

APPROPRIATENESS OF ACCESS TO INNOVATIVE DRUGS IN NON-SMALL CELL LUNG CANCER (NSCLC): THE FOIFVG (INNOVATIVE ONCOLOGY DRUGS FRIULI VENEZIA GIULIA) PROJECT

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Introduction: Lung cancer is still a leading cause of cancer-related mortality worldwide. Non-small cell lung cancer (NSCLC) accounts for ~ 85% of all lung cancer patients (pts). Two different histologies has mainly ascribed to NSCLC: squamous or non-squamous. Several mutations has been reported, including: EGFR (epidermal growth factor receptor), ALK (anaplastic lymphoma kinase) or ROS1 (Proto-oncogene 1 Receptor Tyrosine Kinase) genes. NSCLC also expresses programmed death-ligand 1. Important prognostic and therapeutic implications derive from biomolecular features of NSCLC. The FOIFVG project aims at giving recommendations for the place in therapy of innovative anticancer drugs used for NSCLC therapies based on the GRADE method (Grading of Recommendations, Assessment, Development and Evaluation) in order to uniform and economically sustain the use by region.

Method: GRADE is a well-developed formal process to assess the quality of scientific evidences in systematic reviews and to develop recommendations in guidelines that are as evidence-based as possible. It is adept by a large number of agencies, such as the Cochrane Collaboration, the World Health Organization, the England's National Institute for Health and Clinical Excellence.

Results: The first step was to define the panel consisting of oncologists, hematologists, radiotherapists, internists, palliativists, pharmacists, organizational physicians, methodologists and other professionals. Then the flow-chart of NSCLC was produced, which consists on the place in therapy of treatments according to AIFA indications. NSCLC was divided in subgroups: NSCLC wild type or mutated, with squamous or not histology, expressing PD-L1 above or below the 50% and EGFR, ALK or ROS1 mutated. Each treatment was colocated in one or more of each subgroups. Then efficacy outcomes (eg overall survival) and those of toxicity were determined. Afterwards, the whole literature of clinical studies or reviews was analyzed making them available to the panel called to formulate recommendations. Each study was also analyzed for its quality as an expression of the degree of confidence in the extent of the beneficial or toxic effects of the intervention. On the basis of these analyzes and through plenary debate, the panel filled out a questionnaire establishing the benefit and risk profiles and the degrees of recommendation of NSCLC therapies. The working group has already published on the website www.foifvg.it the dossiers about NSCLC recommendations.

Discussion and conclusion: Recommendations correspond to a percentage of pts to whom therapy is advised. Thanks to this association it is possible to observed if aspectative of treatments use are respected. Recommendations are essential for spenditure preview and its management, avoid waste. The usage and spenditure monitoring of NSCLC treatments is still ongoing. However, analysis of quarterly expenses of the Oncological Reference Center (CRO) in Aviano are promising. Multidisciplinarity is the strong point of the project. The experience and professionalism of partners involved will be made available to pts, guaranteeing them greater confidence. The whole studied process may become a regional reference point by other Italian regions or in a national level. Furthermore, the process used for the new oncology drugs will also serve as a reference for other innovative non-oncological drugs.