CMED 305

Research Questions, Hypotheses and Objectives

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Learning Objectives: By end of this session students will be able to:

1   Formulate research questions

2   State and describe research hypotheses
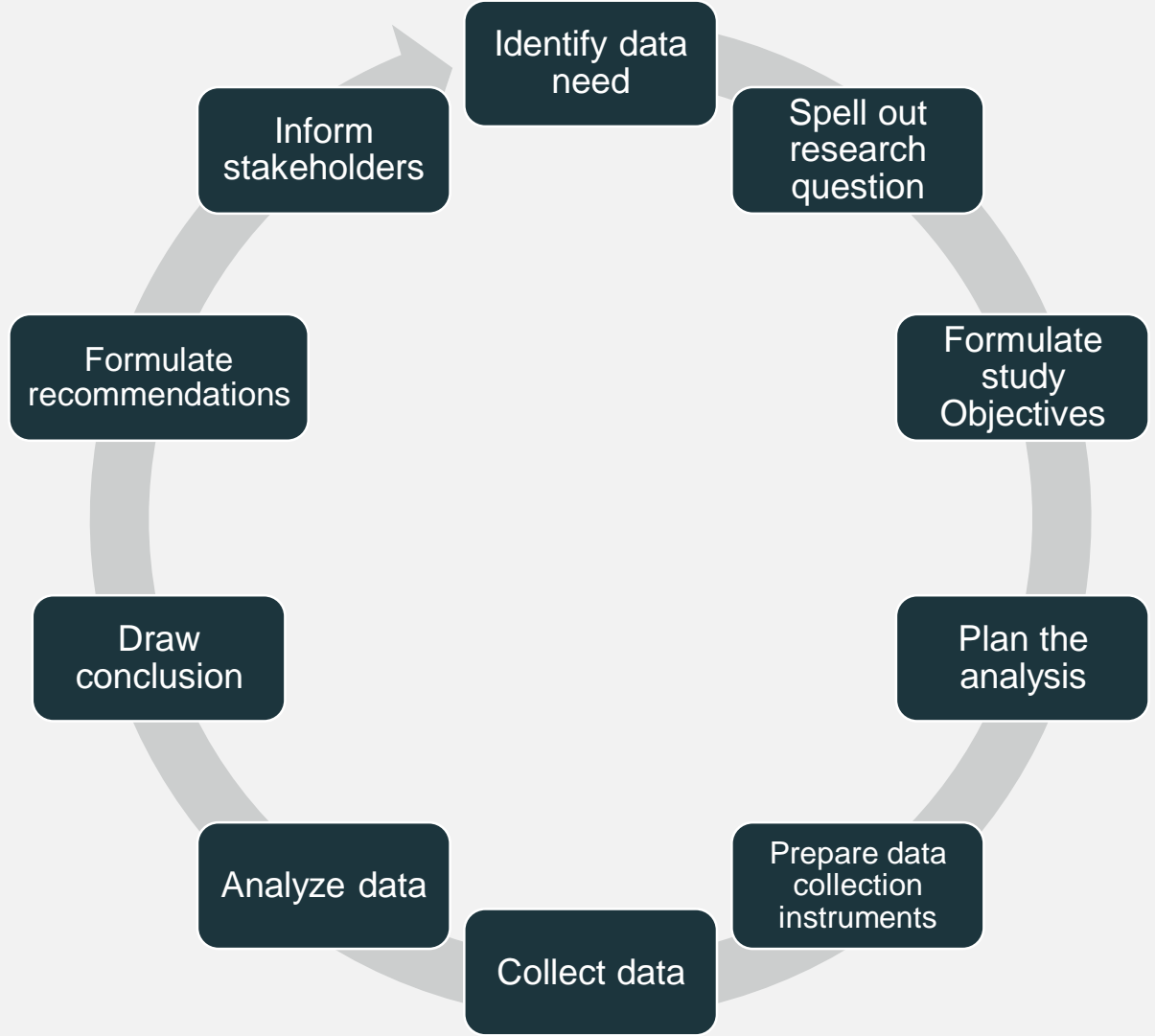
3   Define specific research objectives

{ **1** Develop research questions }

Life Cycle of Research

What is a research question?

- Uncertainty about the something in the population that the investigator wants to resolve by measurements in the population.
- Uncertainty = Data needs
- Clear research question facilitates:
1. Choosing the optimal **study design**
2. Identify **who** should be included, **what** outcomes to measure and **when** to measure

Translating Uncertainty to Research Questions

- Frames problem in specific terms (clinical / public health / … etc)
- Focuses on one issue
- Written in everyday language
- Links to a potential action once the question is answered
- **Is stated as a question**

Sources for Research Questions

Literature Review

New ideas, technologies, and innovation

Careful observations

Mentors / Guides

Two Categories of Research Questions

Descriptive Questions

- Involve observations to measure quantity
- No comparison groups / Interventions

Analytical Questions

- Involve comparisons / interventions to test hypothesis

Steps in Conceiving a Research Question

1 Review of up to date literature and information

2 Raise a question!

3 Decide worth investigating by peer-review

4 Define measurable exposures and outcomes

5 Sharpen the initial question

6 Refine the question by specifying details (PICOT!)

Is vaping bad?

1) Review of up to date literature and information

- E-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products.
- E-cigarettes are not safe for youth, young adults, pregnant women, or adults who do not currently use tobacco products.
- While e-cigarettes have the potential to benefit some people and harm others, scientists still have a lot to learn about whether e-cigarettes are effective for quitting smoking.
- If you've never smoked or used other tobacco products or e-cigarettes, don't start.
- **Additional research can help understand long-term health effects.**

2) Raise a question!

Can vaping help in quitting smoking?

Vague question, need to define:
"vaping" and "quitting smoking"

3) Decide worth investigating by peer-review

- What is the optimal type of vaping, frequency, and duration?

- What is the rate of quitting smoking? *(How many cigarettes smoked? Length of quitting (days, weeks, moths))*

- What are the risks? What are the other benefits?

4) Define measurable <u>exposures</u> and <u>outcomes</u>

- <u>Exposure:</u> **Vaping**
    - Smoking vapors produced from electronic nicotine delivery systems.
    - Daily for the past 30 days.

- <u>Outcome:</u> **Quitting Smoking**
    - Discontinuing the habit of smoking cigarettes.

5) Sharpen the initial question

Initial Question

Can vaping help in quitting smoking?

Now

Among cigarette smokers, does vaping daily for at least 30 days increase the chance of smoking abstinence?

6) Refine the question by specifying details (PICOT)

PICOT Criteria			
P	**P**opulation / **P**atients	Who are the relevant patients? Think about age, sex, geographic location, or specific characteristics that would be important to your question.	3rd year medical students at KSU who smoke cigarettes in the last 12 months
I	**I**ntervention / **I**ndicator	What is the treatment, diagnostic test, or exposure that you are interested in?	E-cigarettes
C	**C**omparison / **C**ontrol	Is there a control or alternative treatment you would like to compare to the intervention or indicator?	Nicotine gum
O	**O**utcome	What do you intend to accomplish, measure, improve or affect?	Smoking abstinence
T	**T**ime	What is the appropriate follow-up time to assess outcome?	30 days

Among 3rd year medical students at KSU who smoke cigarettes in the last 12 months, does vaping daily for 30 days increase the chance of smoking abstinence in comparison to daily nicotine gums?

So What?!

Passing the "So What?!" Test: FINER

FINER criteria for a good research question		
F	**F**easible	• Adequate number of subjects • Adequate technical expertise • Affordable in time and money • Manageable in scope
I	**I**nteresting	• Getting the answer intrigues investigator, peers and community
N	**N**ovel	• Confirms, refutes or extends previous findings
E	**E**thical	• Amenable to a study that institutional review board will approve
R	**R**elevant	• To scientific knowledge • To clinical and health policy • To future research

{ 2 } State research hypotheses

Statement of Research Hypothesis

- **Hypothesis:** is a **specific** and **measurable** version of the research question.
- Hypothesis is important for two reasons:
  - Summarizes the 3 main elements of the study: sample, exposure and outcome
  - Establishes the basis for the statistical tests of significance.
- Hypotheses are <u>only for Analytical Questions</u> (Comparisons).
- Purely Descriptive Questions: No!

Vaping vs Nicotine Gum Hypothesis

Among 3rd year medical students at KSU who smoke cigarettes in the last 12 months, vaping daily for 30 days increase the chance of smoking abstinence by 80% in comparison to daily nicotine gums.

Hajek, Peter, et al. "A randomized trial of e-cigarettes versus nicotine-replacement therapy." *New England Journal of Medicine* 380.7 (2019): 629-637.

Characteristics of Good Hypothesis

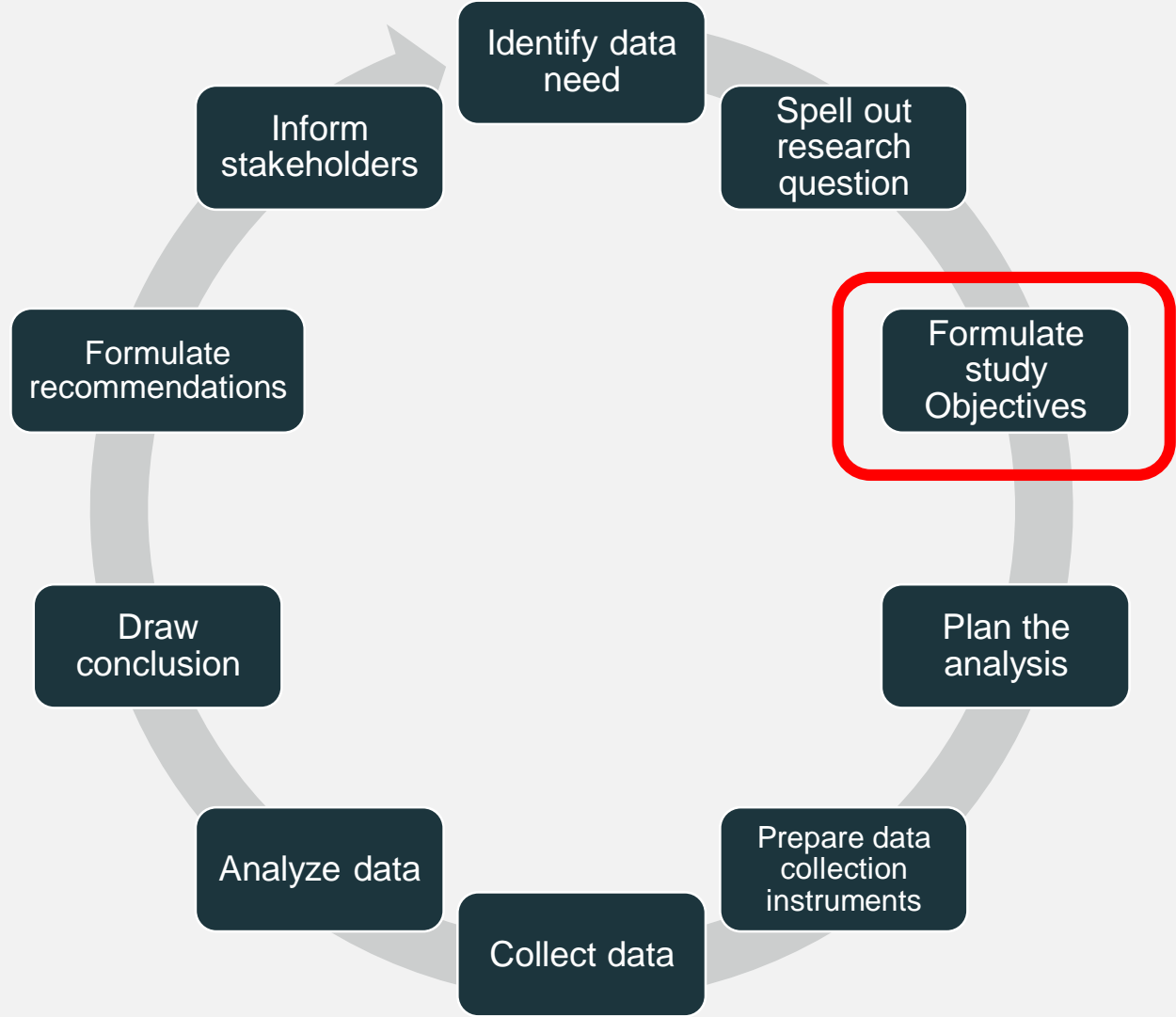| Simple	Specific	Stated in Advance
• One exposure • One outcome	• Clear study participants and variables	• Written at the start of the study • Focused on primary objective

{3 Formulate research objectives}

Life Cycle of Research

Research Objectives

- **Objective:** an active statement about **how** the study is going to answer the specific research question.

- Objectives are important for two reasons:
  - For the development of the protocol and design of study
  - For the sample size calculations and determining the power of the study

Research Objectives

- **<u>Contrary to hypotheses, both descriptive and analytical questions require objectives.</u>**

- Framed in scientific / epidemiological terms

- Use no more than one verb for each objective

- State primary and secondary objectives

Objectives for Descriptive vs Analytical Studies

Descriptive Studies

- Estimating a quantity
- Use the verb **"Estimate"**
- Example: To estimate the prevalence of vaping among medical students.

Analytical Studies

- Testing a hypothesis
- Use the verb **"Determine"**
- Example: To determine whether vaping increases the chance of smoking abstinence

Vaping vs. Nicotine Gum Objectives

- **<u>Primary Objective:</u>**
    - To determine whether vaping increases the chance of smoking abstinence in comparison to nicotine gums at 30 days.

- **<u>Secondary Objectives:</u>**
    - To determine whether vaping increases the chance of smoking abstinence in comparison to nicotine gums at 30 days in females and males subsets.
    - To evaluate withdrawal symptoms of vaping, relative to nicotine gums.

Tips for developing research questions, hypotheses and objectives

1) Perform a literature review to increase knowledge and familiarity with the topic and to assist with research development.

2) Learn about current trends and technological advances on the topic.

3) Seek careful input from experts, mentors, colleagues and collaborators to refine your research question as this will aid in developing the research question and guide the research study.

4) Use the FINER criteria in the development of the research question.

5) Ensure that the research question follows PICOT format.

6) Develop a research hypothesis from the research question.

7) Develop clear and well-defined primary and secondary (if needed) objectives.

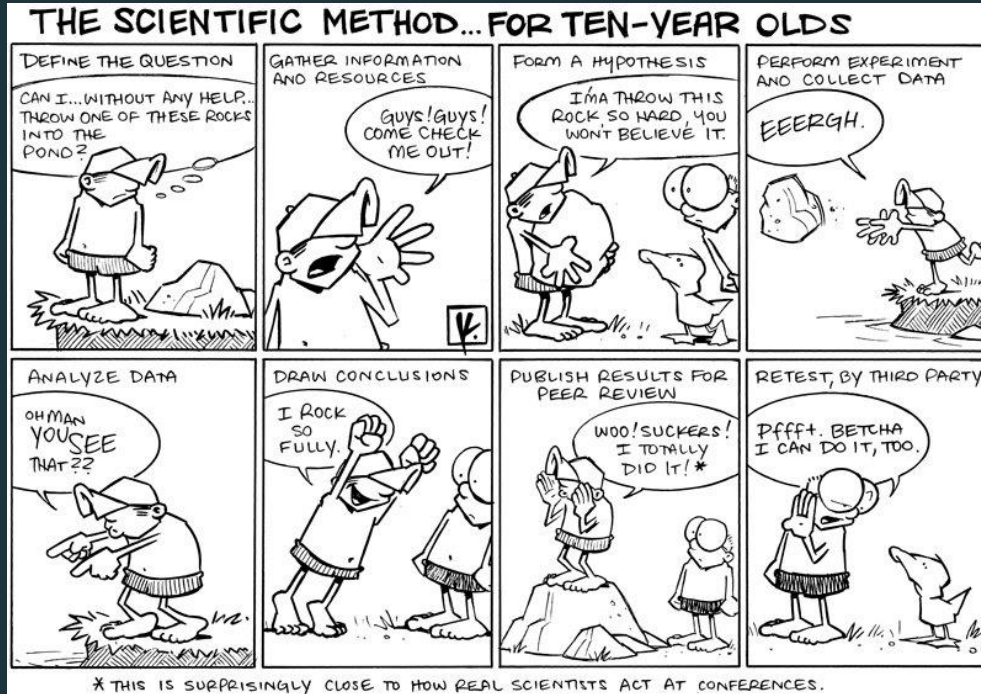8) Ensure that the research question and objectives are answerable, feasible and relevant.

THANK YOU

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Thank you!

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References:

- Hulley, Stephen B., ed. *Designing clinical research*. Lippincott Williams & Wilkins, 2007.

- Farrugia, Patricia, et al. "Research questions, hypotheses and objectives." Canadian Journal of Surgery 53.4 (2010): 278.

- Haynes, R. Brian. *Clinical epidemiology: how to do clinical practice research*. Lippincott williams & wilkins, 2012.

- Hanson, Beate P. "Designing, conducting and reporting clinical research.: A step by step approach." *Injury* 37.7 (2006): 583-594.

- CDC. Electronic cigarettes. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm

- Hajek, Peter, et al. "A randomized trial of e-cigarettes versus nicotine-replacement therapy." *New England Journal of Medicine* 380.7 (2019): 629-637.

- Google images. https://images.google.com