have been recommended by NCCN guidelines. At the same time, we identified many instances where the recommendations given by the NCCN guidelines have not been endorsed by HZZO. **CONCLUSIONS:** Considering process related inconsistencies and consequential differences in reimbursement outcomes and patient access to cancer drugs in Croatia compared, there is a strong need for the expedited implementation of transparent HTA processes for cancer drugs. Multiple technology assessments of the main indication groups and the highest cost drivers are highly needed to ensure the full transparency of the reimbursement system and the equity of patients' access to the treatment options irrespectively of the disease.

PCN178

REIMBURSEMENT OF CANCER DRUGS IN THE UK: NEW APPROACH TO END-OF-LLIFE TREATMENTS AND THE TECHNOLOGY APPRAISAL PROGRAMME OF NICE

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OBJECTIVES: Determine the impact of new end of life criteria on reimbursement decisions of cancer drugs appraised by NICE. **METHODS:** Review of Single and Multiple Technology Assessments on cancer treatments appraised by NICE from January 2009 to April 2011. **RESULTS:** NICE appraised 30 cancer treatments. 16 were recommended with restrictions and 13 were not recommended. The reason for not recommending was poor cost effectiveness (7) and lack of evidence (6). The Committee considered the impact of giving a greater weight to QALYs achieved in the later stages of terminal diseases in nine of the positive recommended drugs. End of life criteria were considered when the most plausible ICERs fall above the threshold normally considered as cost-effective. End of life criteria were not taken into account when the appraised drugs had ICERS below £30,000 per QALY gained (6 cases) or when it resulted in cost saving for the NHS. When ICERs estimates exceeded what NICE considers a reasonable use of NHS resources for the whole population covered by the marketing authorisation the Committee discussed whether the magnitude of weight required for the ICER to be in a cost effective range was acceptable in special subgroups of population. **CONCLUSIONS:** The discussion of end of life criteria was straight forward when the new drug provided a marked change in the treatment of the disease or its high price was compensated by a patient access scheme agreement. On contrary, it was more difficult to decide whether survival benefits offered the extension of life required in order the supplementary advice to be considered. The supplementary advice facilitated the appraisal process of cancer drugs however the Committee had to make judgments to interpret the incomplete evidence in order to decide what is good for patients and who can benefit from new cancer treatments.

PCN179

CLINICAL TRIALS IN ONCOLOGY IN GREECE

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OBJECTIVES: Reducing the burden of cancer through interventions based on clinical trials remains an important strategy of oncology research. Public access to information on clinical trials increases transparency of medical research and helps patients to find information. The aim of this study was to investigate the number of clinical trials in oncology carried out in Greece. **METHODS:** We searched the EU Clinical Trials Register website. We analyzed the trends regarding the number of approved by the National Organization for Medicines trials in a 7-year basis. We also examined the number of trials by the type of cancer, the Phase and the status of the trial and the trends in funding. In our survey we included only Phase II and Phase III interventional trials, recruiting by adults and elderly, both men and women, between 2004-2010. **RESULTS:** Greece ranks 14th among EU countries for the clinical trials conducted in oncology, as 24,29% of all clinical trials carried out in Greece concern cancer. Since 2004, 44 Phase II and 95 Phase III trials were approved, the majority of which were related to target therapies of breast cancer (21.73%) and non-small cell lung cancer (21.01%). 81.88% are still ongoing trials, 6.52% have been completed while there is no feedback about the results. Finally, in Greece the main sponsor in clinical research is industry (88.4%) while only 11.59% is funded by research institutes. **CONCLUSIONS:** Although in Greece there is significant clinical investigation in oncology, the need for the development of a new framework as well as a well organized network that will inform key stakeholders, reduce bureaucracy and increase the number of clinical trials remains and calls for international cooperation.

PCN180

THRESHOLD VALUES FOR COST-EFFECTIVENESS IN AHTAPOL AND NICE FOR CANCER DRUG TECHNOLOGIES

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OBJECTIVES: To identify empirical threshold values for cost-effectiveness on the basis of past decisions in Agency for Health Technology Assessment (AHTAPol) in Poland and National Institute for Health and Clinical Excellence (NICE) in the UK for cancer drug technologies. **METHODS:** Review of recommendations issued by AHTAPol and NICE for cancer drug technologies was performed. Period under investigation was August 2007 to March 2011 for AHTAPol and March 2000 – March 2011 for NICE. To identify empirical threshold values in both agencies, a comparison of ICER cost/QALY and past decisions was made. **RESULTS:** In the studied period AHTAPol and NICE issued, respectively, 44 and 54 recommendations for cancer drug technologies. Negative recommendations prevailed in Poland (43%). Most common recommendations in NICE were positive recommendations with major restriction (39%).The most commonly used measure of cost-effectiveness in NICE was ICER cost/QALY (41 recommendations) while in Poland it was identified only in 16 recommendations. As a result of a comparison of ICER cost/QALY and past decisions empirical threshold values in both agencies were not identified. In Poland four positive recommendations with restrictions and 9 negative ones were placed above official AHTAPol's threshold. In the same time, only 3 positive recommendations with or without restriction were below the threshold. In NICE, 17 positive recommendations with or without restrictions and 11 negative ones were above the official threshold value of £30,000/QALY. Below this threshold, there were 13 positive recommendations with or without restrictions. **CONCLUSIONS:** AHTAPol, as well as NICE, don't have definite empirical cost-effectiveness threshold values for cancer drug technologies. The official threshold values set in both agencies are not respected in the case of cancer drugs. Implementation of additional guidelines for "end-of-life" treatment in NICE may have potential impact on decisions concerning cost-effectiveness of cancer drug technologies.

PCN181

THE HEALTH RELATED QUALITY OF LIFE DATA (HRQOL) FOR HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESS IN EUROPE: THEIR UTILIZATION AND IMPACT ON OPINIONS ACROSS HTA AGENCIES

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OBJECTIVES: After marketing authorization, European HTA agencies may take HRQoL data into account to support reimbursement. We want to explore here how HRQoL have been included into HTA process and what their impact was on reimbursement decisions. **METHODS:** Initially, we've analyzed French HRQoL data on oncology drugs to assess quality, type and impact of these data on the reimbursement opinions made by the French National Autority (HAS). In the second stage, we have performed a qualitative analysis to explore the main similarities and differences across HTA bodies in assessment of HRQoL to support reimbursement. **RESULTS:** First stage: since 2008, 23 files were assessed by HAS. HRQoL data were available for 11 oncology drugs; for 3 drugs HRQoL data were not taken into account (open trial or missing data). For 5 drugs, no difference in HRQoL (on EORTC QLQ-C30) was observed and in 3 cases, change in HRQoL might have had an impact on final decisions.Second stage: more and more often HRQoL data are included into files submitted for HTA and their quality is gradually improving over time. However, confusion still remains between functional measures and HRQoL. Some countries only consider HRQoL data from randomised clinical trials. For other countries, data from observational studies may also be of interest to provide additional information in real conditions of use. In addition, many countries consider utility measures as one of HRQoL. In all cases, HRQoL remains a secondary endpoint in relative effectiveness assessment (REA) process. **CONCLUSIONS:** In Europe, the impact of HRQoL on reimbursement decisions could be enhanced if the quality of data increases. Our analysis confirms the interest of the ongoing work on the EUnetHTA guideline that should help assessors of European HTA agencies deal with HRQoL and contribute to the harmonization of HRQoL definitions and use across agencies.

PCN182

WHAT KIND OF CHANGES DID THE PUBLICATION OF TWO LARGE-SCALE RCTS LEAD TO IN PROSTATE CANCER SCREENING GUIDELINES?

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OBJECTIVES: Although prostate-specific antigen (PSA) screening is conducted worldwide, its effectiveness in reducing mortality from prostate cancer has remained controversial. In March 2009, intermediate results from the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial were released. However, the results of the two studies were inconsistent: the PLCO trial demonstrated no benefits to screening, whereas the ERSPC study reported a 20% reduction in prostate cancer mortality. We found and compared the assessment of the two RCTs in guidelines, evidence reports and statements. **METHODS:** A search was performed from March 2009 to May 2011 using MEDLINE, the Guideline International Network library and the National Guidelines Clearinghouse to identify guidelines, evidence reports and statements which have evaluated the two RCTs. Additional reports recommended by experts were also included as needed. The changes in the revised guidelines, evidence reports and statements were compared. **RESULTS:** Four guidelines, two evidence reports and one statement matching our criteria were found, but none contained any change in basic recommendation for PSA screening. In addition, the American Society of Clinical Oncology evaluated the results of the two studies in their review for major research in 2009. Although the American Urological Association recommended PSA screening for men 40 years of age and over, in other guidelines, PSA screening was not recommended for asymptomatic persons. Most of the US reports were for opportunistic screening and pointed out the necessity of shared decision-making for PSA screening. The European Urological Association and the UK-NHS Cancer Screening Committee did not recommend PSA for population-based screening. In contrast, the Japanese Urological Association strongly recommended PSA screening in communities. **CONCLUSIONS:** Even after the releases of two RCTs results, most reports have not revised their assessment of PSA screening.

PCN183

A POPULATION-BASED REGISTRY FOR THE EVALUATION OF NEW TREATMENT OPTIONS FOR PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

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