

Plan Overview

A Data Management Plan created using DMP Tool

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Title: COMPARISON OF THE RESULTS OF SEROLOGICAL AND MOLECULAR TESTS FOR HBV, HCV AND HIV IN BLOOD DONORS

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Template: Digital Curation Centre

Project abstract:

The transmission of infectious agents through blood transfusion is attributed to four reasons: the first, and most important, is the collection of blood during the window period. For human immunodeficiency viruses (HIV) and hepatitis B virus (HBV), at least 90% of the risk is attributable to this period, while for hepatitis C virus (HCV) it is 73 to 88%. Although atypical viral strains, atypical seroconversion and laboratory errors can cause the transmission of viral infections, currently the most common cause is related to the serological window period for HBV, HCV and HIV because the immunoassays used For blood screening they do not detect the initial period of acute infections. A single unit of blood can benefit many patients. Depending on how the blood is separated into different therapeutic components; A single unit of blood could be used to treat 1 to 5 recipients.

Around 117.4 million units of blood are collected worldwide; 42% takes place in high-income

countries, where 16% of the population lives. In developing nations the annual average per center is 1,300 donations. The World Health Organization (WHO) estimated that between 5% and 10% of HIV infections were transmitted by transfusion. It is also estimated that each year, unsafe transfusions and injections would explain between 8 and 16 million cases of hepatitis B virus, 2.3 to 4.7 million cases of hepatitis C virus and 80,000 to 160,000 HIV infections. in the world. As of 2014, it is mandatory for Colombian blood banks to test antibodies for HTLV I and II subtypes in donors. Meanwhile, in most advanced countries the search for HCV and HIV is carried out by NAT ((The nucleic acid amplification test)) mainly in pooled plasma. South Africa was the first country in the world to implement ID-NAT (individual donor nucleic acid). After its implementation, the risk has been reduced to approximately one case per two million transfusions and the possibility of transfusion transmission of the human immunodeficiency virus has decreased to a level 20 times lower compared to the period before the introduction of the ID -NAT. This precedent suggests the implementation of mandatory NAT testing for donations. Considering that NAT tests are a precautionary principle and a good transfusion safety measure, because it eliminates or reduces the risk of transmission of viral infections through contaminated donations, the present study proposes to calculate the seroprevalence for HBV surface antigen (Ag -HBVs), antibodies to HCV (anti-HCV) and antibody to HIV (anti-HIV) (Aim 1). Then determine the frequency of reactivity for HBV, HCV and HIV nucleic acids detected by NAT molecular biology techniques (Aim 2). Subsequently, compare the results of the NAT molecular tests for HBV, HCV and HIV against those of chemiluminescence (Objective 3). Finally, the association of the variables gender, age, occupation, type of donor and marital status with the results will be calculated. of serological and molecular tests (Objective 4). The study aims to compare the results of serological and molecular tests for HBV, HCV and HIV performed on blood donors to evaluate their diagnostic value in reducing the window period. By detecting the RNA or DNA of the virus itself, NAT can identify very low-level viral infections that immunoassays may miss. This is useful for reducing what experts call the "window period," that is, the time between infection and when that infection can be detected with a test. By shortening this “window period,” NAT can help make the blood supply safer for patients who rely on donated blood for their health.

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COMPARISON OF THE RESULTS OF SEROLOGICAL AND MOLECULAR TESTS FOR HBV, HCV AND HIV IN BLOOD DONORS

Data Collection

What data will you collect or create?

A database is presented in Microsoft Excel spreadsheet format (.xlsx) with 19,622 blood donor records, including sociodemographic data and results of screening and molecular tests for infectious markers of HIV, Hepatitis B. and Hepatitis C.

Size 1.66 MB (1,751,311 bytes)

How will the data be collected or created?

Sociodemographic data will be collected from the survey applied to donors and the tests carried out to determine the infectious markers of HIV, Hepatitis B and Hepatitis C using chemiluminescence and NAT techniques.

Documentation and Metadata

What documentation and metadata will accompany the data?

For the calculation of seroprevalence for HBV surface antigen (HBV-Ag), antibodies to HCV (anti-HCV) and antibody to HIV (anti-HIV) processed individually using chemiluminescence immunoassays (Cobas e 601 from Roche Laboratories) The number of reactive results reported in the database for each marker will be related to the total number of donors analyzed multiplied by one hundred.

The determination of the frequency of reactivity for HBV, HCV and HIV nucleic acids detected by NAT molecular biology techniques using the Cobas s 201 system from Roche Laboratories will be carried out by measuring the number of times that reactive cases occur in the database. for each of the markers analyzed (Relative frequency). Additionally, the absolute frequency will be calculated to compare the results. The data obtained will be presented in summary tables.

For the evaluation of the results of the NAT molecular tests for HBV, HCV and HIV compared to chemiluminescence tests in the reduction of the window period, the association of each variable studied on the positivity of the samples will be estimated; The universe of donors will be stratified into two groups: those reactive to any of the 3 markers studied and those not reactive. The percentages of the number of reactive samples for the 3 markers studied, by one method or another, will be calculated in relation to the total number of donors.

The window period will be defined with the Nat test positive and the serological test negative.

Each variable such as sex, age, occupation/profession, marital status and type of donation will be tabulated to calculate the percentage of individuals. Once the percentages have been tabulated and calculated, the Chi square statistical test will be applied to establish significant differences between the reactive and non-reactive groups.

Ethics and Legal Compliance

How will you manage any ethical issues?

The way information is collected will have no effect on human dignity. Likewise, the development of the project will not have repercussions on the environmental context.

- Regarding biosafety protocols, they do not apply to this research.
- This research has no financial, family, membership or intellectual conflict of interest. No situations are foreseen that could affect the actions within the research project of the responsible persons or others that could affect objectivity.
- Donor personal data and results will be treated with strict confidentiality.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

The data belongs to the Hemocentro y Unidad de Aféresis de Valledupar. For the purposes of sharing or reusing data, permission must be requested from the entity to which it belongs in this case Hemocentro y Unidad de Aféresis de Valledupar .

Storage and Backup

How will the data be stored and backed up during the research?

In the event of an incident, the data can be recovered with the Hemocentro y Unidad de Aféresis de Valledupar and on the computer equipment of Bacteriology and clinical laboratory, University of Santander in Valledupar, Educon user, to which a backup copy is made.

How will you manage access and security?

Access to the data is permitted safely for collaborators, through access credentials, only for authorized personnel.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data must be preserved. Its predictable use is mainly for the description of the distribution of sociodemographic variables in donors and the evaluation of the tests against the detection with NAT of the infectious markers HIV, Hepatitis B and C, before detection by screening tests.

What is the long-term preservation plan for the dataset?

In the event of an incident, the data can be recovered with the Hemocenter and Apheresis Unit of Valledupar and on the computer equipment of Bacteriology and clinical laboratory, University of Santander in Valledupar, Educon user, to which a backup copy is made.

Data Sharing

How will you share the data?

Potential users will learn about the data by publishing and socializing the analysis of the results. The data will be shared with those who require it and requests will be handled directly.

Are any restrictions on data sharing required?

A data sharing agreement is required. It is considered that a confidentiality agreement will provide sufficient protection for confidential data.

Responsibilities and Resources

Who will be responsible for data management?

The authors are responsible for implementing the DMP and ensuring its review.
Those responsible for data capture, metadata production, data quality, storage and backup, archiving and data sharing are the authors.
Authors will be responsible for ensuring that relevant policies are followed.

What resources will you require to deliver your plan?

Among the resources necessary to execute the plan, the Spss software is suggested

Related Works

Books

- <https://www.cunorte.udg.mx/investigacion/publicaciones/aproximaciones-multidisciplinarias-en-el-estudio-de-la-salud-medicina>