Estimation of theoretical cost preventability achievable with an effective pharmacovigilance activity in a Pharmacovigilance Regional Centre in Italy

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The management of patients with adverse drug events (ADEs) has a significant economic impact owing to hospitalization and treatment costs. Recently, social and healthcare costs related to ADEs have become a relevant issue, and therefore they are increasingly being included in budget estimations for health resource allocations. To evaluate the costs of ADEs and their predictability, and to estimate the impact of a pharmacovigilance facility on ADE-related cost savings within a regional health system. The cost of ADEs was estimated by a systematic review of the English medical literature quoted in PUBMED between January 2005 and March 2015. We included all studies, performed in high-income countries (Western Europe, USA and Canada) to investigate direct costs of ADEs in inpatient settings, for which the mean cost of serious and/or not-serious ADEs was reported or could be estimated. Studies focused on specific side effects or drug classes were excluded. The following data were extracted: mean cost of serious and not-serious ADEs; estimated percentage of preventable ADEs (type A reactions and medical errors); charges for outpatient care and medications. The mean cost (converted into Euros) of serious and not-serious ADEs and the mean percentage of preventable ADEs were estimated. We used the mean costs and standard deviations to calculate the theoretical cost of ADEs in Tuscany (3,704,152 inhabitants), based on spontaneous ADE reports recorded by the Tuscan Pharmacovigilance Centre in 2014. A sensitivity analysis of cost and preventability was performed using mean cost ± standard deviation ± 50% and the maximum and minimum percentage of the estimated preventable ADEs. The range of costs resulting from ADEs and the costs-saving that can be theoretically achieved with the implementation of effective pharmacovigilance activities were then assessed. Fourteen studies were analyzed: 13 reported on serious ADEs; 3 evaluated the costs of not-serious ADEs; 8 estimated the percentage of preventability. The mean cost of a serious ADE was €3,526±1,927 and the mean cost of a not serious ADE was €172±93. We estimated a mean preventability of 51.3±21% of ADEs. In 2014, the Italian National Network of Pharmacovigilance database accounted for 1,498 serious ADEs and 2,997 not-serious ADEs in Tuscany (1,214 ADEs per million inhabitants). According to our literature assessment, the overall costs of ADEs incurred by the Tuscan Regional Health System was: €5,281,948 (€1,425,953 per million inhabitants; sensitivity analysis: €3,304,827-322,957 per million inhabitants) for serious ADEs; €515,484 (€139,164 per million inhabitants; sensitivity analysis: €321,094–32,117 per million inhabitants) for not-serious ADEs. Based on the estimation of preventable costs in Tuscany, an effective Pharmacovigilance system could allow to save €2,974,083 (€802,905 per million inhabitants; sensitivity analysis: €1,697,370–237,115 per million inhabitants) over one-year period. In conclusion, resource allocations to improve the efficiency of regional pharmacovigilance systems might increase the appropriateness and safety of therapies, thus reducing the costs incurred by regional health systems for ADEs. A reduction of preventable ADEs could be obtained through an implementation of: ADE evaluation systems; computer-assisted medication management systems with prescription alerts; continuing education of health professionals; multidisciplinary support to the management of medical therapies.