FORMULATING THE RESEARCH QUESTION

Eric van Roon – September 29 2017 – EAHP Academy Seminar

mcl
medisch centrum leeuwarden

university of groningen

CONFLICT OF INTEREST

THERE ARE NO CONFLICTS OF INTEREST TO DECLARE

QUESTIONS

1. Yes or no: the 'research question' concerns the question whether or not to proceed with the proposed study?

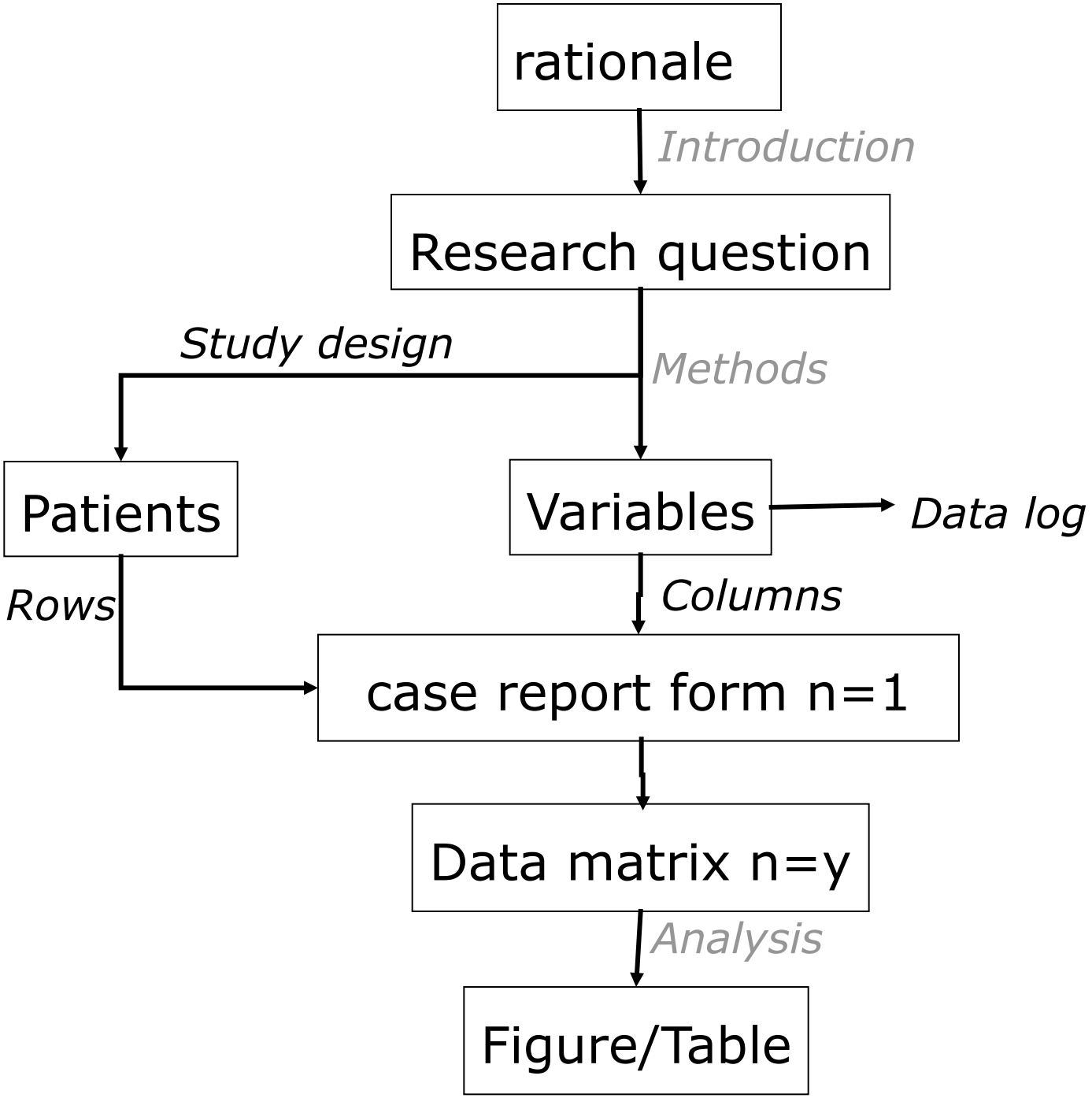
2. Yes or no: quality control of a proposed research question is possible

MC: Which part of the final scientific publication is most likely to contain the answer to the research question?

1. Methods
2. Table 1
3. Figure 1

MAKING CHOICES…..

THE -RATIONS OF SCIENTIFIC RESEARCH


rationale
Introduction
Research question
Study design
Methods
Patients
Variables
Data log
Rows
Columns
case report form n=1
Data matrix n=y
Analysis
Figure/Table

RESEARCH: 5 STEPS

THINKING

1. What is the reason why I want to answer which research question?
2. How do I want to answer the research question?
   - Variables
   - Operationalisation of variables
   - Study design (RCT, observational)
   - Population (number, in- and exclusion)

DOING

3. Study conduct
4. Datavalidation and –analysis
5. Reporting and presentation

THE 'THINKING' - PHASE

Why which research question?

- What?
- Why?

Introduction section of protocol/report/publication

- Rationale
- Goal

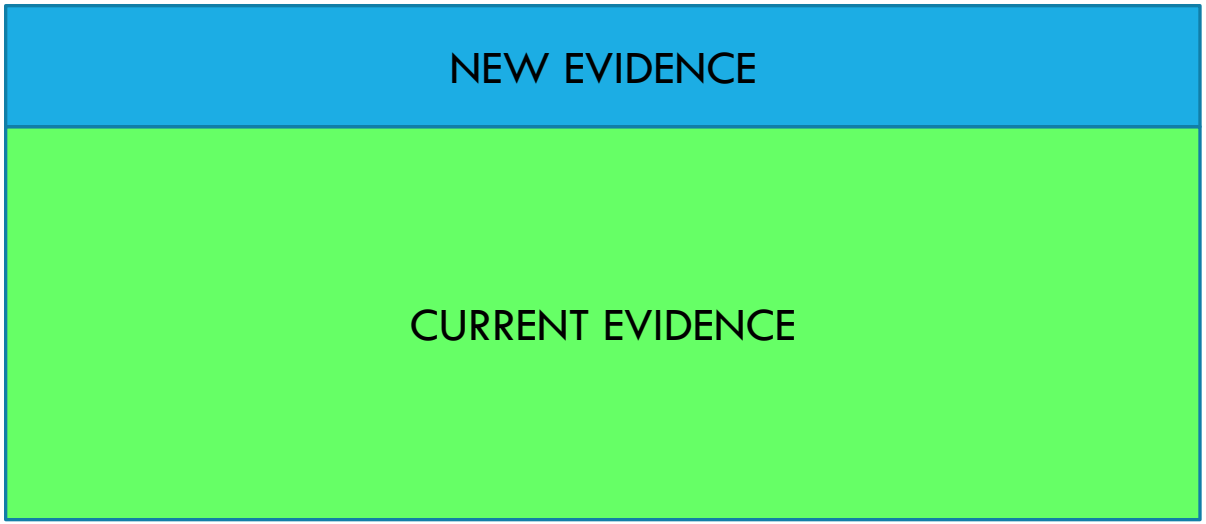
Operationalisation

- How?

- Methods section of protocol/report/publication

STEP 1 – THE RESEARCH QUESTION

What do I want to know, and why?



STEP 1 – THE RESEARCH QUESTION

STEP 1 – THE RESEARCH QUESTION

‘HOW’ VERSUS ‘WHAT’

HOW: MEASURING TOOL

Key aspects of a measuring tool

Sensitive for change?

Validated?

Reproducible?

Relevant?

HOW: SENSITIVITY OF THE MEASURING TOOL

For example:

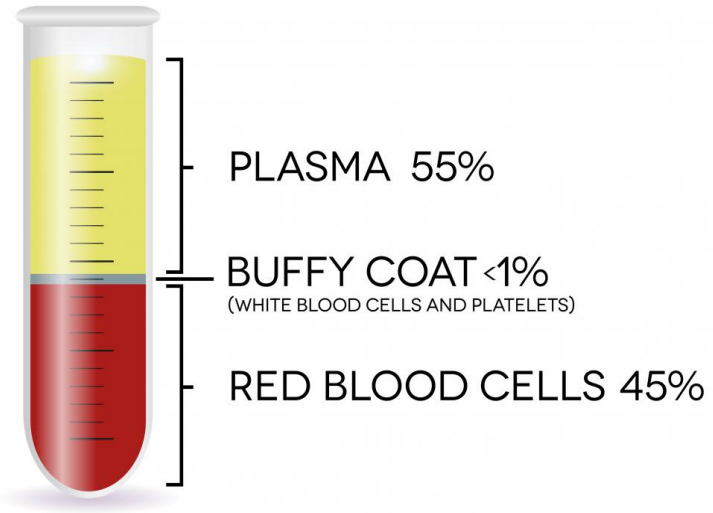
Measuring an inflammatory state

Options:

- C-reactive protein (CRP)
- Erythrocyte sedimentation rate (ESR)

CRP: quick with a high amplitude

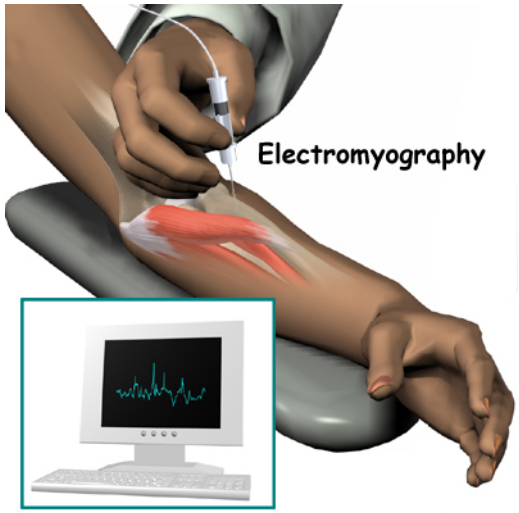
ESR: slow with low amplitude



HOW: VALIDATION OF THE MEASURING TOOL

For example:

Peripheral neuropathy in multiple myeloma



Options:

- Electromyography (EMG)
- ICPN Questionnaire

EMG: one fibre or muscle, invasive; reflects presence of peripheral neuropathy?

ICPN-Q: holistic determination, including ADL; validated for MM.

HOW: REPRODUCIBILITY OF THE TOOL

For example:

Measuring ‘hoarding’ (OCD in DSM V)

HOW: REPRODUCIBILITY OF THE TOOL

WHAT? THE RESEARCH QUESTION AN EXAMPLE

Prophylactic Intravenous Ondansetron and Dolasetron in Intrathecal Morphine-Induced Pruritus: A Randomized, Double-Blinded, Placebo-Controlled Study

Christos A. Iatrou, MD, PhD, Christos K. Dragoumanis, MD,
Theodosia D. Vogiatzaki, MD, PhD, George I. Vretzakis MD, PhD,
Constantinos E. Simopoulos, MD, PhD, and Vasilios K. Dimitriou, MD, PhD

Departments of Anesthesia and Surgery, Democritus University of Thrace, Alexandroupolis, Greece, and the Department of Anesthesia, "G. Gennimatas" Hospital, Athens, Greece

Anesth Analg 2005;101:1516–20

Intrathecal morphine improves postoperative analgesia, but it is accompanied by a frequent incidence of postoperative nausea and vomiting (PONV) and pruritus (1). Pruritus is the most common side effect of intrathecal morphine, with a reported incidence of 62% to 94% (2–4). It is unpleasant for patients and difficult to treat, and its prevention remains a challenge for anesthesiologists (5,6). Although the exact mechanism is unclear, it seems that intrathecal morphine's interaction with central 5-hydroxytryptamine subtype 3 (5-HT3) receptors (6) plays some role in the genesis of pruritus. As a result, 5-HT3 receptor antagonists could be effective in its control. Ondansetron has been used for this purpose with conflicting results (3,4,7,8). Dolasetron, another 5-HT3 receptor antagonist, is usually used to control nausea and vomiting associated with chemotherapy and PONV (9,10). However, its antipruritic activity has not been evaluated. Therefore, we conducted a prospective, randomized, double-blind, placebo-controlled study to determine the effectiveness of dolasetron and ondansetron for the prevention of pruritus after spinal anesthesia performed with bupivacaine and morphine in patients undergoing elective vascular, orthopedic, or urologic surgery.

The clinical problem

The rationale for this Rx

The study goal / research question

Anesth Analg 2005;101:1516–20

COMPONENTS OF THE RESEARCH QUESTION

Therefore, we conducted a prospective, randomized, double-blind, placebo-controlled study to determine the effectiveness of dolasetron and ondansetron for the prevention of pruritus after spinal anesthesia performed with bupivacaine and morphine in patients undergoing elective vascular, orthopedic, or urologic surgery.

Determinant

The effect of ….

Independent variable

X-axis

Anesth Analg 2005;101:1516–20

COMPONENTS OF THE RESEARCH QUESTION

Therefore, we conducted a prospective, randomized, double-blind, placebo-controlled study to determine the effectiveness of dolasetron and ondansetron the prevention of pruritus after spinal anesthesia performed with bupivacaine and morphine undergoing elective vascular, orthopedic, or urologic surgery.

End point

… on …

Dependent variable

Y-axis

Anesth Analg 2005;101:1516–20

COMPONENTS OF THE RESEARCH QUESTION

Therefore, we conducted a prospective, randomized, double-blind, placebo-controlled study to determine the effectiveness of dolasetron and ondansetron for the prevention of pruritus after spinal anesthesia performed with bupivacaine and morphine in patients undergoing elective vascular, orthopedic, or urologic surgery.

Domain

… in …

Population

Anesth Analg 2005;101:1516–20

THE RESEARCH QUESTION: OVERVIEW

Determinant	End point	Domain
The effect of ….	… on …	… in …
Independent variable	Dependent variable	Population
X-axis	Y-axis	

COMPARE PICO-MODELL IN EBM

P:	POPULATION	= DOMAIN
I:	INTERVENTION	= DETERMINANT
C:	CONTROL	= PLACEBO
O:	OUTCOME	= END POINT

RESEARCH QUESTION: THE ESSENTIALS

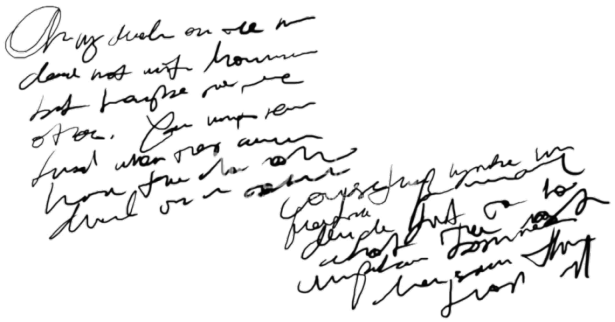
1. CLEAR

2. FOCUS

3. RECOGNIZABLE ELEMENTS
   - DETERMINANT, END POINT, DOMAIN

4. CONSISTENT USE IN
   - TITLE
   - OBJECTIVE
   - FIGURE 1 OR TABLE 2

RESEARCH QUESTION QUALITY CHECK



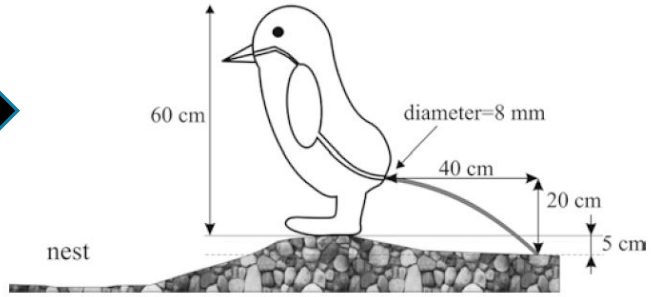


Fig. 1 Position of model penguin during defaecation and physical parameters used to calculate rectal pressure necessary to expel faecal material over a distance of 40 cm

1. DRAW PRIMARY FIGURE OR TABLE IN DEVELOPMENT PHASE
2. IF NOT POSSIBLE: INSUFFICIENTLY DEVELOPED RESEARCH QUESTION

BACK TO OUR EXAMPLE

Table 2. Incidence of the Pruritus and Postoperative Nausea and Vomiting, Sum of Pain Visual Analogue Scale Scores for Observations in Postanesthesia Care Unit, 2, 4, 8, and 24 h, Rescue Meperidine Delivered by Patient-Controlled Analgesia for 24 h

	Placebo (n = 35)	Dolasetron (n = 35)	Ondansetron (n = 35)
Incidence of pruritus*	23/35 (66%)	7/35 (20%)‡	12/35 (34%)§
95% CI	51% to 81%	8% to 32%	18% to 50%
Males	14/20 (70%)	3/18 (18%)	5/19 (26%)
Females	9/15 (60%)	4/17 (29%)	7/16 (44%)
Incidence of PONV†	15/35 (43%)	6/35 (17%)	8/35 (23%)
95% CI	27% to 59%	5% to 29%	9% to 37%
Sum of pain VAS scores (cm)	5.5 ± 2.5	4.9 ± 2.3	5.7 ± 2.5
Rescue meperidine (mg)	17.1 ± 13.8	13.4 ± 13.9	16.3 ± 12.1

Values are number of patients (%) or mean ± SD.
PONV = postoperative nausea and vomiting; VAS = visual analog scale; PACU = postanesthesia care unit; CI = confidence interval.
* $P < 0.01$; † $P < 0.05$ when compared with chi-square test; ‡ $P < 0.001$; § $P < 0.01$ when compared to placebo with chi-square test.

Anesth Analg 2005;101:1516–20

KEY MESSAGES

- Scientific research and its 4 –rations

- Discriminate between ‘what’ and ‘how’

-The essentials of a research question are

- DETERMINANT
- END POINT
- DOMAIN

- Draw a figure or table based on virtual data as a quality check

- Be consistent in using the essentials of the research question in Title, Goal, Rationale and Figure 1/Table 2.

THANKS FOR YOUR ATTENTION
QUESTIONS?

mcl
medisch centrum
leeuwarden

university of
groningen

QUESTIONS & ANSWERS

1. Yes or no: the 'research question' concerns the question whether or not to proceed with the proposed study?

- No, the research question concerns the question on which the proposed study will provide the answer.

2. Yes or no: quality control of a proposed research question is possible

- Yes, by checking whether or not the researcher can draw Figure 1 or Table 2 on basis of virtual data.

33. MC: Which part of the final scientific publication is most likely to contain the answer to the research question?

1. Methods
2. Table 1
3. Figure 1