cancer staging or surveillance in asymptomatic patients. Further studies are needed to characterize patients’ typology who deserve intensive staging and follow-up procedures.

**DECIDING UPON NEW AND EXPENSIVE TECHNOLOGIES IN HEALTHCARE: REAL OPTIONS ANALYSIS IN PROTON THERAPY**

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**OBJECTIVES:** Radiotherapy with protons is a promising new treatment modality, for which targeted applications are being made worldwide. However, the investment costs of proton therapy (PT) are high (roughly €90 million) and limited clinical evidence is available. Also, previous studies have indicated that PT may be cost-effective, but show considerable decision uncertainty. Consequently, it is unclear whether we should adopt PT now, or wait for more information. Adoption involves a risk of facing high sunk costs, while delay may impose opportunity losses because patients receive sub-optimal treatment. Real options analysis (ROA), a technique originating from financial economics, assists in making this trade-off. METHODS: We examined whether to adopt PT, as compared to stereotactic body radiotherapy, in the treatment of stage I non-small cell lung cancer (NSCLC). Three options are available: adopt without further research (AN); adopt and undertake a trial (AT); or delay and undertake a trial (DT). The decision depends on the expected net gain of each option, which is calculated by subtracting its total costs from its expected benefits. RESULTS: The expected net gain of AT and DT were positive, indicating that we should not decide to adopt without further research (AN). Up to a sample size of 1000 patients, the expected net gain of AT was higher than DT, indicating that the best option was to adopt and trial. The expected net gain of AT was highest for a sample size of 450 patients, which is thus considered the optimal sample size. CONCLUSIONS: Based on these results, we recommend to adopt PT in the treatment of stage I NSCLC, and to perform a trial with 450 patients. We have shown that ROA provides a transparent method of weighing the costs and benefits of all available options, to assist in decision-making upon new and expensive technologies.

**SYSTEMATIC LITERATURE REVIEW ON THE INTER- AND INTRA-LABORATORY VARIABILITY OF MOLECULAR TESTING OF RESPONSE TO TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA (CML) PATIENTS AND THE ASSOCIATED COSTS AND COST-EFFECTIVENESS**

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**OBJECTIVES:** During disease monitoring of patients with CML, for patients with a complete response, residual leukemia can be assessed by real-time quantitative polymerase chain reaction (RQ-PCR). There are several “home-brew” and commercially available BCR-ABL gene transcript detection methodologies in use, each requiring inter-laboratory validation for the specific laboratory and giving rise to laboratory specific data. Harmonisation of results according to an international scale is underway, but use is limited for several technical reasons. Information is required for decision makers on the accuracy and reproducibility of the tests and their costs and cost-effectiveness. The objective of this study was to assess the quantity and quality of such information. METHODS: English language systematic literature review on the intra- and inter-laboratory variability for BCR-ABL molecular monitoring test, inter-rater reliability across manual assays and the costs and cost-effectiveness of molecular testing in CML. CONCLUSIONS: There is a reasonable body of evidence on certain aspects of analytical validity for CML molecular testing, but other aspects of analytical validity and the costs and economics of molecular diagnostics in CML appear to be an unexplored area. Testing variability has potentially serious implications for patient outcomes and more information for decision-makers to assess relative costs and cost-effectiveness is required.

**A COMPARISON OF HTA RECOMMENDATIONS FOR CANCER TREATMENT TECHNOLOGIES Published by Agency for Health Technology Assessment (AHTAPoL) and National Institute for Health and Clinical Excellence (NICE)**

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**OBJECTIVES:** The objective of this study was to compare HTA recommendations for cancer drug technologies issued by both Agency for Health Technology Assessment (AHTAPoL) in Poland and National Institute for Health and Clinical Excellence (NICE) in the UK. METHODS: The review of HTA recommendations concerning cancer technologies published online in the period August 2007–June 2010 (AHTAPoL) and March 2000–June 2010 (NICE) was performed. The classification of HTA recommendations based on Raftery’s approach labeling them as positive, positive with major or minor restriction, and negative was conducted. Negative guidance was categorized as clinical or nonclinical. Reasons for HTA recommendations for drug technologies appraised by both AHTAPoL and NICE were compared. Contradictory and noncontradictory recommendations were identified as well. RESULTS: A total of 149 drug technologies were appraised by AHTAPoL, of which 39 concerned cancer technologies (seven resubmissions). NICE published 136 drug appraisals, of which 59 related to cancer technologies (12 resubmissions). In total, 12 cancer drug technologies were recommended by both AHTAPoL and NICE. Among them, there were nine contradictory and three noncontradictory pairs of guidance (two negative and one positive). In the group of drug technologies appraised by both agencies, there were 42% and 67% positive HTA recommendations issued by AHTAPoL and NICE, respectively. Negative recommendations based on nonclinical reasons prevailed in Poland (58%). At the same time, there were as many positive recommendations with major restrictions (33%) as negative recommendations based on nonclinical reason (33%) in the UK. The positive guidance without restriction constituted 8% and 17% of all appraisals for cancer drug technologies published by AHTAPoL and NICE, respectively.
CONCLUSIONS: In a studied period, NICE published more positive recommendations for cancer drug technologies than AHTAPoL. The contradictory recommendations prevailed in the group of drug technologies appraised by both jurisdictions.

KNOWLEDGE TRANSFER REGARDING CANCER SCREENING BASED ON INTERESTS OF DIFFERENT TARGET POPULATIONS
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OBJECTIVES: To develop targeted leaflets regarding cancer screening guidelines that take account the knowledge required by different target groups. METHODS: Before developing leaflets, public interest data regarding cancer screening were collected by the Oncology Analyzer (the so-called KJ method developed for field surveys in Japan). The KJ method includes two steps: label making of information corresponded to specific issues and grouping similar concepts. Contents of leaflets were edited based on the results of the KJ methods but changed in the final version according to discussions at a committee meeting involving public members. We compared the results of the KJ method and contents of the final version of the leaflets for the following groups: cervical cancer screening targeted at 20-year-old subjects (first group), cervical cancer screening targeted at subjects aged 30 years and older (second group), and colorectal cancer screening targeted at subjects aged 40 years and older (third group). RESULTS: Common interests among the three groups included targeting cancer and screening methods. Although the KJ method revealed that the first group expected broad information, in the final version of the leaflet, only basic information regarding participation in cancer screening programs remained. The final versions in group 2 and 3 almost corresponded to the first interest of an actual plan to participate in a screening program including details of the screening methods as well as physical and financial burden expected. Although information regarding the harm of cancer screening was initially included according to the results of the KJ methods in the second and third groups, there was no expectation in the first group. CONCLUSIONS: A targeted leaflet is a powerful tool to share knowledge regarding cancer screening. We must understand the expectations of different target groups and prepare appropriate leaflets that support the decision to take part in cancer screening.

REASONS FOR DISCONTINUATION OF HORMONAL THERAPY IN BREAST CANCER PATIENTS ACROSS FIVE EUROPEAN COUNTRIES
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OBJECTIVES: Recent evidence suggests that many breast cancer patients discontinue their hormonal therapy treatment regimen before the end of the recommended treatment period, but reasons for treatment discontinuation are not well understood. Therefore, we examined reasons for hormonal therapy discontinuation in a European treatment cohort of female breast cancer (BC) patients. METHODS: Female patients ages 21+ with a diagnosis of BC between January 2006 and December 2008 were identified within the IMS Oncology Analyzer which provides retrospective, cross-sectional, cancer-treatment data from 14 countries including France, Germany, Italy, Spain, and the United Kingdom and encompasses over 60,000 de-identified BC patient records from a physician panel of nearly 800 doctors in the EU5. Patients within the EU5 with early-stage BC (stages I-IIA) who received hormonal therapy and for whom their physician provided a reason for discontinuing first course of therapy were included in the study. Patients enrolled in clinical trials were excluded. Reasons for discontinuation of therapy include course completion, progression of disease, stabilization of disease, adverse events, terminal outlook, poor performance, and patient’s choice. RESULTS: 10,949 patients were identified. Approximately 57.2% discontinued their first course of hormonal therapy prior to course completion. Of these patients, the top reasons for early discontinuation included progression of the disease (59.5%), adverse events (21.7%) and patient choice (10.1%). Mean duration of therapy for all patients was 95.4 months (range 45.5–152.1). Time to discontinuation was significantly shorter for those who quit due to AEs than those who quit by choice (36.2 months vs. 57.8 months, P < 0.0001). Of patients that discontinued due to AEs, hot flushes (46.1%), pain (19.1%), and nausea and vomiting (14.0%) were the most commonly reported events. CONCLUSIONS: This analysis in a real world setting provides new insight into reasons for early discontinuation of hormonal therapy in the EU5.

TREATMENT DECISION CHANGE WITH 21-GENE RECURRENCE SCORE IN PATIENTS WITH EARLY STAGE BREAST CANCER (ESBC): A META-ANALYSIS
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OBJECTIVES: The 21-gene Recurrence Score® (RS) is a validated assay for estimating a woman's recurrence risk and chemotherapy benefit after the diagnosis of estrogen receptor positive (ER+), ESBC. We conducted a meta-analysis of RS's influence on treatment recommendations/decisions in lymph node negative (LN-) disease. METHODS: Literature was abstracted on cohort studies that reported the change in the recommendation or actual use of adjuvant chemotherapy (CT) for patients with ER+, LN-, ESBC before and after the RS. Outcomes evaluated were: treatment decision change from 1) CT plus hormone therapy (HT) to HT-only or 2) HT-only to CT plus HT. Actual treatment change was used when available. Reductions in the relative and absolute CT use associated with the RS were computed with Review Manager (5.3). RESULTS: Seven published studies (n = 912 patients) were eligible for the meta-analysis. One was a prospective physician survey; six were retrospective chart reviews, of which a total of 569 (62%) patients were recommended CT prior to RS testing. After RS testing, 272 (30%) patients were recommended or received CT. In six of seven studies (n = 652 patients) that reported a treatment change, 212 (32%) patients switched from HT before RS to HT-only after RS. The absolute reduction in CT before and after RS testing was 30% (95% CI [39%–21%]). The relative reduction in CT before and after RS was 49% (95% CI [42%, 58%]). Estimates varied little when analysis omitted a single study. Limitations include heterogeneity in study designs. CONCLUSIONS: The meta-analysis shows consistent overall reduction in CT with the use of RS.

CANCER – Conceptual Papers and Research on Methods
PCN160
THE ROLE OF PATIENT SELECTION CRITERIA IN IDENTIFYING OVARIAN CANCER PATIENTS
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BACKGROUND: Retrospective claims databases are commonly used in outcomes research. Since physician charts are rarely available to confirm diagnoses, care must be taken when choosing patient populations. OBJECTIVES: To show how patient selection criteria affects sample size and chemotherapy treatment rates using an ovarian cancer (OC) population. METHODS: Patients were initially selected if they met the following inclusion criteria: at least one diagnosis of OC (ICD-9-CM codes 183.0x) between 3/1/2002 and 12/31/2006. First OC diagnosis date termed index, 6 months pre-index and 12 months post-index eligibility, and no OC diagnosis in the 6 months pre-index. Additional criteria were imposed to further refine the sample and assess variations in chemotherapy treatment rates. First, patients were required to have at least two diagnoses of OC at least 14 days apart. Next, patients were required to have both OC diagnoses on a record labeled as medical, surgical, facility, or pharmacy (i.e., ancillary records were excluded). RESULTS: A total of 37,172 patients had at least one diagnosis of OC. Of those, 16,418 had 6 months pre-index and 12 months post-index eligibility with no pre-index OC diagnoses. In this population, 26% of patients received chemotherapy. When patients were also required to have one additional OC diagnosis at least 14 days from index, the sample size dropped to 7431 patients, of whom 47% received chemotherapy. When OC diagnoses on ancillary records were excluded, a total of 6233 patients were identified, of which 52% received chemotherapy. CONCLUSIONS: Patients included in the study population varied significantly by the sample selection criteria used. Care must be taken to identify the correct patient sample in any retrospective database analysis since selection criteria affect the appropriateness of the sample, and thus the study results.

PCN161
DECISION-ANALYTIC MODELING IN CHRONIC MYELOID LEUKEMIA—A SYSTEMATIC OVERVIEW
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OBJECTIVES: To provide an overview on published decision-analytic models evaluating various treatment strategies in chronic myeloid leukemia (CML). We sought to describe and analyze the structural and methodological approaches used and to derive recommendations for future CML models. METHODS: We performed a systematic literature review in electronic databases (Medline/PreMedline, EconLit, EMBASE, and others) to identify published studies evaluating CML treatment strategies using mathematical decision models. The models were required to compare different treatment strategies and to comprise relevant clinical health outcomes such as life-years gained or QALYs over a defined time horizon and population. We used standardized forms for data extraction, description of study design, methodological framework, and data sources. RESULTS: We identified 14 different decision-analytic modeling studies and to among patients varied significantly by the sample selection criteria used. Care must be taken to identify the correct patient sample in any retrospective database analysis since selection criteria affect the appropriateness of the sample, and thus the study results.

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