



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



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Study protocol : Introduction

A 1.3 ppt; Lesson 1

first presentation on day 1 of training A



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Learning Objectives

At the end of the development of the protocol :

1. You are able to develop a study protocol that is appropriate to analyse the issue that is the object of study.
2. With this protocol you will demonstrate your ability to understand and apply knowledge of occupational epidemiology.
3. You will be able to start or to participate actively in an epidemiological project.
4. You will be able to evaluate a study proposal of your colleagues in a critical but also constructive way.

Summary of this presentation



- Why are we proposing this study (research) related to workers' health surveillance?
- Conceptualization of the problem or issue of your investigation

Development of a Study Protocol

**An introductory course in applied research in the
field of Occupational Safety and Health**

General introduction

These slide series is an adapted translation, first from Spanish to English, then from English to Turkish of a slide series (and Manual) developed for the yearly starting “**Master of Science in International Occupational Safety and Health**” course for Latin America. This course, launched in 2012, is given by prof. Katja Radon and her team, collaborating with many partners in Latin America (www.osh-munich.de). Frank van Dijk, working in the ESPriT consortium program for Turkey, is part of her team since 2009.

Prof. Katja Radon is head of the Occupational and Environmental Epidemiology & Net Teaching Unit at the University Hospital in Munich, Germany (LMU).

Parts of the text came originally from Sweden (NIWL, International Training Program: OSH & Development 2001-2003) and from PAHO (Washington USA. Guide for writing a research protocol. 2002).

We are very grateful for the permission for the translation, adaptation and use of this material.

International collaboration can help us to meet the huge global challenges in education and training in Occupational Safety and Health.

Who has already developed a study protocol or has done a study?

Topic?

Experiences?

Why to develop a protocol for a study?

A protocol for a project is a written base for the planning of a successful project!

A
project
protocol
is
necessary

To request for resources

To request the ethical
commission

To structure an epidemiological study in
a logical format, focused and efficient

To guarantee the quality of the study

Why should you plan a project and draft a study protocol?

1. Drafting a protocol is part of the education!
Education based on projects, has proven to be highly effective in adult learning.
2. Contribute to the development of OSH policies in the long run!
3. Supports international collaboration on scientific level: talking the same language

Benefits of the project?

- Learn how to prepare fieldwork and preparation of an epidemiological OSH project
- Learn how to provide information on a specific problem
 - risk factors in your region
 - risks in a specific occupation or branch of industry
 - a selected occupational disease

Which could result in evidence-based actions and a publication

- **Have fun in the project**

Outlines of your protocol

- **Length:** 5-10 pages (without references and summary)
- **Language:** Turkish or English
- **Chapters:**
 - **Title of the investigation / of the project**
 - **Objectives of the study**
 - **Theoretical base or foundation**
 - **Methods**
 - **Study type and design**
 - **Target population, sample, study population (power)**
 - **Instruments to collect information**
 - **Methods to control the quality of the data / data management**
 - **Procedures to guarantee ethical aspects**
 - **Analysis plan and use of the results**
 - **Strong and weak points of the project**
 - **Contributions and resources**
 - **Bibliographic references**
 - **Time table**

Content of course A

Workshop I Introduction

Workshop II Theoretical background

Workshop III Methods: design, population

Workshop IV Instruments, operational planning

Workshop V Plan of analysis

Workshop VI Writing final protocol, presentation

Individual task or group task?

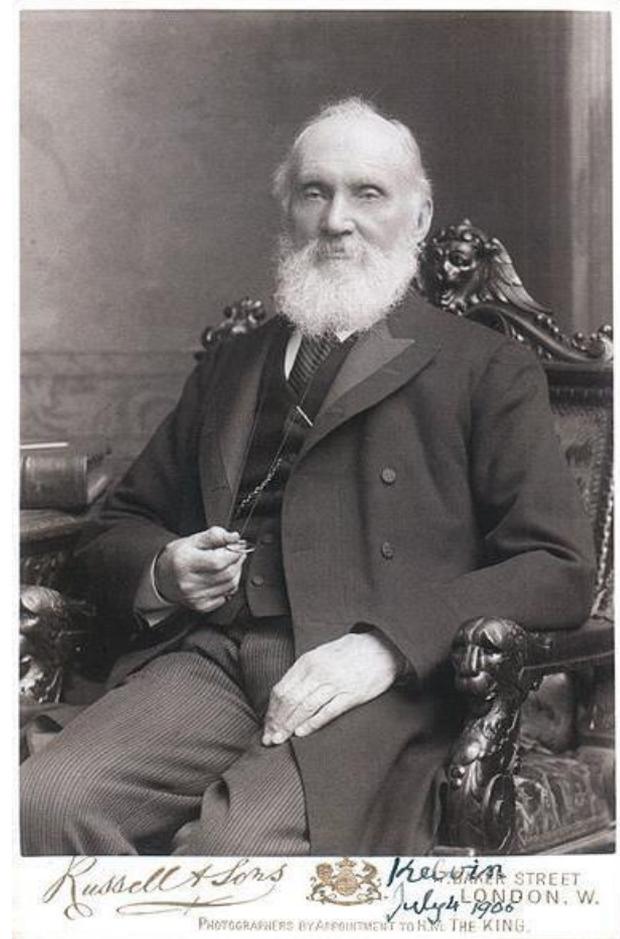
- The protocol development is a small group task with a clear division of individual tasks
- Feedback from the group, other groups and tutor

The role of the tutor

- *The tutor is not the promotor of the project!*
- The tutor can give you a hand, but you have to walk
- Regular contact with your tutor is essential during this course.

Why investigate?

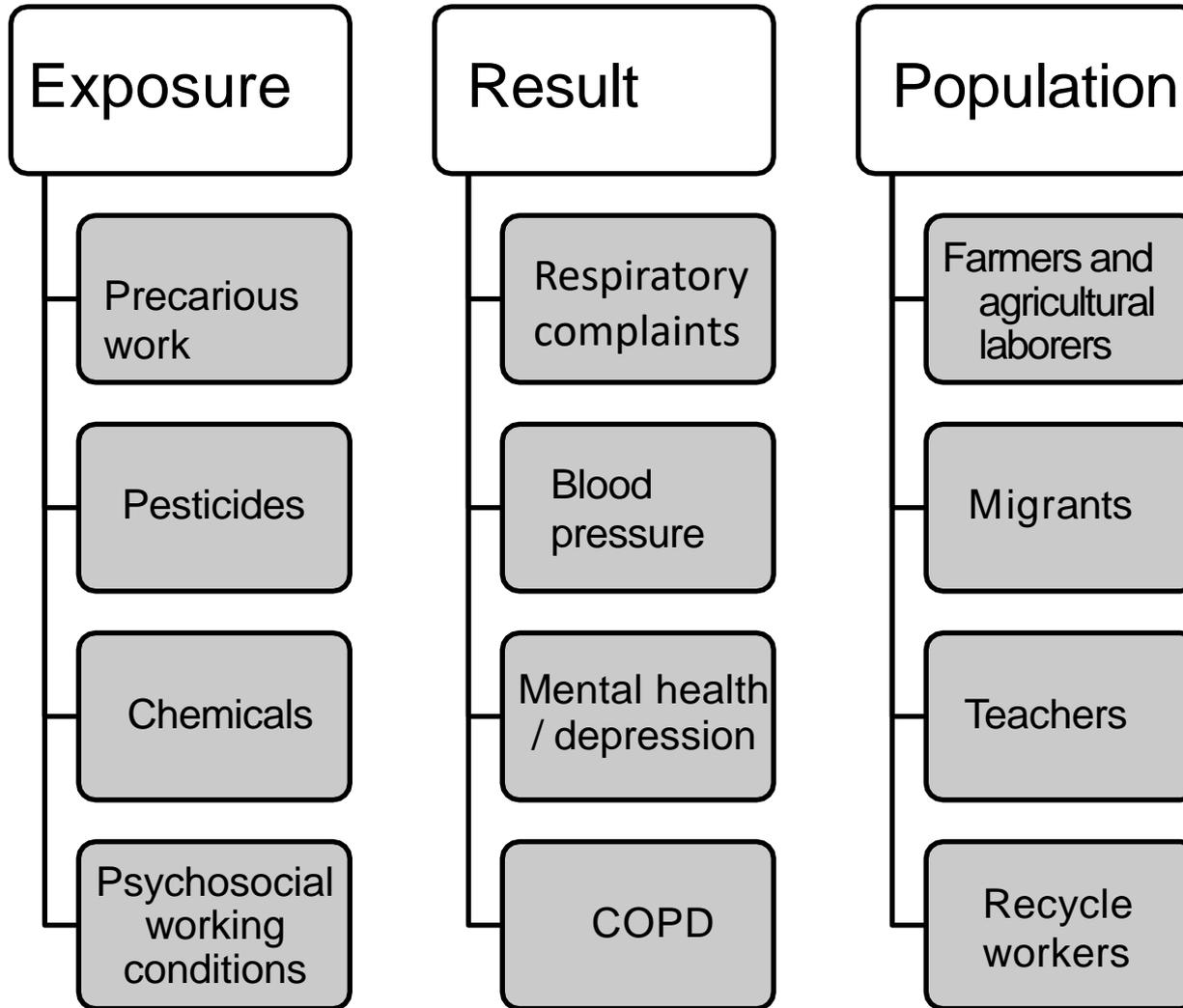
„When you can measure what you are talking about, and express that in numbers, then you can say that you know something about that“



Lord Kelvin, Físico, 1824-1907

http://de.wikipedia.org/wiki/William_Thomson,_1._Baron_Kelvin

Potential topics for your projects



Examples of studies

- Occupational and work-related diseases in workers in the recycling industry in Turkey.
- Exposure to aerosols in hairdressers in one region in Turkey and the 'prevalence' of asthma.
- Association between working as physicians in hospitals in Turkey and serious mental health problems.

Studies on work-related and occupational diseases. Why are you important?

OSH professionals are important leaders or participants in the process because they have the opportunity to

- Record and analyse data on work and health and disseminate reliable information
 - in the own region
 - for a specific occupational group / branch
 - related to a specific disease or injury
- Plan interventions

You are important in this process!

Assessment / measurement instruments

- **To assess working conditions, you need e.g.**

Questionnaire on work pressure

Noise level measurement equipment

- **To assess work-related health effects , you need e.g.**

Questionnaire on musculoskeletal complaints

Medical diagnosis of contact dermatitis or bladder ca

Equipment and protocols for

Spirometry

Audiometry

Cholinesterase level assessment

Abstract from Turkey: Occupational health of Turkish Aegean small-scale fishermen

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Background Fishing has always been a dangerous occupation, and numerous factors have a direct or indirect impact on the health of fisherman.

Aims To examine the health, safety and working conditions of small-scale fishing fleets in the Turkish Aegean Sea coasts.

Methods Data were obtained from a questionnaire distributed to a random sample of small-scale fishermen along the Aegean Sea coast. Data collection took place between September 2009 and January 2010.

Table 1. Frequency of health problems according to ICD-10 codes

	<i>N</i> (%)
Diseases of the musculoskeletal system and connective tissue (M51.9, M50.9; M54, M62.6, M79.8, M79.6) Rheumatism (M79-0) (<i>n</i> = 479)	984 (84)
Diseases of the eye and adnexa (H52: 385 cases; H10.1: 55 cases; H01: 31cases)	471 (41)
Diseases of the digestive system (K21, K25, K26, K27, K30, K45.8)	319 (27)
Diseases of the ear and mastoid process (H60.9, H66.0, H72.9, H90, H91, H93.1)	248 (21)
Diseases of the circulatory system (I10–11, I20, I25, I83) Haemorrhoid problems (I84) (<i>n</i> = 69)	196 (17)
Diseases of the genitourinary system (N20–23, N30.0, N28.1, N49.9)	193 (17)
Diseases of the respiratory system (J01, J03, J06, J15, J20, J22, J30–35, J41)	155 (13)
Diseases of nervous system (G31.2, G40.9, G44.8) Migraine (G43) (<i>n</i> = 56)	91 (8)
Diseases of the skin and subcutaneous tissue (L24–25, L40, L55.9)	66 (6)
Endocrine, nutritional and metabolic diseases (E11, E13, E14)	38 (3)
Diseases of mental and behavioural disorders (F10, F32, F41, F51.9)	6 (0.5)

Fishermen may experience more than one health problem.

Example from the Netherlands: Annual incidence of occupational diseases in economic sectors in The Netherlands

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ABSTRACT

Objective To report the annual incidence of occupational diseases (ODs) in economic sectors in The Netherlands.

Methods In a 5-year prospective cohort study (2009–2013), occupational physicians were asked to participate in a sentinel surveillance system for OD notification. The inclusion criteria for participation were (1) covering a population of employees, (2) reporting the economic sectors and the size of their employee population and (3) willingness to report all diagnosed ODs. In this study, an OD was defined as a disease with a specific clinical diagnosis that was predominantly caused by work-related factors. The economic sectors ($n=21$) were defined according the NACE (Nomenclature des Activités Économiques dans la Communauté Européenne) classification.

Results In a total working population of 514 590 employees, 1782 ODs were reported over 12 months in 2009. The estimated annual incidence for any OD was 346 (95% CI 330 to 362) per 100 000 worker-years. Of all the ODs, mental diseases were reported most frequently (41%), followed by musculoskeletal (39%), hearing (11%), infectious (4%), skin (3%), neurological (2%) and respiratory (2%) diseases. The four economic sectors with the highest annual incidences per 100 000 workers were construction (1127; 95% CI 1002 to 1253), mining and quarrying (888; 95% CI 110 to 1667), water and waste processing (832; 95% CI 518 to 1146) and transport and storage (608; 95% CI 526 to 690).

Conclusion ODs are reported in all economic sectors in The Netherlands. Up to 91% of all ODs are mental, musculoskeletal and hearing diseases. Efforts to increase the effective assessment of ODs and compliance in reporting activities enhance the usability of incidence figures for the government, employers and workers.

What this paper adds

- ▶ In The Netherlands occupational diseases are reported but incidence rates are lacking.
- ▶ A sentinel surveillance system with motivated occupational physicians is a feasible approach to estimate the incidence rates of occupational diseases in economic sectors.
- ▶ Up to 91% of all medically reported occupational diseases are mental, musculoskeletal and hearing diseases.
- ▶ Annual incidence rates of occupational diseases could be helpful for selecting and prioritising activities to prevent work-related diseases.

Table 1 Number (n) and incidence (I) of occupational diseases (ODs) in The Netherlands in 2009

Economic sector	OD, n	I per 100 000 worker-years	95% CI
Agriculture, forestry and fishing	16	421	215 to 628
Mining and quarrying	5	888	110 to 1667
Manufacturing industries	323	436	389 to 484
Electricity, gas and water supply	9	281	97 to 464
Water and waste processing	27	832	518 to 1146
Construction	311	1127	1002 to 1253
Wholesale and retail	87	139	109 to 168
Transport and storage	210	608	526 to 690
Hotels and restaurants	19	146	80 to 211
Information and communication	60	374	279 to 469
Financial services	35	171	114 to 227
Real estate	6	100	20 to 180
Scientific and free occupations	27	243	151 to 335
Administration	48	230	165 to 295
Government, defence	117	376	308 to 444
Education	125	320	264 to 376
Health	294	246	218 to 275
Arts, amusement, recreation	26	369	227 to 511
Services, associations, repair	13	76	35 to 118
Household activities	4	517	10 to 1023
Extraterritorial organisations	3	104	0 to 222

J Hosp Infect. 2012 Apr;80(4):326-30. doi: 10.1016/j.jhin.2011.12.020. Epub 2012 Feb 25.

Laboratory-acquired brucellosis in Turkey.

Sayin-Kutlu S¹, Kutlu M, Ergonul O, Akalin S, Guven T, Demiroglu YZ, Acicbe O, Akova M;
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BACKGROUND:

Laboratory healthcare workers (HCWs) are at risk of laboratory-acquired brucellosis (LAB).

AIM:

To describe the risk factors of LAB among HCWs.

METHODS:

A multicentre survey study was conducted by face-to-face interview in 38 hospitals from 17 provinces of Turkey. A structured survey was administered to the HCWs, working in infectious diseases clinics and microbiology departments, who were at risk of brucella infection.

FINDINGS:

The survey response rate was 100%. Of the 667 laboratory workers, 38 (5.8%) had a history of LAB. In multivariate analysis, factors independently associated with an increased risk of LAB included working with the brucella bacteria (odds ratio: 5.12; 95% confidence interval: 2.28-11.52; $P < 0.001$) and male gender (2.14; 1.02-4.45; $P = 0.042$). Using a biosafety cabinet level 2 (0.13; 0.03-0.60; $P = 0.009$), full adherence to glove use (0.27; 0.11-0.65; $P = 0.004$) and longer duration of professional life (0.86; 0.80-0.92; $P < 0.001$) were found to be protective.

CONCLUSIONS:

Working with the brucella bacteria, being male, a lack of compliance with personal protective equipment and biosafety cabinets were the independent risk factors for the development of LAB in our series. Increased adherence to personal protective equipment and use of biosafety cabinets should be priority targets to prevent LAB.

Advantages of using the same reliable instrument/protocol in different locations and time periods

1. You can use a already existing valid/reliable methodology (easy)
2. You can compare the results with the other participants, with others in different countries,with results in other time periods
3. The results can be pooled in a regional, national or international data collection, even used for a trend analysis

Disadvantages to use the same instruments in various countries

1. Asks for the same study design, instruments and definition of the study population
2. In some countries they prefer simple, in other more expensive instruments
3. Not much variety in studies
4. Less an individual project

Study protocol Part 1

Conceptualization of the problem or issue

Part of the Chapter Introduction of the protocol

Basic scheme of a study protocol

1. Conceptualization of the problem or issue of the investigation
2. Selection of the study strategy and methods
3. Operational planning

Conceptualization of the problem

- Definition of the problem and the objectives of the project
- Revision of the actual state-of-the-art of relevant knowledge
 - > search for literature and other sources
 - > critical reading
- Description of the theoretical background

Title

The title is the 'soul' of your protocol

An attractive title is not obligatory but the title may converse your study in a more attractive study for

- those who evaluate your protocol
- managers
- financers
- participants

- Be careful , avoid titles suggesting associations that are under study

Title

The title should be

- Short
- Concise
- Clarifies the objective and the parameters of the project
- You may change the title after the specification of the objectives and defining the target population.

Objectives of the project

- A good question is a necessary condition for a good project
- The most important part of your protocol!

- Other ways to name the objectives of the study:
 - Hypothesis
 - The study question(s)
- These are different ways to describe the objective.
- You need only to write one of these possibilities!

Orientation of the European questionnaire (Dublin)

General objective

To understand, to have insight in the conditions in which people in the different countries work, in order to result in

- Better working conditions
- A higher productivity
- Higher work participation rates

This is very general

Alternative formulations

Specific objective

Obtain information about associations between working conditions and health of the European workers.

Hypothesis:

The working conditions are associated with the health of the European workers.

Study question:

Which working conditions are associated with the health of the European workers?

Still rather general

A good question

1. Has to be important for OSH in your region or company
2. Has to be interesting for you, your colleagues and the participants
3. The answer to your question is not yet known.
Check the scientific literature.

A good question

4. Contains a clear hypothesis
Do you have a target and study population?
5. It is necessary to answer the question, so the question has to be
Feasible
Ethically sound
Simple
You have the instruments to implement the project
6. Will result in a suggestion for a change

Summary:

Question/objective of the study project

Objectives have to be SMART	Indicators of objectives should respond to
Specific	Which risk factors? Which health effects? Where?
Measurable	How to measure project results? Instruments?
Achievable (feasible)	How to do? Resources? Opportunities? Challenges?
Relevant	For who? Why relevant for a stakeholder?
Time-bound	When starts the project? Which period?

Example 1



Example 1

The objective of this cross-sectional study is to evaluate the **working conditions and health** of workers (employees) in the transport sector in Istanbul, Turkey in 2017

- Relevant?
- Measurable?
- Feasible?
- Time enough?
- Ethical?
- New?
- Specific?



Example 1

The objective of this cross-sectional study is to evaluate the **working conditions and health** of workers (employees) in the transport sector in Istanbul, Turkey in 2017

- Relevant? Yes, it is public sector
- Measurable? Yes, with a questionnaire
- Feasible? Yes, when you have contacts
- Time enough? Yes, 2017
- Ethical? Yes
- New? We have to check this
- Specific? Not so, how can we improve that?
Controls needed? OD diagnosis needed? Feasible?

Example 1

First version (general objective of the study)

The objective of this cross-sectional study is to evaluate the working conditions and the health of the employees in the transport sector (metrobus) in Istanbul in 2017

Revision (specific objective of the study or project):

The specific objective of this cross-sectional study is to evaluate

- The ergonomic and psychosocial working conditions, and
- The association with the prevalence of musculoskeletal complaints of the employees in the transport sector (Metrobus) in Istanbul in 2017

Example 2

Assess the working conditions and health of informal workers in the recycling industry in one region in Turkey in 2017.

- Specific? Not so
- Relevant? Yes
- Measurable Yes
- Feasible? Yes, when the workers agree
- Time enough? Yes, 2017
- Ethical ? Yes
- New? Presumably, but we have to check

Example 2

First version (general objective of the study)

Assess the working conditions and health of informal workers in the recycling industry in one region in Turkey in 2017.

Revision (specific objective of the study):

The specific objective of this cross-sectional study is to assess the **toxicological risks** at work, especially systemic health effects, of informal workers in the recycling industry in one region in Turkey in 2017.

Workshop 1

In the group:

- Conceptualize the problem of your project:
 - Discuss the objectives of the study
 - Refine the general objective of the study
 - Define more specific objectives of the study
 - **Questions?** Ask your tutor

Tomorrow: we check the literature once again, to be sure that

- The topic is sufficient new , and
- To get (better?) ideas about the specific objectives of the project
- To refine your project question according to the literature!