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Virtual Clinical Trials: A tool for the Study of Transmission of Nosocomial Infections

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Abstract

A clinical trial is a study designed to demonstrate the efficacy and safety of a drug, procedure, medical device, or diagnostic test. Since clinical trials involve research in humans, they must be carefully designed and must comply strictly with a set of ethical conditions. Logistical disadvantages, ethical constraints, costs and high execution times could have a negative impact on the execution of the clinical trial. This article proposes the use of a simulation tool, the MRSA-T-Simulator, to design and perform "virtual clinical trials" for the purpose of studying MRSA contact transmission among hospitalized patients. The main advantage of the simulator is its flexibility when it comes to configuring the patient population, healthcare staff and the simulation environment.

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1 Introduction

In the medical field, the transmission of Nosocomial Infection (NI), which is an infection acquired within hospital settings, is a widely studied phenomenon. According to data published by the European Center for Disease Prevention and Control [21], about 7.1% of hospital patient acquire at least one NI during their stay. There are several hospital microorganisms which are capable of producing a nosocomial infection, but we will focus on Methicillin-resistant Staphylococcus Aureus (MRSA) [4]. Since MRSA is transmitted by physical contact, the frequent interaction between patients and Healthcare Workers (HCWs) or the hospital environment, and long length of stays all increase the transmission risk of MRSA. To minimize the percentage of patients who acquire NI several actions such as washing and disinfecting hands and the use of isolation material are performed by HCWs. We called these actions Infection Control Measures (ICM). The application of the ICM has an impact on the rate of propagation, as many studies published

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in this line demonstrate [20][15] [5]. However, it is very difficult to quantify the importance of compliance with ICM or to know what would happen if we stop applying them.
One of the mechanisms used to assess the efficacy of some medical procedures on transmission rates are the Clinical Trials (CTs). The World Health Organization defines the CT as "Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include, but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."[13]. CTs should be based on a protocol or plan of action which describes what is done in the study, how it is done and why each part of the study is necessary. All of these characteristics define who participates in the CT (inclusion criteria: age, sex, presence of a particular disease, among others). At times, it is not easy to ensure that the population studied meets all the necessary characteristics, affecting both the quality of the results obtained and the increased time and costs of conducting the CT. Moreover, CTs are always subject to the approval of an ethics committee, which seeks to ensure that the study is ethical and the well-being of the participants is protected at all times. In other words, in a real CT there will be certain situations that cannot be considered because these are dangerous for patients.
This article proposes the use of a simulation tool, the MRSA-T-Simulator, to design and perform " Virtual Clinical Trials" (VCTs) for the purpose of studying MRSA contact transmission among hospitalized patients. The VCT could be a cost-effective alternative in situations where, due to ethical, economic or time limitations, it was difficult to design and implement a CT. The validity of the simulation results would not be comparable to a real CT, but could offer relevant information in those situations in which the CT cannot be performed or as a pre-implementation situation.
The simulation began to be used in the 1970s as a tool for the solution of problems related to the healthcare field. Issues such as the improvement in the planning of the configuration of HCWs, the influence of the lengh of stay of patients in the hospital system, the optimization of resources, or the transmission of diseases acquired in the healthcare environment have been widely studied through the application of different techniques. Some simulations used mathematical models to simulate aspects such as studying the impact of infection control programs on the spread of MRSA [16], or to studying the transmission dynamics of MRSA [18][2]. Another simulation technique is the Agent Based Model and Simulation (ABMS). This approach has the advantage that it provides more flexibility when we need represent stochastic processes. There are several studies that apply ABMS models to study MRSA transmission. For instance, in [11] an agent-based simulation to determine how the problem might be managed and the risk of transmission reduced is developed. Another study [12] showed an individual-based model and simulator to investigate MRSA outbreaks in a hospital ward. Additionally, ABMS approach has been used to provide information to support decisions makers to healthcare services[8].
Simulation techniques have also been used to design CTs with different approaches. They can help refine dose selection [1] [9] and study design, and to represent dose-response and time-response behaviour of safety and efficacy endpoints [14]. Some studies use preclinical data to construct simulation models and to provide prior information on model parameters. Thus, the results from a proof-of-concept study can be used to study a similar model to be used in a subsequent study [19] [7].
As we can see, the use of simulation in the field of healthcare has multiple applications. From its use as a tool to make decisions at the managerial level, to the development of simulations of CTs related to the design of drugs and other applications. In our case, the main objective is to show that a real CT can be replicated through the use of an ABMS simulation tool through

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