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

PCN149

DECIDING UPON NEW AND EXPENSIVE TECHNOLOGIES IN HEALTH CARE: REAL OPTIONS ANALYSIS IN PROTON THERAPY

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OBJECTIVES: Radiotherapy with protons is a promising new treatment modality, for which adoption decisions 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.

PCN150

SYSTEMATIC LITERATURE REVIEW ON THE INTER AND INTRA LABORATORY VARIABILITY OF MOLECULAR TESTING OF RESPONSE TO TREATMENT OF CHRONIC MYELOID 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 internal validation for the specific laboratory and giving rise to laboratory-specific data. Harmonization 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 testing, inter-rater reliability across manual assays and the costs and cost-effectiveness of molecular testing in CML. **RESULTS:** From 88 papers retrieved for detailed analysis, we found no studies which conducted a repeated test procedure on the same patient sample using the same technical approach in the same laboratory. There are a large number of studies which have compared alternative approaches using the same patient sample in molecular monitoring in the same laboratory. Several well-conducted studies have examined the variability of results from different laboratories in controlled environments. We found no studies which compared inter-rater reliability or examined the costs or 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 unresearched 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.

PCN151

TARGETED CANCER THERAPIES: PRICING, ACCESS, AND UPTAKE

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OBJECTIVES: The oncology market has become one of the major focus areas for pharmaceutical and biotech firms. As of March 2009, 15,752 of 39,747 Phase I, II, and III trials listed on clinicaltrials.gov were related to cancer (approximately 40%). This large interest in oncology stems from market success of cancer therapies launched in the past decade and the existence of high unmet need to treat different types of cancers. As the number of FDA approved cancer therapies increases, there is a need to understand treatment patterns of these cancer drugs. **METHODS:** To understand the trends in usage and sales of cancer therapies, we analyzed the US market (sales and prescription) 2005–2008 data for all FDA-approved cancer drugs. Drugs were categorized as targeted cancer therapies, chemotherapies, monoclonal antibodies, small molecules, branded, and generics. **RESULTS:** During the past 5 years, the usage of both targeted cancer therapies and chemotherapy drugs has increased by high double digit rates. From 2005 to 2008, the total prescriptions for targeted cancer therapies and chemotherapies increased by 66% and 30%, respectively. While the sales of both types of these drugs are expanding, the majority of sales growth is attributed to an increasing uptake of targeted cancer drugs. The sales share of targeted cancer therapies in the US oncology market increased from 36% in 2004 to 56% in 2008. Among targeted cancer therapies, majority (more than 75%) of uptake belongs to monoclonal antibodies. **CONCLUSIONS:** The usage and sales trends show a significant increase in the use of cancer drugs. The high usage of targeted cancer therapies versus chemotherapies shows the rapidly changing nature of cancer treatment regimen.

PCN153

HOW DO HTA AGENCIES RECOGNIZE AND REWARD INNOVATION? CASE STUDIES IN BREAST CANCER AND COLORECTAL CANCER

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OBJECTIVES: This paper examines how different payers and health technology assessment (HTA) agencies recognize and reward innovation, using treatments for breast and colorectal cancer as case studies. **METHODS:** Breast and colorectal cancer were chosen given the extent of clinical advancements to date and supporting publicly available data. Sixteen cancer medicines across these two tumor types were considered. For each medicine/indication, the reimbursement decision and the reasons behind it were obtained from assessment reports published by the respective agencies in Australia, Canada, England and Wales, France, and Scotland. **RESULTS:** Seventy-seven decisions were reviewed (39 and 38 for breast and colorectal cancer, respectively). Twenty-four (62%) and 16 (42%) were positive for breast and colorectal cancer, respectively, while 21% and 45% were negative. In general, HTA agencies appear to consider advancements in breast cancer treatments as representing good uses of health-care resources with some assessments yielding less positive or more restrictive results. The majority of appraisals for newer colorectal cancer treatments have failed to receive positive recommendations. **CONCLUSIONS:** We identified some broad areas where differences of approach have led to different decisions. These relate to the: 1) acceptability of surrogate end points (e.g., progression-free survival) in cases where improvement in overall survival has not been established; 2) extent to which agencies formally consider input from clinical and patient representative organizations as part of their decision-making process; 3) methods used to assess medicines where pivotal trial did not use a comparator reflecting standard therapy; and 4) mechanisms for re-review or adopting performance-based risk-sharing arrangements following rejection due to uncertain clinical and/or cost-effectiveness. Addressing these issues may improve the likelihood of innovative medicines meeting reimbursement requirements, for breast and colorectal cancer as well as other therapeutic areas, thereby increasing the overall health benefit from pharmaceutical development that accrue to patients.

PCN154

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 appraised 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.