OBJECTIVES: To investigate Time to Progression (TTP) in two pilot countries and thus assess the feasibility of such studies in a wider European setting. The primary comparison was bevacizumab-based therapy versus non-bevacizumab-based therapy in first-line non-squamous NSCLC.

METHODS: Data were drawn from the Adelphi NSCLC Disease Specific Programme, a large cross-sectional study of consecutively presenting patients in France and Germany in 2010. Physicians provided retrospective information regarding disease status and treatment patterns. TTP was defined as time from start of treatment to physician-reported disease progression or two weeks before the start of second-line presentation of the results, the stakeholders changed their ranking to 1) ERCC1, 2) BC markers, and 3) EGFR. The majority of stakeholders found the VOR information to be useful (69%), with 53% changing their ranking after consideration of the VOR presentation of the results, the stakeholders changed their ranking to 1) ERCC1, 2) BC markers, and 3) EGFR. The majority of stakeholders found the VOR information to be useful (69%), with 53% changing their ranking after consideration of the VOR.

CONCLUSIONS: Our findings indicate that research assessing the use of breast cancer recurrence biomarkers and consequent earlier treatment could be highly valuable. The EVPI of approximately $2.1 billion represents the upper bound of the value of additional research, and is driven by the affected population, testing sensitivity and specificity, costs, and uncertainty in the choice of optimal strategy. We are currently conducting EVSI analyses for various trial designs, compared to the cost of conducting these trials. Our analysis allows decision makers to quantitatively assess and prioritize research efforts in biomarker testing for breast cancer recurrence relative to alternative research investments.

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VALUE OF RESEARCH ANALYSES IN RESEARCH PRIORITIZATION OF CANCER GENOMIC APPLICATIONS

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OBJECTIVES: The object of this study, as part of the Center for Comparative Effectiveness Research in Cancer Genomics (CANCERGENX), was to evaluate and evaluate a process for incorporating formal value of research (VOR) analyses into a stakeholder-informed research prioritization process for genomic applications for study in a prospective, randomized comparative effectiveness trial within the SWOG clinical trials cooperative. METHODS: Six candidate genomic applications identified through a landscape-analysis, were prioritized by 13 stakeholders based on 9 criteria: population impact, adequacy of standard care, analytic and clinical validity, benefits, harms, economic impact, evidence of need, clinical trial feasibility, and market factors. We developed decision-analytic based models for the top three prioritized options and presented the results to stakeholders. We evaluated the impact of the VOR analyses on the test ranking and stakeholder perceptions about the usefulness of VOR using an online survey. RESULTS: The top three genomic applications based on the initial rankings were: 1) ERCC1 testing in early stage non-small cell lung cancer (NSCLC), 2) EGFR mutation testing in advanced NSCLC, and 3) tumor marker testing to detect recurrence in early stage breast cancer (BC). The VOR was estimated to be $2.2 to $2.8 billion, $33 million, and $2.1 billion, respectively. After presentation of the results, the ranking for their ranking to 1) ERCC1, 2) BC markers, and 3) EGFR. The majority of stakeholders found the VOR information to be useful (69%), with 53% changing their ranking after consideration of the VOR findings. In addition, all stakeholders indicated that they would use VOR analyses in future prioritization processes. CONCLUSIONS: Stakeholder prioritization of genomic research prioritization of genomic applications is a function of many evidence domains. Our study suggests that with adequate resources, VOR analyses can be incorporated into this process and provide useful information for research prioritization.

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