

Original article

## Analysis of economic and social costs of adverse events associated with blood transfusions in Spain

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### ABSTRACT

**Objective:** To calculate, for the first time, the direct and social costs of transfusion-related adverse events in order to include them in the National Healthcare System's budget, calculation and studies. In Spain more than 1,500 patients yearly are diagnosed with such adverse events.

**Method:** Blood transfusion-related adverse events recorded yearly in Spanish haemovigilance reports were studied retrospectively (2010-2015). The adverse events were coded according to the classification of Diagnosis-Related Groups. The direct healthcare costs were obtained from public information sources. The productivity loss (social cost) associated with adverse events was calculated using the human capital and hedonic salary methodologies.

**Results:** In 2015, 1,588 patients had adverse events that resulted in direct health care costs (4,568,914€) and social costs due to hospitalization (200,724€). Three adverse reactions resulted in patient death (at a social cost of 1,364,805€). In total, the cost of blood transfusion-related adverse events was 6,134,443€ in Spain. For the period 2010-2015: the trends show a reduction in the total amount of transfusions (2 vs. 1.91 M€; -4.4%). The number of adverse events increased (822 vs. 1,588; +93%), as well as their related direct healthcare cost (3.22 vs. 4.57M€; +42%) and the social cost of hospitalization (110 vs 200M€; +83%). Mortality costs decreased (2.65 vs. 1.36M€; -48%).

**Discussion:** This is the first time that the costs of post-transfusion adverse events have been calculated in Spain. These new figures and trends should be taken into consideration in any cost-effectiveness study or trial of new surgical techniques or sanitary policies that influence blood transfusion activities.

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## Análisis de costes económicos y sociales asociados a reacciones adversas de transfusiones sanguíneas en España

### RESUMEN

**Objetivo:** Calcular por primera vez los costes económicos y sociales relacionados con las reacciones adversas postransfusionales para actualizar estudios e incluirlos en los presupuestos del Sistema Nacional de Salud. En España, anualmente, más de 1500 pacientes sufren dichas reacciones adversas.

**Método:** Se estudiaron retrospectivamente (periodo 2010-2015) las reacciones adversas a la transfusión recopiladas anualmente en los informes nacionales de hemovigilancia. Dichas reacciones se codificaron mediante clasificación de Grupos Relacionados con el Diagnóstico. Los costes directos sanitarios se obtuvieron de fuentes públicas de información. La pérdida en productividad (coste social) asociada a las reacciones adversas se contabilizó utilizando los métodos del capital humano y salarios hedónicos, respectivamente.

**Resultados:** En el año 2015, en España, 1588 pacientes tuvieron reacciones adversas que derivaron en costes sanitarios (4.568.914 €) y costes sociales debido a hospitalización (200.724 €). Tres reacciones adversas resultaron en muerte del paciente (1.364.805 €). Como suma, el coste total de las reacciones

**Palabras clave:**

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adversas a la transfusión fue de 6.134.443 €. Periodo 2010-2015: la tendencia refleja una reducción en el número total de transfusiones (2 vs. 1,91 M€; -4,4%), un incremento en el número de reacciones adversas (822 vs. 1.588; +93%), en costes sanitarios (3,22 vs. 4,57M€; +42%) y en costes sociales (110 vs. 200M€; +83%), y un descenso en costes de mortalidad (2,65 vs. 1,36M€; -48%).

**Discusión:** Por primera vez se han calculado en España los costes de las reacciones adversas a la transfusión. Los nuevos datos y tendencias deberían ser considerados en estudios de coste-eficiencia sobre técnicas quirúrgicas o políticas sanitarias con repercusión en actividades de transfusión sanguínea.

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## Introduction

Blood transfusions have shown adverse events (AEs) that augment morbidity and mortality.<sup>1</sup> An adverse reaction or event is an undesirable response or effect in a patient, temporally associated with the administration of blood or blood component.<sup>2</sup> Transfusion-related AEs increase morbidity and mortality and, therefore, the overall cost of their treatment. These AEs include fever, allergic reactions, viral and bacterial infections, edema and pulmonary injury, or heart damage, leading to emergency consultations, hospital admissions with diverse duration and even deaths.<sup>3</sup>

So that, the aim of this study was to assign, for the first time, a complete economic value, including social costs due to losses of productivity, of AEs attributed to blood transfusions in Spain. Secondary aim was to assess the trend in such costs during the last few years and, finally, to update the actual cost of the transfusion unit in Spain. AEs total costs' information is crucial to update clinical trial-based cost-effectiveness analyses.

## Methods

### *Methodology for the calculation of the health care direct overhead cost of transfusion-related adverse reactions*

To calculate the associated direct costs of the adverse reactions due to transfusion, we have matched information of three different sources. Firstly, the hemovigilance report that the Spanish Ministry of Health publishes annually.<sup>4</sup> Secondly, the international classification of diseases (ICD) in its ninth version (ICD-9),<sup>5</sup> and finally the DRGfinder™ program.<sup>6</sup>

We coded the diagnosis categories of post transfusion-related AEs accounted in the hemovigilance report according to the ICD-9 and then, allocated to a Diagnosis-Related Groups (DRG) by means of the DRGfinder™ program. The allocation to a given known DRG permitted to assign the direct health care costs that such AEs have for the NHS.

The DRG system is in widespread use worldwide.<sup>7,8</sup> DRG classify patients with similar clinical grounds and similar consumption of resources into homogeneous groups and offer a structure for a precise assessment of the costs of treating a given patient.<sup>9</sup> In Spain, the Ministry of Health, Social Services and Equality (hereinafter, the Ministry of Health) publishes annually the complete listing of DRG<sup>10</sup> together with costs associated to each category.

The hemovigilance report scores every AE according to clinical severity and the likelihood of being attributable to transfusion (causality). This imputability level is classified in four categories and reflects the degree of probability that the AE had been caused by the transfusion, as shown in Table 1. The hemovigilance report only takes into account and enumerates those transfusion-related AEs with an imputability level equal to or greater than 2 (likely or certain), therefore the figures expressed in the results section refer only to these episodes. In year 2014, 89% of public and 71% of private

**Table 1**

Imputability levels of adverse events due to transfusion and description in Spanish hemovigilance report.

Imputability level	Classification	Description
0	Excluded or unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components
1	Possible	When the evidence is clearly in favor of attributing the adverse reaction to causes other than the blood or blood components
2	Likely	When the evidence is clearly in favor of attributing the adverse reaction to the blood or blood component
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component

hospitals have dedicated personnel responsible of hemovigilance and 66% of all centers have a transfusion committee.

Hemovigilance reports are disclosed on an annual basis, showing inter-year variation in the number of blood recipients who suffer from transfusion-related AEs, their relative prevalence and the number of recipient's deaths. Also, DRG systems need to be updated regularly to ensure that DRGs remain clinically meaningful and economically homogeneous.<sup>9</sup>

### *Methodology for the calculation of the social cost of transfusion-related adverse events*

To calculate the social costs of transfusion-related AEs we classified the social costs into two categories: the cost of working days lost per day of hospital stay due to adverse reactions; and, the cost of deaths attributed to such AEs.

For the calculation of working days lost, each DRG, besides charging the rate corresponding to the clinical management, refers an average length of stay (ALOS) expressed in days upon admission, according to the information provided by all the hospitals belonging to the NHS. The human capital model<sup>11</sup> was used to assess the cost in terms of lost productivity, as recommended for economic evaluations.<sup>12</sup> This method is relatively straightforward since it involves multiplying the number of lost working days by the salary of an employee who is absent. For the purpose of this study we have used a gross average income of 22,935€ in year 2015 as reported by the Spanish National Institute of Statistics.<sup>13</sup> Daily average salary was calculated dividing the annual income by 365 days, because the number of hospitalization days referred in the DRG listing provided by the Ministry of Health does not distinguish between working and non-working days. Accordingly, the average daily salary in year 2015 in Spain resulted 62.83€ (22,935€/365 days). However, 50% of patients transfused in Spain are over 70 years and 6.4% are under 20,<sup>14</sup> therefore only 42.6% of the transfused recipients fit into

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