Mapping of HTA methodologies in EU

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HTA Network

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Study aims

- Provide a concise and accurate overview of the scientific methodologies implemented by the Member States' HTA bodies in their assessments
- Contribute to a better understanding of the current HTA organisational and methodological framework in each country

Project

- Literature Review
- Survey
  - Focus and development
  - Survey by way of EUSurvey instrument
- Results
  - Standard description (Country Profile)
  - Analysis of similarities and discrepancies
- Scientific and technical policy options
- Conclusions

Survey

- All MoH designated organisations in EUnetHTA JA3 were contacted: 79
- Respondents by February 2017: 62
- Survey study Sample: **48 institutions** in 27 EU and 1 EEA (Norway) countries that confirmed a defined role of **informing a defined decision maker**

Results

- Country Profiles
  - applied scientific and technical **methodology**
  - formal **context** where HTA methodology is applied
  - formal **background** for scientific and technical methodology choices
- Similarities and differences in applied scientific and technical methodology

Selected results

Country profile tables

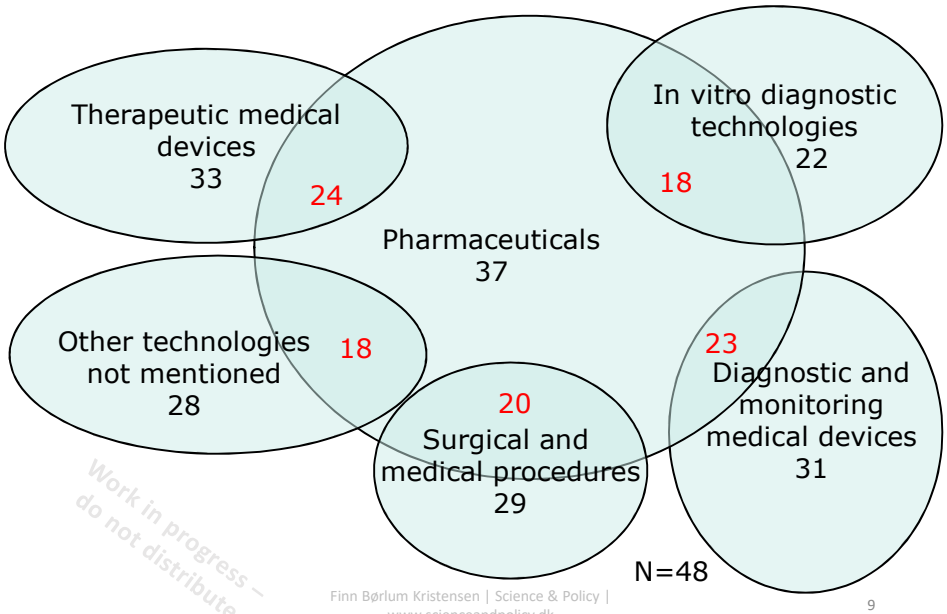
Isssues in HTA research methodology

Table 1 Choice of assessment comparators
Austria

Institution	Hauptverband der Österreichischen Sozialversicherungsträger (HVB)	Ludwig Boltzmann Institute of Health Technology Assessment (LBI-HTA)	Gesundheit Österreich GmbH (GÖG)
Pharmaceuticals			
Technologies considered potentially relevant comparators	Pharmaceuticals	Pharmaceuticals Medical devices Surgical and Medical Procedures Other Therapeutic Technologies Providing advice	
Criteria for choice of comparator(s) in assessments	The comparator is supported by evidence on its efficacy and safety profile for the respective clinical indication/population	Europe-wide agreed reference comparator The comparator technology(ies) likely to be replaced by the assessed technology if proven inferior to it The comparator is supported by evidence on its efficacy and safety profile for the respective clinical indication/population	
Medical devices and other non-pharmaceutical technologies			
Technologies considered potentially relevant comparators	Pharmaceuticals Medical devices Surgical and Medical Procedures Other Therapeutic Technologies	Pharmaceuticals Medical devicesSurgical and Medical Procedures Other Therapeutic Technologies Providing advice	Medical devices Surgical and Medical Procedures Other Therapeutic Technologies Providing advice
Criteria for choice of comparator(s) in assessments	The comparator technology(ies) likely to be replaced by the assessed technology if proven inferior to it The comparator is supported by evidence on its efficacy and safety profile for the respective clinical indication/population	Europe-wide agreed reference comparator The comparator technology(ies) likely to be replaced by the assessed technology if proven inferior to it The comparator is supported by evidence on its efficacy and safety profile for the respective clinical indication/population	The comparator technology(ies) likely to be replaced by the assessed technology if proven inferior to it The comparator is supported by evidence on its efficacy and safety profile for the respective clinical indication/population

European HTA institutions assess a wide range of health technologies

Fig. 1. Health technologies assessed by the 48 institutions



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Emerging European practice?

All institutions in 27 Member States and Norway include the four clinical domains in the scope of their assessments – always or depending on what is assessed

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Fig. 2. **Health problem and current use of technology** included in assessments of pharmaceuticals – always or depending on the technology

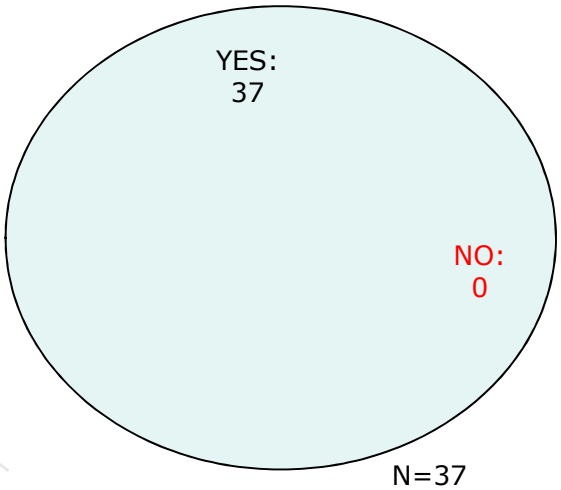

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Fig. 3. **Health problem and current use of technology** included in assessments of non-pharmaceutical technologies – always or depending on the technology

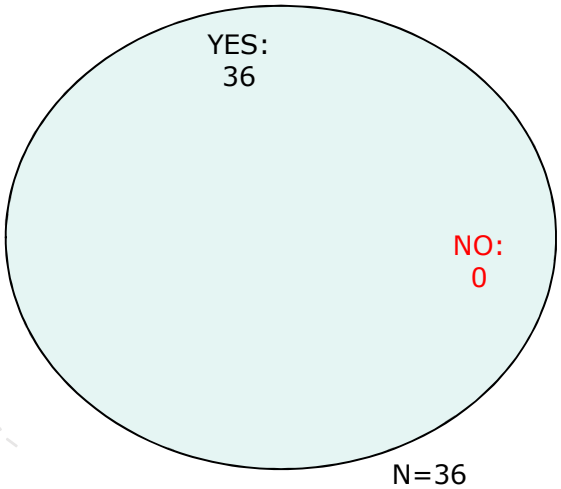

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Fig. 4. **Description of technical characteristics of the technology** included in assessments of pharmaceuticals – always or depending on the technology

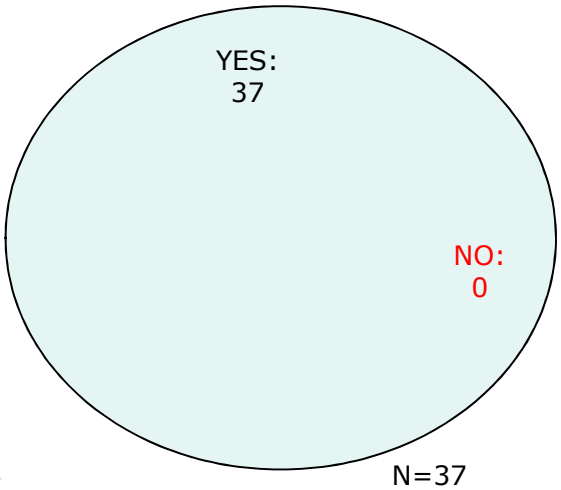

Fig. 5. **Health problem and current use of technology** included in assessments of non-pharmaceutical technologies – always or depending on the technology

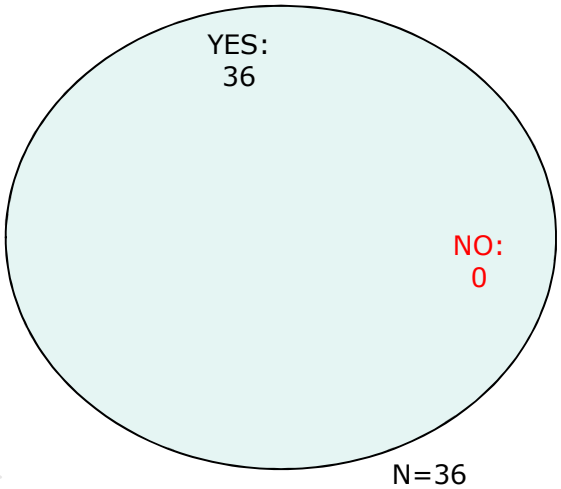

Fig. 6. **Clinical effectiveness/efficacy** included in assessments of pharmaceuticals – always or depending on the technology

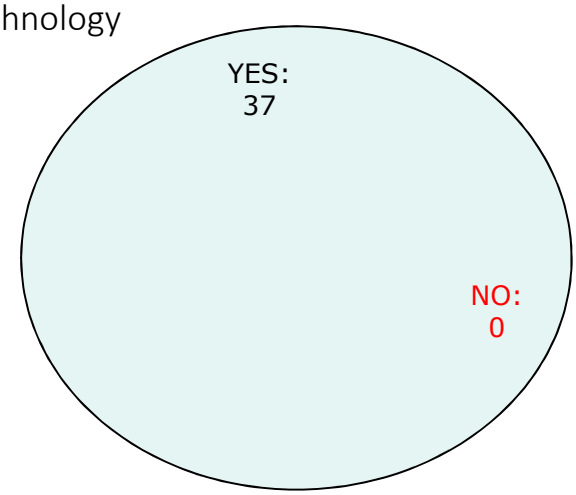

Fig. 7. **Clinical effectiveness/efficacy** included in assessments of non-pharmaceutical technologies – always or depending on the technology

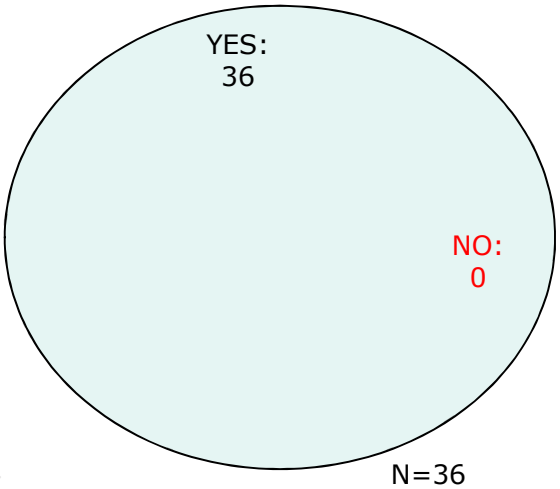

Fig. 8. **Safety** included in assessments of pharmaceuticals – always or depending on the technology

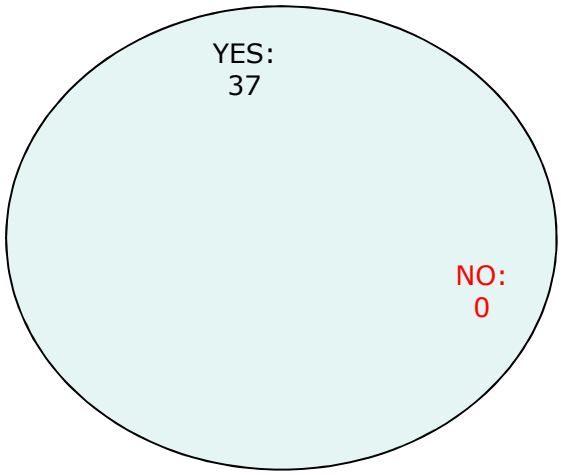

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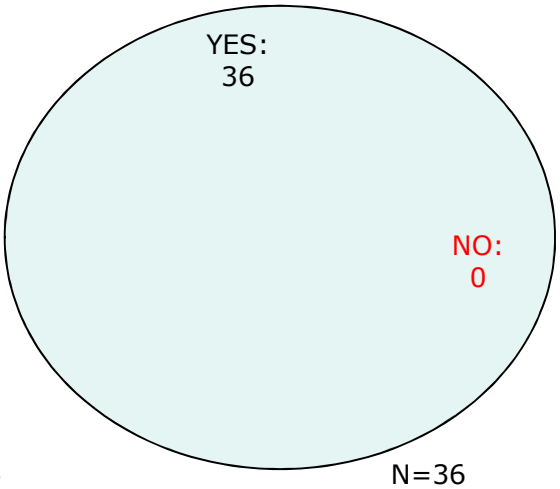
Fig. 9. **Safety** included in assessments of non-pharmaceutical technologies – always or depending on the technology



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Emerging European practice?

A large majority of institutions include non-clinical domains in the scope of their assessments – always or depending on what is assessed

Fig. 10. **Non-clinical domains** included in assessments of pharmaceuticals – always or depending on the technology

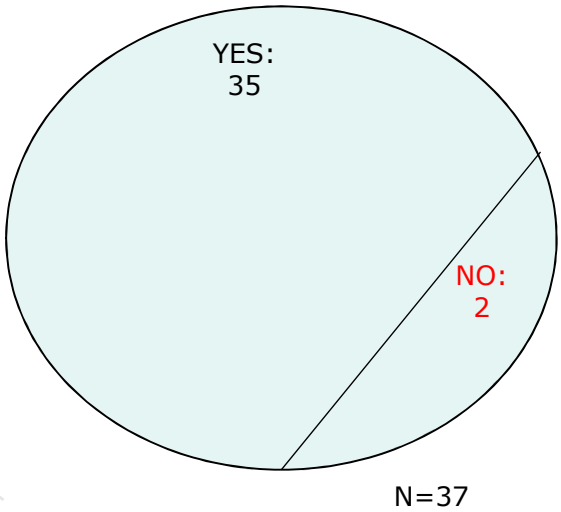

Fig. 11. **Non-clinical domains** included in assessments of non-pharmaceutical technologies – always or depending on the technology

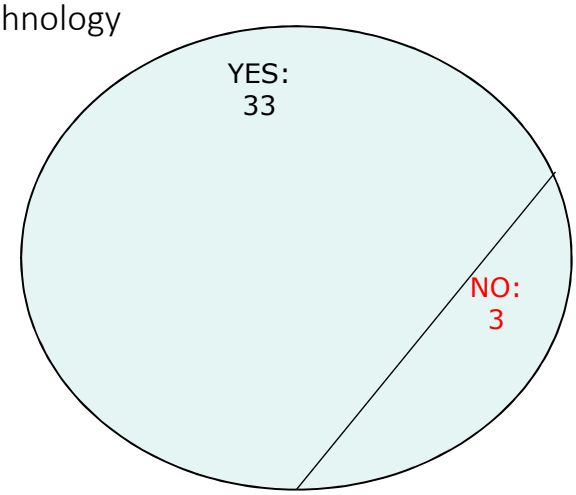

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Fig. 12. **Cost, budget impact, economic evaluation** included in assessments of pharmaceuticals – always or depending on the technology

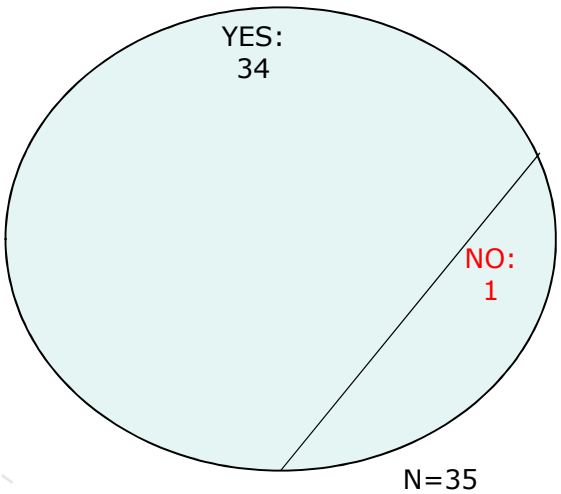

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Fig. 13. **Cost, budget impact, economic evaluation** included in assessments of non-pharmaceutical technologies – always or depending on the technology

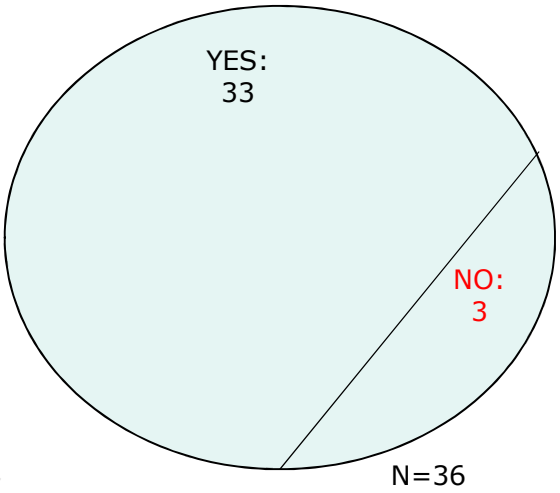

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Fig. 14. **Patient aspects** included in assessments of pharmaceuticals – always or depending on the technology

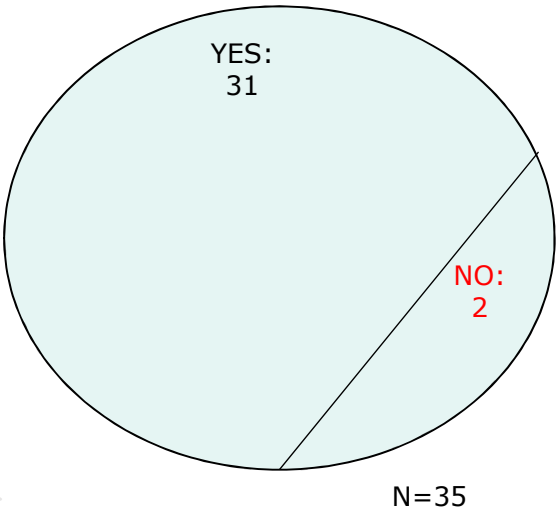

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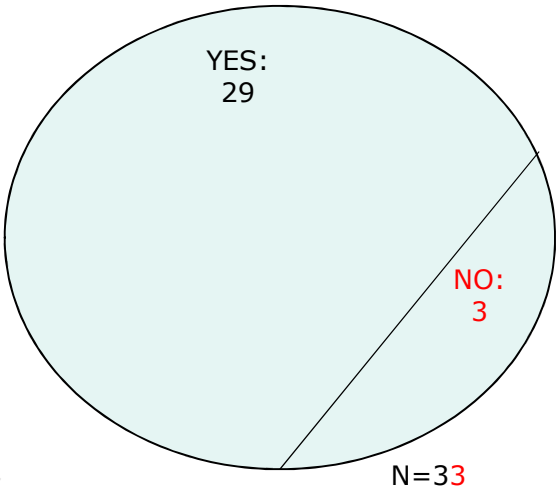
Fig. 15. **Patient aspects beyond the clinical aspects** included in assessments of non-pharmaceutical technologies – always or depending on the technology



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Policy consideration

Continuing the development of scientific and technical cooperation in the non-clinical fields such as organisational, economic and patient aspects may create European added value

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Emerging European practice?

A large majority of institutions declare a pragmatic decision oriented approach to comparative assessment using best available evidence

Fig. 16. Decision oriented and/or methodology oriented **choice of comparator** - in assessments of pharmaceuticals

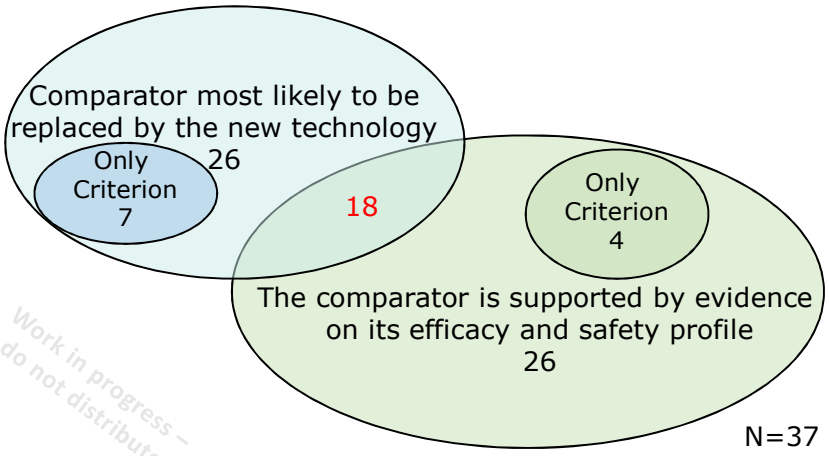

Fig. 17. Decision oriented and/or methodology oriented **choice of comparator** - in assessments of non-pharmaceutical technologies

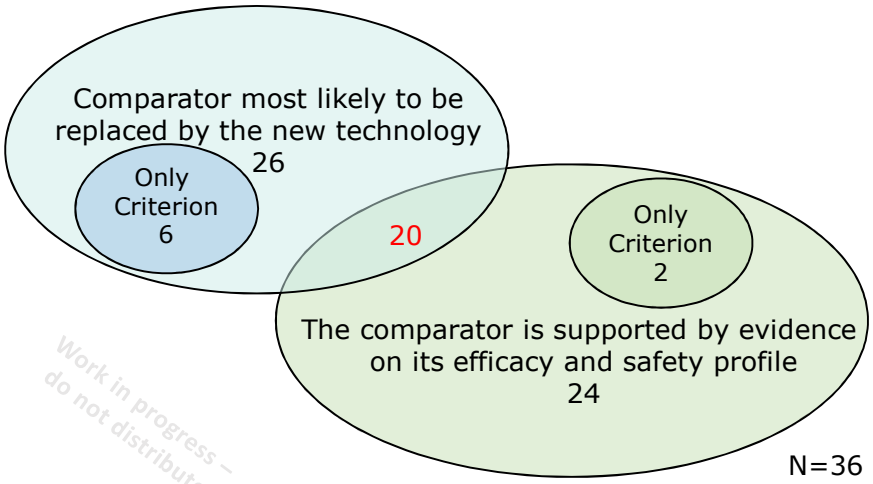

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Fig. 18. Non-pharmaceutical technologies seen as **relevant potential comparators** in assessments of pharmaceuticals

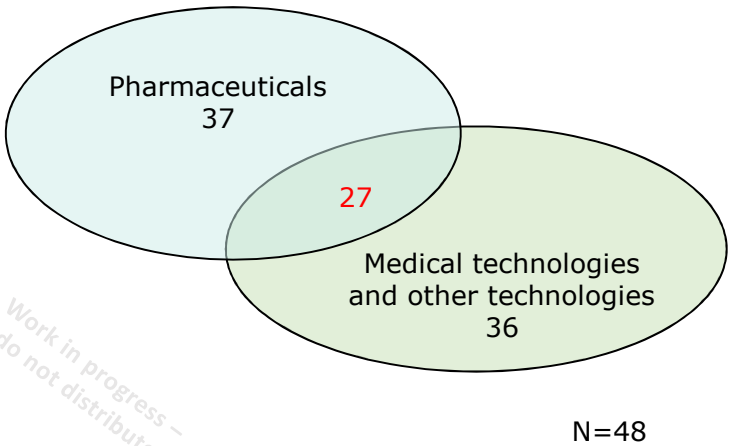

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Fig. 19. Pharmaceuticals seen as **relevant potential comparators** in assessments of non-pharmaceutical technologies

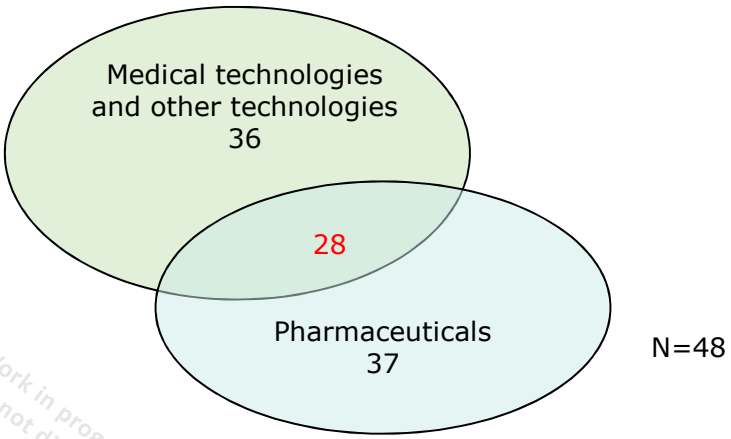


Fig. 20. **Indirect comparisons** may be used when estimating effectiveness or risk in assessments

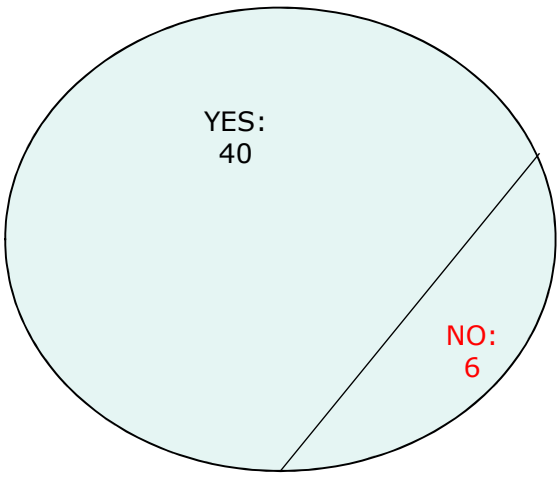
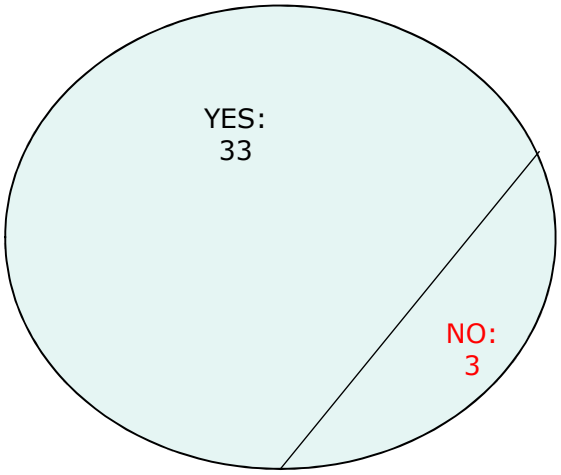


Fig. 21. **Network meta-analysis** may be used when estimating effectiveness or risk in assessments



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Policy consideration

The distance is not long to having good scientific and technical solutions in using best available evidence for valid and reliable comparison of technology options. Aiming at having joint guidelines that are used at both national and EU level is not unrealistic

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Emerging European practice?

Surrogate and composite endpoints (outcomes) are accepted in the absence of single standing endpoints such as disease state and mortality in assessments done by the large majority of HTA institutions

Fig. 22. **Surrogate endpoints** accepted when estimating effectiveness or safety in assessments

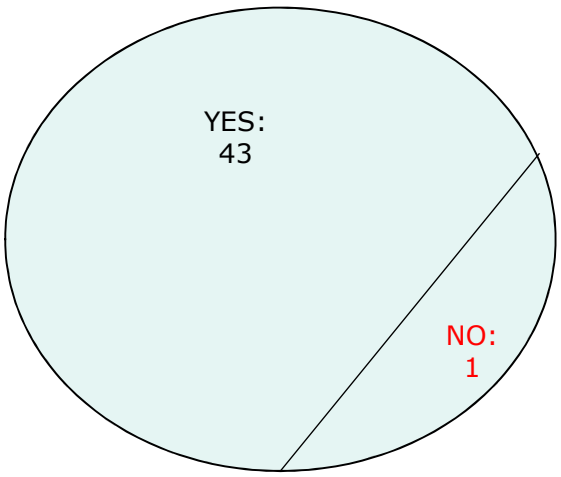

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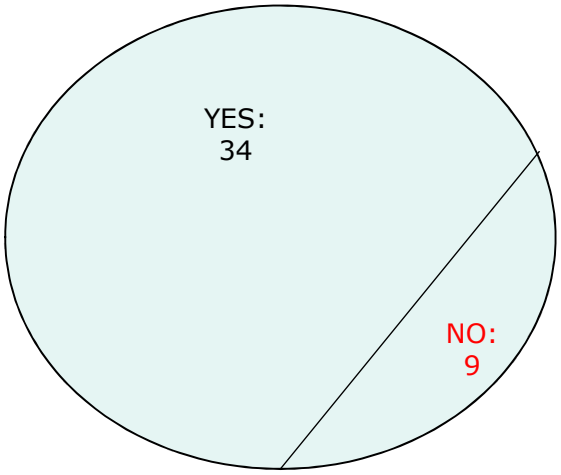
Fig. 23. **Composite endpoints** accepted when estimating effectiveness or safety in assessments



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Policy consideration

Surrogate and composite endpoints (outcomes) in the absence of single standing endpoints such as disease state and mortality are under certain conditions accepted by regulators. Synergies between regulatory science and HTA should be further intensified

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Emerging European practice?

Reports from other countries are used in assessments by a large majority of HTA institutions

Fig. 24. Content of **assessment reports from HTA bodies in other countries** formally used when producing reports on pharmaceuticals

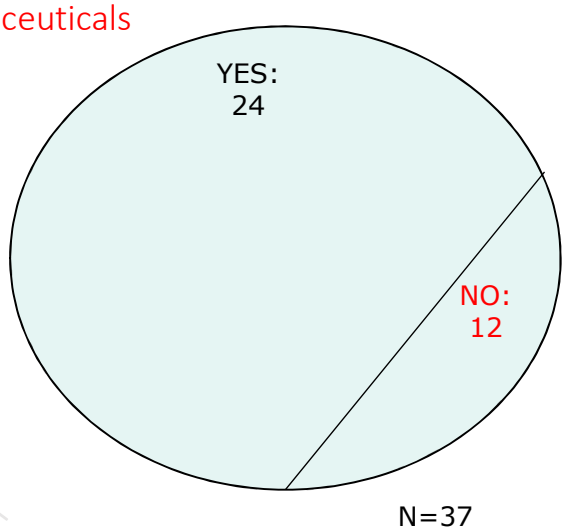
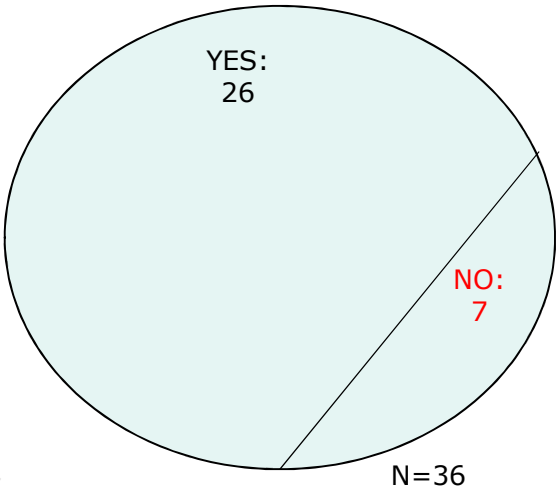


Fig. 25. Content of **assessment reports from HTA bodies in other countries** formally used when producing reports on non-pharmaceutical technologies



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Policy consideration

As reports from other countries are used in assessments by a large majority of HTA institutions it makes sense to pursue scientific and technical harmonisation/standardisation in the production of HTA information

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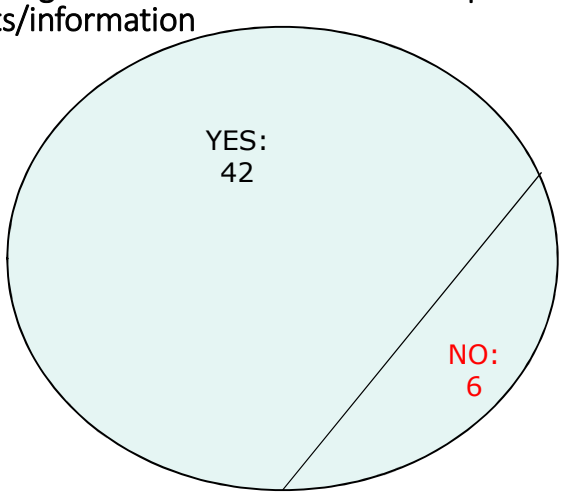
Emerging European practice?

With a limited number of exceptions HTA institutions in Europe have written guidelines for assessments

Fig. 26. **Written guidelines for the institution's production of HTA reports/information**



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Policy consideration

Having good research practices and written guidelines for assessments aiming to inform decision making based on best available evidence should have the attention of the HTA Network. This should be at the core of EU cooperation on HTA - also beyond 2020