RESULTS: A total of six systematic reviews (SR) were found and met our inclusion criteria. For the irrelevant indication: a) Wake et al. 2002 and Schulz et al. 2007 evaluated the treatment as first line or subsequent therapies; b) Vidal et al. 2009 and Aksoy et al. 2009 assessed the maintenance therapy; c) Cheung et al. 2007 evaluated first line and subsequent therapies, maintenance and aggressive NHL; and d) Knight et al. 2004 evaluated aggressive NHL. Only three studies developed a meta-analysis (Vidal, Schulz and Aksoy). According to the SRs rituximab induced remission, improved overall survival and disease control. Twenty five HTAR were found: 5 indicated the analysis through inconstant links; 2 belonged to sites with content blocked to non-members; 2 related to other drugs; 3 indicated ongoing analysis; 3 related to other indications. Consequently, 10 reports met the survey criteria. Seven out of 10 published HTAR support the use of rituximab for indolent or aggressive lymphomas. There are three assessments which are not conclusive. CONCLUSIONS: Findings from systematic reviews suggest that rituximab offer better clinical outcomes to patients. Most of the Health Technology Assessment reports indicate rituximab as a cost-effective alternative.

TRAZTUZUMAB ON ADJUVANT BREAST CANCER TREATMENT: EVIDENCE SYNTHESIS AND A HEALTH TECHNOLOGY EVALUATION

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OBJECTIVES: The use of Trastuzumab (T) for the adjuvant treatment of breast cancer patients (BCP) has been tested in clinical trials. Our goal is to perform a health technology evaluation in order to establish if the scientific evidences are strong enough to support the use of T and to compare its cost-effectiveness ratio (CER) with other treatments covered by the public sector in Brazil. METHODS: We performed a literature search, looking for randomized controlled clinical trials (RCTs), systematic reviews (SR), guidelines, pharmacoeconomic analysis and endorsements from regularly regulatory agencies on the use of T for BCP. RESULTS: We found five RCTs, three SR, six guidelines / health technology assessments and three endorsements from regulatory agencies. Four RCTs tested Trastuzumab 2 mg/kg/week or 6 mg/kg/ every 3 weeks during 1 year with tumors ≥ 5 cm. T of these tumors revealed a 50% reduction on risk of relapse and a 40% reduction in death risk. SR confirmed these findings. The only study that did not show a survival gain, used T only for nine weeks. Guidelines and regulatory agencies recommend the use of T for one year. On the pharmacoeconomic perspective, T has a CER similar or better than other procedures covered by the public sector in Brazil, such as heart transplant, tacrolimus for kidney transplan- tation, ribavirin plus peg-interferon for C hepatitis and bone marrow transplant. These procedures have a CER between US$35,000 and US$45,000 / QALY (or above). The CER of adjuvant T is around US$20,000/QALY. CONCLUSIONS: Trastuzumab is indicated for the adjuvant treatment of BCP, and must be considered as standard treatment for these patients. Also, from a pharmacoeconomic point of view, it’s CER is similar to other medical interventions covered by the Brazilian health care public system.

REVIEW OF THE DECISIONS OF HEALTH TECHNOLOGY ASSESSMENT AGENCIES FOR CAPECITABINE FOR THE TREATMENT OF COLORECTAL CANCER

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OBJECTIVES: To conduct a review of the Health Technology Assessments (HTA) recommendations published on the International Network of HTA (INAHTA) website concerning the use of capecitabine to treat breast cancer in order to support decision making in Brazil. METHODS: A search was conducted on INAHTA website (www.inahta.org), in English language, for the key word “capecitabine”. Nineteen results were found, from which 5 referred to other drugs; 10 to other capecitabine indications; consequently, 4 results met our objective. RESULTS: The economic assessments found were conducted in Europe (3) and Argentina (1). From these, 3 positively recom- mend the use of capecitabine for breast cancer and 1 did not state a clear recommenda- tion, though considering that capecitabine seems to be a cost-effective therapy. The analysis conducted in 2003 by the NHS of Scotland for metastatic breast cancer, and that of the NICE (England) for locally advanced or metastatic breast cancer were replaced by NICE guidance CG81 (2009), which recommended capecitabine as monotherapy for second or third line in patients for whom anthracycline-containing regimens are unsuitable or have failed. In 2004, the ICES(Argentina), concluded that capecitabine can be a therapeutic option for locally advanced or metastatic breast cancer combined with docetaxel or as monotherapy. The assessment stated that capecitabine should be used when patients failed or are not eligible for anthracy- line-containing regimens. The assessment by NIHR Health Technology Assessment programme (England, 2004), indicated that capecitabine treatment as monotherapy or combined with docetaxel for locally advanced and/or metastatic breast cancer appears to be cost-effective. However, the authors stated that the evidence base for assessment was poor and further investigation is necessary. CONCLUSIONS: According to this review, the published economic assessments up to the present date suggest capecitabine as an option for the treatment of breast cancer (locally advanced or metastatic) for patients who failed or are not eligible for anthracycline-containing regimens.

PUBLIC REGULATION OF THE CANCER DRUGS MARKET IN FRENCH HOSPITALS

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OBJECTIVES: Since 2004, hospital cares are financed by allotted amounts at a specific diagnosis-based level. In order to guarantee access to innovative drugs, high-cost drugs are gathered on a positive list and are paid out of the budget with a total reimbursement under conditions of good use. As hospital drugs prices are free, the regulator sets up a reimbursement price cap in 2005, named responsibility tariff (RT), to avoid uncontrolled increase of prices due to a low interest in negotiation between hospitals and firms. The aim of this work is to assess the impact of this regulation on cancer drugs market between 2004 and 2007. METHODS: This study uses data from the technical agency of information on hospitals and included establish- ments previously under fixed global models. Those data, from 2001 to 2005, provide quantities, expenditures and purchase prices of cancer drugs on this list belonging to the L01 level of the world health organization anatomical therapeutic and chemical classification. Furthermore, an index representing the ratio of the purchase prices and the RT is built. RESULTS: The consumption of L01 drugs shows an important evolution with a 17.2% yearly growth rate between 2005 and 2007. Expenditures exceed 1.6 billions of euros in 2007. The contribution of L01 in spending of the high-cost drugs list reaches 66% in 2006 and 37% in 2007. The RT leads to a transient prices decrease in 2005 before an alignment on regulated prices. Only competitive market allows low prices under RT. CONCLUSIONS: The rising spending of cancer drugs is due to the consumption of recent and expensive drugs. Their rationalization implies a strict innovation evaluation. The optimal level of innovation still needs to be defined.

IDENTIFYING STRUCTURAL UNCERTAINTY IN ECONOMIC MODELS OF CANCER TREATMENTS: A CASE STUDY OF BIUNOTECAN IN COLORECTAL CANCER (CRC)

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OBJECTIVES: Due to wide variations in prescribing practice, a key methodological challenge for an economic analysis in oncology is describing current practice. Robust methods of eliciting the full range of expert opinion are necessary to ensure clinical relevance and validity of economic models. Insufficient information on management can lead to model underestimation of uncertainty. This study aims to determine the appropriate model structure for an economic evaluation of a pharmacolog- ic test to inform irinotecan prescribing, by identifying current practice. METHODS: Expert opinion was elicited to inform model structure. Through semi-structured postal survey (May-August 2008), clinical experts were asked to describe: the general management of advanced CRC patients on chemotherapy, place of irino- tecan-based regimens within the clinical pathway and management of patients on these regimens. Since data on the frequency of key adverse events (neutropenia and...