

CHRIS Study

Drug information

Version 1.1

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1. Introduction

This module stores the drugs of the participants, whose packages were scanned at the CHRIS study center.

Participants book a morning appointment at the CHRIS study center, ranging from 7.45 to 8.45 a.m. Each study participant is assigned a workflow at the reception. If there are ten study participants (maximum capacity), there are ten different workflows, marked with the letters from “A” to “K”. The current workflow is as follows: A-B-C-D-E-F-G-H-I-K. All the workflows can be found in the documentation of CHRIS Baseline/General information/Administrative data, in the file named “Workflows at baseline assessment”. The drugs are scanned after the neurological tests, which occur after the interview.

Participants are asked to bring all the packages of the medications they have taken in the last 7 days or that they take regularly.

For each drug package that was brought by the participant, the interviewer had to ask a set of questions on the dosage, prescription, route of administration, and the therapy length. More precisely, the participant is first asked *“In the last 7 days have you taken drugs, or food integrators as vitamins or minerals? Please also consider anti-inflammatory and painkiller drugs, insulin preparations, galenics and injections. Please indicate drugs with prolonged action, even if they have been taken more than 7 days ago. Also consider preparations bought at the supermarket/grocery.”*

If drug usage is reported, then other information on drugs are entered in the database.

Among all the information collected, the relevant variable to classify drugs is the ATC (Anatomical Therapeutic Chemical Classification System) code, which has been extensively cleaned and assigned to all the drugs.

In the ATC classification, the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological, and chemical properties.

There are, however, cases when the drug information is inserted by hand, specifically when

- the drug package is scanned with the barcode reader, but it is not found (database not updated, or drug from abroad),
- the drug package is forgotten by the participant, and just the name is reported.

In these cases, operators can enter free text and choose among drugs in a scrolling list.

Therefore, some codes with AIC (*“Autorizzazione all’Immissione al Commercio”*) and an ATC seem apparently scanned but were actually inserted by hand. It is not possible to know which records fulfill this condition. This type of data entry might be responsible of additional heterogeneity observed (e.g. in pharmacological forms in R03 drugs). If a record is not found in the scrolling list, it is inserted by hand, and the quality of information is highly variable.

Therefore, the drug database has one or more lines per participant, depending on the number of drugs taken. If no drug usage was reported, then there is a single line for this participant. If instead drug usage was reported, then for this participant there are as many lines as the number of reported drugs.

The guidelines for scanning the drugs package are available at CHRIS Baseline/Drugs data in the documents named “Drugs data insertion guidelines”.

2. History version changes

The drug data were collected since August 24th, 2011 and no version change occurred. The cleaning process has produced the following changes:

variables added: x0dd02a, x0dd04, x0dd05, x0dd06, x0dd09, x0dd10a, x0dd16, x0dd18a, x0dd20-x0dd44

3. Data cleaning

1. The CHRIS drug dataset was loaded.
2. The drug dataset was reshaped into a wide format to have one row per participant, and the following dichotomic variables were created:
 - a) Anti-hypertensive medication, x0dd20: “Yes” if the treatment subgroup of any reported drug was C02, C03, C04, C05, C07, C08, or C09, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - b) Diabetes medication, x0dd21: “Yes” if the ATC code of any reported drug started with A10A or A10B; “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - c) Lipid modifying agents, x0dd22: “Yes” if the treatment subgroup of any reported drug was C10, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - d) Metabolic syndrome drugs, x0dd23: “Yes” if the ATC code of any reported drug started with C10AB, C10AD, C10BA01, C10BA03, or C10BA04, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - e) Thyroid disease drugs, x0dd24: “Yes” if the treatment subgroup of any reported drug was H03, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - f) Asthma-COPD medication, x0dd25: “Yes” if the treatment subgroup of any reported drug was R03, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - g) Osteoporosis medication, x0dd26: “Yes” if the ATC code of any reported drug started with M05B, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - h) Antiglaucoma medication, x0dd27: “Yes” if the ATC code of any reported drug started with S01E, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,
 - i) Arthritis medication, x0dd28: “Yes” if the ATC code of any reported drug started with P01BA02, L04AX03, L04AB, L04AX02, or M01AH, “No” if x0dd02a=“At least one ATC drug” and the ATC code condition did not hold,

- j) Antineoplastic and immunomodulating agents, x0dd29: "Yes" if the ATC code of any reported drug started with L, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - k) Angina medication, x0dd30: "Yes" if the ATC code of any reported drug started with C01D, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - l) Beta blockers, x0dd31: "Yes" if the ATC code of any reported drug started with C07, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - m) Class I and III antiarrhythmics, x0dd32: "Yes" if the ATC code of any reported drug started with C01B, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - n) Digoxin, x0dd33: "Yes" if the ATC code of any reported drug was C01AA05, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - o) Calcium antagonist, x0dd34: "Yes" if the ATC code of any reported drug started with C08D, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - p) Cardiac therapy, x0dd35: "Yes" if the ATC code of any reported drug started with C01, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - q) Antithrombotics, x0dd36: "Yes" if the ATC code of any reported drug started with B01, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - r) Acid related disorders, x0dd37: "Yes" if the ATC code of any reported drug started with A02, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - s) Psycholeptics, x0dd38: "Yes" if the ATC code of any reported drug started with N05, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - t) Psychoanaleptics, x0dd39: "Yes" if the ATC code of any reported drug started with N06, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - u) Sex hormones, x0dd40: "Yes" if the ATC code of any reported drug started with G03, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - v) Anti-Parkinson drugs, x0dd41: "Yes" if the ATC code of any reported drug started with N04, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - w) Hypnotics and sedatives, x0dd42: "Yes" if the ATC code of any reported drug started with N05C, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - x) Antivertigo preparations, x0dd43: "Yes" if the ATC code of any reported drug started with N07CA, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - y) Warfarin, x0dd44: "Yes" if the ATC code of any reported drug was B01AA03, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold,
 - z) Antiepileptics, x0dd46: "Yes" if the ATC code of any reported drug started with N03, "No" if x0dd02a="At least one ATC drug" and the ATC code condition did not hold.
3. The missing observations of x0dd20-x0dd46 were set to:
- a) "Unexpected missing" if the participant reported regularly taking drugs but gave no other information (x0dd02a="At least one ATC drug" and all other variables were missing),

- b) “Missing by design” if the participant did not report regularly taking drugs (x0dd02a!=“At least one ATC drug”).
- 4. The drug summary dataset was saved.

4. Advice for the analysis

The content of the nurse’s notes includes information on drug acquired abroad, dosages that are not constant (e.g. thyroid therapies), treatments that were discontinued (for a pregnancy or a drug change), and dosages split in multiple times of the day.

Furthermore, in rare occasions the information reported in the interview might disagree with the drugs scanned (or lack thereof) at the CHRIS center: either some participants reported chronic diseases that are regularly treated, but did not bring the relative drug package, or other participants might have omitted to suffer from severe diseases at the interview and have brought drug packages that are highly specific of a severe disease. The variables of the drug summary (x0dd20-x0dd44) help highlight the main and most common drugs reported, that can help identify such cases.

Finally, the analyst should always take into account that the operator in charge of scanning the medication package and asking the relative questions might have influenced how the participant reported their answers. The analyst should therefore adjust for the study assistant variable, x0dd19, when possible.

5. References

Information about ATC codes can be found at http://www.whooc.no/atc/structure_and_principles/

ATCs can be found at http://www.whooc.no/atc_ddd_index/

Route of administration database: <https://www.fda.gov/drugs/data-standards-manual-monographs/route-administration>