



Strengthening the Occupational Health Expertise and Scientific Performance of Public Health Institution of Turkey



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Study protocol Lesson 4 : Instruments

A 3.1 ppt 2; second presentation on day 3 of training A

Part of the Chapter Methods of the protocol



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Learning Objectives

You will be able to further operationalize your study :

1. by selecting the appropriate instruments and tools
2. by collecting data in a highly standardized and ethical way

Summary of presentation



- Validated and reliable study instruments
- Questionnaires, other instruments (see Manual)
- Validity, reliability
- (Ethical aspects, later)
- Quality control

Study Protocol Part 4

Operational planning:

**definition of variables,
measurement instruments,
collection of the data**

Study plan

Study design?

Population?

Instruments for the study?

Errors?

Statistical tests?

Instruments

In your project you may use:

- Validated questionnaires (same context?)
- Interviews (trained interviewers)
- Risk assessment data (protocol)
- Job exposure matrices (validated?)
- Job descriptions (quality?)
- Data from biological monitoring (quality?)
- Existing diagnostic data (protocol?) from occupational or other health care
- New diagnostic assessments (protocol)

Validity

A valid indicator reflects the 'truth'

Validity example

You are organizing your shopping and you ask your daughter how many apples are still in the living room.

She reports: 1

Her counting is not valid as it does not reflect the reality: one pear but many apples.



Reliability

Reliability is the consistency in a series of measurements

Reliability example

You ask your daughter to recount the apples.

She comes back and reports again:1

The reliability or internal (intra-observer) consistence is high (but her measurement is not valid)



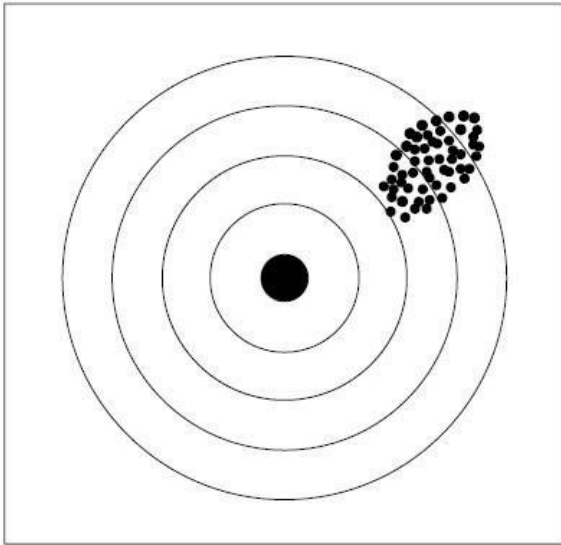
Reliability example

You have doubts about the answer of your daughter and you ask your son to count the apples.

He returns and reports as well:1

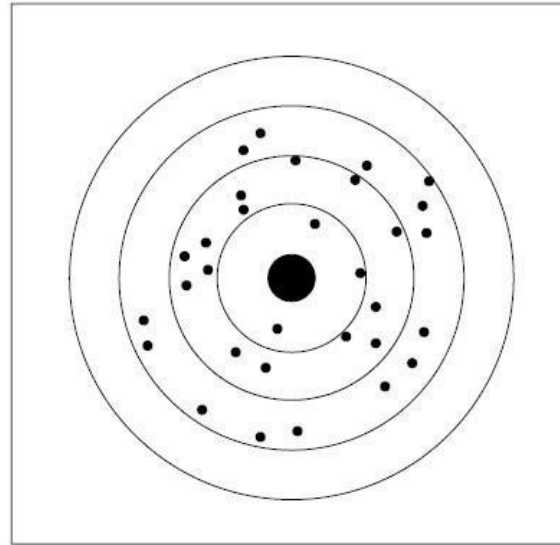
The inter-observer reliability of your children is high (but their measurement is still not valid)





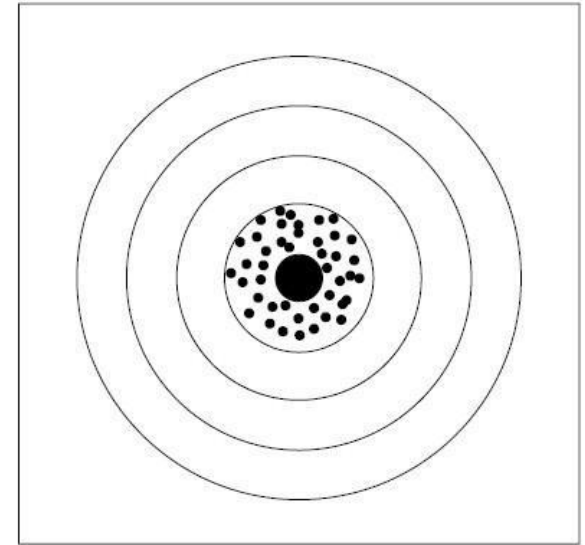
The participant always reports that he has no COPD complaints but he has COPD complaints

Reliable, not valid



One day the participant tells that he has no COPD complaints, the other day he reports COPD complaints
(independent of the real respiratory incidents).
The mean is correct

Not reliable, but valid



The participant always reports some complaints and has COPD complaints

Valid and reliable

Instruments

Use – when possible - existing instruments with a high validity and reliability

When you translate a questionnaire, verify the validity and reliability

The validity and reliability should be equal for

- the participants with and without exposure
- for formal and informal workers, e.g. when precariousness of work is the topic of study

Your protocol

- For a ‘vertical’ surveillance focusing on one disease, we suggest to use a validated disease-specific questionnaire or module such as for respiratory diseases, musculoskeletal disorders, burnout, skin diseases, GHQ-12 for mental health, etc. (See the Manual, search in international literature and ask experts)
- For specific diseases, measurements can be part of the assessment/diagnose (e.g. audiometry, spirometry)
- For an integrated (‘horizontal’) health surveillance measuring a large number of health complaints or diseases, use a questionnaire including such a wide range of health complaints or diseases.

Advantages of validated instruments

- ☺ The data are relatively more corresponding to reality than when using self-made questions (in general)
- ☺ The instruments have been used successfully in previous studies.
- ☺ A number of questionnaires are translated in other languages.
- ☺ You can compare your results with results from your colleagues in your country and in other countries; and with figures published in the scientific literature.
- ☺ It is not necessary to design and validate an instrument yourself.

Validated instruments

- ☹ When you want to compare the results with others
Do not change the questions!
- 😊 The only reason to change a question is when the question cannot be understood at all by your participants, or when preset answers such as for 'levels of education' or for 'income categories' are not valid in your country. All changes to the questions are to be recorded in the study protocol (!).

Disadvantages of validated instruments

- ☹ The questions are not flexible on the issues that are covered.
- ☹ When using 'scales', this means adding scores on several items (questions) that gives an estimation (measurement) of an abstract concept such as 'burnout', you are not allowed to change or delete any of the questions.
- 😊 However, separately, you can add a number of questions that you consider of special importance in your study.

Parts of the questionnaire

1. Personal data:
Sex / gender, age, education, living place
2. Employment conditions (hours, type of contract)
3. Working conditions
(ergonomic, chemical, physical, biological and psychosocial factors; PPE)
4. Health status, occupational and/or work-related diseases
5. Work accidents

Parts of the questionnaire

Modules on health and safety such as

1. Work accidents
2. Musculoskeletal disorders
3. Respiratory health
4. Mental health, etc

*We will use subchapter 4.3.4 in the Manual
‘A global overview of instruments’
to discuss various options to measure
exposure (work) and effects (health)*

Your protocol

- This should briefly describe the study
- More details are presented in the Manual.

Performing a study (survey)

Option 1:

You visit the participants and interview them.

- You can do this on paper or enter data directly into a database (E.g. EpiInfo or SPSS)
- If you enter data directly into the database, data need not be entered again.
- When interviewing participants you should not explain the questions otherwise than indicated in the instructions for the interview!

Performing a study (survey)

Option 2:

You visit the participants and ask them to complete the written questionnaire or send the questionnaire by post or e-mail.

- This costs less time than to do an interview
- Take into account that your participants could be not capable to read or not be able to understand what they are reading.
- It could happen that some participants do not have enough time to complete the questionnaire which can affect the representativeness of the study.

Performing a study (survey)

Option 3:

Call the participants (telephone, Skype)

- The experience in Europe is negative with this method; it is less probable that people accept to be interviewed by telephone.
- Another problem could be that not everyone has a telephone, and
- How would you get the telephone numbers (if you do not use random numbers)?

Performing a study (survey)

Option 4:

Questionnaire or interview by Internet or Skype

- Problem of literacy.
- Lack of internet capabilities or lack of digital literacy will increase the problem.
- In general, it could be a good solution when you know that the people that you are studying have access to internet and consult their e-mail regularly.
- The response in Internet-surveys is usually very low (only 10-20%).

Your protocol

- Describe in detail which method you will use for the questionnaire that you are using.
- When you include objective measurements explain how you are measuring (instrument, protocol) and how you have collected the samples.
- This part of the protocol has to be presented on a maximum of one page, but in case you use objective measurements, it could be larger.
- Appropriate selection and use of instruments depends
 - on the precise research question
 - on the specific exposure or disease
 - is often context sensitive
 - So, ask expert advice.

Quality control

- Everyone makes errors. It does not matter how careful you are, no one is perfect.
- However, you want the results of the project the best it can (and that makes it something outstanding!).
- In the protocol you must describe what you consider to do with possible errors. Consider at least the next measures.

Quality control

- Write a good study protocol that everyone has to follow.
- Do you have persons who do the interviews or measurements for you? You are lucky!
- However,
 - How do you know that they did the interviews or measurements really and that they did not invent the data? Check a random number of interviews or measurements.
 - How do you know if they do the interviews or measurements well, affecting or not the response or measurement result? Therefore, train the co-workers carefully.

Quality control

When you need to enter the data,

- Organize that another person (your husband or daughter/son) enters the data as well (double entry).
- Do not forget to put a unique number on the written questionnaire or measurement result form and enter the same number in both versions!!
- Afterwards, compare both versions to find errors (this can be done automatically)
- The data have to be entered in a database such as EpiInfo. Another option is that PHIT selects specific software and databases. From 2017 LMU Munich uses SPSS.

Quality control

- A random number of questionnaires or measurements has to be revised by experienced colleagues.
- Back-up your archives daily on a pen-drive (USB stick) or external hard disk.
- Keep paper questionnaires and measurement result forms in a safe place.

Ethical aspects

- In your research protocol you have to show that the study will be performed according to good epidemiological practice.
- More details are to find in the Manual and in a special lecture (A/B 4.2 on “Issues”)

Workshop 4

Complete the instruments and quality management in the Methods of the study protocol.