
Modelo multivariável para prever tempo de duração de cirurgia: desenvolvimento e validação

A Data Management Plan created using DMPTool

Creator: Gabriel Guimaraes

Affiliation: Non Partner Institution

Template: Digital Curation Centre (DCC)

ORCID iD: 0000-0001-6289-2233

Project abstract:

Data for developing a multivariable model to predict surgery times

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Data Collection

I will create a table where the first column is called id. Each surgery will be represented by a unique ID, a number not correlated to any other variable to prevent identification.

Following columns will be age (ordinal variable 18-29, 30-39, 40-49, 50-59, 60-64, 65-74, 75-84, 85-96, >96), body mass index (kg/m²), previous surgeries at the same site (count), surgeries planned (compound variable representing every surgery planned), main surgeon code (an internal unique code for each surgeon), week day (sunday to saturday), starting time (morning, afternoon), main anesthesiologist code (an internal unique number for each anesthesiologist), surgery time estimated by the main surgeon, surgery time estimated by the anesthesiologist.

Data will be stored in CSV format and we expect thousands of cases.

CSV enables sharing and long-term access to the data because it is very simple and universal.

We plan to use RedCap for data collection but if it fails, we will adopt FormSUS which handles versioning and can export to CSV format. Twelve independent research assistants will help in data collection. Weekly, i will audit two random records. Also, i will perform summary statistics for the collected data (minimum, maximum, median, mean and standard variation, to assure consistency) and will also audit extreme cases (outliers). Some cases will also be collected more than once by independent research assistants at random, to assure data consistency. If any error is detected, i will call the responsible for the collection of the wrong data and we will study the error source and plan new strategies to mitigate it.

Data entry will be standardized by the RedCap or FormSUS forms.

Documentation and Metadata

A readme file will accompany the data to help secondary users to understand and reuse it. Full columns names including units of measurement or possible classes.

It will include the study title and public study register (which includes methodology used), where to find the official data (it is important to give an official source because modified data may be shared between users), who created the data, the date of creation and file version and conditions to access and use it. A link to the public source code used in data analysis will also be shared.

Ethics and Legal Compliance

Before the study starts, we need to gain approval from our local ethics comitee. We will ask authorization for individual patient data preservation and sharing.

No indentification variable will be collected in this study. No sensitive data is expected.

Data is owned by Hospital Universitário de Brasília. We plan to publish the data using Creative Commons Attribution 4.0 International licence. We plan to publish the versions of the shared data every 12 months or more, because we intend to shuffle the cases order to make individual identification even harder.

Storage and Backup

Redcap and FormSUS have sufficient storage, free of charge. We plan to download data and make backups every 6 months in an encrypted file stored in Mendeley Data. The principal investigator will be responsible for the data backup. In the event of an incident in RedCap or FormSUS server, data from the Backup will be recovered from Mendeley Data.

We do not plan to collect any sensitive data. The data collected does not need to be secured.

I will comply with law 13.709 published in 14/08/2018, retrieved September 13, 2018, from http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2018/Lei/L13709.htm and HIPAA (*Health Insurance Portability and Accountability Act*).

Selection and Preservation

All the collected data have medium-term value because they are specific for our hospital. The data does not need to be destroyed for contractual, legal or regulatory purposes, but from surgeries not performed anymore or from professionals who do not work for the hospital anymore will not be used anymore. We intend to preserve the data in Mendeley Data up until Mendeley Data drops it.

It will be held in Mendeley Data and RedCap or FormSUS. We do not expect any direct cost for us using those technologies.

Data Sharing

Users will know about our data from our website, from Mendeley Data and from future published articles. I intend to share the data using CC BY 4.0 licence. I will make new versions available every year up until we finish our study. I will pursue a DOI for the data.

No, i intend to share it using CC BY 4.0 licence.

Responsibilities and Resources

The principal investigator, Gabriel Magalhaes Nunes Guimaraes, is the responsible for implementing the DMP and to revise it when necessary. Twelve anesthesiology residents will be responsible for the data collection. RedCap / FormSUS will be responsible for data storage. The principal investigator will be responsible for backups, data quality and data sharing. The principal investigator will also be responsible for ensurance of relevant policies respect.

I plan to use RedCap, but if it fails, FormSUS will be used because it allows creation of intelligent forms and audit trails. No specific additional software or hardware is expected.