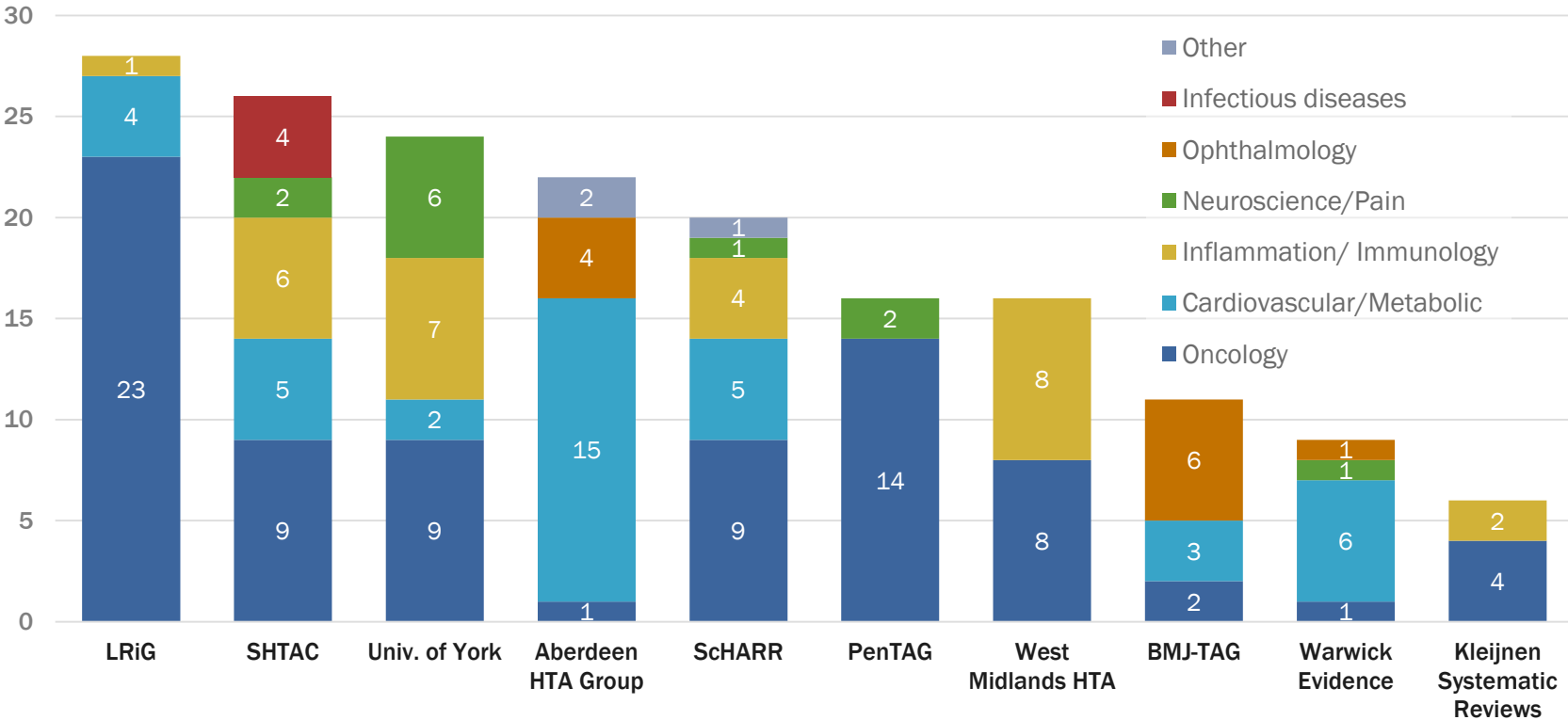
Oncology drugs were the most frequently assessed.

Number of Assessments by Therapeutic Area



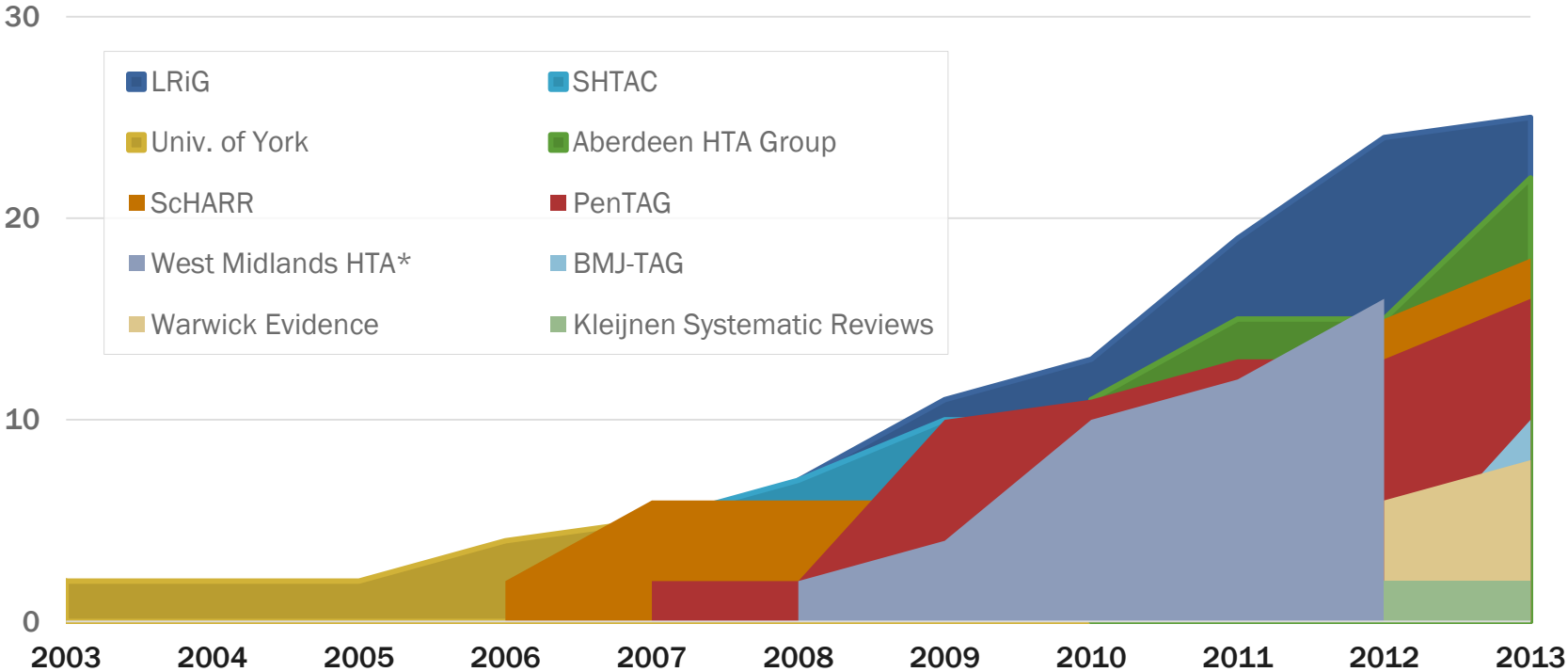
ERGs by Therapeutic Area

There was a difference in the therapeutic areas each ERG evaluated.



Cumulative ERG Assessments by Year

There was a difference in the years that ERGs were commissioned.



* The West Midlands HTA is no longer listed as an ERG on NICE's website.

Decisions and ERGs

The relationship between ERGs and NICE's
reimbursement decisions

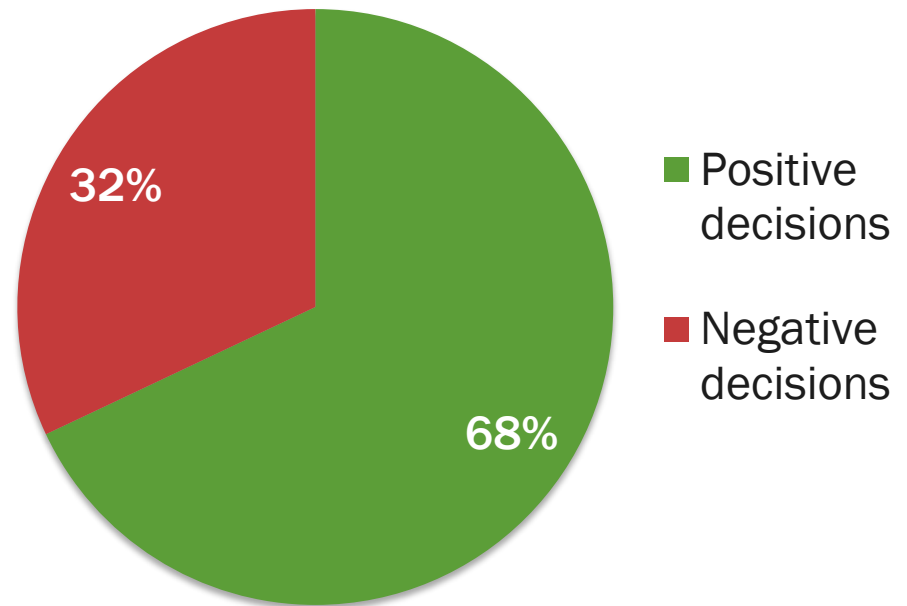
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Methods

NICE decision	Definition	Decision classification
Recommend	Drug is recommended in line with the marketing authorisation from the European Medicines Agency	Positive
Optimised	Drug is recommended for a smaller subset of patients than stated by the marketing authorisation	Positive
Only in Research	Drug is recommended for use only in the context of a research study (clinical trial)	Positive
Not recommended	Drug is not recommended	Negative

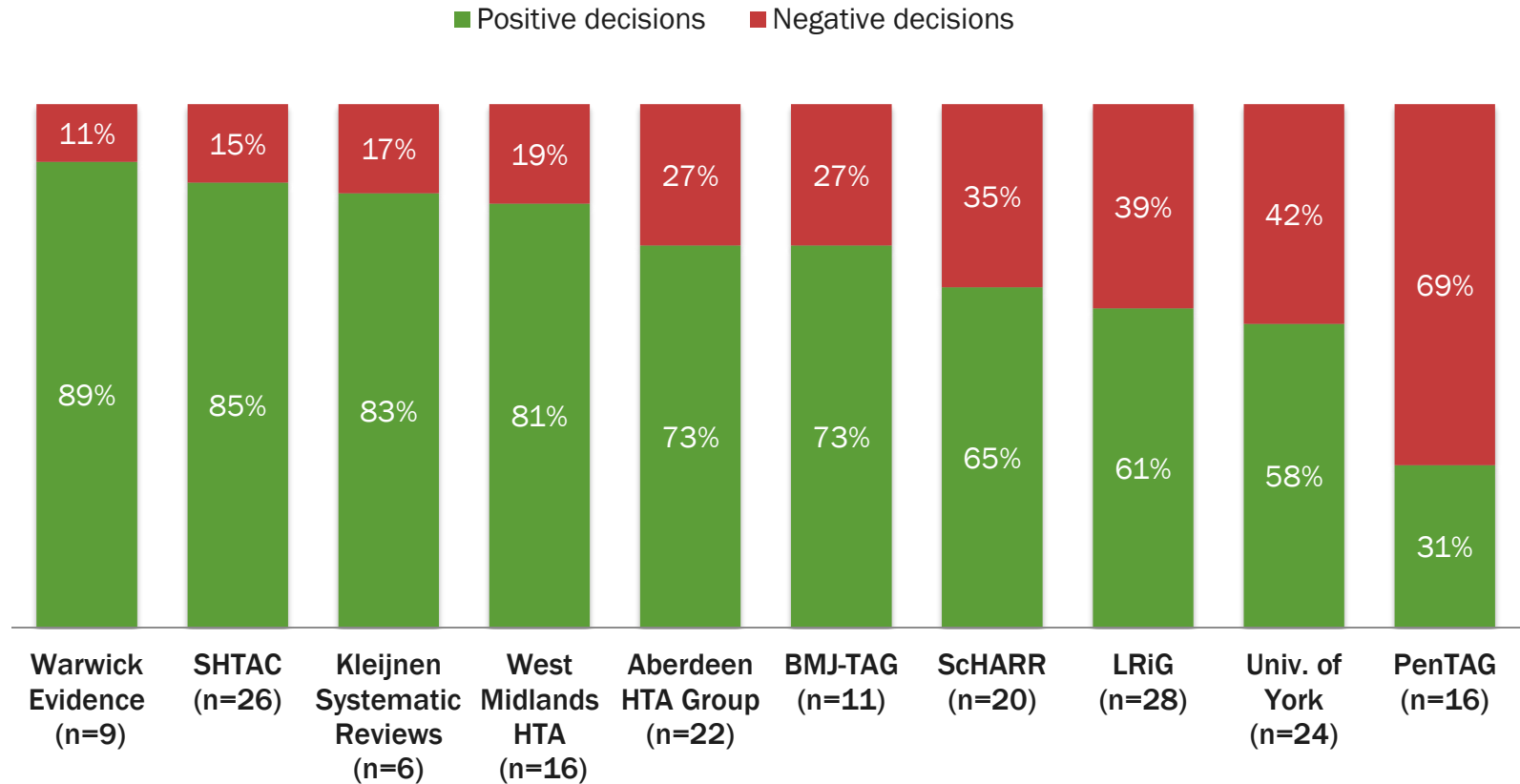
Reimbursement Decisions

The majority of reimbursement decisions were positive.



Reimbursement Decisions by ERG

There was a correlation between ERG and decision ($p=0.024$).



Decisions by ERG: Controlling for Therapeutic Area

In logistic regression, when controlled for therapeutic area:

SHTAC: 8x odds of positive reimbursement decisions

West Midlands HTA: 10x odds of positive reimbursement decisions

No difference was found for the 8 other ERGs.

ICER Analysis

Manufacturer base-case ICER compared to the
NICE most-plausible ICER

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Methods

Ex: Lung Cancer, Xalkori (Sept 2013)

Comparator	Manufacturer base-case ICER	NICE's most-plausible ICER	ICER difference
Docetaxel	£41,544	£100,001	£58,457
BSC	£35,455	£50,201	£14,746

Determination of ICER difference:

NICE most-plausible ICER – Manufacturer base-case ICER

Assumptions:

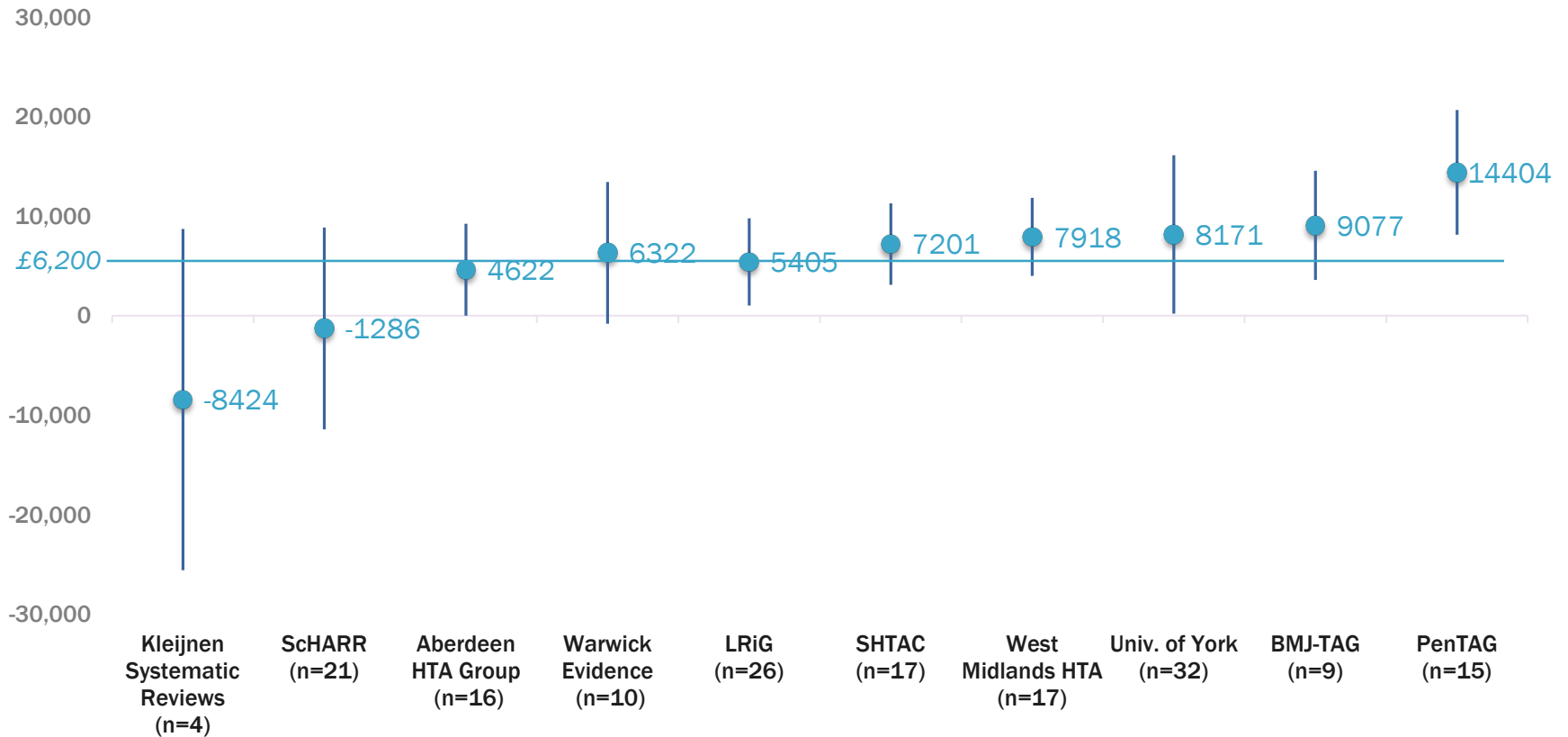
The difference between NICE's most-plausible ICER and the manufacturer's base-case ICER can be attributed to the ERG report.

A large ICER difference indicates a stricter ERG assessment of the economic model.

A small ICER difference indicates ERG agreement with the manufacturer's economic analysis.

ICER Difference

On average, NICE's most-plausible ICER was £6,200/QALY more than the manufacturer's base-case ICER.



Conclusions

Implications for the objectivity of the NICE approval process.

NICE commissioned ERGs differently.

They were commissioned for different therapeutic areas.

They were commissioned during different years.

NICE's decisions were different across ERGs.

When controlled for therapeutic area, SHTAC and West Midlands HTA were more likely to be associated with positive decisions.

On average, manufacturers underestimated their drugs' ICERs by £6,200/QALY.

There was wide range in ICER differences across ERGs.

Maximum: PenTAG (£14,000); Minimum: Kleijnen Systematic Reviews (-£8,424)

What do these differences mean for manufacturers?

Thank You.

Your Blueprint for Market Access™

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