United Journal of Pharmacovigilance

Clinical Records in Pharmacovigilance: An Active Monitoring Program in the Context of a Pandemic

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Article Information
Article Type: Review Article
Article Received: 11-21-2020
Article Accepted: 12-19-2020
Article Published:12-28-2020
Vol:1, Issue:1

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In the past he was a member of the European Union's H2020 research team "Smart and Healthy Ageing through People Engaging in Sup-portive Systems – SHAPES", at Abel Salazar Institute of Biomedical Sciences of the University of Porto (ICBAS) and CINTESIS R&D; and he was also a researcher at Porto4Ageing - Competences Centre on Ac-tive and Healthy Ageing of the University of Porto.

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OPEN ACCESS

Citation: : Inês Ribeiro-Vaz, et al. / United Journal of Pharmacovigilance 1(2020):1-7

Pharmacovigilance is an essential component of pharmaceutical safety [1]. The United Journal of Pharmacovigilance opens a new space for the dissemination of scientific data in this area of research, based on the methodological and operational principles of clinical research and its implementation in the context of evidence-based decision-making. This short communication aims to highlight the importance of accessing clinical records to perform retrospective evaluations of drug safety issues. We will focus particularly on pandemic situations, as the present COVID-19.

The COVID-19 rapidly spread throughout the world after emerging in China in December 2019[2]. From that time to the present, almost 58 million individuals were infected with the SARS-CoV-2, and unfortunately, even with the possible symptom-driven treatments, more than 1,3 million have died. During this period, insufficient data about adverse drug reactions (ADR) has been reported by health services to pharmacovigilance centers around the world, possibly due to the tremendous burden that these services have experienced since.

Spontaneous reporting (or passive monitoring), although useful, has many limitations, such as underreporting, biased reporting rates, incomplete patient information, and indeterminate population exposure [3]. In contrast, active monitoring (or active surveillance) seeks to comprehensively ascertain the number of ADR via a continuous pre-organized process [4]. This approach can be achieved by reviewing clinical records or interviewing patients and/or health professionals in a sample of sentinel sites to ensure complete and accurate correspondent data. Besides that, the selected sites can provide useful information, such as data from specific patient subgroups, that would not be available in a passive spontaneous reporting system [4].

Information sources can be classified as primary or secondary. The first are those in which data are specifically collected and for the first time (primary data collection), usually to support a particular study, such as a survey, a randomized clinical trial, or a case study. For instance, information collected in the context of monitoring a suspected drug will be considered as a primary source as it is being collected for a specific purpose. Differently, secondary sources are those that precede a study, as is the case for clinical records or disease registration databases. As an example, information about adverse reactions in the daily clinical records of a hospital, that can be used in the context of pharmacovigilance [5]. Traditional sources of data used for detecting new, rare, and serious ADR are clinical trials, pharmaceutical industry reports, and adverse-event spontaneous reporting databases [6,7].

Clinical records may include a wide range of data, from demographics to medical history, medication therapy and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and other clinical information [8]. Despite being a very useful source of information, clinical records can generate some methodological difficulties, such as the absence of important information, since they already exist by the time of their evaluation [5]. Another challenge related to clinical records, particularly in the case of pandemics like the COVID-19, is the abnormally high number of patients and associated amount and complexity of information available, especially concerning hospitalized patients. Finally, pharmacovigilance concerns the report of real clinical situations, which may contain sensitive information. Even if the patients are not identified, the events described may indirectly lead to their identification, which is why access to this information in a detailed or disaggregated form is not possible for most pharmacovigilance experts. As so, access to clinical information (of COVID-19 patients or others) must be based on one of two premises. One: a pattern of adverse events should be known so that the study of all pharmacotherapy of a patient population is prioritized in order to detect risk signs for one or more drugs – ADR-directed monitoring. Other: risk signs should be known for a given drug (or its interactions with others), prioritizing the study of all patients taking that drug - drug-directed monitoring. However, ADR are frequently due not to medications themselves but to the patients' underlying conditions, which is another factor highlighting the importance of accessing the full clinical record of each patient [9]. Pharmacovigilance centers that propose to carry out retrospective studies based on clinical records will have to take this into account.

Once reported, every ADR should be analyzed to establish the causality link between the drug(s) and the event [10-14]. The causality assessment is a step of major importance for an accurate benefit-risk evaluation, which is essential for all drugs and, most of all, for those that, although not being new, are being used in a new context ("drug repurposing"), as is the case within the current pandemic. Quite often, the causality link is difficult to establish due to contradictory information or lack of proper data. Thus, the importance of implementing active monitoring systems prevails, particularly by the exhaustive search for suspected ADR in the clinical records of patients diagnosed with SARS-CoV-2 infection. Accessing clinical records is of uttermost relevance since they include certain parameters crucial for causality analysis, like demographics, clinical history, suspected drug(s), date and time of onset of the ADR, temporal relationship, description of the reaction, dechallenge, rechallenge, previous knowledge about the ADR, management, and outcome of the ADR.

Since March 20201, an immense amount of data concerning COVID-19 patients is being registered in the health systems platforms. We endorse the view that it is of great value to settle a commitment between the different agents involved in treating COVID-19 patients, essentially the ethics commissions and health systems administrations, in order to make these data available. The Porto Pharmacovigilance Centre, one of the 9 regional units in Portugal, has established collaboration protocols with some central hospitals to ensure access to the clinical records of COVID-19 patients. Moreover, other protocols are being considered with local health units and nursing homes so that we can also analyze community data, i.e., patients recovering at home.

With this first contribution to the United Journal of Pharmacovigilance, we leave an incitement to all local and regional pharmacovigilance centers in every country to establish protocols to access clinical records, in the sense of intensively monitor risk signs in the use of medicines for COVID-19. We will contribute soon with results regarding the safe use of drugs in this new pandemic disease (in Portugal) and expect to cross-check these results with those reported for other countries.

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