submissions, in 53% of cases a high ICER was reported in the summary of guidance as a reason for rejection. In about 30% of these cases, the high drug cost was specified as the driver of the high ICER. The lack of a robust economic case was mentioned in 45% of rejections. Limited evidence of clinical benefit was shown in 43% of cases. Of the reasons provided inadequate type or quality of clinical data (21%) and non-acceptance of clinical positioning (11%). In 45% of cases the rejections were largely due to economic reasons; 6% of cases were not accepted due primarily to clinical reasons and in 49% of rejections the criticisms related to both the economic and clinical methods in the HTA. In 2009 was identified using HTAinSite™. We classified these recommendations into: ‘recommended’, ‘restricted’ and ‘not recommended’, and calculated the percentage. We then analyzed these recommendations according to disease areas; cardiovascular/metabolic, ‘mental health’, infectious diseases, musculoskeletal conditions, oncology, and ‘others’. RESULTS: In 2007, NICE assessed 25 drugs, 31 in 2008 and 18 in 2009. Of these, in 2007 NICE recommended 8 drugs (31%) for all eligible patients, restricted 13 (53%), and did not recommend 4 (16%). In 2008, 3 (10%) were recommended, 21 (68%) were restricted, and 7 (22%) were not recommended. Finally, in 2009, 2 (11%) treatments were recommended, while 11 (61%) received restricted recommendations and 5 (28%) were not recommended. Between 2007 and 2009 NICE completed 7 appraisals in cardiovascular/metabolic of which 4 received a full recommendation, while in ‘mental health’ 2 out of 2 were fully recommended. In contrast, in ‘infectious diseases’, 1 out of 5 was fully recommended. In ‘musculoskeletal conditions’ only 1 out of 21 were recommended (17 restricted and 3 not recommended) while in oncology only 1 out of 23 received a full recommendation (13 restricted, 9 not recommended). In the ‘others’ group, 4 out of 12 received a recommendation (6 restricted, 2 not recommended). If manufacturers had not proposed Patient Access Schemes (PAS) the proportion of guidance not recommended in 2009 would be 44%. CONCLUSIONS: Appraisal outcomes have become more restrictive over time. Furthermore, low cost primary care therapeutics are more likely to receive a positive NICE recommendation than high cost specialty care interventions.

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NICE GUIDANCE: AN ANALYSIS OF LEVELS OF RESTRICTION BY DISEASE AREA

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OBJECTIVES: To assess the outcomes of NICE's guidance in totality and different disease areas. METHODS: A list of NICE Guidance published between 2007 to the end of 2009 was identified using HTAinSite™. We classified these recommendations into: 'recommended', 'restricted' and 'not recommended', and calculated the percentage. We then analyzed these recommendations according to disease areas; cardiovascular/metabolic, 'mental health', infectious diseases, musculoskeletal conditions, oncology, and 'others'. RESULTS: In 2007, NICE assessed 25 drugs, 31 in 2008 and 18 in 2009. Of these, in 2007 NICE recommended 8 drugs (31%) for all eligible patients, restricted 13 (53%), and did not recommend 4 (16%). In 2008, 3 (10%) were recommended, 21 (68%) were restricted, and 7 (22%) were not recommended. Finally, in 2009, 2 (11%) treatments were recommended, while 11 (61%) received restricted recommendations and 5 (28%) were not recommended. Between 2007 and 2009 NICE completed 7 appraisals in cardiovascular/metabolic of which 4 received a full recommendation, while in 'mental health' 2 out of 2 were fully recommended. In contrast, in 'infectious diseases', 1 out of 5 was fully recommended. In 'musculoskeletal conditions' only 1 out of 21 were recommended (17 restricted and 3 not recommended) while in oncology only 1 out of 23 received a full recommendation (13 restricted, 9 not recommended). In the 'others' group, 4 out of 12 received a recommendation (6 restricted, 2 not recommended). If manufacturers had not proposed Patient Access Schemes (PAS) the proportion of guidance not recommended in 2009 would be 44%. CONCLUSIONS: Appraisal outcomes have become more restrictive over time. Furthermore, low cost primary care therapeutics are more likely to receive a positive NICE recommendation than high cost specialty care interventions.

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DESIGNING EUROPEAN GUIDELINES FOR HEALTH OUTCOMES AND COST-EFFECTIVENESS ASSESSMENTS: THE ECHOOUTCOME EUROPEAN COMMISSION PROJECT


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OBJECTIVES: Over the last decade the National Institute of Clinical Excellence in the UK has published guidelines for health technology assessments (HTA) that includes recommendations on health outcomes and cost-effectiveness assessments. In Europe, this has opened the opportunity for countries to either propose their own guidelines or use the British ones. The ECHOUTCOME project is an interdisciplinary European research platform funded by the seventh Framework Program of the European Commission with the aim of designing new European guidelines in Health Outcomes and Cost-Efffectiveness assessments. METHODS: This three years project is structured in three phases. Phase 1 aims to conduct a pan-European survey of HTA organizations and health outcomes use in the 27 European countries. Multiple correspondence and factor analyses will be carried out to study the potential similarities and differences across Europe. The objective of Phase 2 is to test the robustness and underlying assumptions such as reproducibility, neutrality to risk, constancy of time-trade-off rate, utility independence, etc. on QALYs, DALYs and HYEs. This testing will be conducted in the general population (n=100 per country) in Belgium, France, Italy and UK. Phase 3 aims to propose new approaches in Health Outcomes and Cost-Efffectiveness analyses. RESULTS: The main deliverable of the ECHOUTCOME project will be new European Guidelines for assessing Health Outcomes and conducting Cost-Efffectiveness assessments. Of particular interest will be the recommendations on the practical usefulness of QALYs, DALYs and HYEs based on the experimental validation of their underlying assumptions. CONCLUSIONS: The ECHOUTCOME project is the first European validation study of health outcomes measures. This work will produce guidelines for public health decision-making in the 27 European countries. The ECHOUTCOME outcomes will enhance the debate and increase the understanding that will improve the knowledge of existing Health Outcomes and Cost-Effectiveness techniques and will promote new approaches for decision-making.