Design of specific tools to evaluate the Cost Of Illness (COI) of Rheumatoid Arthritis

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Rheumatoid arthritis (RA) is an autoimmune disorder, affecting 1% of the population approximately. It is characterized by pain, joint swelling, progressive destruction of joint tissue. The patients not properly treated develop a progressive permanent joint damage with serious disabilities, and have increased mortality compared with the general population. The European League Against Rheumatism recommends the use of Tumor Necrosis Factor alpha antagonists (anti-TNFα) in case of failure of methotrexate or others DMARDs (Disease Modifying Antirheumatic Drugs). Anti-TNFα agents (such as Infliximab, Adalimumab, Etanercept), in fact, were the first to be successfully used to induce remission or very low disease activity in treating RA. However, the anti-TNFα therapies impose a significant economic burden on hospitals budgets and they are in the top twenty most expensive drugs in Piedmont region.

From a societal perspective is important not only the evaluation of cost of medicines, medical care and special devices (direct costs), but also the quantification of costs associated with the illness (COI) that consists in: indirect costs (mainly for the productivity losses) and intangible costs (those represented by the deterioration in the quality of life). In Italy, there is a lack of data regarding the societal economic impact of RA after the introduction of anti-TNFα agents, and the aim of our work is to set up specific tools to perform a pharmacoeconomic investigation in Piedmont region aimed to identify the COI of RA. Afterward, the same tools should be exploited in order to perform a pharmacoeconomic investigation at national level. We will analyze the payer's and societal perspective, investigating direct costs associated with health care utilization and indirect costs related to productivity loss.

The specific tools consist of three questionnaires: 'Clinical Form', 'Patient Questionnaire', 'Patient Diary'.

'Clinical Form' is filled in by the rheumatologists and consists of: patient's code, clinical history such as disease duration, disease activity index (DAS28; CDAI), HAQ score, ACR classification criteria, Sharp index, systemic manifestations related to disease, pharmacologic treatments, prescribed anti-TNFα. The Clinical Form is repeated in: screening period, baseline period, follow up (on a quarterly basis).

'Patient Questionnaire' is given by the rheumatologists to the patients and permits the collection of: demographic and socio-economic status of the patient (type of work), hospitalisation, day hospital admissions, specialist visits, laboratory tests and diagnostic investigations, physical therapy sessions, drug therapies, the loss of working days or the loss of work, the loss of working days by relatives, caregivers services, domestic help, drug therapies, technical aids, travel expenses. The Patient Questionnaire is repeated in: screening period, baseline period, follow up (on a quarterly basis).

The 'Patient Diary' helps patients to record hospitalisations, specialist visits, therapies, costs due to the purchase of technical aids, costs due to informal care provided by caregivers.

All the recorded data can be easily transferred to a database created ad-hoc and used to estimate direct and indirect costs of RA. We expect that indirect costs will be higher than direct costs. Cost-effectiveness of an intervention depends on the maximum the decision makers are willing to pay for an extra unit of health effect, but it should be considered that treatments with anti-TNFα, in a societal perspective, decrease health resources utilization and raise productivity.

The specific tools that we have created will be used in a just started perspective, observational, multicentric, cost-effectiveness analysis of RA biological drugs, involving about 100 patients in Piedmont region.