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Exploring sociodemographic and economic factors that promote adverse drug reactions reporting by patients^{☆,☆☆}

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ABSTRACT

Background: Adverse drug reactions (ADRs) are recognized as a leading cause of morbidity and mortality, and an important cost factor to health systems. Patient reporting of ADRs has emerged as an important topic in recent years but reporting rates are still low in many countries.

Objective: To explore different countries' sociodemographic and economic features as explanatory factors for population ADRs reporting, including the propensity of patients' reporting to pharmacovigilance authorities.

Methods: Cross-sectional observational design. A data set of 42 global sociodemographic and economic factors for 44 countries were retrieved, as to analyse statistical associations between these factors and the patient reporting rate of ADRs. Multivariate logistic regression models were designed to identify the predictive covariables.

Results: Health investment indicators, such as per capita public health expenditure, hospital bed density and under five mortality rate were the relevant factors responsible to discriminate between countries that have higher patient reporting rates.

Conclusions: This study shows that healthcare investment-related factors help explain the propensity of patients to report suspected ADRs, while pharmacovigilance features were not directly associated with higher patient participation in drug safety mechanisms. Although general, these results point a direction in further policy making to improve resources allocation concerning the promotion of patients' participation.

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1. Introduction

Adverse drug reactions (ADRs) are recognized as a leading cause of morbidity and mortality, and an important cost factor to health systems in different countries [1]. The economic impact of ADRs is complex and multifactorial [2]. It seldom leads to hospitalization of patients, with corresponding pharmacotherapy problems and increasing costs during their hospital stay [3]. ADRs are among the

top ten causes of death in some countries [4]. In the European Union (EU) alone, it is estimated that the total costs are high as €79 billion, causing over 197,000 deaths annually [3].

Pharmacovigilance aims to improve public health and safety in relation to the use of medicines by reducing the substantial burden of disease resulting from ADRs, through better monitoring of medicines in the post-marketing setting [3].

In the past few years there has been a greater focus on patient-reported outcomes. The patient has turned from being a passive receptor of care to become an active player in the management of its own health status [5]. Patient-centeredness and patient safety have emerged as core elements in today's interactive and responsive healthcare systems. Regulators and the pharmaceutical industry are compelled to meet increasing patient expectations and engage in shared decision making [6]. In a survey of eleven countries worldwide authorities reported that engaging the public in pharmacovigilance activities is an important issue [7]. Most countries are nowadays accepting ADR reports from patients [8]. Evidence

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has been building on the complementary information patients add. Patients help in signal detection, reporting new suspected ADRs for different system organ classes and groups of medicines when compared with healthcare professionals (HCPs). Patient reports deliver a more personalized description of the ADRs, providing detailed information on the impact and severity that ADRs cause in daily life [9]. Despite that, patient participation is limited. The level of awareness is still low, an element that could be attributed to the fact that many countries only started accepting patient ADR reports from 2012 and 2013 [10]. Currently, research has been done focusing primarily on patients' individual characteristics and experiences [11–13].

Since the year 2000 the access to medicines has been increasing in many parts of the world. In Africa, Asia and Latin America there has been increased access to prevent and treat communicable diseases like malaria, tuberculosis and HIV/AIDS [14]. In the developed world there has been a shift in the disease burden towards chronic diseases, which require more complicated therapeutic regimens [15]. In many countries, developed or developing, the practice of self-medication is also common [7]. A bigger medicines consumption can bring many prospective benefits, but the probability of harm is also higher. These changes can have an impact on public health, especially if ADRs are not monitored, detected and managed. Especially in lower income countries, patient reporting could have the potential to complement HCP reports and highlight possible drug-related public health issues. More needs to be done to investigate which societal factors can influence patients to report more proactively.

This study aims to explore associations between various sociodemographic and economic factors in different countries of the world, and the reporting of suspected ADRs by patients to national pharmacovigilance authorities. The knowledge generated from this study will help decision making on where to place resources to stimulate patient reporting on a global scale.

2. Methods

The study followed a cross-sectional observational design, with data collection and analysis consisting of three parts: (1) identification of relevant sociodemographic and economic factors, (2) search for and collection of relevant data, and (3) development and application of a statistical model on the dataset.

2.1. Identification of relevant sociodemographic and economic factors

Fifty countries from different geographical areas that participate in the World Health organization (WHO) Programme for International Drug Monitoring were included following previous relevant studies, especially one conducted by Florence Margraff and colleagues [10]. This study presented an exhaustive comparison between 44 countries that have patient reporting (Table 1), with the aim of identifying differences in the pharmacovigilance systems, as well as presenting data about the percentage of how much patient reporting contributes to national pharmacovigilance activities.

Information that could be associated with patient reporting mainly comprised indicators of global public health and economic performance. The selection of relevant factors at this point was based on prior knowledge and theoretical value to address study aims and allowing for further statistical estimations [16]. Here, a total of 42 different factors were possible to identify, comprising demographic, socioeconomic and healthcare related information, mainly resulting from the evaluation of the databases mentioned in the next subheading.

2.2. Data collection

For these 44 countries, data were retrieved from databases maintained by several organizations. These included the United Nations Educational, Scientific and Cultural Organization (UNESCO) Institute of Statistics database, World Health Organization (WHO) WHO Global Health Observatory Data Repository, the Organization for Economic Cooperation and Development (OCDE) Health Statistics, complemented by the Central Intelligence Agency (CIA) World Factbook, and the World Bank Databank on missing data. Information on the desired outcome, i.e. the percentage of population reporting ADRs, was only possible to access for 35 different countries (Table 2).

Data from all relevant factors were extracted, providing a comprehensive summary of the circumstances of the economy and general health status of the considered countries. As the data was retrieved from multiple sources, we adapted and used the principles of data quality described by Brown et al. [17]. The data was checked by two researchers (PI and AC) and disagreement was sorted by consensus. Information was collected for the most recent and comparable year that values were available, falling in 2013, where a minimum number of missing information for each individual country existed, diminishing uncertainty. When data were not available for 2013, a range of ± 2 years was searched for all countries. If again unavailable, information was searched retrospectively until 2005 for specific factors, addressing all countries for the same time interval (e.g. proportion of births attended by skilled health personnel). The factors were disaggregated by sex and age groups, whenever possible.

2.3. Development and application of the statistical model on the dataset

The raw variables were retrieved to an Excel spreadsheet (Supplementary File 1) and the final dataset was checked for consistency prior analysis using the R-CRAN V3.2.0 software (R Development Core Team, 2011). Statistics aimed to evaluate the propensity for a country to have a significant patient reporting level ($>5\%$ for all population) based on the existing information associated with each country.

2.3.1. Outcome and predictor variables selection

Patient reporting percentage was used as the outcome or dependent variable. Patient reporting can be defined as the reports submitted by patients themselves or consumers in general about suspect ADRs to pharmacovigilance authorities, using means of passive or active surveillance. By screening the database for level of response, it was possible to confirm that most countries presented less than 5% of patient reporting, naturally establishing this value as the cut-off for dichotomisation. Accordingly, a binary variable was defined to allow for studying the propensity for each country to report significantly (i.e. $>5\%$) against those with only a residual report ($\leq 5\%$) (see Table 3 in Results).

From the initial 44 countries, data was complete for 35 countries, considering the identified 42 predictors or covariables, all presented in Table 3. Some of these, as marked in the table, had too many missing values, thus raising numerical problems and were removed from further analysis. Univariate logistic regression models [18] were computed for all considered covariables, as indicated in Table 3. Association with the outcome variable, even if small, was tested through the Wald test, considering at this phase 0.25 as the maximum value for the probability of type I error (i.e. p -value $< 2.5\%$). The most significant covariables were selected both from the numerical point of view, as well as from the point of view of interpretation and representativeness. These covariables were then homogeneously grouped by type of information conveyed: health

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