

A Wide Database for a Multicenter Study on *Pneumocystis jirovecii* Pneumonia in Intensive Care Units

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Abstract. *Pneumocystis jirovecii* pneumonia (PJP) is an opportunistic fungal infection that may affect patients with immunosuppression. In order to improve the diagnosis accuracy for PJP, facilitating the collection of data across Europe to reliably assess the performance of diagnostic tests for PJP is essential to improve the care of critically ill patients developing this severe condition. Such large data can be collected thanks to the contribution of several European hospitals in the compilation of a dedicated electronic Case Report Form (eCRF). The main focus of this work is to create an interface with high ergonomics both in the compilation and in the subsequent validation of the records.

Keywords. *Pneumocystis Jirovecii*, Pneumonia, eCRF, Relational Database

1. Introduction

Pneumocystis jirovecii pneumonia (PJP) is an opportunistic fungal infection. Classically, PJP has been described in patients with human immunodeficiency virus (HIV) infection, but it may also develop in patients with solid organ transplantation, hematological malignancies and some other pathologies and medical treatments [1-3]. PJP may present as a severe disease with respiratory insufficiency requiring admission to intensive care unit (ICU) and mechanical ventilation. The diagnosis of PJP in ICU (especially in non-HIV patients) is not standardized, and large studies to solidly evaluate the accuracy of diagnostic tools are currently lacking. The aim of this paper is to present a database and a structured system that will be used to collect hundreds of high-quality pseudonymous samples to further improve the early recognition and proper treatment of PJP.

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2. Methods

The study and its electronic Case Report Form (eCRF) was approved by the Liguria ethics committee (305/2021-11538). The protocol requires the collection of features from several fields: Medical History, Hospitalization, Radiology, Microbiology and Laboratory results (specific for PJP or not), Therapy and Outcome. The database structure was developed following the precepts of the Class Diagram in the Unified Modeling Language (UML). More than 20 European centers take part in the data compilation. The structure was designed to support further development, allowing future automatic extraction and storage of congruent data collected by already existing parallel projects like Liguria HIV Network [4], according to the service-oriented approach [5].

3. Results

The designed and developed architecture is composed by a *Blazor* web interface (client), that is able to format and automatically validate the data that will be saved into a *SQL Database* thanks to an *API RESTful service*. The communication and data conversion are managed by *Entity Framework Core*, with a *code first* approach starting from *C# Classes*. Most fields of the eCRF consist in multiple choice questions, whose values come from a dedicated dataset. The compiler can alternatively indicate a new free-text value, and the revisors will both validate its congruity and evaluate its eventual addition to the dataset.

4. Discussion and Conclusion

The main focus of the project was to create a dedicated eCRF able to guarantee a complete control over the logic relations between its features and their subsequent revision and validation. Providing a similar structure is necessary to facilitate adequate collection and control of data from several centers on a controversial topic which cannot be assessed in single-center or national cohorts: small samples would not provide sufficient power for statistical analyses. The present project may ultimately improve both the prompt recognition and the care of critically ill patients with PJP in European ICUs.

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