

Ssegonja Richard<sup>1</sup>, Sun Sun<sup>2,3</sup>, Borisenko Oleg<sup>2</sup>

<sup>1</sup> Uppsala University, <sup>2</sup> Synergus AB, <sup>3</sup> Karolinska Institutet

## CONCLUSION

This study revealed similarities in evidence requirements for in-vitro diagnostic tests in health technology assessments in England and France. However, economic evidence is not a part of French assessments of new codes for biological tests and a mandatory part of Diagnostic Assessment Programme at NICE in England. Analysis of factors, which can influence recommendations of health technology assessments is provided. Good diagnostic performance, high level of evidence, supportive opinion of experts and cost-effectiveness of the test were among the most common factors of positive recommendations.

## OBJECTIVE

To explore the evidence requirements needed for obtaining positive recommendations for in-vitro diagnostics (IVDs) by health technology assessment (HTA) bodies in Europe.

## BACKGROUND

In-vitro diagnostics have an essential role in diagnosis and treatment pathway across all clinical areas. The evidence base for IVD tests may vary on a scale between operational characteristics of the test (e.g. sensitivity, specificity, etc.) and impact of the test on the hard health outcomes (e.g. survival, incidence of clinically relevant events, etc.). It is therefore important for the clinical community, authorities and industry to understand requirements for evidence to ensure that this evidence is available to assist informed decision-making.

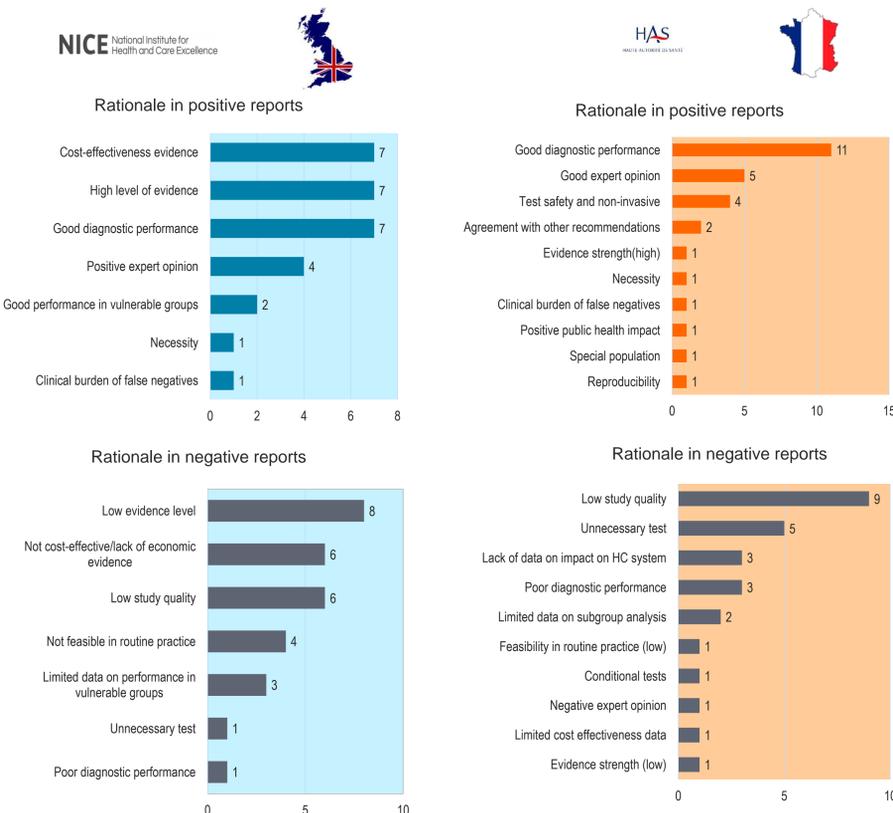


Figure 3. Rationale for positive and negative recommendations

## RESULTS

Out of the 30 reports, majority were from England (n=9) and France (n=19). Most reports (70%, n=21) evaluated only one test, four reports evaluated two tests, and three reports evaluated more than two tests. In total, 48 recommendations were made in the 30 reports, which are classified as positive, positive with restrictions, negative, and negative only for research (Figure 1), there is significant differences for recommendations between England and France. The IVD covers different disease area (Figure 2). In England, the most commonly evaluated clinical area was oncology (64%) while in France it was infectious diseases (32%).

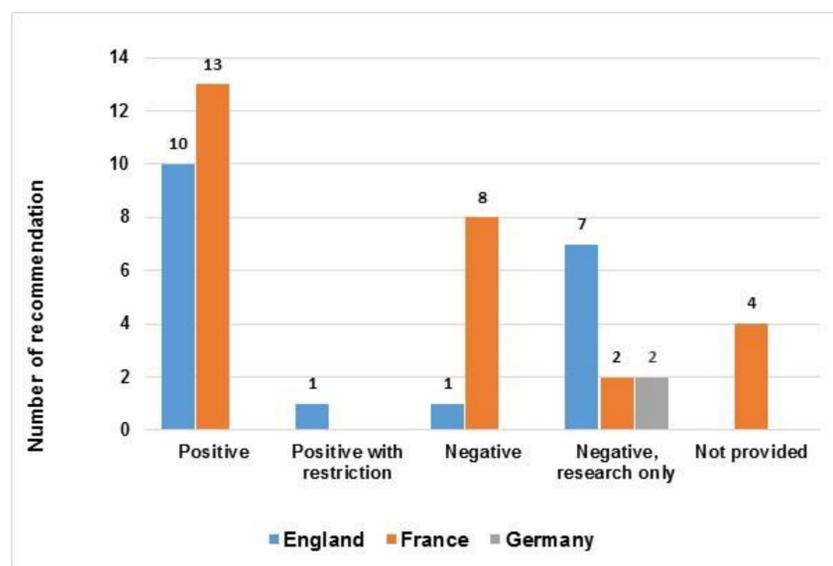


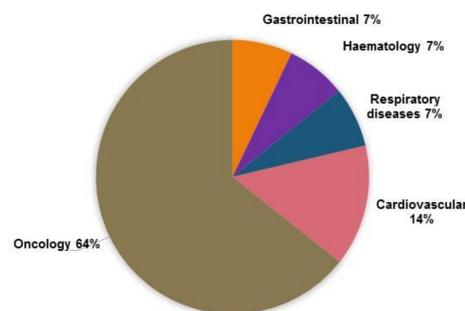
Figure 1. Recommendations for IVD tests, by country

There was no differences between England and France, in relation to mean number of considered studies (16 compared to 14), median sample size of the studies (1256 pts. and 1096 pts.), mean sensitivity (88% compared to 85%) and mean specificity (84% compared to 86%). Meta-analysis of outcomes was reported more often in England (58% compared to 5%). Economic evidence was provided in NICE reports mostly. Analysis of factors, which can influence recommendations of health technology assessments is provided in the Figure 3. Good diagnostic performance, high level of evidence, supportive opinion of experts and cost-effectiveness of the test were among the most common factors of positive recommendations.

## METHODS

A systematic search for health technology assessments, evaluating IVD tests, from HTA bodies in France, England and Germany was performed. In England, NICE reports from the Diagnostic Assessment Program for the period 2013-2015 were reviewed. In France, HAS opinions/recommendation reports about proposals for new NABM codes were reviewed for the period 2005-2015. In Germany, IQWiG reports issued between 2013 and 2015 were considered. The search was conducted in May 2015. Only published/completed HTAs for diagnostic IVDs, based on systematic literature review and economic analysis (optional) were considered. HTAs of IVDs used in screening methods, imaging methods, and monitors of vital functions were excluded from the analysis. The search yielded a total 291 articles/reports. Based on the eligibility criteria, 30 reports were selected for the final analysis. Presentation of detailed results was limited only to England and France due to small number of reported identified in Germany.

### ENGLAND



### FRANCE

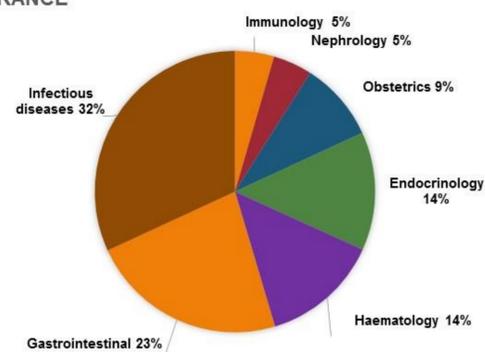


Figure 2. Recommendations for IVD tests, by disease area, England compared to France