



KLINIKUM
DER UNIVERSITÄT MÜNCHEN

**Unit for Occupational and Environmental
Epidemiology & Net Teaching**
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**Institute and Outpatient Clinic for
Occupational, Social and Environmental Medicine**
Director: Prof. Dr. med. Dennis Nowak



Research question



Readings

- "Designing Clinical Research: An Epidemiologic Approach" by Stephen B. Hulley
- Papers and protocols provided during the course
- Background information about your study question
(to be selected by the participants)

What can you expect?

- This course will teach you the research methods applied to writing a research protocol.
- Over the next weeks you will step-by-step develop your group protocol.
- You will also learn to critical read and evaluate your colleagues' protocols

Protocol preparation

- The preparation of a research protocol will be the major method used in this course.
- With this protocol you will demonstrate your ability to understand and apply principles of epidemiology.
- Your group may choose any research question in the field of epidemiology.

Your protocol

- **Lengths:** at maximum 5-10 pages (excluding references and abstract)
- **Language:** English or German
- **Parts:**
 - Abstract (150 words)
 - Background (literature review)
 - Research question/objective
 - Research design and rationale
 - Methods and instruments used
 - Main approach to data analysis
 - Ethics (confidentiality, consent)
 - References

Guidelines (although longer)

- DFG Sachbeihilfen:

English:

http://www.dfg.de/forschungsfoerderung/formulare/download/1_02e.pdf

German:

http://www.dfg.de/forschungsfoerderung/formulare/download/1_02.pdf

- FöFoLe LMU:

http://www.med.uni-muenchen.de/forschung/foefole/foefole_merkblaett.pdf

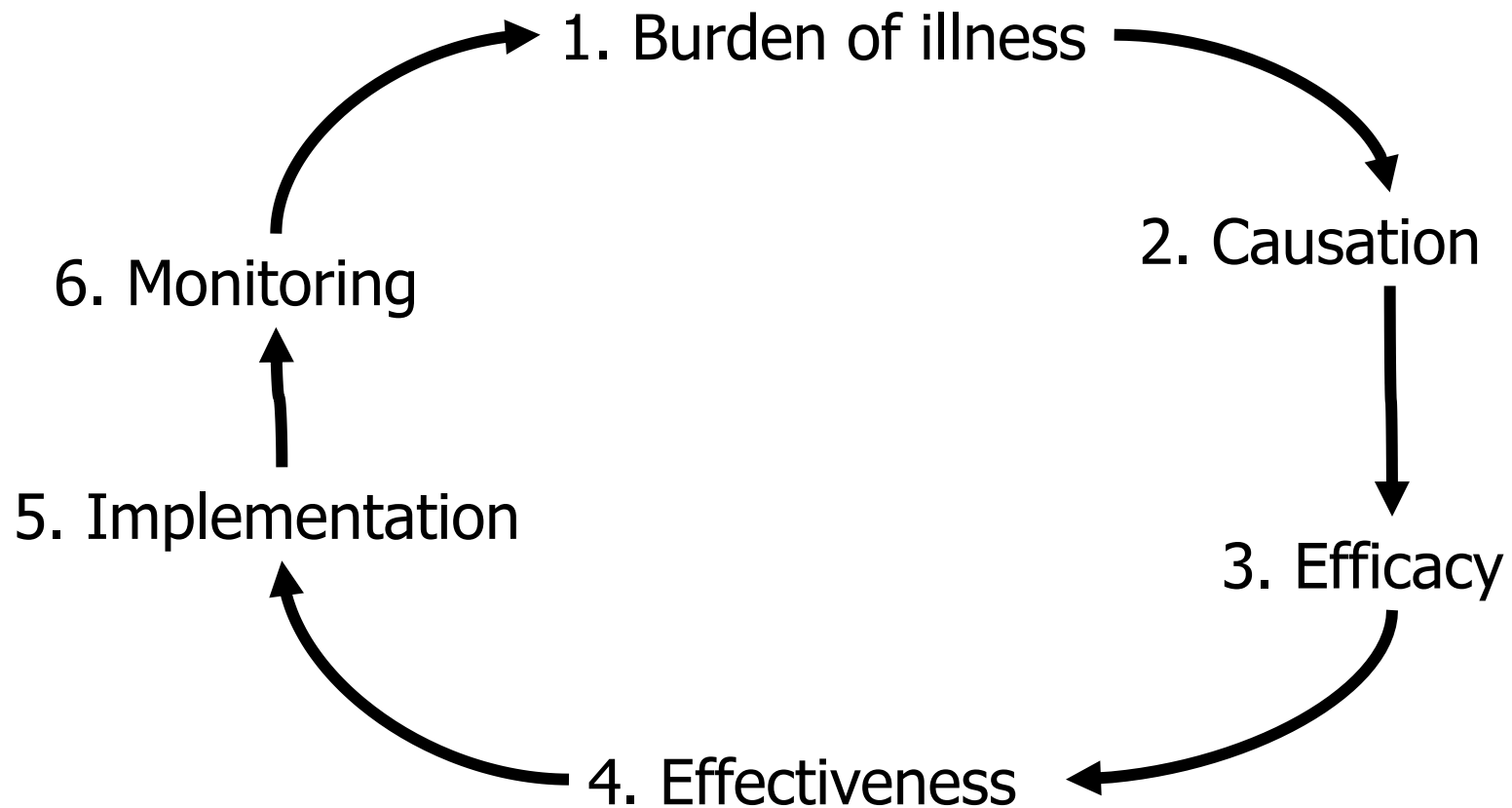
Introduction:

How to design a promising protocol for epidemiology?

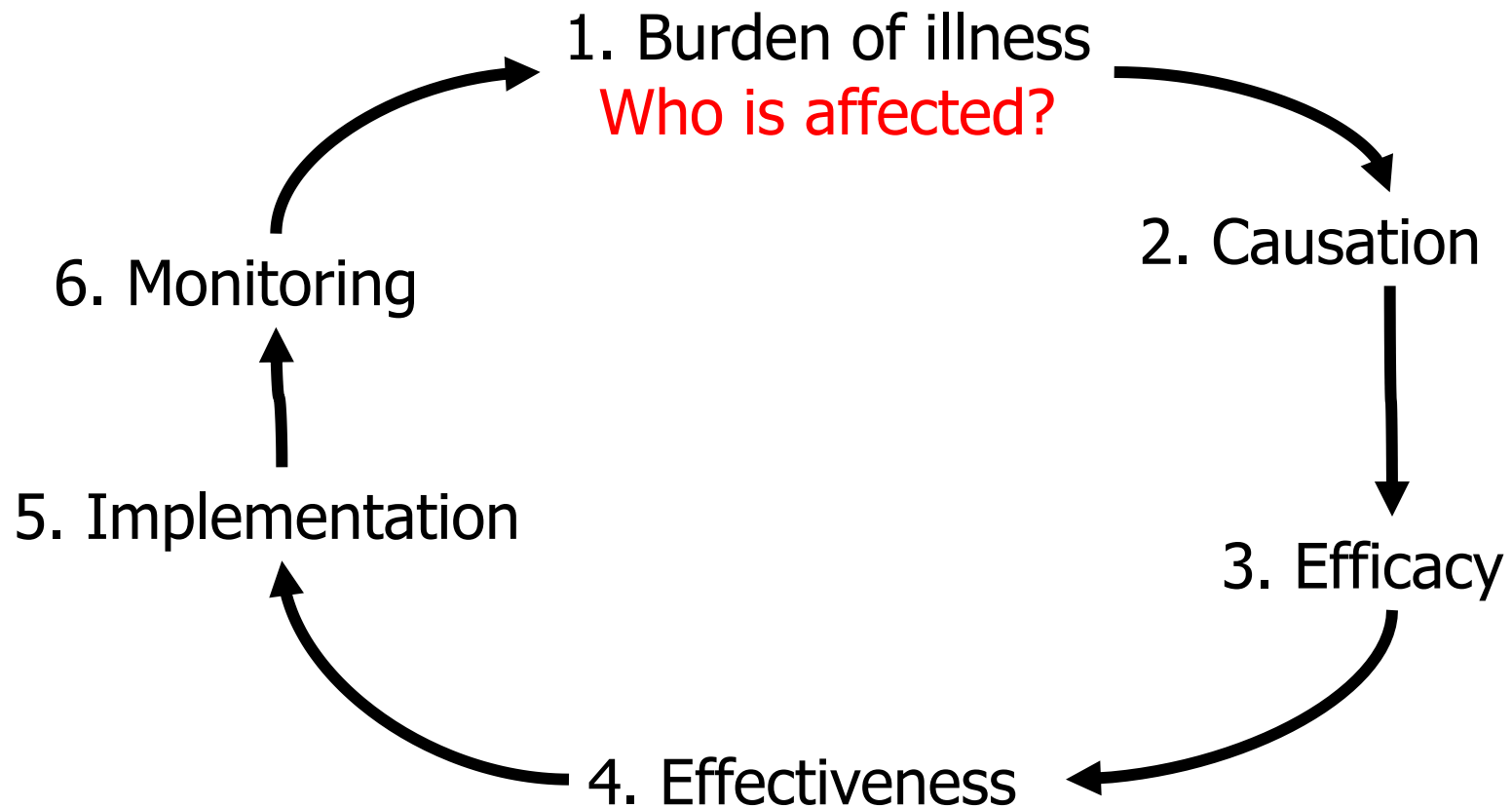
What for?

- A study protocol is the written plan of the study
- A protocol is needed
 - To apply for funding
 - To apply for ethics
 - To structure an epidemiologic study (logical, focused, efficient)
 - Makes it easier to publish a study in the end

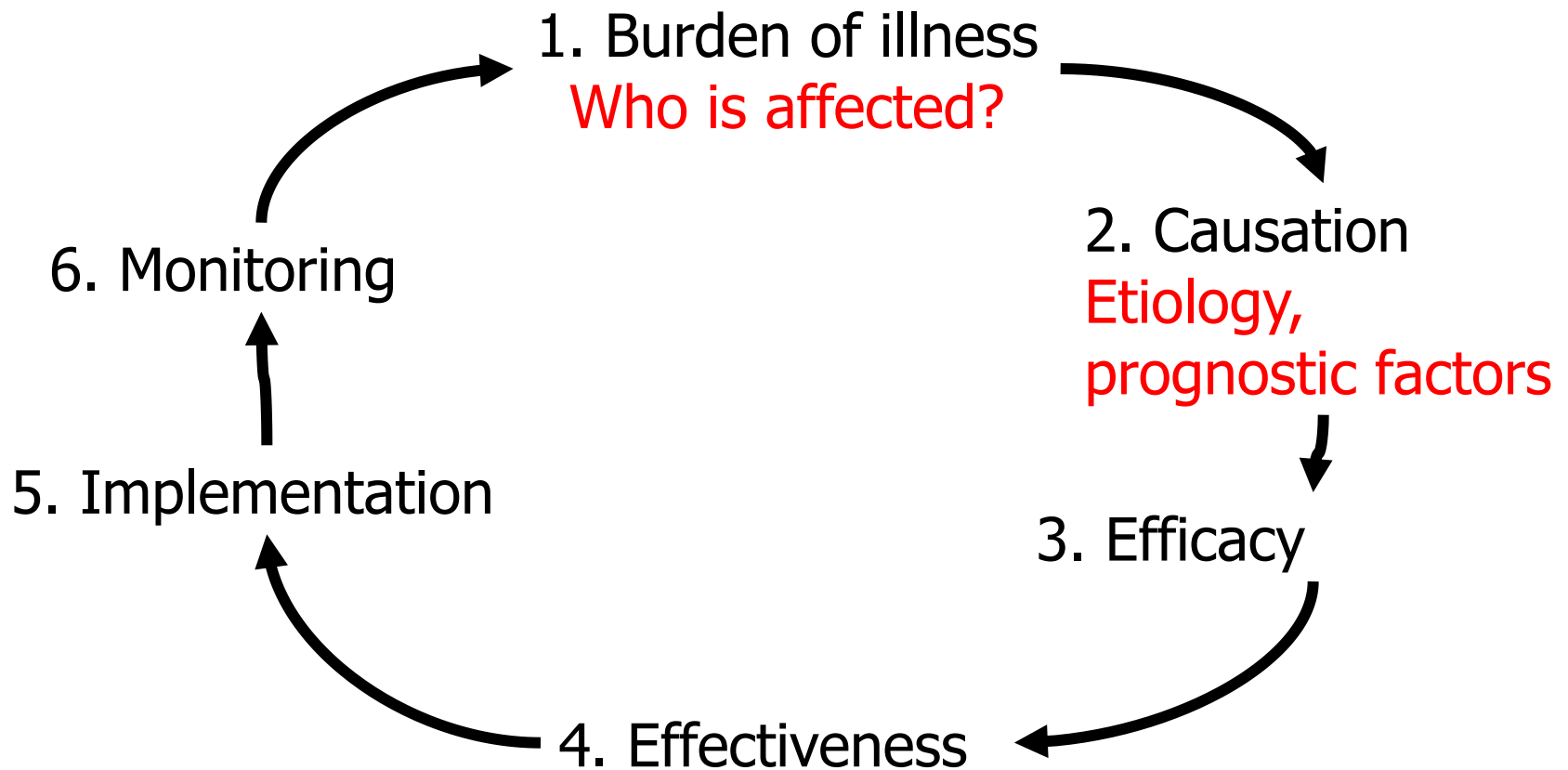
Where to start from: WHO Health care planning cycle



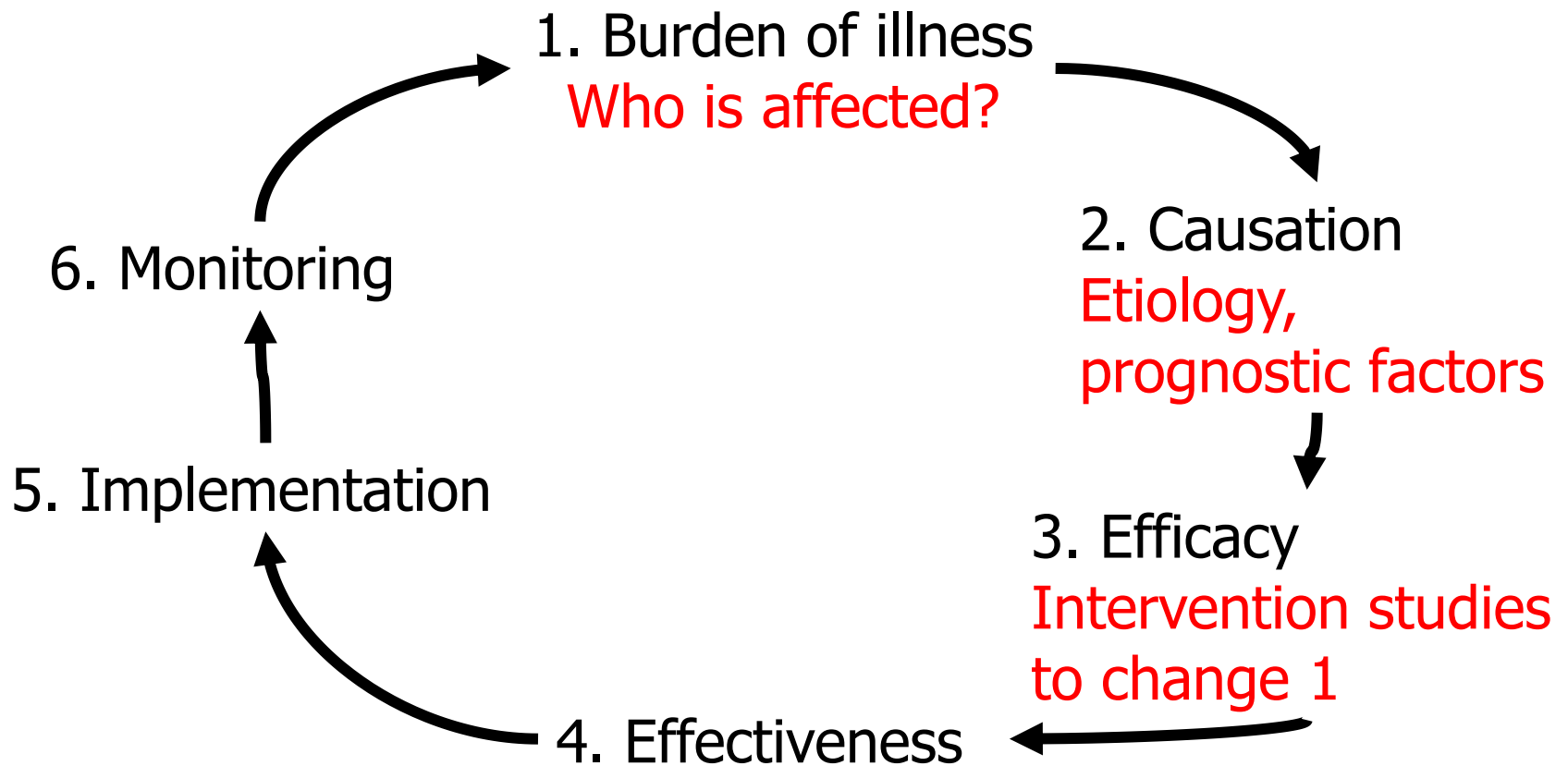
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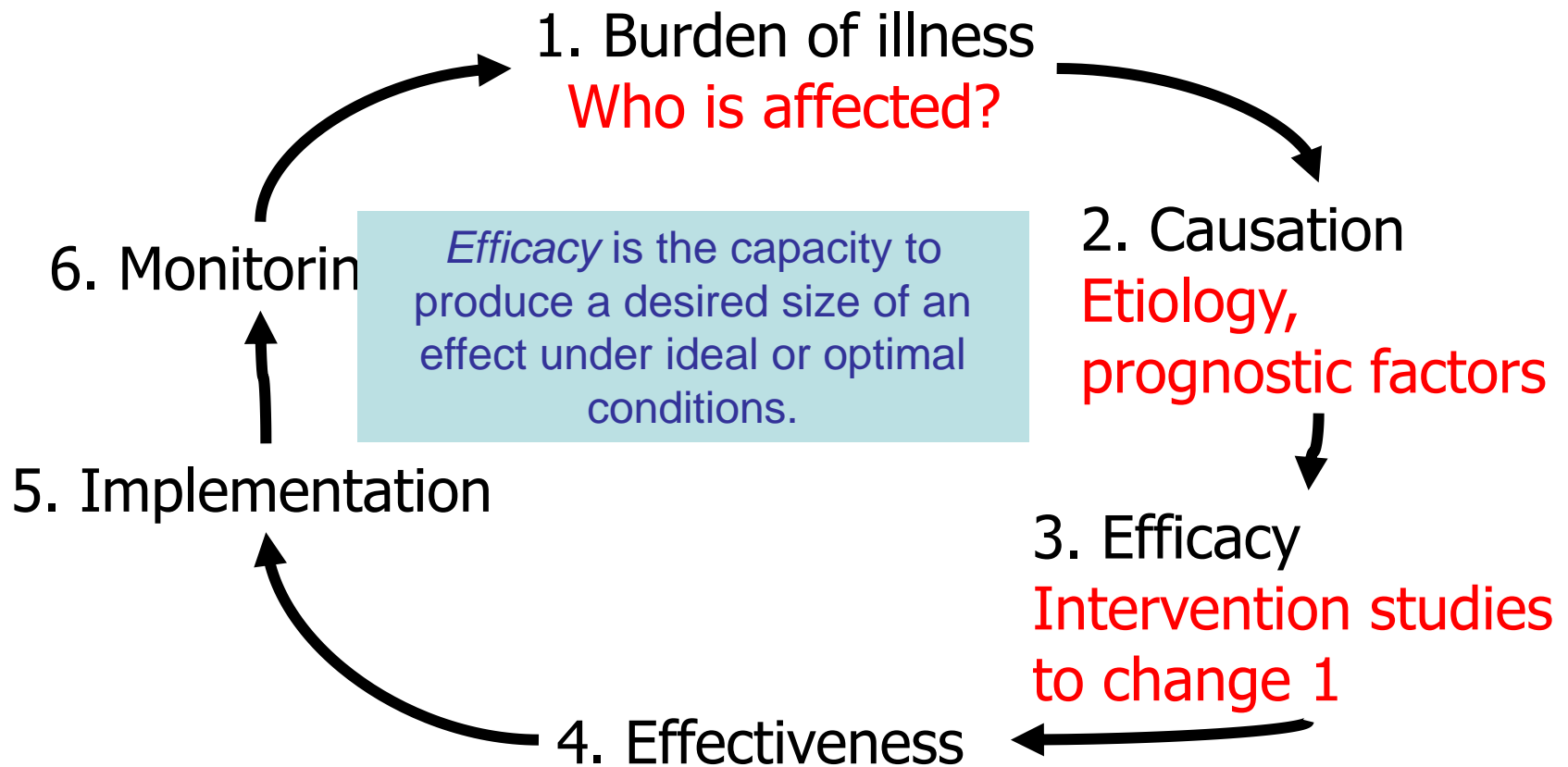
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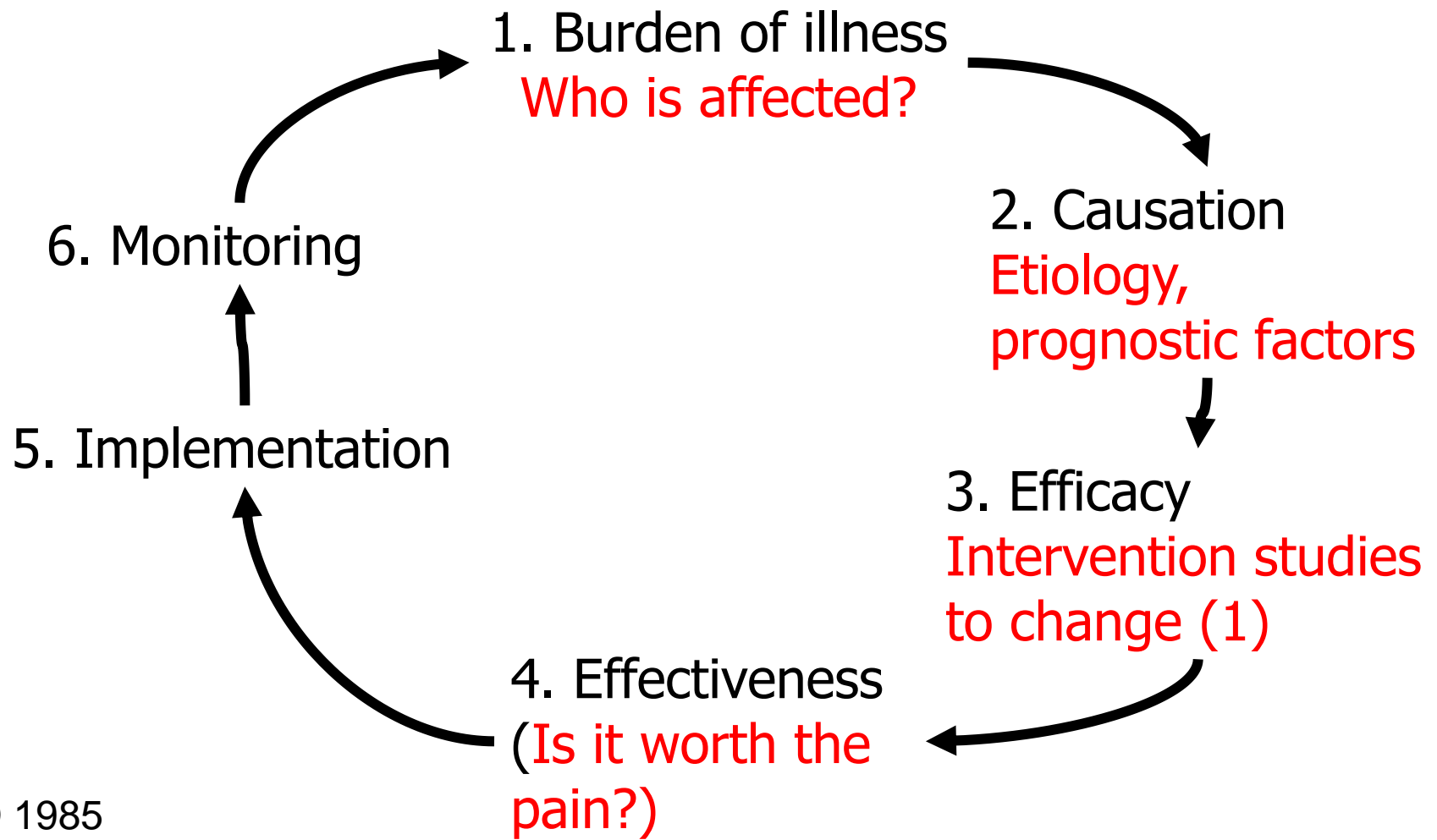
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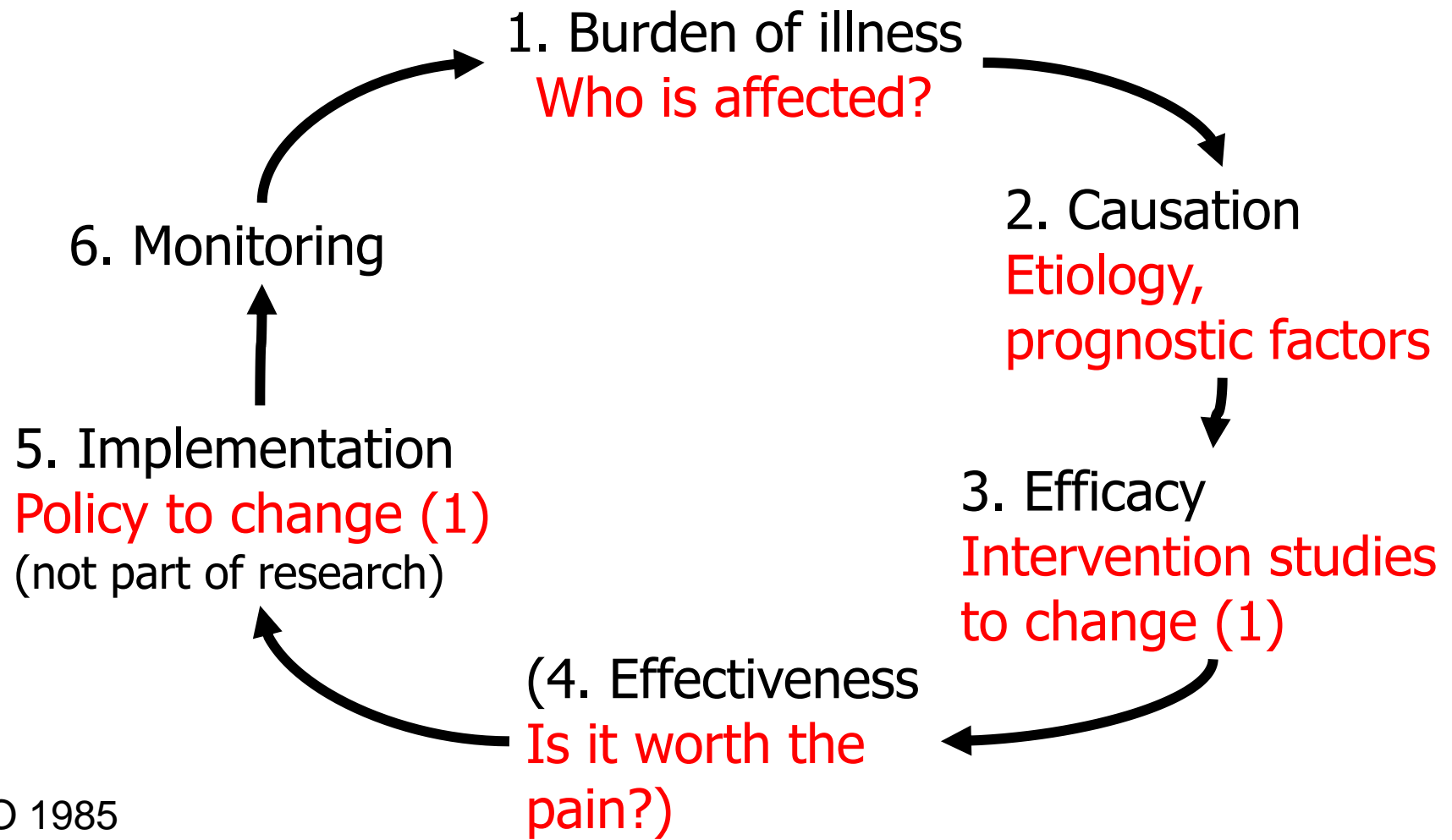
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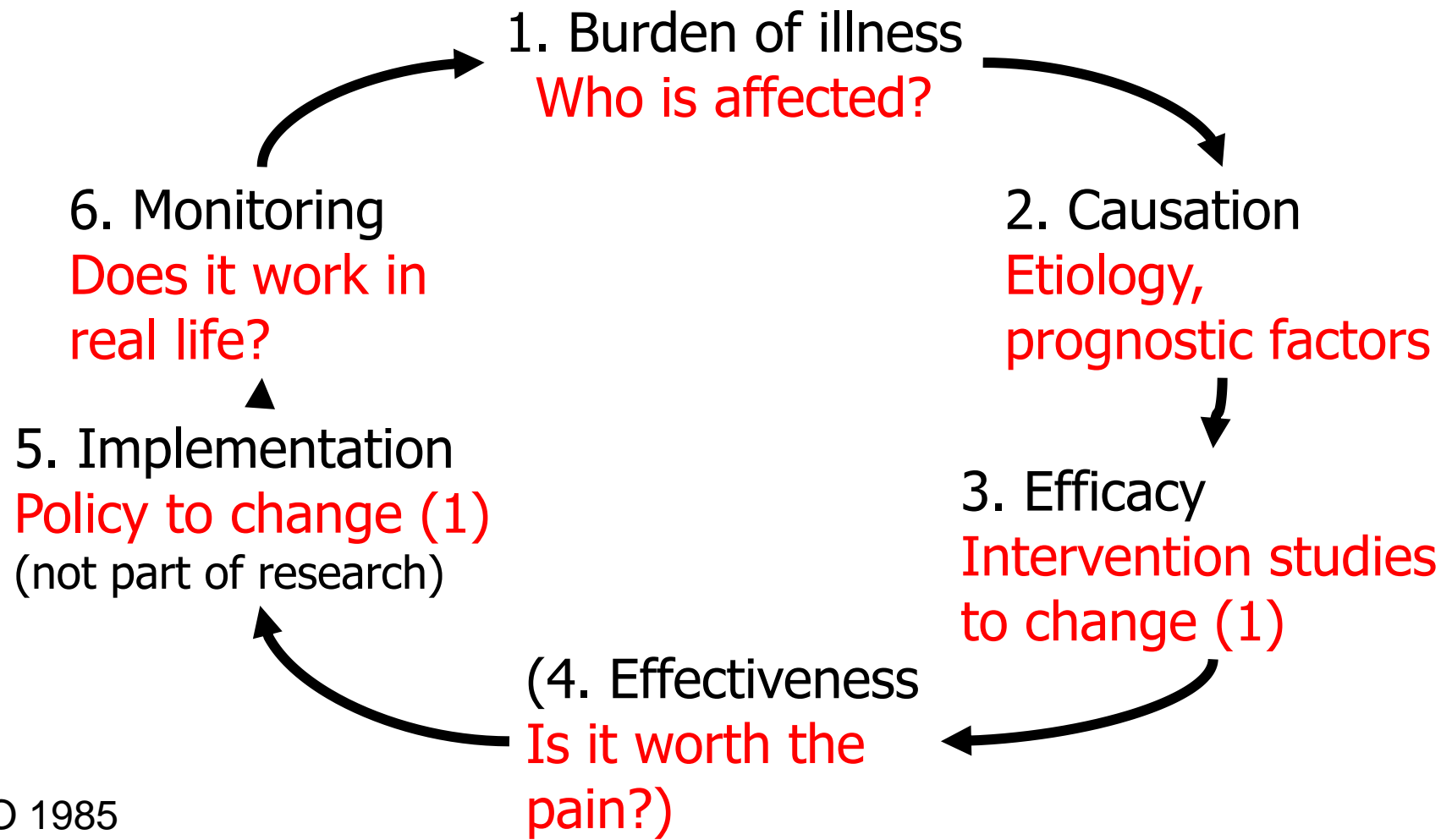
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Where to start from: WHO Health care planning cycle



Where to start from: WHO Health care planning cycle



Where in the research cycle are these studies located?



- a. Reduction of sensitization to latex in newly hired health care workers introducing non-powdered gloves
- b. High prevalence of asthma in the health care sector
- c. Reduction in the prevalence of asthma demonstrated in the German health care sector
- d. Latex exposure is associated with asthma in health care sector
- e. New guideline reduces the use of powdered gloves in the German health care sector

1. Ingredients of your protocol



Ingredients

(0. Title: Appetizer)

1. Research question: **What?**
2. Background and significance:
Why is this question important?
3. Design (**Structure**)
 1. Time frame / epidemiologic approach
 2. Subjects inclusion/exclusion criteria
Sampling
 3. Variables: Predictors/Exposure, Confounders,
Outcome
 4. Statistical analysis

Example

Title: Occupational asthma in the modern aluminium industry

1. Research question:

Do current exposure levels protect aluminium potroom workers from new onset of occupational asthma?

Title: Occupational asthma in the modern aluminium industry

2. Background and significance:

- „Potroom asthma“ is since long the major health thread for aluminium potroom workers.
- Five new cases of asthma occurred in the early 90ies in a modern aluminium plant in Germany even so current exposure limits were estalished.
- Managment and workers are concerned about workers health.

Ingredients

3. Design (**Structure**):

1. Epidemiologic approach: **Cross-sectional study**
2. Subjects inclusion: **All workers in different parts of the plant**
Exclusion: **Women**
3. Variables:
Predictors: **Job title**;
Outcome: **Asthma**;
Potential confounders: **Smoking, age, allergies**
4. Statistical analysis: **Logistic regression**

Exercise

Fill in the Excel sheet:

1. For each of the four abstracts, write a single sentence that specifies the design and research question; the latter should include the main predictor and outcome, and the population sampled
2. Where in the research cycle is the question located?
3. Think about the main inference that can be drawn from the study: To what phenomena and which populations can the findings be generalized?
4. What are the potential errors in drawing and applying these inferences?

2. Title

The title is a kind of appetizer to your application.

A good title is not a must, however, it might make the difference 😊.

Title: Examples

- Informal settlements, economic and environmental change, and public health - Strategies to improve the quality of life in Dhaka
- Asthma and inflammatory bowel disease in changing environments – Two faces of the same story?
- A community based study on occupational asthma

Acronym / Logo

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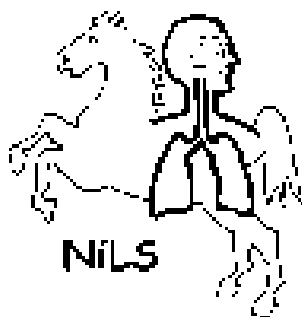
Likewise, a good acronym/logo makes things easier (for you, the reviewers and the participants). It is like a label for your project.

Acronyms: Examples

- **INNOVATE II**: Informal settlements, economic and environmental change, and public health - Strategies to improve the quality of life in Dhaka
- **VERMEE!**: Valdivia encontrando Munich – Estudio epidemiológico
- **GA²LEN** Global Asthma and Allergy European NetWork
- **SOLAR**: Study on Occupational Allergy Risks
- **ISAAC**: International Study on Asthma and Allergies in Childhood
- **NiLS**: Niedersächsische Lungenstudie

Studie zu beruflichen Allergierisiken

SOLAR



NILS



3. Research question

- „There is no shortage of good research questions, and even as we succeed in producing answers to some questions, we remain surrounded by others.“
- **E.g.:** Atopics are more likely to develop occupational asthma. However, the positive predictive value is too low to base any recommendations upon this characteristic.

Finer criteria for good research questions

- 1. Feasible**
- 2. Interesting**
- 3. Novel**
- 4. Ethical**
- 5. Relevant**

Reading: Hulley et al. Chapter 2

8 criteria to develop a good research question....

1. Is the question interesting?
„I wonder whether...”
2. Do I already know the answer?
Systematic literature review with focus on high quality studies
3. Is the question important?
Depends on perspective: Patient, population, science

8 steps to develop a good research question....

4. What is the hypothesis?
To do what to whom, how and when
Phrased to represent the most likely or most desirable answer
5. What effect do I want to see?
How big a difference on the main outcome measure do I anticipate?
6. Can I test the hypothesis?
Practical/ethical reasons that prevent finding the answer?
Lack of instruments?
Question too complex?

8 steps to develop a good research question....

7. What do I hope to change by answering this question?

What do you want to change?

8. Will the answer produce the desired change?

Feasibility?

Go back to the research questions you extracted from the abstracts

- Having the 8 steps in mind, how could you improve the study questions?
 - 10 min group discussion

Assignments

To be completed at 2:45 pm!!!!:

- Define and refine the **research question** you might design a study around and word-process a one sentence version.
- Think about a potential “appealing” **title** for your study
- (Acronym)
- Put your research question on the flip chart