(Lefebvre & Ang 2009) worked out a list of guidelines for better outcome-specification after organ preservation therapy, which should be used in further clinical trials. The paper introduced a new endpoint: "laryngo-esophageal dysfunction-free survival" and addressed the growing problem of lat dysphagia in larynx preservation programs. Due to this discussion, many surgeons come back to more surgical driven decision making since late toxicity outcome after surgery seems to be limited compared to current protocols of simultaneous chemoradiation. Standards in surgery of HNSCC are defined as state of the art tumour resection procedures and reconstruction, following consented resection criteria like clear margins (R0-resection). Also neck dissection is standardized (AJCC) and should be included into the tumour stage related surgical concept. Altogether, primary surgery in HNSCC and additional adjuvant treatment is generally recommended if R0 resection is possible. Regarding late functional outcome, instruments for objective comparison of results are lacking. Health related quality of life (EORTC) and International classification of function (ICF WHO) are relatively new tools for better evaluation of late functional outcome.

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Special Session (Sat, 24 Sep, 14:15−15:15)
Issues in Economic Evaluation of New Cancer Therapies

43 INVITED

Cancer Drug Costs − Forecast for Europe − Will the Cost Explode?

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We have seen a number of new cancer drugs being approved over the last 10−15 years. During the first part of this time period an average of 2−3 new drugs were approved each year and over the last years 8−10 drugs. This increase in available drugs is results of improved understanding of cancer biology that we have seen develop during the last three decades. These new treatment options have, however, come at a significant cost. Spending on cancer drugs has increase 5−6 fold, in some countries even more, over the last decade (www.comparatorreports.se). This should be put into the context of about 2−3 times increase in the total costs of cancer care seen in most European countries during the same period of time.
Will this increase in cost of cancer drugs continue and if so, will society be able to handle the costs of cancer care? First we must realize that much of the spending we see on cancer drugs relates to "mature" drugs, i.e. drugs that have been available for more than a decade. Many of these drugs have just gone off patent or will soon go off patent; the price of docetaxel, constituting about 8−10% of the cost for treatment of solid tumours in Sweden, decrease by >95% in just 2−3 months. We will most probably witness a similar cost reduction for the aromatase inhibitors, as all of them are likely to go off patent during 2011. As a majority of the top 20 selling cancer drugs will be generic in a couple of years, this will leave us with some budget available over the next 3−4 years.
We have also seen a number of drugs with similar mode of action (for example TKIs) being approved, resulting in substitution price competition rather than more patients being treated. This, at least temporary, situation will give us opportunity to improve the way we evaluate new cancer drugs and drug combinations, introducing HTA as a key part of the introduction process. We also have time to set up proper, population based, systems for monitoring the effects of new treatments in the "real" world. We can, in addition, continue to develop new innovative pricing models.
Meanwhile, we must also address the inequalities we have within Europe, with many countries in central/ eastern Europe (most of them new members of the EU) having a significantly lower access to up-to-date cancer care, including drugs. These inequalities may need political action on a central EU level. Our aim should be to bring new innovative, evidenced based, cost effective cancer treatment to all cancer patients in need across Europe.

44 INVITED

Methodological Issues in Economic Evaluation of New Cancer Therapies

Abstract not received

45 INVITED

Performance-Based Agreement − Theory to Practice- the Current Use in Oncology and Future Trend

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Health care systems are increasingly evaluated on performance and outcome, rather than for availability and use of resoruces. The background to this is the slow growth in health care expenditures and fiscal problems in most developed economies. Improvements in quality of care and outcome through a more cost-effective use of existing resources is the main option for development of the services. Relative effectiveness and cost-effectiveness are new criteria for decisions about adoption and use of new cancer drugs, which gives HTA and reimbursment bodies acting on behalf of payers, an increasing influence over therapeutic decisions.
A problem for decision makers is that there is limited information available for undertaking such evaluations before there is evidence from acual clnical use of the drugs. In addition, payers are concerned that expensive new drugs are used for the patients that can benefit most. The increasing use of coverage by evidence schemes and risk-sharing agreements between manufacturers and health authorities are responses to the above. In performance based agreements, the payment for the drug is dependent on the outcome or result of the intervention. The theoretical arguments for such arrangements are for the payers that it gives incentives for an efficient use of resources and access for patients, and for manufacturers that it may give a faster introuduction on the market.
Oncology drugs seems to dominate the among the performance-based agreements we know today. In Italy for example, 16 out of 18 risk sharing agreements until October 2010 relate to cancer drugs. However, it shold be noted that not all contracts are based on performance. Many risk sharing agreements include just a price discount, for example related to the number of cycles given. Most contracts in cancer use response as criteria for perfomance. The precise definition of "performance", or more often non-performance, is obviously of great importance for both parties of the agreement. But those criteria are seldom very explicit, carefully followed up, and openly discussed.
The trend is for an increasing number of performance based agreements in the future. So far private and public health insurers have mainly requested and paid for data on patient characteristics, but the new interest in comparative effectiveness research will likely result in payments are related to outcome. Public health care systems in Europe, usually organized as a payer-provider split, will increasingly look for conract that help them manage costs and outcome.

Special Session (Sat, 24 Sep, 14:15−15:15)
Too Little or Too Much Surgery for Melanoma

46 INVITED

For Sentinel Node Positive Patients − is Complete Lymph Node Resection Still the Standard of Care?

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Standard of care is defined as how reasonable and similarly qualified physicians would act under the same or similar circumstances. The largest study on what surgeons do in case of a tumour positive sentinel node concerns 2942 patients in the USA. Of these patients, 1470 were subjected to a completion node dissection (50.0%). The other 50.0% were spared a node dissection. Apparently, there is no standard of care. This is understandable because the only prospective randomized study addressing this important question is in progress. For now, the practicing surgeon has to rely on circumstantial evidence.
Completion node dissection reveals additional metastases in 11−20% of the patients. Half of these patients will develop distant metastases from which they will die irrespective of a node dissection. Another third can still be cured if the node dissection is deferred until the development of palpable nodal disease. So, the potential gain in survival is limited.
A watch and wait policy limits the node dissection to the minority of patients who do have metastases and spares the vast majority of individuals an unnecessary operation. The downside is that the disease may disseminate from the nodal basin to distant organs in the time before the first nodal metastasis becomes palpable.