Amsterdam Public Health

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Aim

To obtain a representative sample appropriate to the research question.

Requirements

Documentation of the recruitment and selection of the subjects including responders and non-responders.

Documentation

Flow chart of the inclusion and exclusion of the subjects.

Responsibilities

Executing researcher:

- Clearly describe the source population;
- Document the study population, including inclusion and exclusion criteria;
- Document the recruitment procedure of the study population, including responders and non-responders;
- Document the reasons for non-participation.

Project leaders:

- To advice the executing researcher in respect of:
- Identification of the source population and study population;
- Selecting a proper sample from the identified study population.

Research assistant:

• Ask reasons for non-participation.

How To

First it is important to make a clear distinction between your source population, study population and sample.

The source population should be the group that you would like to make inferences about, based on what you see in your sample. It is the population to which inclusion and exclusion criteria were applied. This results in the study population, i.e., the group you actually defined because of the inclusion and exclusion criteria. The group under study is your sample, which is in the best case representative of the study population.

For example, you study children with a mental disability, in the age of 6-12 years old, with an IQ between 50 and 70, and you select 30 people from this group for interviews.

- Source population: children with mental disability
- Study population: 6-12 years old, IQ between 50 and 70
- Sample: n =30 selected children.

Epidemiological research implies conducting measurements on people and deriving estimates from this. A valid sample from a well-described source population prevents you from bias in the final results and, therefore, ensures you to be able to generalize the study outcomes.

Three steps need to be completed in specifying a study population:

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- 1. Describe the source population: describe to which group of people you want the study results to apply to (referring to your research question).
- 2. Identification of the study population: the population among which you will recruit your subjects. In this step a detailed description of inclusion and exclusion criteria needs to be made. Write down how many patients were excluded for every step. It is suggested you do this, especially when using a selection from a larger database, at the start of your analysis / export out of a database.
- 3. If necessary, select a sample from the study population, preferably a random sample. In a patient-control study, both the patients and controls need to be selected from the same study population (e.g. select controls [patients without the disease of interest] from the same hospital as the patients). The sample size should be based on power calculations, in which the expected non-response and dropouts were taken into account.

There are different ways to draw a sample. For more information you can consult the following websites:

- http://www.statisticshowto.com/simple-random-sample/
- <u>https://www.openepi.com/Menu/OE_Menu.htm</u>

Once the sample of the study population has been established, individuals from the sample will be invited to participate in the study. An important principle in medical research is that participation should always be voluntary and individuals should only be bothered a limited number of times with invitations to participate. When individuals do not want to participate or do not respond to the invitation, this should be documented as 'non-response'. It is advised to ask the non-responders what their reason is for non-participation. Document these reasons and, if possible, the characteristics of the non-participants. Be careful in collecting data of patients who have not given consent for their participation!

The selection process is generally documented in publications by means of a flow diagram. See for an example: <u>http://www.consort-statement.org/consort-statement/flow-diagram</u>

Audit questions

- 1. Have the domain, source population and study population been documented?
- 2. Have the steps been documented why this specific study population was selected?
- 3. How was sampling undertaken?
- 4. How many people refused to participate? Have the reasons for refusal been documented?

LINKS

	Link
Simple Random Sample	https://www.statisticshowto.com/simple-random-sample/
The CONSORT Flow	http://www.consort-statement.org/consort-statement/flow-diagram
Diagram	

DOCUMENT HISTORY

Version	Status	Date	Name
4.0	Revision	15DEC2020	Laura van Dongen
3.0	Revision guideline	17MAY2017	EMGO
2.0	Revision format	16JUN2015	EMGO
1.1	Translation into English	01JAN2010	EMGO

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