Institute of Hygiene and Environmental Medicine

HUMAN-IC, Cohort Based Training 2

Using Evidence-based medicine (EbM) for clinical decision making

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- 3 hospital facilities
- 800,000 cases / year
- 140,000 admissions / year
- 3,200 beds

Institut für Hygiene und Umweltmedizin

Infection prevention:

- Surveillance of nosocomial infections

- Surveillance of multi-drug resistant organisms

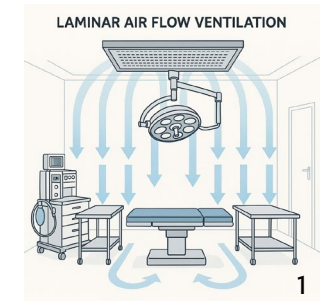- Implementation of evidence-based infection prevention measures

Agenda

- Introduction to EbM

- Formulating a research question

- Conduct the literature search

- Critical appraisal of the evidence

  → Study designs

  → Quality assessment

  → Risk of bias

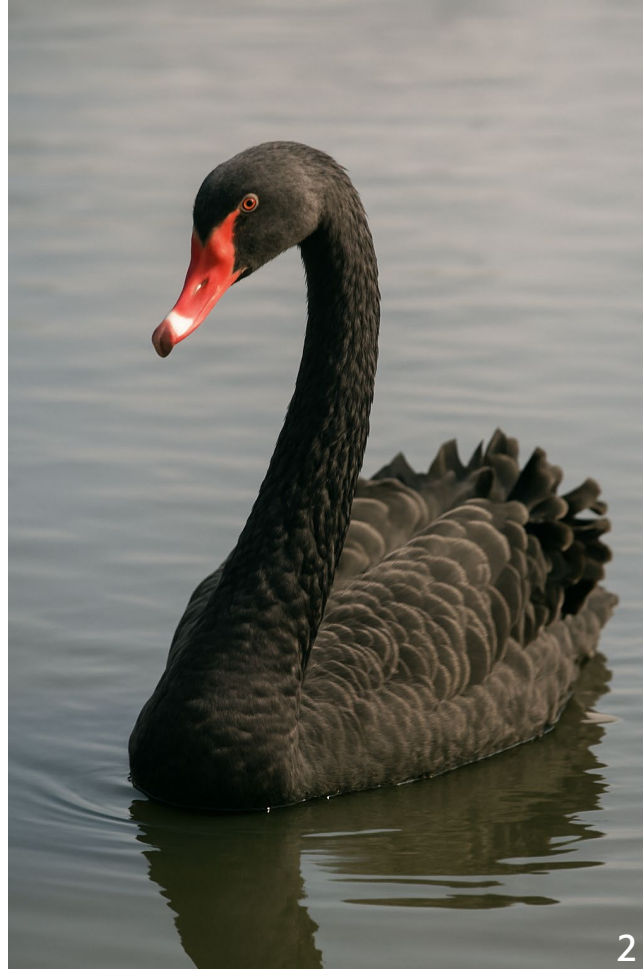- Application of the evidence

- Case example

Theory

Case example

1

Introduction to Evidence-based Medicine (EbM)

Individual observations / experiences may not reflect the reality

2 Generated with ChatGPT, 24/06/2025, prompts: one black swan

Individual observations / experiences may not reflect the reality

1 Generated with ChatGPT, 24/06/2025, prompts: one black swan

3 Generated with ChatGPT, 19/06/2025, prompts: one black swan, many white swans

Most important tool in epidemiology

Four by four table

- Which proportion of the reality does your individual observation represent?

- Strong associations between outcome (lung cancer) and exposition (smoking) → Many observations in A

Outcome

	YES	NO
Exposition YES	A	B
NO	C	D

Lung cancer

	YES	NO
Smoking YES	A	B
NO	C	D

Evidence-based Medicine (EbM)

Definition according to David Sackett

- "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."

- "The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research".

- Patients values and preferences need to be considered

Patient
Individual values

EBM

Research
Best available current evidence

Clinic
Individual clinical expertise

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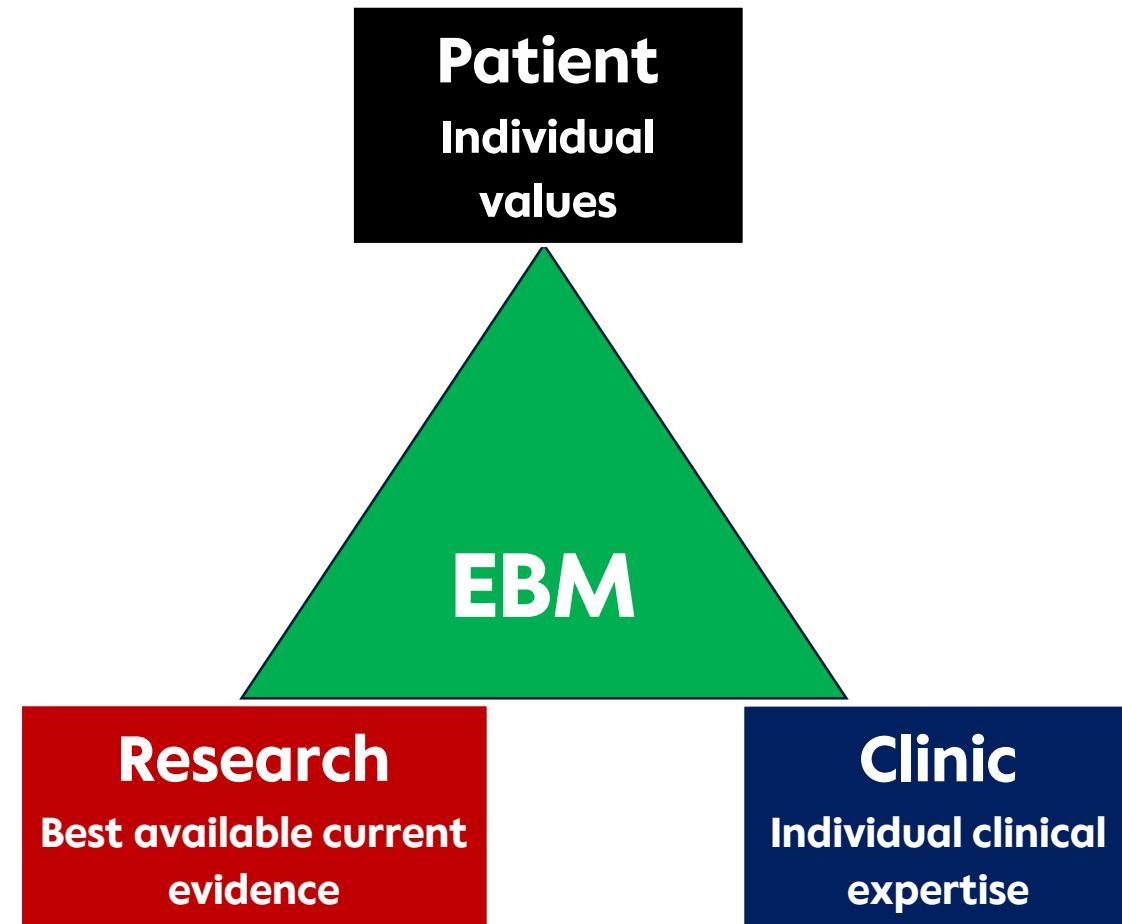
Practical Approach

Of EbM

- EbM = toolbox

- EBM provides **tools** to identify the best possible solution for a practical problem

- Structured Approach to Problem Solving

- Steps:

  →Formulate research question

  →Conduct a literature search

  →Critically appraise the evidence

  →Apply the evidence to the patient / case / problem

Case Example

EbM

- As a hospital ventilation engineer you are consulted for the construction of a new operating theatre in the orthopedic department of a hospital

  → Which ventilation system (laminar air flow / conventional turbulent ventilation) do you recommend based on the effect on surgical site infections (SSI)

  → Which other factors should be taken into account?

LAMINAR AIR FLOW VENTILATION
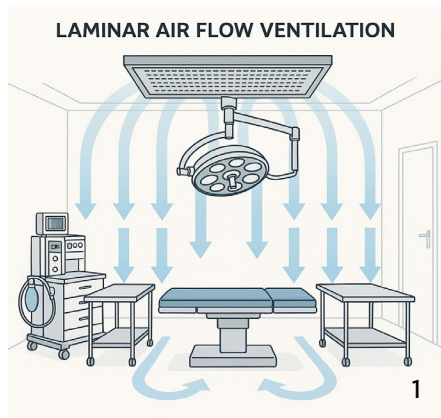
Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

Systematic review

EbM tool / results

- A structured, comprehensive, and reproducible method to identify, evaluate, and synthesize all relevant studies on a specific research question

- Follows a predefined protocol with clear inclusion/exclusion criteria

- Aims to minimize bias by using a transparent and replicable process

- Often includes both qualitative and quantitative synthesis of findings

- Steps typically include:

  → Formulating a research question (PICO format often used)

  → Comprehensive literature search

  → Selection of studies

  → Data extraction

  → Quality assessment of included studies

  → Synthesis of results

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier
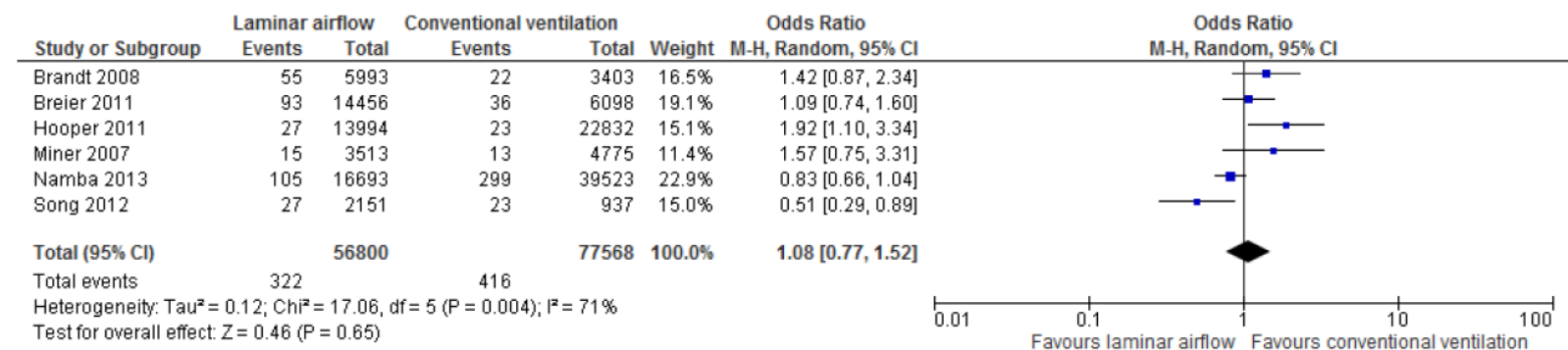
Meta-analysis

Case example

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

- A statistical technique used within a systematic review to combine the results of multiple studies

- Produces a pooled estimate of effect size (e.g., risk ratio, odds ratio)

- Increases statistical power and precision compared to individual studies

- Can explore heterogeneity between studies (e.g., via I^2 statistic)

- May include subgroup analyses or meta-regression to investigate sources of variation

- Results often presented using forest plots

Forest plot of odds ratio for deep SSI comparing laminar airflow *vs.* conventional ventilation in total knee arthroplasty (comparison 1b)

Study or Subgroup	Laminar airflow Events	Laminar airflow Total	Conventional ventilation Events	Conventional ventilation Total	Weight	Odds Ratio M-H, Random, 95% CI
Brandt 2008	55	5993	22	3403	16.5%	1.42 [0.87, 2.34]
Breier 2011	93	14456	36	6098	19.1%	1.09 [0.74, 1.60]
Hooper 2011	27	13994	23	22832	15.1%	1.92 [1.10, 3.34]
Miner 2007	15	3513	13	4775	11.4%	1.57 [0.75, 3.31]
Namba 2013	105	16693	299	39523	22.9%	0.83 [0.66, 1.04]
Song 2012	27	2151	23	937	15.0%	0.51 [0.29, 0.89]
Total (95% CI)		56800		77568	100.0%	1.08 [0.77, 1.52]
Total events	322		416			

Heterogeneity: Tau² = 0.12; Chi² = 17.06, df = 5 (P = 0.004); I² = 71%
Test for overall effect: Z = 0.46 (P = 0.65)

Odds Ratio M-H, Random, 95% CI

0.01   0.1   1   10   100
Favours laminar airflow   Favours conventional ventilation

SSI: surgical site infection; M-H: Mantel-Haenszel; CI: confidence interval

2

Formulate a research question

Research question

PICO

PICO - Scheme	Description
Patient	Who is your patient? What are their conditions /clinical characteristics or underlying diseases?
Intervention	What intervention are you planning to implement?
Comparison	What is the alternative to your intervention (e.g. standard care)
Outcome	What do you want to achieve? What are relevant outcomes?

Research question

PICO -Example

PICO - Scheme	Description	Example
Patient	Who is your patient? What are their conditions /clinical characteristics or underlying diseases?	Adult (≥ 18 years)
Intervention	What intervention are you planning to implement?	Smoking
Comparison	What is the alternative to your intervention (e.g. standard care)	Non-smoking
Outcome	What do you want to achieve? What are relevant outcomes?	Lung cancer

Research question: **Do smokers have a higher risk of developing lung cancer compared to non-smokers?**

[4] Generated with ChatpGPT, 19/06/2025, prompts: 100 years old man, birthday cake, smoking

Research question

PICO – Practical example

Generated with ChatpGPT,
25/06/2025, prompts:
Surgical patient, lower leg, dressing

PICO - Scheme	
Patient	
Intervention	
Comparison	
Outcome	

Research question

PICO – Practical example

Generated with ChatpGPT, 25/06/2025, prompts: Surgical patient, lower leg, dressing

PICO - Scheme	Bischoff et al. 2017, Lancet ID
Patient	Patients (any age) undergoing surgery (any kind)
Intervention	OR **with** laminar airflow ventilation
Comparison	OR ventilation **without** laminar airflow: Conventional / mixed / turbulent ventilation systems
Outcome	Surgical site infections (SSI): Overall / deep SSIs

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

3

Conduct a literature search

Medical databases

Selection

- Medline

- Embase

- Cochrane Central Register of Controlled Trials

- CINAHL

- …

Medical databases

Medline

- Medical Literature Analysis and Retrieval System Online

- MEDLINE is the National Library of Medicine's (NLM) premier bibliographic database that contains references to journal articles in life sciences, with a concentration on biomedicine

- MEDLINE content is searchable via PubMed and constitutes the primary component of PubMed, a literature database developed and maintained by the NLM National Center for Biotechnology Information (NCBI)

- https://pubmed.ncbi.nlm.nih.gov/
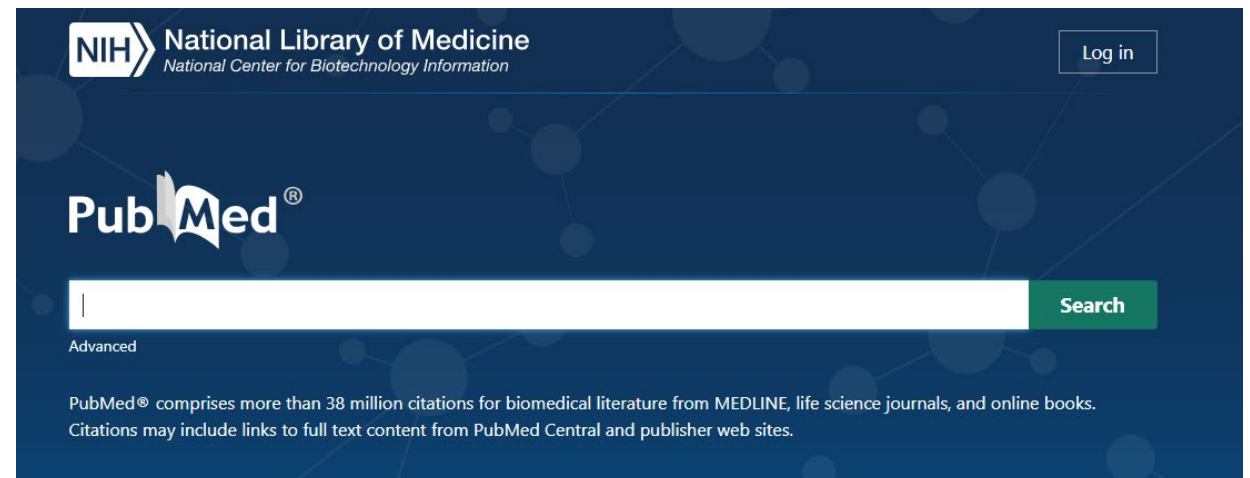
Medical databases

Embase

- Embase is a comprehensive biomedical database that optimizes literature searches

- contains the full content of MEDLINE and additionally includes references from international literature with a strong focus on Europe, covering the entire field of human medicine and related disciplines, particularly pharmacy and drug research.

- More than 8,400 journals from 90 countries are indexed

- Starting May 2025, a new publication type called "Clinical Trials" will be available

- Search machine Embase: OVID

- https://www.embase.com, registration needed

ELSEVIER

Embase

Home > Products > Embase

Embase is a comprehensive *biomedical database* that optimizes literature searches

Discover, innovate and develop with confidence. Regulators recognize Embase as a premier literature source. Find relevant and current results based on Emtree indexing of full-text content and dedicated search terms.

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Medical databases

Cochrane Central Register of Controlled Trials

- **The Cochrane Library** comprises several databases containing high-quality, independent evidence to support informed decision-making in healthcare

  → 6 databases: Cochrane Database of Systematic Reviews
  https://www.cochranelibrary.com/cdsr/reviews | Database of Abstracts of Reviews of Effects | Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register | Health Technology Assessment Database | NHS Economic Evaluation Database

- **Cochrane Central Register of Controlled Trials (CENTRAL)**

  → Rich database of bibliographic reports of randomized controlled trials

  → Most records from bibliographic databases including PubMed and EmBase,

  → Other published / unpublished sources: e.g. CINAHL, ClinicalTrials.gov (https://clinicaltrials.gov/), WHO's International Clinical Trials Registry Platform (https://www.who.int/tools/clinical-trials-registry-platform)

  → First publication in 1996

Search Strategy

Theory

- Identification of appropriate search terms

  → Synonyms, word truncations

- Combination of search terms

  → Boolean Operators

- Inclusion / exclusion criteria

  → Time, Age, Study design

A AND B

A OR B

A NOT B
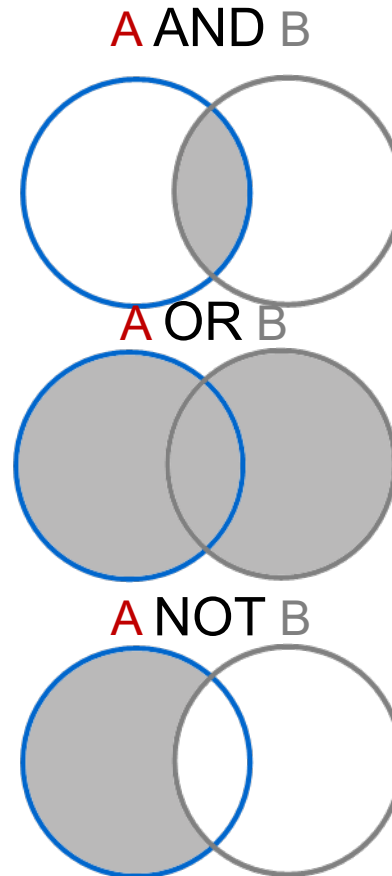
AND	Links to terms	Term A **AND** term B	Articles must contain both terms
OR	Selection	Term A **OR** term B	Article must contain term A OR term B (or both)
NOT	One of the terms einer von zwei Begriffen	Term A **NOT** term B	Article must contain term A, but NOT term B

MESH-Terms

Medical Subject Heading

- Key word indexing

- Defined terms that enable precise indexing of documents in databases such as MEDLINE

- Updated annually

- Each article in MEDLINE is assigned a MeSH term (Medical Subject Headings)

- To further specify articles, additional subheadings (qualifiers) are assigned

- https://meshb.nlm.nih.gov/search

Example:

Lung cancer

All MeSH Categories
Diseases Category
Neoplasms
Neoplasms by Site
Thoracic Neoplasms
Respiratory Tract Neoplasms
Lung Neoplasms
Adenocarcinoma of Lung
Adenocarcinoma, Bronchiolo-Alveolar
Bronchial Neoplasms
Carcinoma, Bronchogenic +
Mesothelioma, Malignant
Multiple Pulmonary Nodules
Pancoast Syndrome
Pulmonary Blastoma
Pulmonary Sclerosing Hemangioma

[4] Generated with ChatpGPT, 19/06/2025, prompts: 100 years old man, birthday cake, smoking

Search query in Pubmed

Search query in Pubmed

Documentation of the search
PRISMA

https://www.prisma-statement.org/prisma-2020-flow-diagram
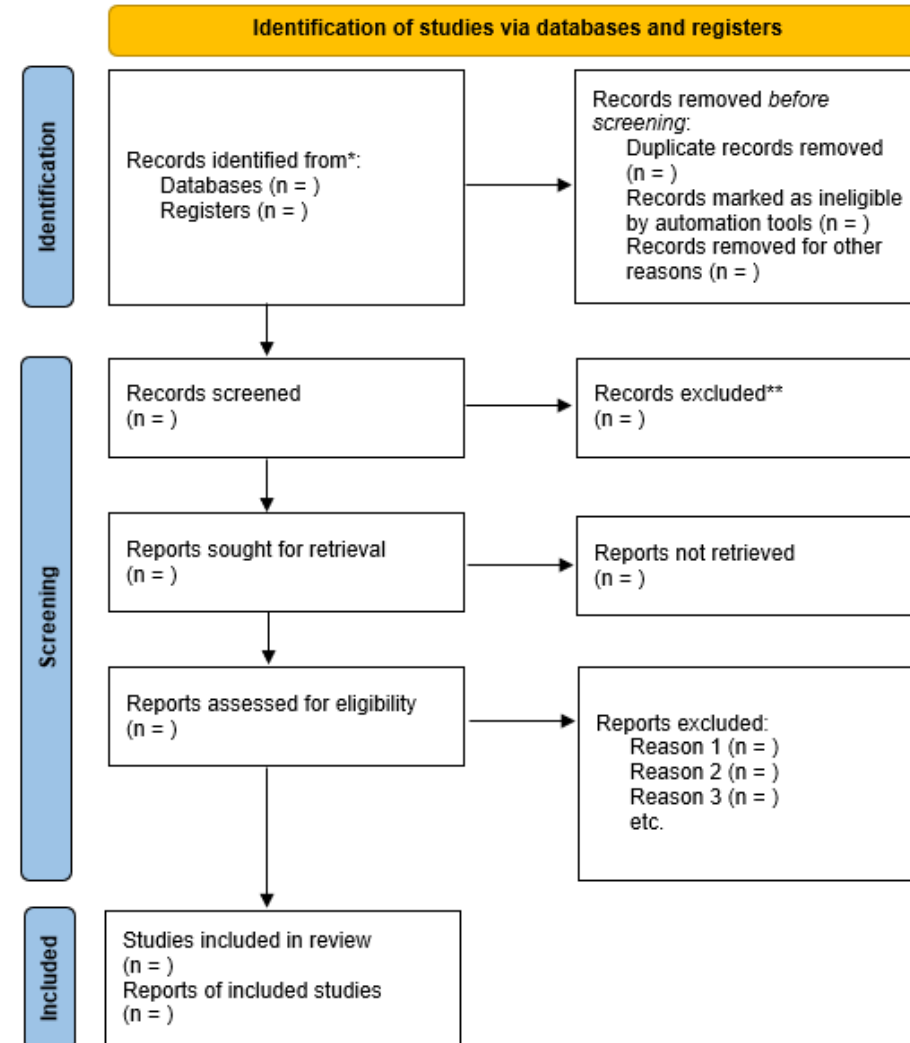
Search strategy

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

Lancet Infect Dis 2017; 17: 553–61

Search strategy I

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

Medline (via PubMed) search terms:

#1 "ventilation" AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#2 "environment, controlled"[Mesh] NOT "ventilation"[mesh]) AND ("surgical wound infection" OR "SSI" OR "surgical site infection"

#3 "air pollution, indoor"[Mesh] AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#4 "operating rooms" AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#5 limit 1-4 to (("1990/01/01"[PDAT] : "2014/01/31"[PDAT]) AND (English[lang] OR French[lang] OR German[lang] OR Spanish[lang]))

PubMed®

Query box

ventilation AND surgical wound infection OR SSI OR surgical site infection

✕

Search ⌄

History and Search Details

⤓ Download   🗑 Delete

Search	Actions	Details	Query	Results	Time
#1	•••	⌄	Search: **ventilation AND surgical wound infection OR SSI OR surgical site infection** (("ventilated"[All Fields] OR "ventilates"[All Fields] OR "ventilating"[All Fields] OR "ventilation"[MeSH Terms] OR "ventilation"[All Fields] OR "ventilate"[All Fields] OR "ventilations"[All Fields] OR "ventilation s"[All Fields] OR "ventilator s"[All Fields] OR "ventilators, mechanical"[MeSH Terms] OR ("ventilators"[All Fields] AND "mechanical"[All Fields]) OR "mechanical ventilators"[All Fields] OR "ventilator"[All Fields] OR "ventilators"[All Fields] OR "ventillation"[All Fields]) AND ("surgical wound infection"[MeSH Terms] OR ("surgical"[All Fields] AND "wound"[All Fields] AND "infection"[All Fields]) OR "surgical wound infection"[All Fields])) OR "SSI"[All Fields] OR ("surgical wound infection"[MeSH Terms] OR ("surgical"[All Fields] AND "wound"[All Fields] AND "infection"[All Fields]) OR "surgical wound infection"[All Fields] OR ("surgical"[All Fields] AND "site"[All Fields] AND "infection"[All Fields]) OR "surgical site infection"[All Fields])	81,197	10:22:03

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Search strategy I

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

Medline (via PubMed) search terms:

#1   "ventilation" AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#2   "environment, controlled"[Mesh] NOT "ventilation"[mesh]) AND ("surgical wound infection" OR "SSI" OR "surgical site infection"

#3   "air pollution, indoor"[Mesh] AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#4   "operating rooms" AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#5   limit 1-4 to (("1990/01/01"[PDAT] : "2014/01/31"[PDAT]) AND (English[lang] OR French[lang] OR German[lang] OR Spanish[lang]))

Search strategy II

**Is the use of laminar airflow in the operating room associated with the reduction
of overall or deep SSI?**

Embase search terms:

#1 (ventilation and (surgical wound infection or SSI or surgical site infection)).mp.
    [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer,
    drug manufacturer, device trade name, keyword]

#2 ((environment not ventilation) and (surgical wound Infection or SSI or surgical site infection)).mp.
    [mp=ti, ab, sh, hw, tn, ot, dm, dv, kw]

#3 (indoor air pollution and (surgical wound infection or SSI or surgical site infection)).mp.
    [mp=ti, ab, sh, hw, tn, ot, dm, dv, kw]

#4 ((operating rooms or operation room or operation theatre) and (surgical wound infection or SSI or
    surgical site infection)).mp. [mp=ti, ab, sh, hw, tn, ot, dm, dv, kw]

#5   limit 1-4 to (1990:2014.(sa_year).)

Search strategy III

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

Cochrane CENTRAL search terms:

#1   MeSH descriptor: [ventilation] explode all trees

#2   MeSH descriptor: [environment, controlled] explode all trees

#3   MeSH descriptor: [surgical wound infection] explode all trees

#4   MeSH descriptor: [operating rooms] explode all tree

#5   (ventilation)

#6   (surgical wound infection) or (SSI) or (surgical site infection)

#7   (operating rooms)

#8   (#1 or #5) and (#3 or #6)

#9   #2 and (#3 or #6)

#10   (#3 or #6) and (#4 or #7)

#11   limit (#8-#10) to (from 1990 to 2014)

Search strategy IV

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

WHO regional medical databases

Latin America and Caribbean Health Sciences

    #1   tw:(mh:("surgical wound infection" AND "ventilation")) AND (instance:"regional")

    #2   tw:(mh:("surgical wound infection" AND "environment")) AND (instance:"regional")

    #3   tw:(mh:("surgical wound infection" AND "operating rooms")) AND (instance:"regional")

    #4   limit 1-3 to (from 1990 to 2014)

African Index Medicus

    #1   ventilation [key word] and surgical wound infection [key word] or surgical site infection [key word]

    #2   environment [key word] and surgical wound infection [key word] or surgical site infection [key word]

    #3   operating rooms [key word] and surgical wound infection [key word] or surgical site infection [key word]

Search strategy IV

Is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI?

WHO regional medical databases

Index Medicus for the Eastern Mediterranean Region Database

#1   ventilation [key word] and surgical wound infection [key word] or surgical site infection [key word]

#2   environment [key word] and surgical wound infection [key word] or surgical site infection [key word]

#3   operating rooms [key word] and surgical wound infection [key word] or surgical site infection [key word]

Index Medicus for the South-East Asian Region

#1   "ventilation" AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#2   (environment) AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#3   ("operating rooms") AND ("surgical wound infection" OR "SSI" OR "surgical site infection")

#4   limit 1-3 to (from 1990 to 2014)

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Documentation of the search

Figure: Flow diagram of study selection
PICO=population, intervention, comparator, and outcome.
www.thelancet.com/infection Vol 17 May 2017

Excluded:

- Combined interventions, e.g.:

    – LAF + increased discipline

    – LAF + closed OR doors (vs. open doors in control)

    – LAF + body exhaust gowns

- Studies older than 1990

1947

1900 records identified through database
searching
634 MEDLINE
361 Embase
467 Cochrane Central Register of
Controlled Trials
438 WHO regional medical databases

47 additional records identified through
other sources

604 duplicates removed

1343 records screened

1234 records excluded on the basis of title and abstract

109 full-text articles assessed for eligibilty

97 full-text articles excluded
89 not relevant to PICO question
4 intervention combined with additional measures
1 study period out of date
1 review
1 primary data not available
1 full text not available

12 studies included in systematic review
and meta-analysis

12

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Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

- No randomised clinical trials, mostly adult patients
- 12 cohort studies:
  - 8 observational studies after total hip arthroplasty
  - 6 observational studies after total knee arthroplasty
  - 4 studies provided data for more than one comparison
  - 3 multicenter studies used data from national joint registries and surveillance systems
  - 3 single observational studies on abdominal and open vascular surgery

	Procedures (intervention/control)	Country	Study period	Point estimate (95% CI) for laminar airflow
Total hip arthroplasty				
Kakwani et al (2007)[39]	435 (212/223)	UK	2000–04	RR 0·06 (0·00–0·95)*
Brandt et al (2008)[30]	28 623 (17 657/10 966)	Germany	2000–04	OR 1·63 (1·06–2·52)
Dale et al (2009)[31]	93 958 (45 620/48 338)	Norway	1987–2008	RR 1·3 (1·1–1·5)
Pedersen et al (2010)[35]	80 756 (72 23/8333)	Denmark	1995–2008	HR 0·9 (0·7–1·14)
Breier et al (2011)[37]	41 212 (29 530/11 682)	Germany	2004–09	Arthrosis OR 1·10 (0·56–2·17); fracture OR 1·28 (0·67–2·43)†
Hooper et al (2011)[38]	51 485 (16 990/34 495)	New Zealand	1999–2008	RR 2·42 (1·35–4·32)*
Namba et al (2012)[33]	30 491 (8478/22 013)	USA	2001–09	HR 1·08 (0·77–1·53)
Song et al (2012)[36]	3186 (2037/1149)	South Korea	2006–09	RR 1·2 (0·6–2·16)*
Total knee arthroplasty				
Miner et al (2007)[40]	8288 (3513/4775)	USA	2000	RR 1·57 (0·75–3·31)
Brandt et al (2008)[30]	9396 (5993/3403)	Germany	2000–04	OR 1·76 (0·80–3·85)
Breier et al (2011)[37]	20 554 (14 456/6098)	Germany	2004–09	OR 0·95 (0·37–2·41)
Hooper et al (2011)[38]	36 826 (13 994/22 832)	New Zealand	1999–2008	RR 1·92 (1·10–3·34)*
Song et al (2012)[36]	3088 (2151/937)	South Korea	2006–09	RR 0·51 (0·29–0·89)‡
Namba et al (2013)[34]	56 216 (16 693/39 523)	USA	2001–09	HR 0·91 (0·71–1·16)

RR=risk ratio. HR=hazard ratio. OR=odds ratio. *Not adjusted (relative risk [RR] calculated with crude data, no multivariable analysis). †Adjusted ORs were provided separately for elective procedures due to arthrosis and for urgent procedures due to fracture. ‡Not adjusted (relative risk [RR] calculated with crude data, not significant in multivariable analysis).

Table 1: Characteristics of primary studies included in the meta-analysis of laminar airflow *vs* conventional ventilation for deep surgical site infection in patients undergoing total hip and knee arthroplasties

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	Procedures (intervention/control)	Country	Study period	Adjusted odds ratio (95% CI) for laminar airflow
Brandt et al (2008)[30]				
Appendectomy	10 969 (7193/3776)	Germany	2000–04	2·09 (1·08–4·02)
Colon surgery	8696 (6201/2495)	Germany	2000–04	1·17 (0·65–2·11)
Cholecystectomy	20 676 (12 419/8257)	Germany	2000–04	1·53 (0·9–2·45)
Herniorrhaphy	20 870 (12 667/8203)	Germany	2000–04	1·67 (0·9–2·91)
Bosanquet et al (2013)[29]				
Open vascular surgery	170 (56/114)	Wales	Not reported	0·38 (0·12–1·19)*
Jeong et al (2013)[32]				
Gastric surgery	2091 (1919/172)	South Korea	2010–11	0·13 (0·08–0·22)*

*Not adjusted (calculated with crude data, the authors provide only adjusted odds ratios for the absence, rather than presence, of laminar airflow: 2·45 [95% CI 1·13–5·31] after gastric surgery and 4·02 [1·18–13·69] after open vascular surgery).

Table 2: Characteristics of primary studies included in the meta-analysis of laminar airflow *vs* conventional ventilation for overall surgical site infection in patients undergoing abdominal and open vascular surgery

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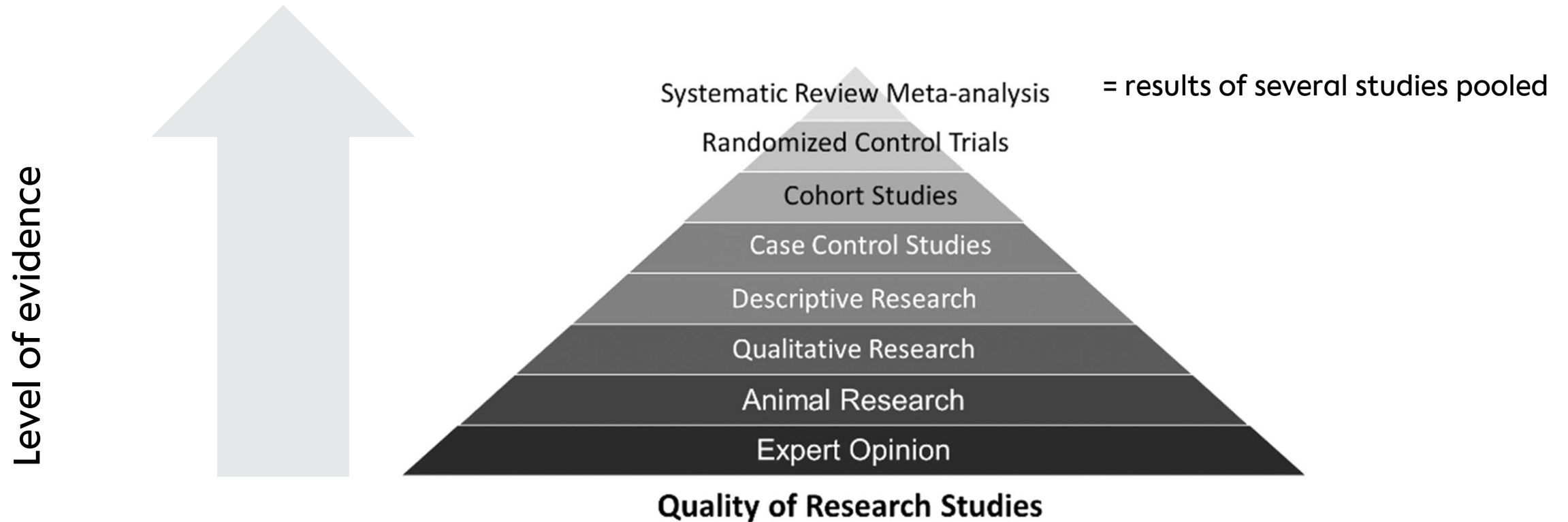
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Reporting of study results

Study results

#	Titel/ Source	Author/ Year/ Country	Study design / type of study (e.g. RCT, case-control-study, cohort study)	Research question	Study population (e.g. hospital patients, adults)	Sample size (Intervention and control group)	Time period and Follow up	Inter-vention/ Control	Outcome	Results

Levels of evidence

Level of evidence →

Systematic Review Meta-analysis = results of several studies pooled

Pyramid (top to bottom):
- Systematic Review Meta-analysis
- Randomized Control Trials
- Cohort Studies
- Case Control Studies
- Descriptive Research
- Qualitative Research
- Animal Research
- Expert Opinion

Quality of Research Studies

Study designs

	Observational	Interventional
Descriptive	Case reports Case series Cross-sectional study	
Analytical	Case-control study Cohort study	Intervention studies • Before-After studies (Interrupted time series analysis) • Controlled before-After Studies • Randomised controlled trial (RCT)

Study designs

	Observational	Interventional
Descriptive	**Case reports** **Case series** **Cross-sectional study**	
Analytical	**Case-control study** **Cohort study**	Intervention studies • Before-After studies (Interrupted time series analysis) • Controlled before-After Studies • Randomised controlled trial (RCT)

Study designs

Observational studies

Descriptive studies describe the frequency and/or occurrence of events and/or exposures.

- **Case Reports**: Report of an interesting or unusual clinical case.

  → Example: Fatal outcome of Clostrididiodes difficile-associated diarrhea (CDI) in a patient undergoing chemotherapy without prior antibiotic history.(Fatal Clostridium difficile infection associated with vinorelbine chemotherapy. J Infect Chemother. 2010 Mar 3)

- **Case Series**: Report of a cluster of several unusual cases.

  → Example: Cluster of systemic lupus erythematosus cases following hepatitis B vaccination. (Ten cases of systemic lupus erythematosus related to hepatitis B vaccine. Lupus. 2009 Nov;18(13):1192–7.)

Study designs

Observational studies

- **Cross-Sectional Study**: Simultaneous collection of the outcome of interest (e.g., disease) and potentially relevant exposure factors.

  → Examples: ECDC PPS (Point Prevalence Survey of nosocomial infections in Europe/Germany organized by the European Center for Disease Prevention and Control)

Figure 10. Distribution of types of HAI by presence of HAI on admission (left) and HAI onset during hospitalisation (right), ECDC PPS 2022–2023

Prevalence of patients with at least one healthcare-associated infection (HAI) in the EU/EEA sample: **7.1% (country range: 3.1–13.8%)**

Levels of evidence

Systematic Review Meta-analysis = results of several studies pooled

Randomized Control Trials

Cohort Studies

Case Control Studies

Descriptive Research

Qualitative Research

Animal Research

Expert Opinion

Quality of Research Studies

Level of evidence
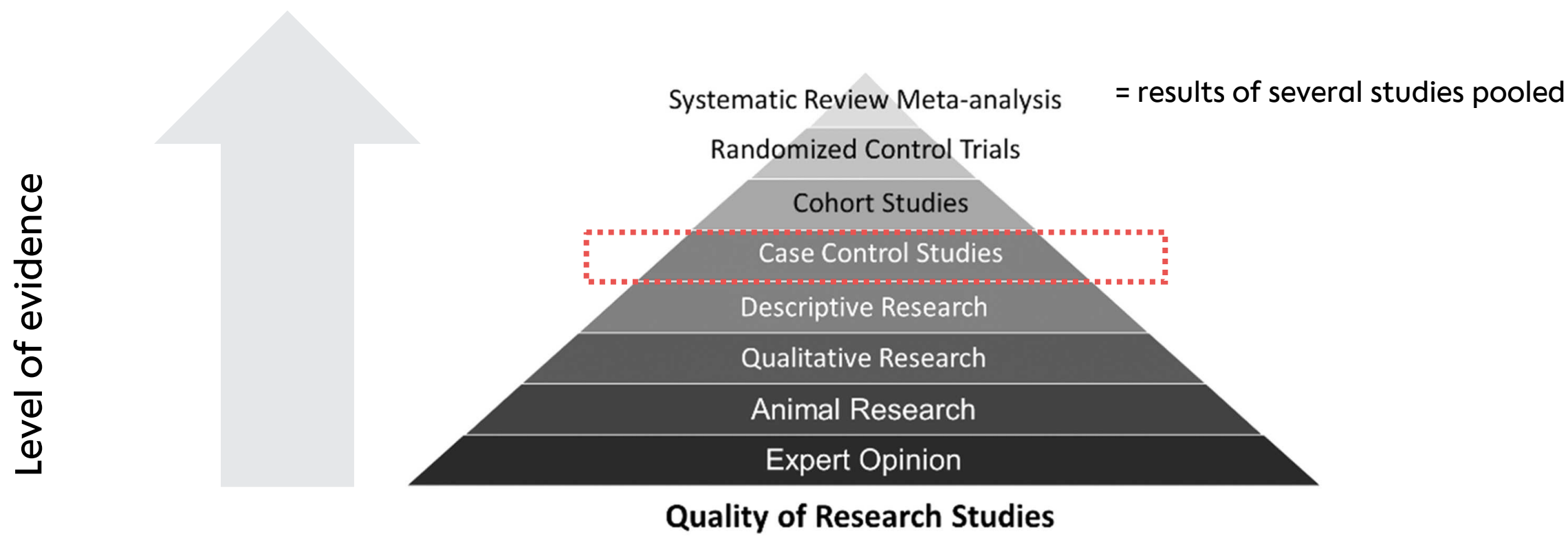
Study designs

Case-control

Study designs
Case-control

Start of the study

Exposition to a risk factor

| YES |
| NO |
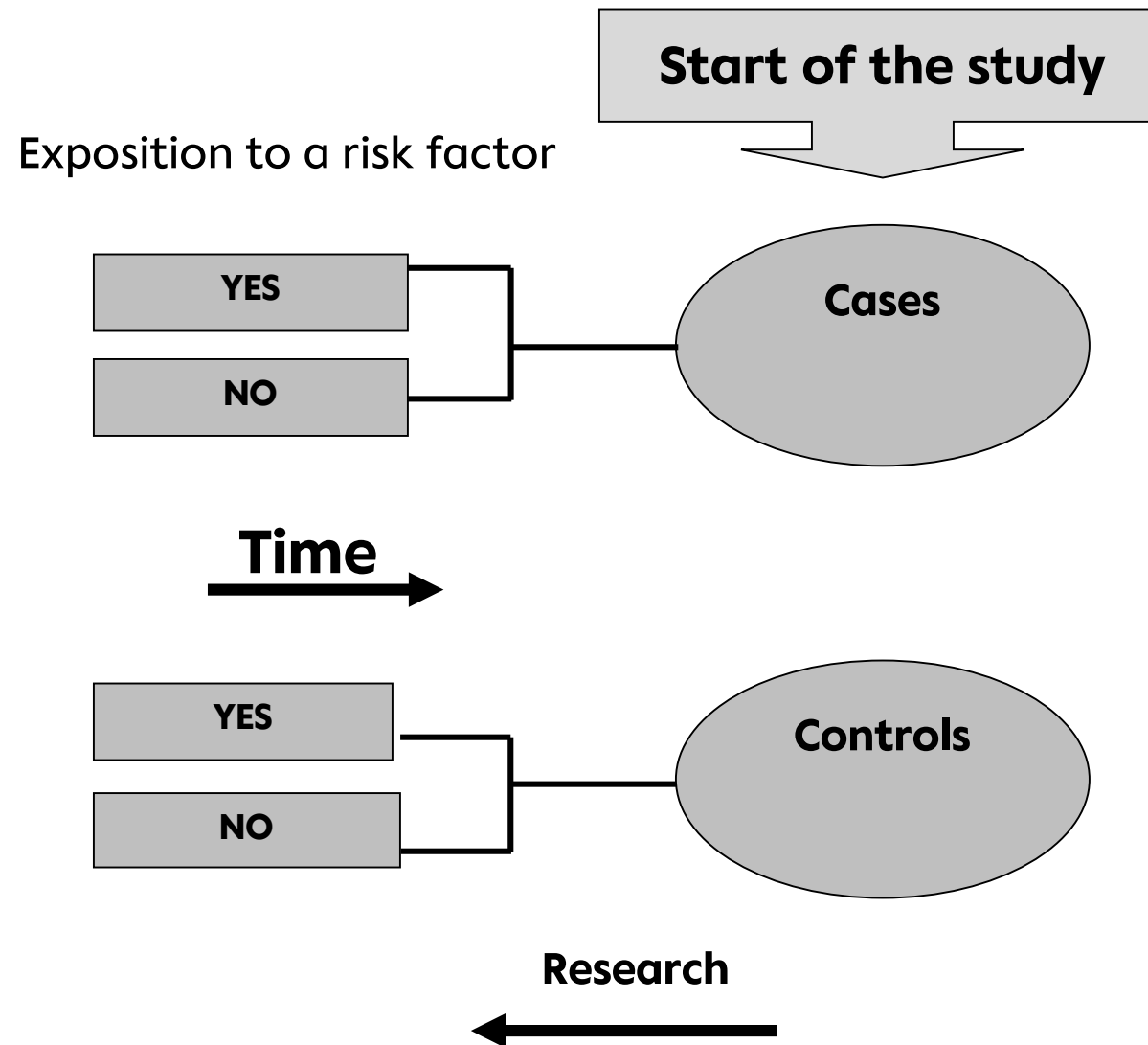
Cases

Comparison of exposition rates in both groups

Time →

| YES |
| NO |

Controls

← **Research**
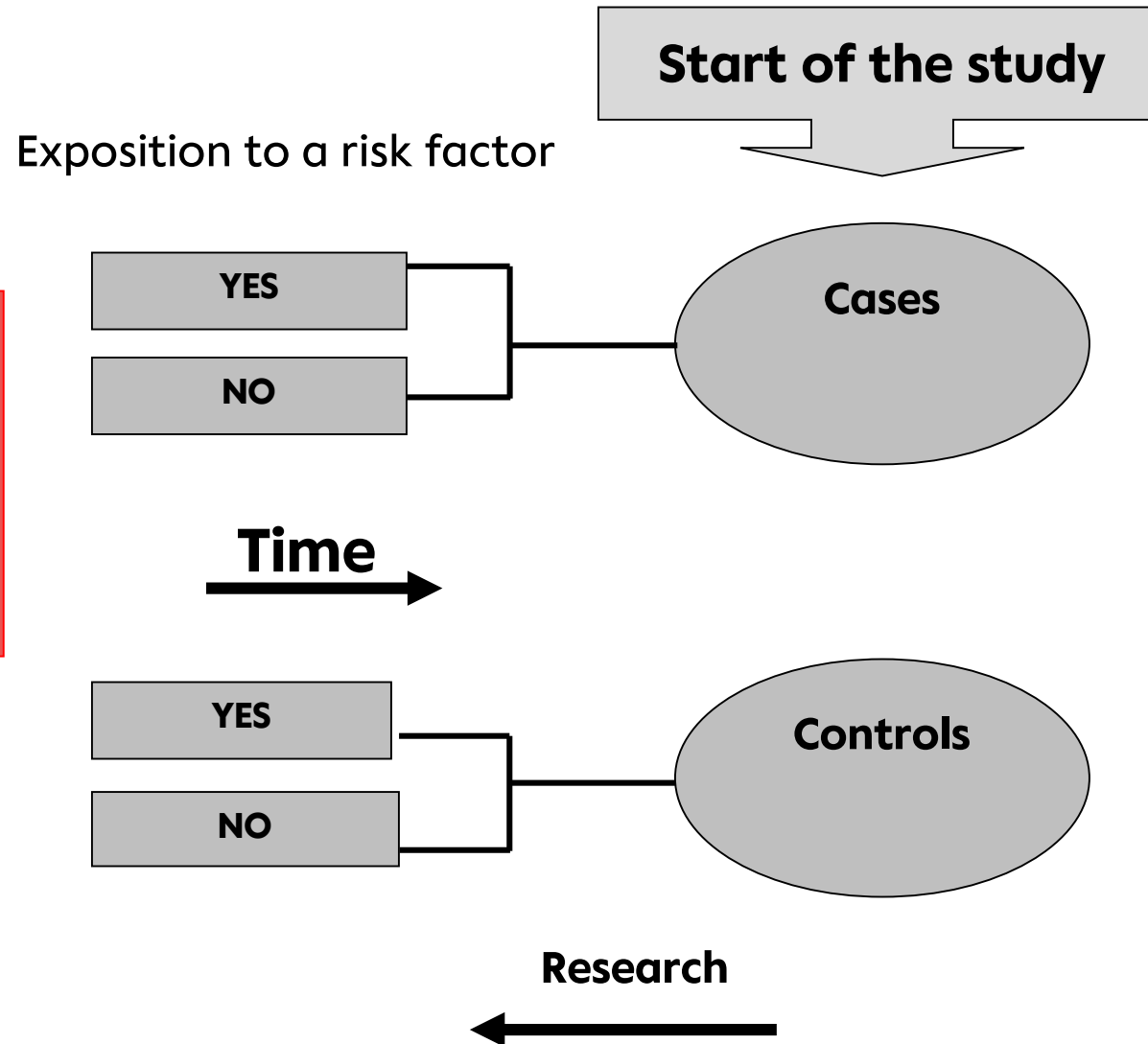
Study designs

Case-control

Start of the study

Smoking as a risk factor

Smokers in the lung cancer group:

45 of 100 patients

| YES (n = 45) |
| NO (n = 55) |

Cases with lung cancer (n = 100)

Time →

Smokers in the no lung cancer group:

20 of 100 patients

| YES (n = 20) |
| NO (n = 80) |

Controls no lung cancer (n = 100)

Research ←

Do smokers have a higher risk of developing lung cancer compared to non-smokers?

4

Four-by-four Table
Case-control study

		LUNG CANCER		
		YES	NO	
SMOKING	YES	45 a	20 b	65
	NO	55 c	80 d	135
		100	100	200

Calculation of Odds Ratio (OR):

$$OR = \frac{a/c}{b/d} = \frac{45/55}{20/80} = \frac{0{,}8}{0{,}25} = 3{,}2$$

Smokers have a 3-fold higher chance to develop lung cancer

[4] Generated with ChatGPT, 19/06/2025, prompts: 100 years old man, birthday cake, smoking

Levels of evidence

Level of evidence

Systematic Review Meta-analysis   = results of several studies pooled

Randomized Control Trials

Cohort Studies

Case Control Studies

Descriptive Research

Qualitative Research

Animal Research

Expert Opinion

Quality of Research Studies
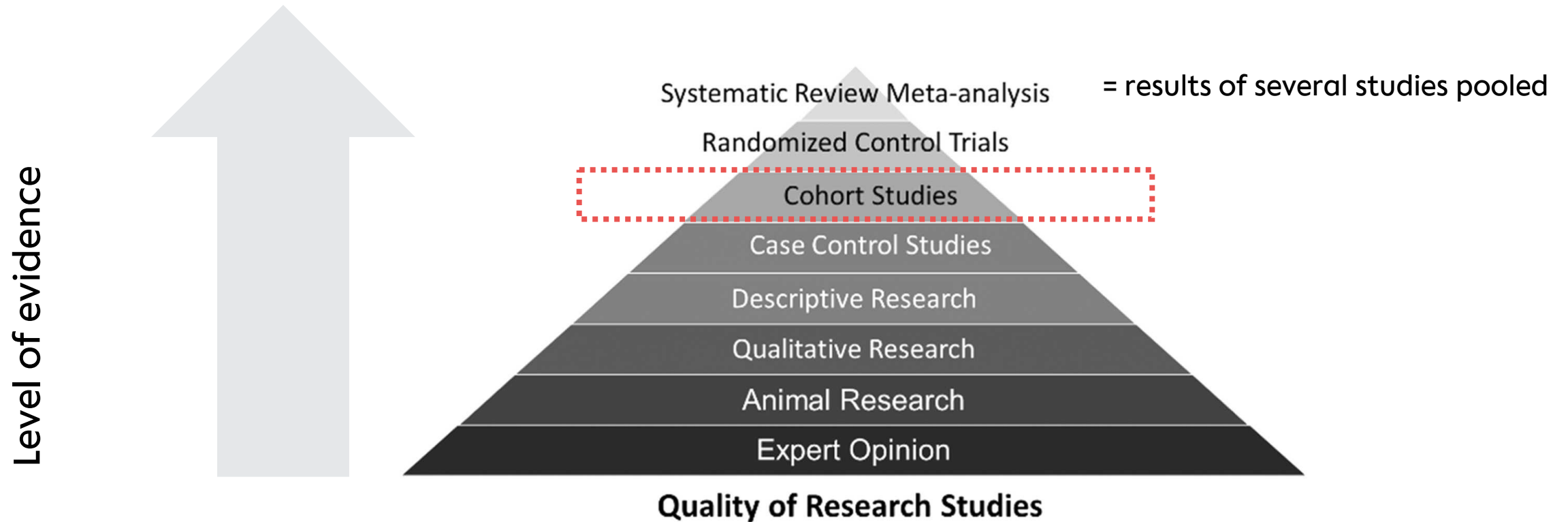
Study designs
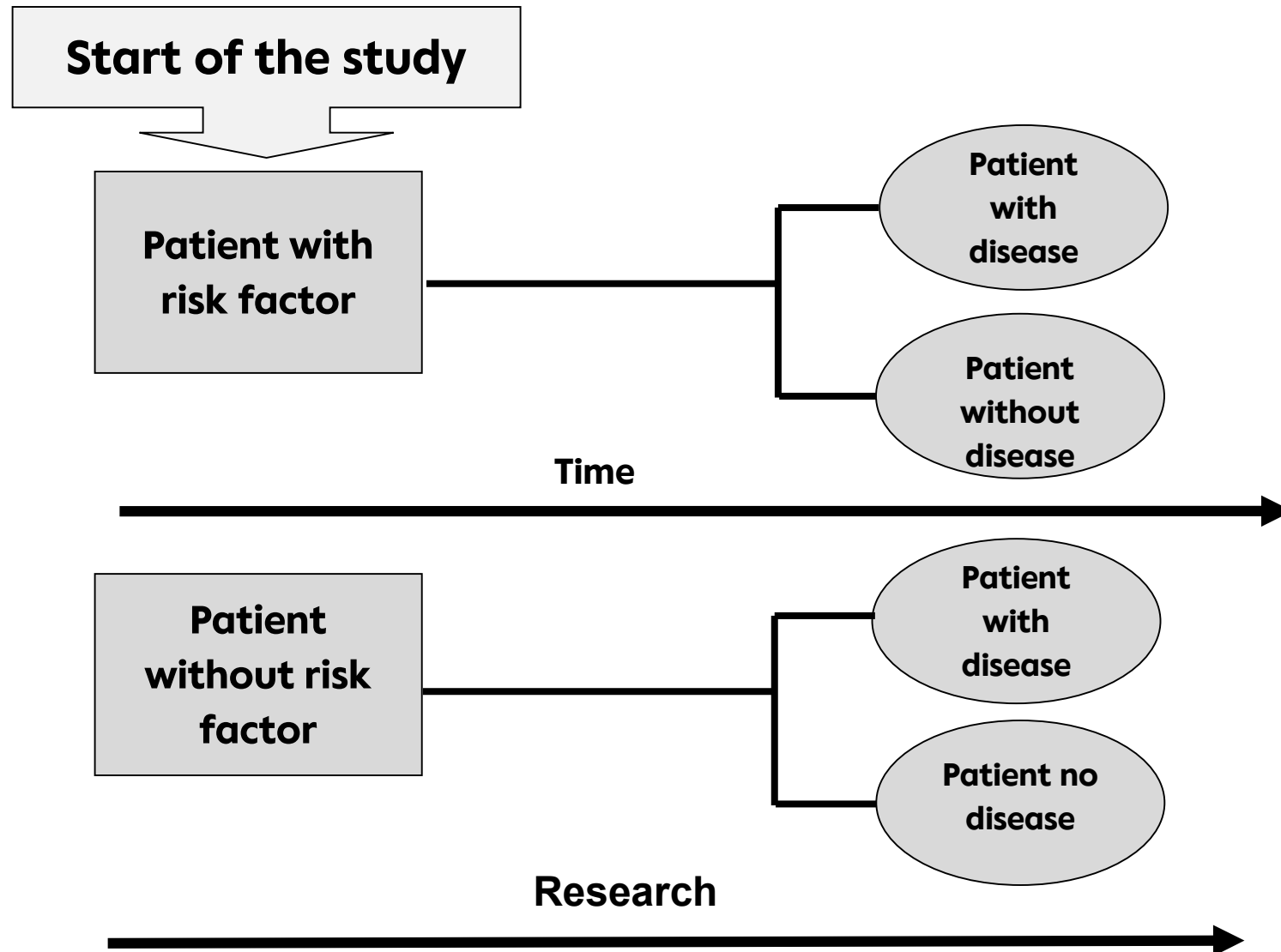
Cohort study

Study designs
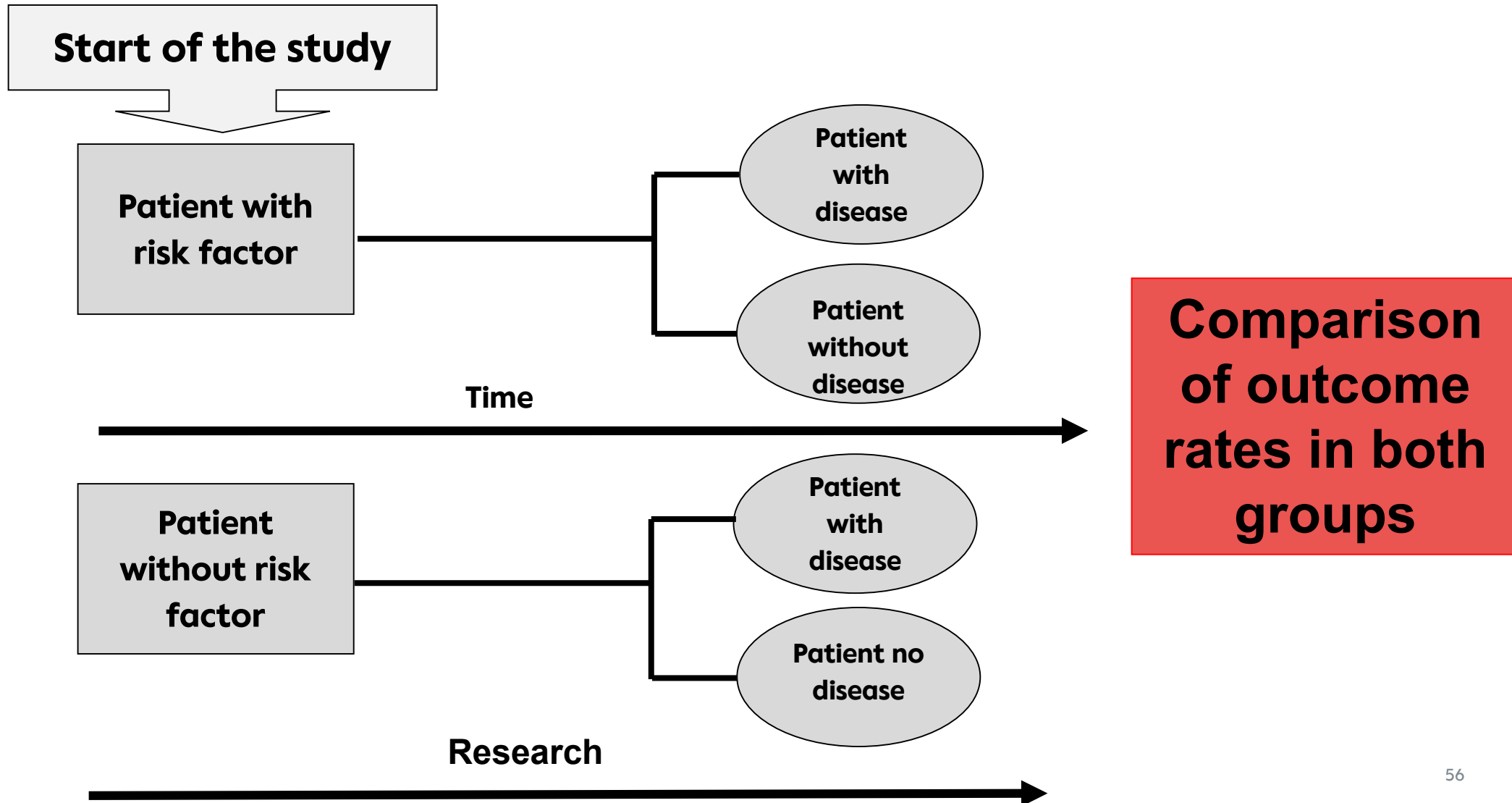
Cohort study

Study designs
Cohort study

Do smokers have a higher risk of developing lung cancer compared to non-smokers?

4

Start of the study

Patient with risk factor (n = 500)

Patient with disease (n = 20)

Patient no disease (n = 480)

Time

Lung cancer in smoker's group:

4 of 100 patients

Patient without risk factor (n = 500)

Patient with disease (n = 5)

Patient no disease (n = 495)

Lung cancer in non-smoker's group:

1 of 100 patients

CAVE: The numbers in this example are fictional.

Research

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[4] Generated with ChatGPT, 19/06/2025, prompts: 100 years old man, birthday cake, smoking
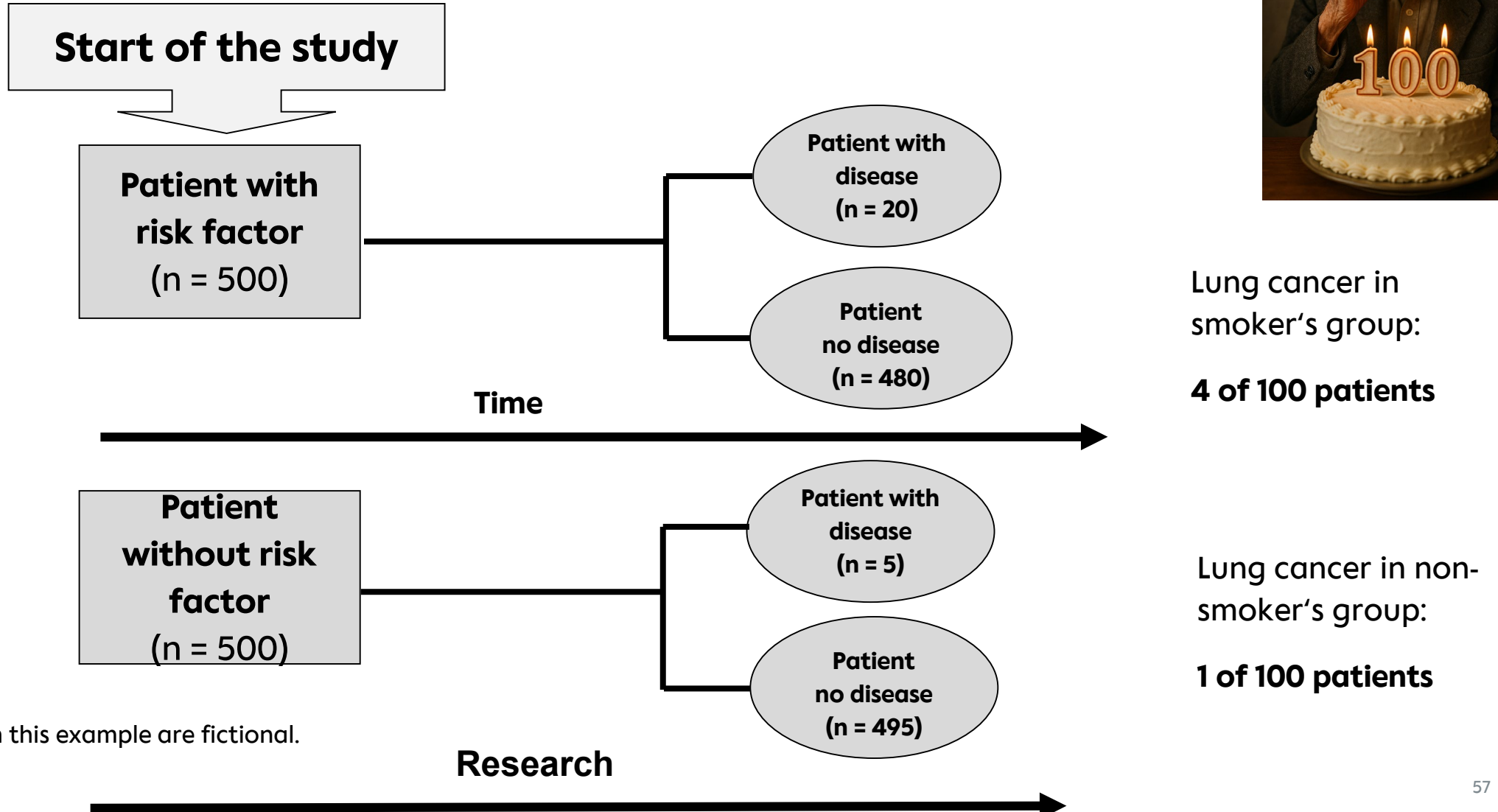
Four-by-four Table

Cohort study

Smokers have a 4-fold higher risk of developing lung cancer

		LUNG CANCER		
		YES	NO	
SMOKING	YES	20 a	480 b	500
	NO	5 c	495 d	500
		25	975	1000

Calculation of Risk Ratio (RR):

$$RR = \frac{a / (a+b)}{c / (c+d)} = \frac{20/(20 + 480)}{5 / (5 + 495)} = \frac{4}{1} = 4{,}0$$

CAVE: The numbers in this example are fictional.

[4] Generated with ChatGPT, 19/06/2025, prompts: 100 years old man, birthday cake, smoking

Levels of evidence

Level of evidence →

Systematic Review Meta-analysis   = results of several studies pooled

Randomized Control Trials

Cohort Studies

Case Control Studies

Descriptive Research

Qualitative Research

Animal Research

Expert Opinion

Quality of Research Studies
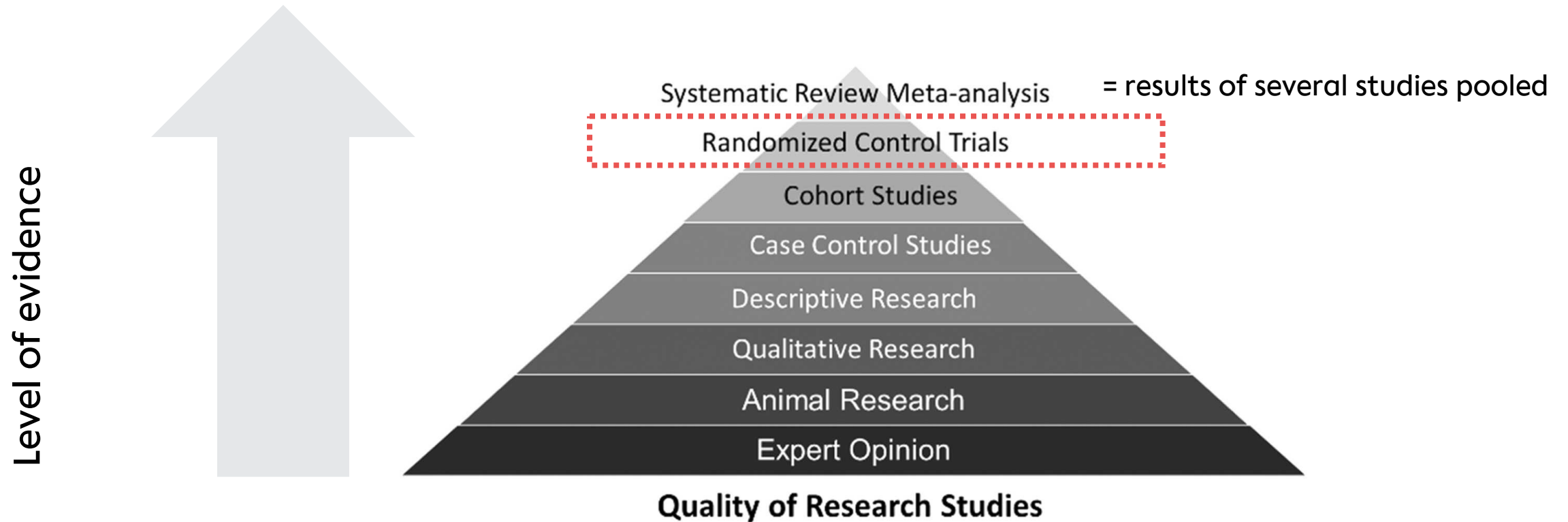
Study designs

Randomized controlled trials
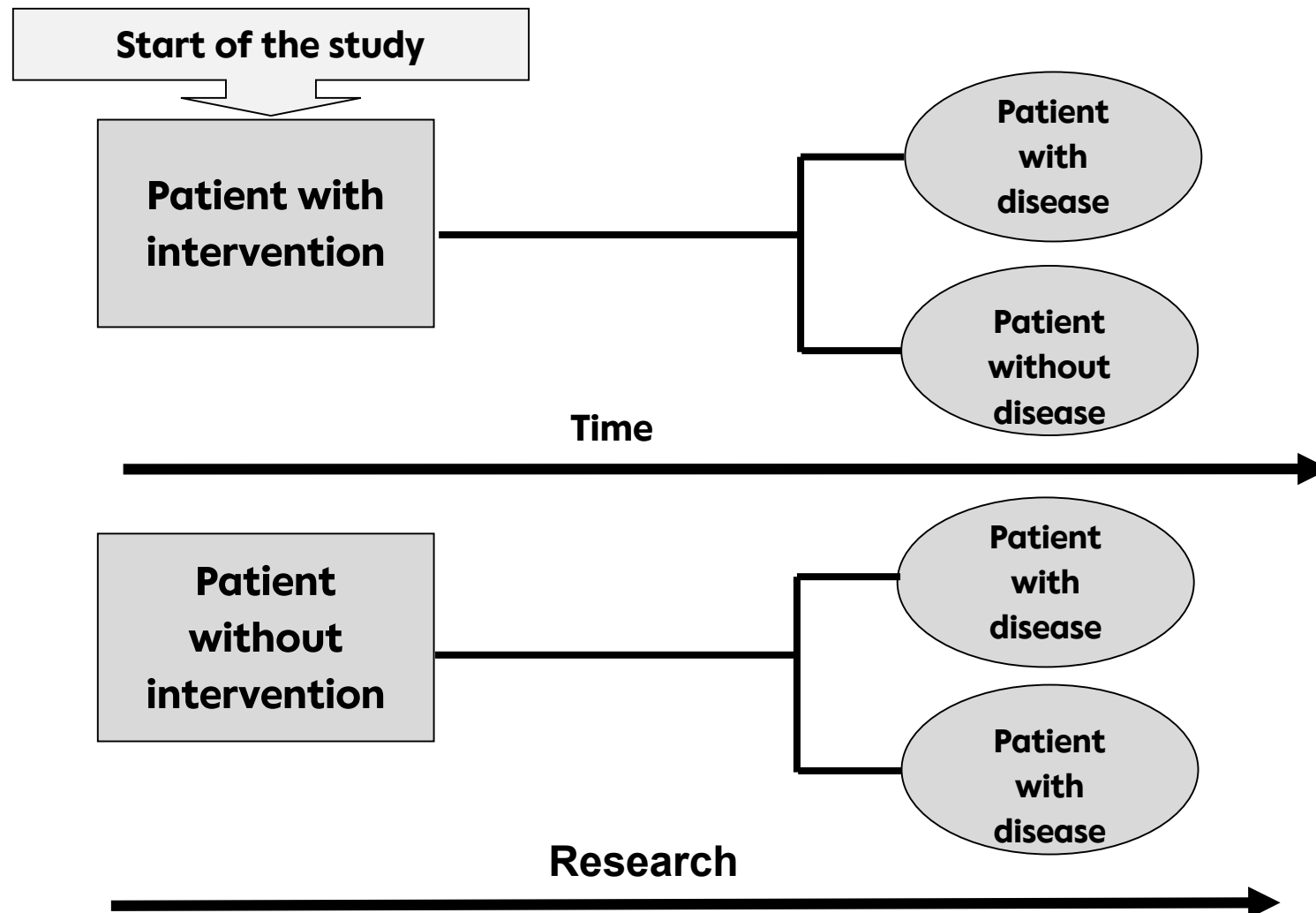
Study designs

Randomized controlled trials
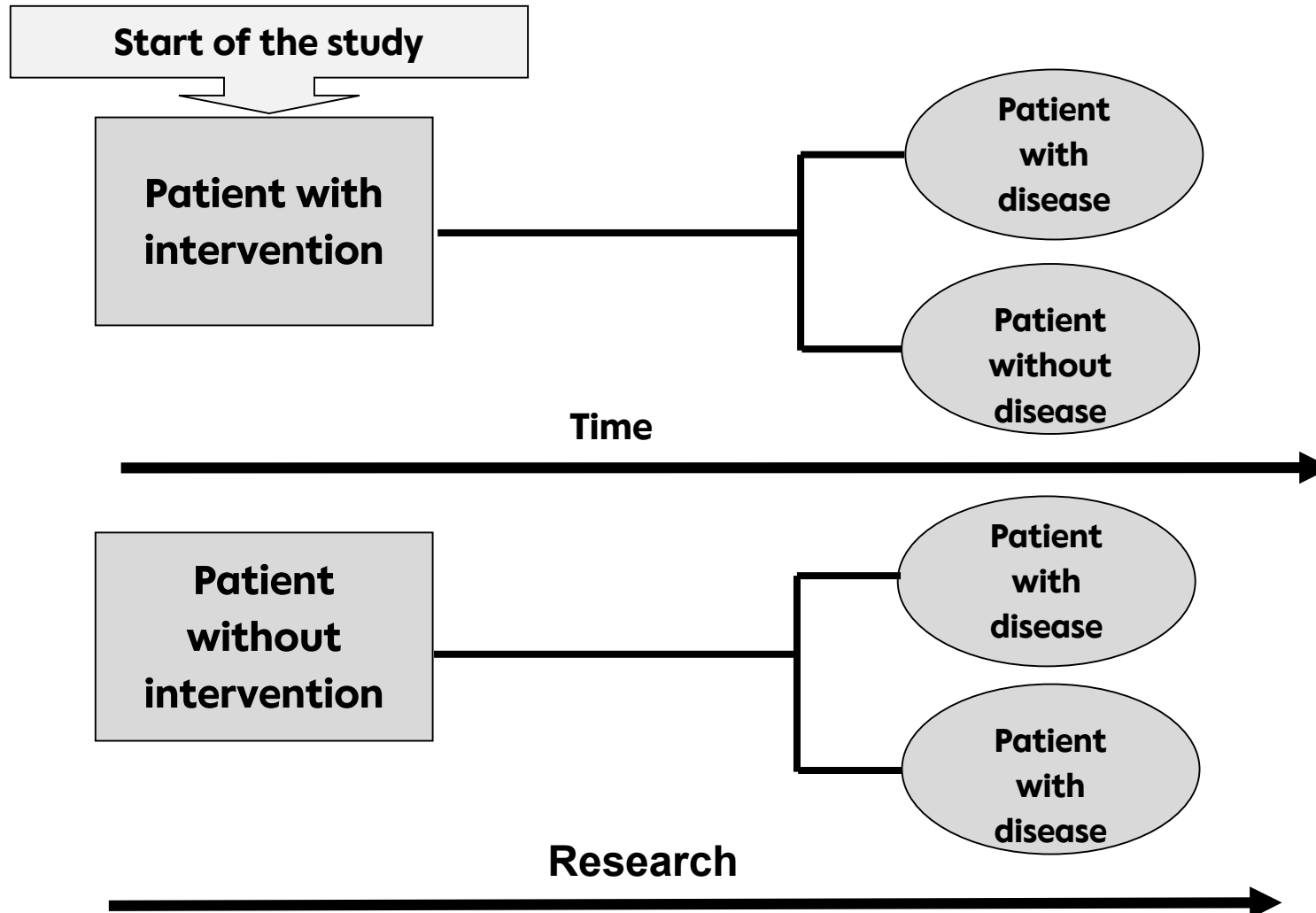
- Clinical intervention studies
- Design of a cohort study
- Experimental exposition (= intervention)
- E.g. pharmaceutical studies
- Robust study designs → Measures to avoid bias

Study designs
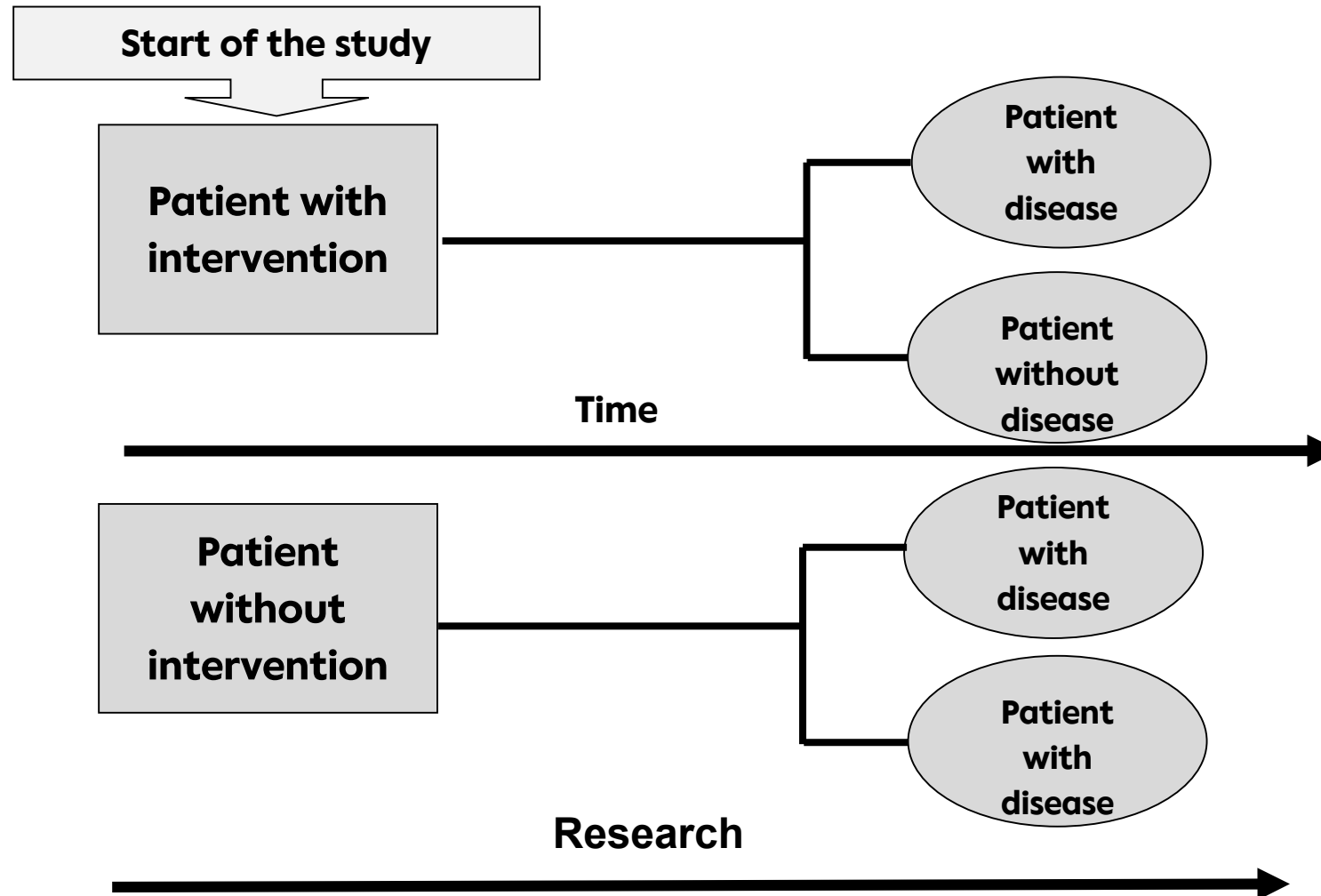
Randomized controlled trials

Bias, errors and confounders

Study designs

Randomized controlled trials
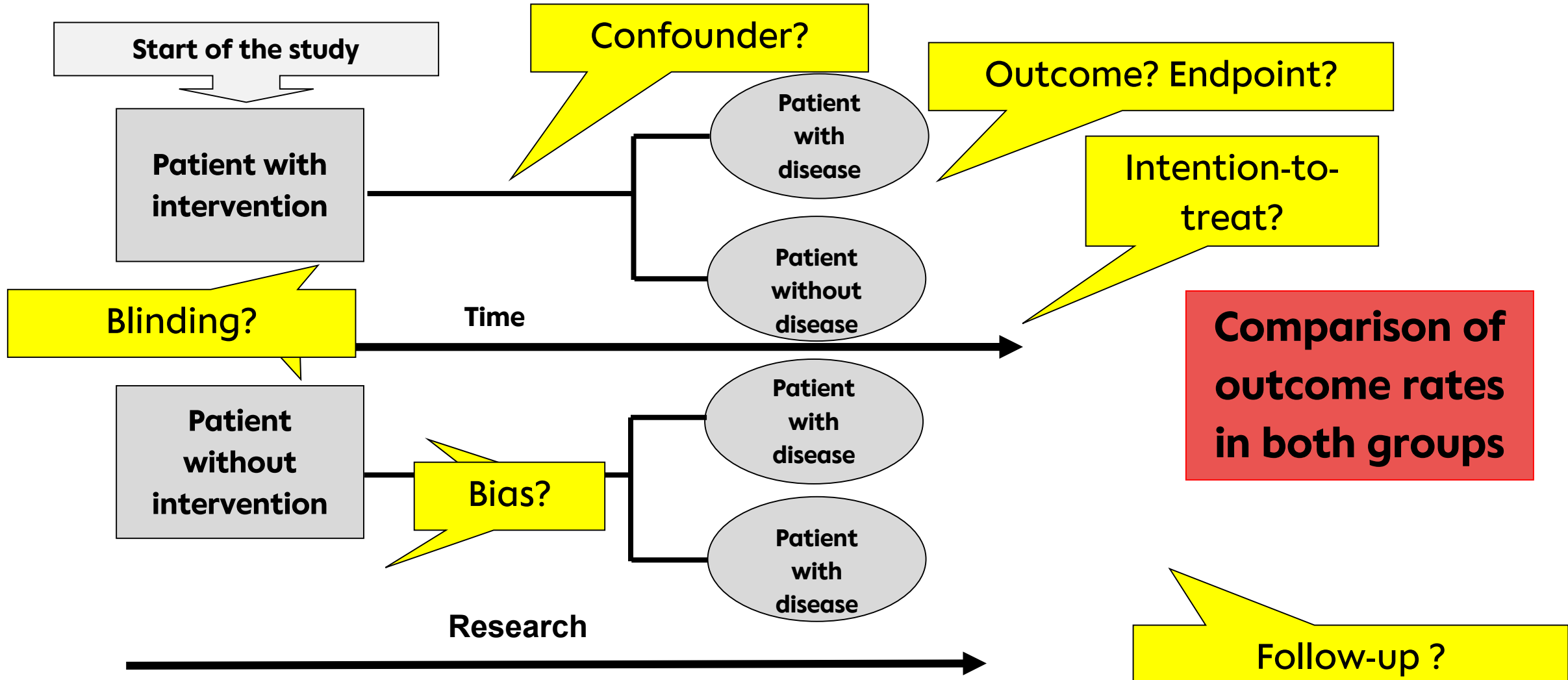
Potential errors in a study

Random errors

- Deviation of an observed measure in a sample from the true value (reality) by chance

- Leads to reduced precision

Sources of random errors

- Sampling error

- Biological variation

- Can be corrected by higher sample size
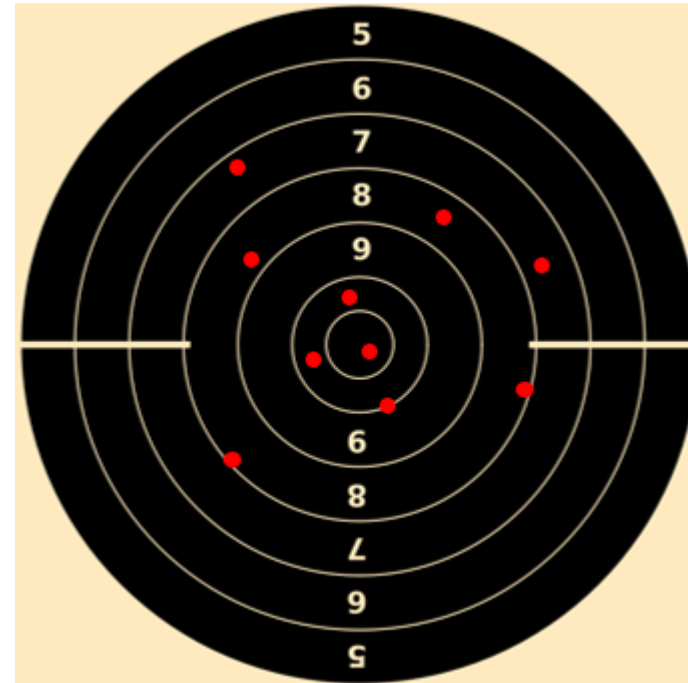
Potential errors in a study

Systematic errors

- Results vary from the true value due to bias, e.g.

    → Selection bias

    → Information bias

- Systematic errors are not corrected by higher sample size
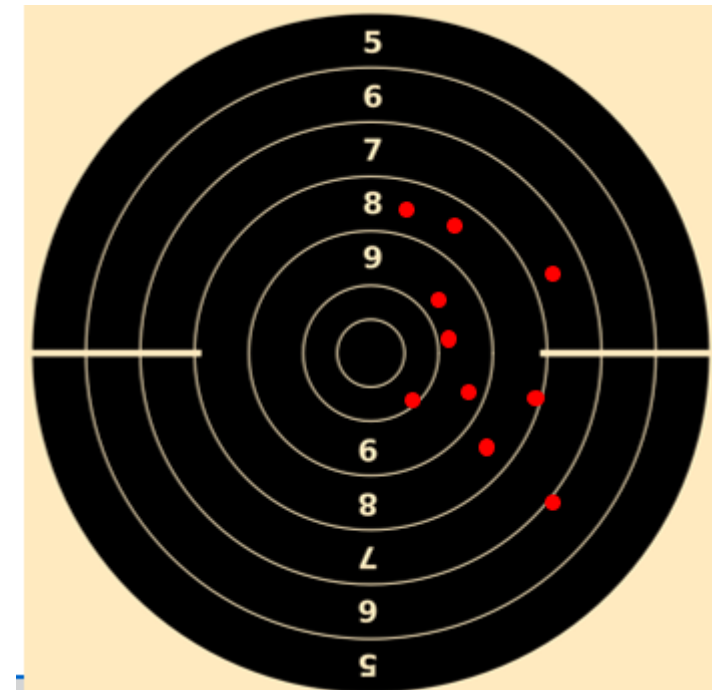
Bias, errors and confounders

Endpoint

- Appropriateness, definitions, no surrogate parameters

- E.g. do not use „clothing size" instead of „body weight" to measure obesity

Follow-up

- Observation time = Time period with monitoring of patients for study endpoints

- Is the observation time long enough for the research question?

Bias, errors and confounders

Confounders

- Factors not considered by the research question

- Association with exposition and endpoint

- Classical confounders: age, gender, comorbidities, smoking, socioeconomic status
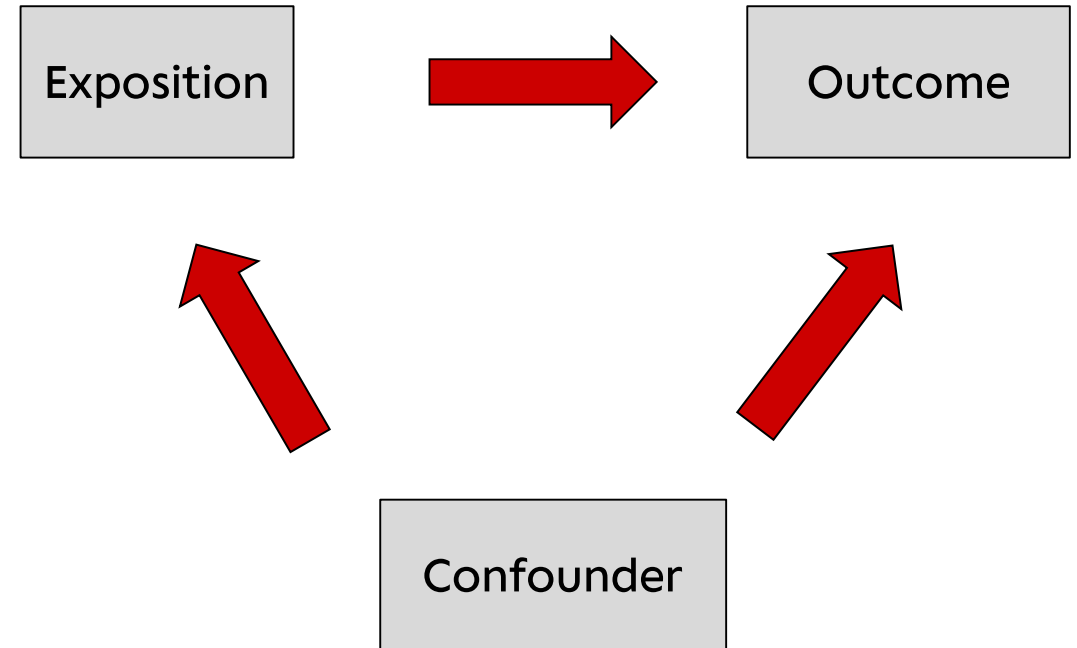
Confounder

Example
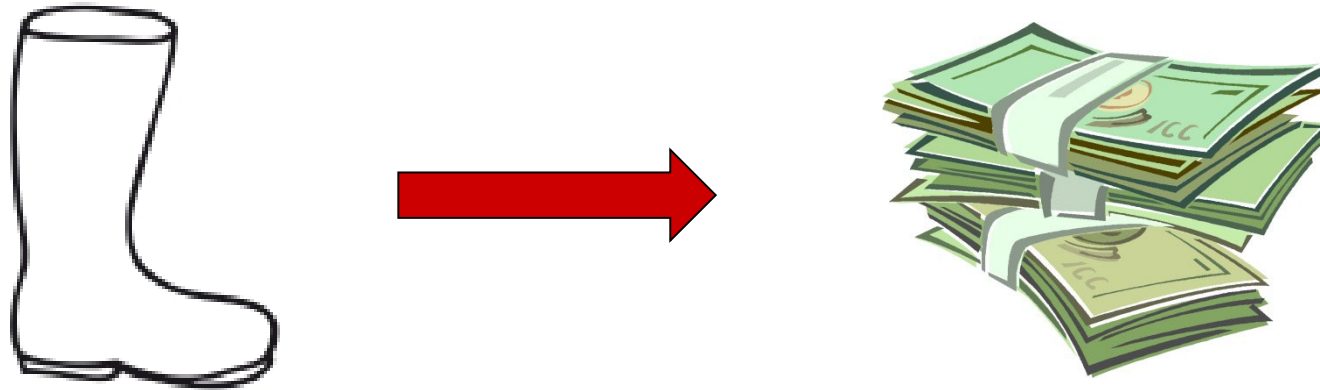
Shoe size	Odds Ratio for Income > 2.500 € Netto
> 44	2.1 (95%CI 1.6 – 3.2)
40 - 44	1.4 (95%CI 1.1 – 1.6)
< 40	1.0 = reference

Confounder

Example
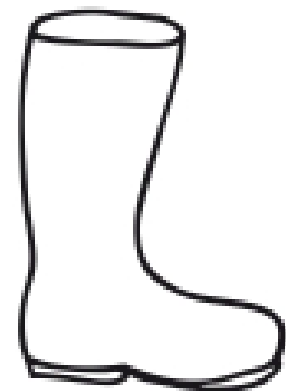
Gender	Men		Women
Shoe size	Odds Ratio for Income > 2.500 € Netto	Shoe size	Odds Ratio for Income > 2.500 € Netto
> 44	1.0 (95%CI 0.8 – 3.2)	> 44	1.1 (95%CI 0.9 – 3.7)
40 - 44	1.1 (95%CI 0.7 – 3.1)	40 - 44	1.0 (95%CI 0.5 – 2.2)
< 40	1.0 = reference	< 40	1.0 = reference

Confounder

Example

Exposition
(shoe size)

Outcome
(income)

Confounder
(gender)
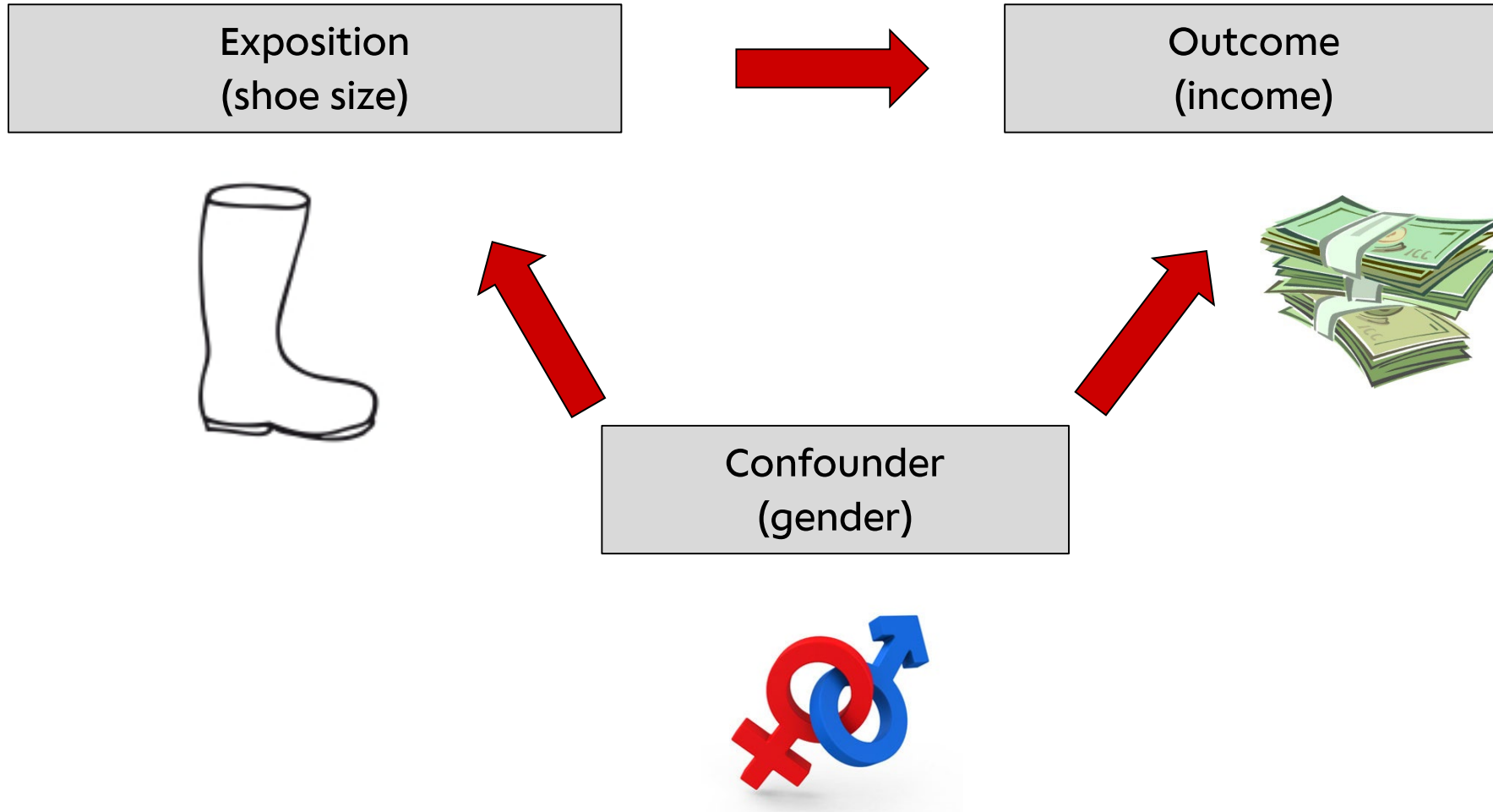
More Bias

Publication bias

- Publication is dependent on result (positive results are more likely to be published)

Outcome reporting bias

- Studies report only outcomes with significant changes (even though other outcomes were also observed)

Language bias

- Most studies are published in English
- Some important findings might be published in other languages (not included in systematic reviews)

Time lag bias

- Studies with signficant results are published first
- Studies with no effect are ofter published later

Measures to reduce bias

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Measures to reduce bias

Blinding

- Concealment of Group Allocation from patient and investigator (double-blind)
- Applies for Intervention studies (RCT), <mark>not applicable for</mark> observational studies

Randomization

- Random allocation of patients to intervention and control
- E.g. by computer-generated randomization
- Applies for Intervention studies (RCT)), <mark>not applicable for</mark> observational studies

Statistical methods

- Adjusting statistical methods to potential confounders
- Stratification of groups (e.g. by gender)
- For cohort studies, case-control studies

Levels of evidence

Level of evidence

Systematic Review Meta-analysis = results of several studies pooled

Randomized Control Trials

Cohort Studies

Case Control Studies

Descriptive Research

Qualitative Research

Animal Research

Expert Opinion

Quality of Research Studies

Study results

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

Lancet Infect Dis 2017; 17: 553–61

Data analysis:

Two investigators (PB and PG)
- extracted data
- populated a predefined evidence table

Appendix 2: Evidence table of the included studies

Authors (year)	Design	Objective	Population, Type of surgery	Setting, Scope	Control, Intervention	Methods	Results	Limitations
Namba et al (2013)[35]	Retrospective review of a prospectively followed cohort	To evaluate risk factors associated with deep surgical site infection (SSI) following total knee arthroplasty in a large U.S. integrated health care system	**No. of Patients:** Total: N=56216 Control group: N=39523 (70.3%) Intervention group: N=16693 (29.7%) **Patient characteristics:** Adult patients: average age: 67.4 yrs **Procedures:** Primary elective total knee arthroplasties only	**Location:** 45 locations in 6 regions in the USA **Dates:** April 1, 2001 – Dec 30, 2009 **Scope:** mutlicentre N=52034 patients (92.6%) received surgical antibiotic prophylaxis (SAP).	**Control group:** Operating rooms (ORs) without laminar airflow (LAF) **Intervention group:** Laminar airflow in the operating room.	**Definitions:** The CDC definitions were used for identifying deep surgical site infections (dSSI). Superficial wound infections were not considered. **Statistical analysis:** Chi-square test (or Fisher's exact test) was used to compare patient, surgeon/ hospital and procedure characteristics between groups with or without dSSI. Continuous variables were compared by using t-test for two independent samples. Univariable Cox proportional hazard models (CpHm) of the association between variables and dSSI were built. All factors found to be independently associated with dSSI were included in the multivariable CpHm. Collinearity and	**Follow-up period:** until the date of diagnosis of dSSI (CDC: 12 months) **lost-to-follow-up:** until date of termination of the insurance policy or death **Control group:** dSSI: 299/39523 (0.8%) (calculated) **Intervention group:** dSSI: 105/16693 (0.6%) LAF: no dSSI: N=16588 (29.7%) (compared with total of no dSSI) dSSI: N=105 (26%) (compared with total of dSSI), P= 0.102 Unvariable (CpHm): Hazard Ratio (HR): 0.83 (95% CI: 0.66-1.04), P=0.1 Multivariable (CpHm): Hazard Ratio (HR): 0.91 (95% CI: 0.71-1.16), P=0.436	Infection risk factors that are not collected in the registry cannot be evaluated (i.e. postoperative wound classification). The investigators did not provide additional information about the ventilation system of the ORs without LAF. Upon request they reported that they have regarded LAF as a "preventive measure" during the surgical procedure within their dataset.

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Study results

Appendix 2: Evidence table of the included studies

Authors (year)	Design	Objective	Population, Type of surgery	Setting, Scope	Control, Intervention	Methods	Results	Limitations
Kakwani et al (2007)[40]	Cohort study	To assess the difference in the re-operation rate following Austin-Moore hemi-arthroplasty between procedures performed under LAF to those performed in conventional (non-LAF) ORs	No. of Patients: TKA: N=435 **Patient characteristics:** 337 females and 96 males Adults, mean age > 80 years **Procedure:** Austin-Moore hemiarthroplasty	**Location:** 1 hospital in the United Kingdom **Dates:** August 2000 – July 2004 **Scope:** single centre SAP (three doses of intravenous cefuroxime, 1.5 g at induction and two post-operative doses of 750 mg at 8 and 16 h after the procedure) and water-impervious surgical gowns and drapes were used in all cases.	**Control group:** Operations performed in ORs equipped with a conventional ventilation system **Intervention:** Operations performed in ORs equipped with a LAF ventilation system	**Definitions:** Any revision for infection. **Statistical analysis:** The Fisher's exact test and Wilcoxon test were used to evaluate the difference in outcomes between the groups	**Follow-up period:** 1 year **Control group:** Reoperation for infection: N=9/223 (4%) **Intervention group:** Reoperation for infection: N=0/212 (0%)	Very limited number of events. The investigators did not describe the number of patients that were lost to follow-up or the attrition rate.

CpHm: Cox proportional hazard model; adj: adjusted; dSSI: deep surgical site infections; LAF: laminar airflow; ORs: operating rooms; SSI: surgical site infection; THA: total hip arthroplasty; TKA: total knee arthroplasty; RR: relative risk; OR: odds ratio; CI: confidence interval; HEPA (filter): high efficiency particulate air (filter); "Greenhouse": operating room environment that refers to the ultraclean ventilation systems with a tent within the room and body exhaust suits as described by Dr John Charnley in the 1960s.

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5

Critically appraise the evidence:
Quality Assessment – Risk of Bias –
Study designs

What should be reported in well-conducted trial?

Domain	Evaluation
Research question	Well formulated? Specific? Up to date?
Study design	Randomized controlled trial Cohort study Case- control study Meta-analysis
Case definition	Appropriate? Sensitivity? Specificity?
Inclusion- / exclusion criteria	Appropriate?
Comparability of the groups?	Reported? Differences?
Follow up?	Conducted? Reported? Appropriate?
Statistics?	Are the methods appropriate? Power calculation? Interntion to treat analyis?
Outcome	Appropriate? Surrogate parameter?
Compliance, costs, side effects	Reported?
Confounder, Bias	Discussed?

Tools for critical appraisal of evidence

- Cochrane Bias Methods Group (BMG) für RCT und Non-RCTs

- **Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)**

- Risk Of Bias In Non-Randomized Studies - of Interventions (ROBINS-I)

- NHS CASP Checklisten

  → RCT

  → Observational studies

  → Systematische Reviews

- Qualitative Reviews

- Jadad Scale (RCT)

- DIMDI: Deutsches Institut für medizinische Dokumentation und Information

Revised Cochrane risk-of-bias tool for randomized trials

(RoB 2)

5 domains for critical assessment of potential bias

- Randomization

- Deviation from allocation to the intervention / compliance

- Missing data

- Bias in outcome measurement

- Selection of reported results
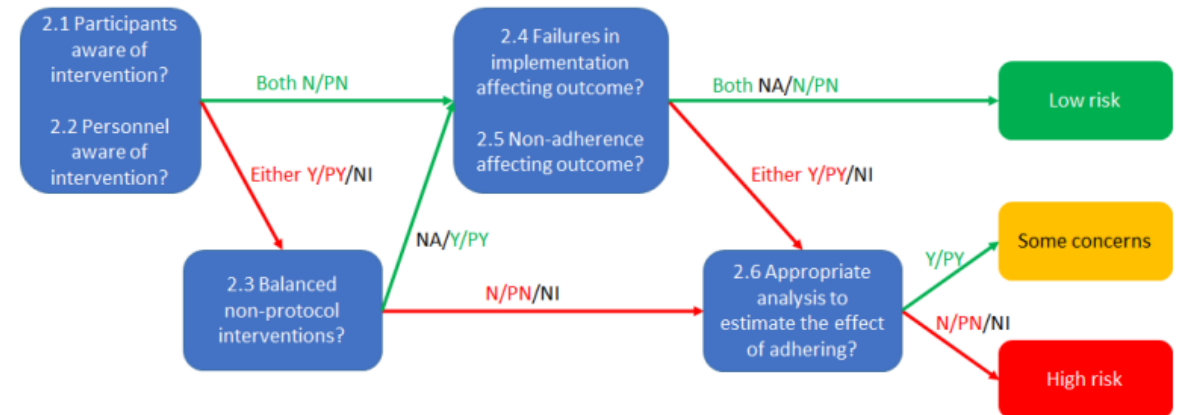
Algorithm for suggested judgement of risk of bias due to deviations from the intended interventions (effect of adhering to intervention)

Overall risk-of-bias judgement	Criteria
Low risk of bias	The study is judged to be at **low risk of bias for all domains** for this result.
Some concerns	The study is judged to raise **some concerns** in at least one domain for this result, but not to be at high risk of bias for any domain.
High risk of bias	The study is judged to be at **high risk of bias** in at least one domain for this result. Or The study is judged to have **some concerns** for **multiple domains** in a way that substantially lowers confidence in the result.
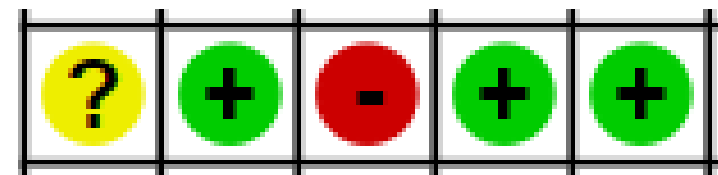
Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

Data analysis:

Two investigators (PB and PG)

- extracted data
- populated a predefined evidence table

All critically appraised the retrieved studies:

- Newcastle–Ottawa Quality Assessment Scale (NOS) for cohort studies
- disagreements were resolved through discussion
- Meta-analyses of available comparisons were done with RevMan (v.5.3)

Newcastle – Ottawa Quality Assessment Scale
for cohort studies

Selection

1) Representativeness of the exposed cohort
a) truly representative of the average _____ (describe) in the community ★
b) somewhat representative of the average _____ in the community ★
c) selected group of users eg nurses, volunteers
d) no description of the derivation of the cohort

2) Selection of the non exposed cohort
a) drawn from the same community as the exposed cohort ★
b) drawn from a different source
c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure
a) secure record (eg surgical records) ★
b) structured interview ★
c) written self report
d) no description

4) Demonstration that outcome of interest was not present at start of study
a) yes ★
b) no

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Newcastle – Ottawa Quality Assessment Scale
for cohort studies

Comparability

1) Comparability of cohorts on the basis of the design or analysis

a) study controls for _____ (select the most important factor) ★

b) study controls for any additional factor ★
   (This criterium could be modified to indicate specific control for a second important factor)

Newcastle – Ottawa Quality Assessment Scale
for cohort studies

Outcome

1) Assessment of outcome
a) independent blind assessment ★
b) record linkage ★
c) self report
d) no description

2) Was follow-up long enough for outcomes to occur
a) yes (select an adequate follow up period for outcome of interest) ★
b) no

3) Adequacy of follow up of cohorts
a) complete follow up - all subjects accounted for ★
b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ %★
   (select an adequate %) follow up, or description provided of those lost)
c) follow up rate < ____% (select an adequate %) and no description of those lost
d) no statement

Quality of cohort studies included in the systematic review

(Newcastle-Ottawa Quality Assessment Scale)

Authors (year)	Selection 1	Selection 2	Selection 3	Selection 4	Comparability 1	Comparability 2	Outcome 1	Outcome 2	Outcome 3	Total
Namba et al. (2013)	★	★	★	--	★	★	★	★	--	7★
Namba et al. (2012)	★	★	★	--	★	★	★	★	★	8★
Song et al. (2012)	★	★	★	--	★	★	★	★	--	7★
Jeong et al. (2013)	★	★	★	--	★	★	★	★	--	7★
Bosanquet et al. (2013)	--	★	★	★	★	★	★	--	--	6★
Pedersen et al. (2010)	★	★	★	--	★	★	★	★	--	7★
Dale et al. (2009)	★	★	★	--	★	★	★	★	--	7★
Brandt et al. (2008)	★	★	★	--	★	★	★	★	--	7★
Breier et al. (2011)	★	★	★	--	★	★	★	★	--	7★
Hooper et al. (2011)	★	★	★	--	--	--	★	★	--	5★
Miner et al. (2007)	★	★	★	--	--	--	★	★	--	5★
Kakwani et al. (2007)	★	★	★	--	★	★	★	★	--	7★

Appendix 4: Comparisons

Forest plot of odds ratio for deep SSI comparing laminar airflow *vs.* conventional ventilation in total hip arthroplasty (comparison 1a)

Study or Subgroup	Laminar airflow Events	Total	Conventional ventilation Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Brandt 2008	242	17657	99	10966	16.1%	1.53 [1.21, 1.93]
Breier 2011	356	29530	77	11682	15.9%	1.84 [1.44, 2.36]
Dale 2009	324	45620	260	48338	17.1%	1.32 [1.12, 1.56]
Hooper 2011	25	16990	21	34495	10.1%	2.42 [1.35, 4.32]
Kakwani 2007	0	212	9	223	0.9%	0.05 [0.00, 0.92]
Namba 2012	46	8478	109	22013	14.2%	1.10 [0.78, 1.55]
Pedersen 2010	517	72423	80	8333	16.0%	0.74 [0.59, 0.94]
Song 2012	34	2037	16	1149	9.8%	1.20 [0.66, 2.19]
Total (95% CI)		**192947**		**137199**	**100.0%**	**1.29 [0.98, 1.71]**
Total events	1544		671			

Heterogeneity: Tau² = 0.11; Chi² = 41.24, df = 7 (P < 0.00001); I² = 83%
Test for overall effect: Z = 1.83 (P = 0.07)

SSI: surgical site infection; M-H: Mantel-Haenszel; CI: confidence interval

Funnel plot for comparison 1a: Laminar airflow ventilation *vs.* conventional ventilation in total hip arthroplasty

Total hip arthroplasty

No publication bias detected; outlier: small single centre study (N=435; Kakwani and colleagues[40])

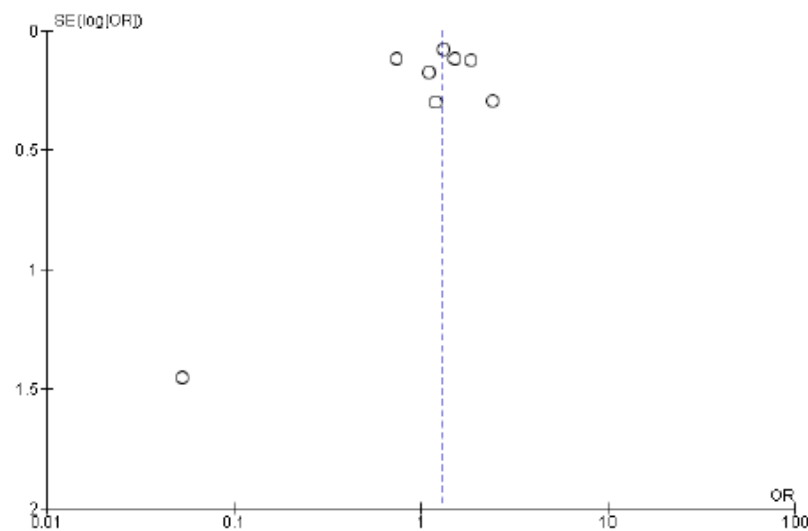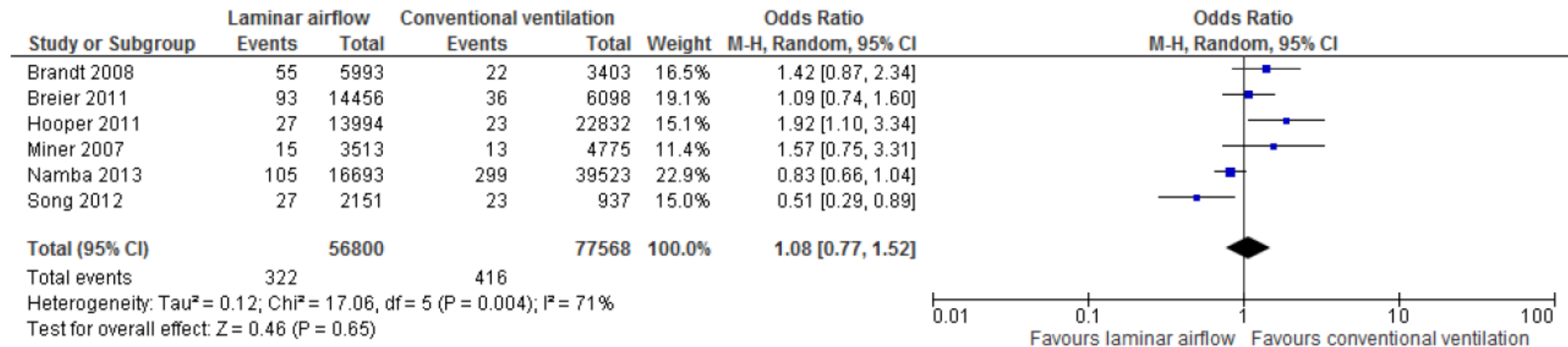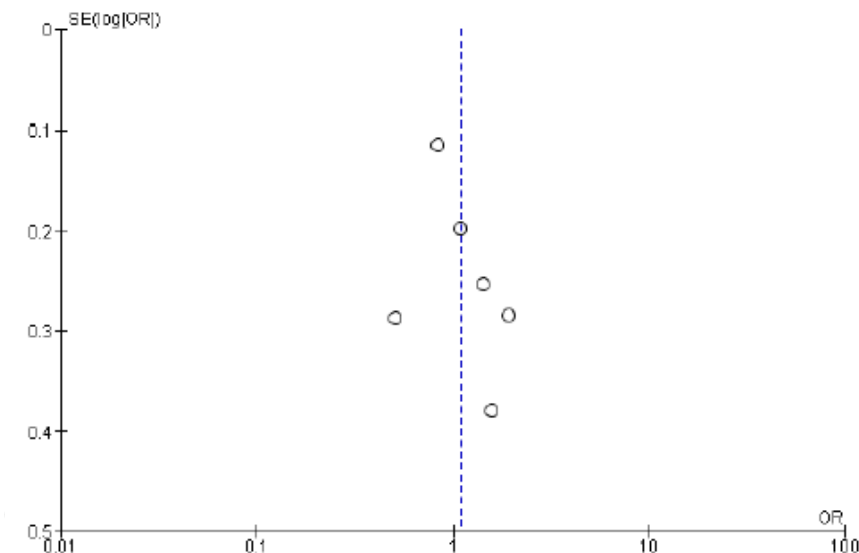## Forest plot of odds ratio for deep SSI comparing laminar airflow *vs.* conventional ventilation in total knee arthroplasty (comparison 1b)

	Laminar airflow		Conventional ventilation			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Brandt 2008	55	5993	22	3403	16.5%	1.42 [0.87, 2.34]	
Breier 2011	93	14456	36	6098	19.1%	1.09 [0.74, 1.60]	
Hooper 2011	27	13994	23	22832	15.1%	1.92 [1.10, 3.34]	
Miner 2007	15	3513	13	4775	11.4%	1.57 [0.75, 3.31]	
Namba 2013	105	16693	299	39523	22.9%	0.83 [0.66, 1.04]	
Song 2012	27	2151	23	937	15.0%	0.51 [0.29, 0.89]	
Total (95% CI)		56800		77568	100.0%	1.08 [0.77, 1.52]	
Total events	322		416				

Heterogeneity: Tau² = 0.12; Chi² = 17.06, df = 5 (P = 0.004); I² = 71%
Test for overall effect: Z = 0.46 (P = 0.65)

Favours laminar airflow   Favours conventional ventilation

SSI: surgical site infection; M-H: Mantel-Haenszel; CI: confidence interval

Funnel plot for comparison 1b: Laminar airflow ventilation *vs.* conventional ventilation in total knee arthroplasty
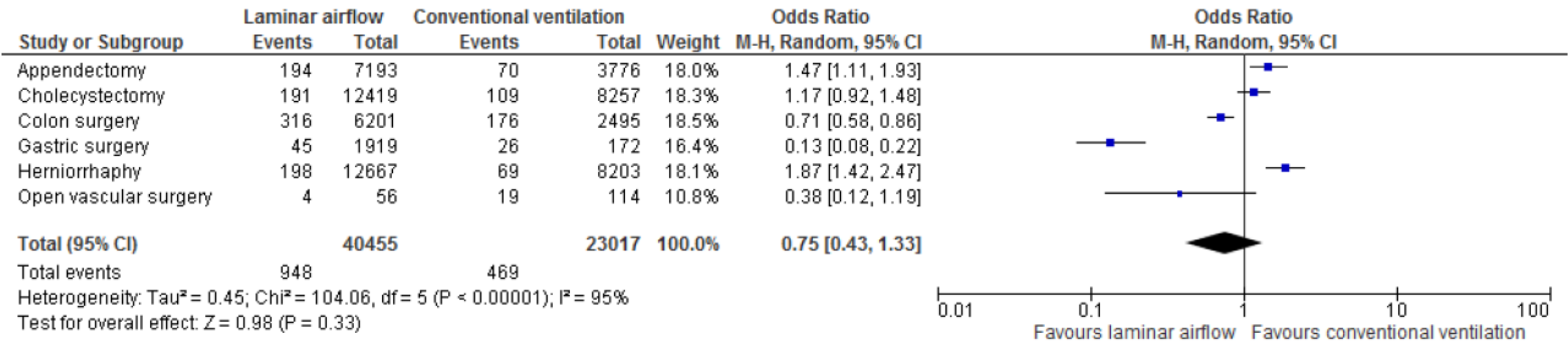
Total knee arthroplasty

www.freepik.com

No publication bias detected

Forest plot of odds ratio for overall SSI comparing laminar airflow vs. conventional ventilation in abdominal and open vascular surgery (comparison 1c)

Study or Subgroup	Laminar airflow Events	Total	Conventional ventilation Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Appendectomy	194	7193	70	3776	18.0%	1.47 [1.11, 1.93]
Cholecystectomy	191	12419	109	8257	18.3%	1.17 [0.92, 1.48]
Colon surgery	316	6201	176	2495	18.5%	0.71 [0.58, 0.86]
Gastric surgery	45	1919	26	172	16.4%	0.13 [0.08, 0.22]
Herniorrhaphy	198	12667	69	8203	18.1%	1.87 [1.42, 2.47]
Open vascular surgery	4	56	19	114	10.8%	0.38 [0.12, 1.19]
Total (95% CI)		40455		23017	100.0%	0.75 [0.43, 1.33]
Total events	948		469			

Heterogeneity: Tau² = 0.45; Chi² = 104.06, df = 5 (P < 0.00001); I² = 95%
Test for overall effect: Z = 0.98 (P = 0.33)

Odds Ratio M-H, Random, 95% CI
Favours laminar airflow   Favours conventional ventilation

Funnel plot for comparison 1c: Laminar airflow ventilation *vs.* conventional ventilation in abdominal and open vascular surgery

No publication bias detected
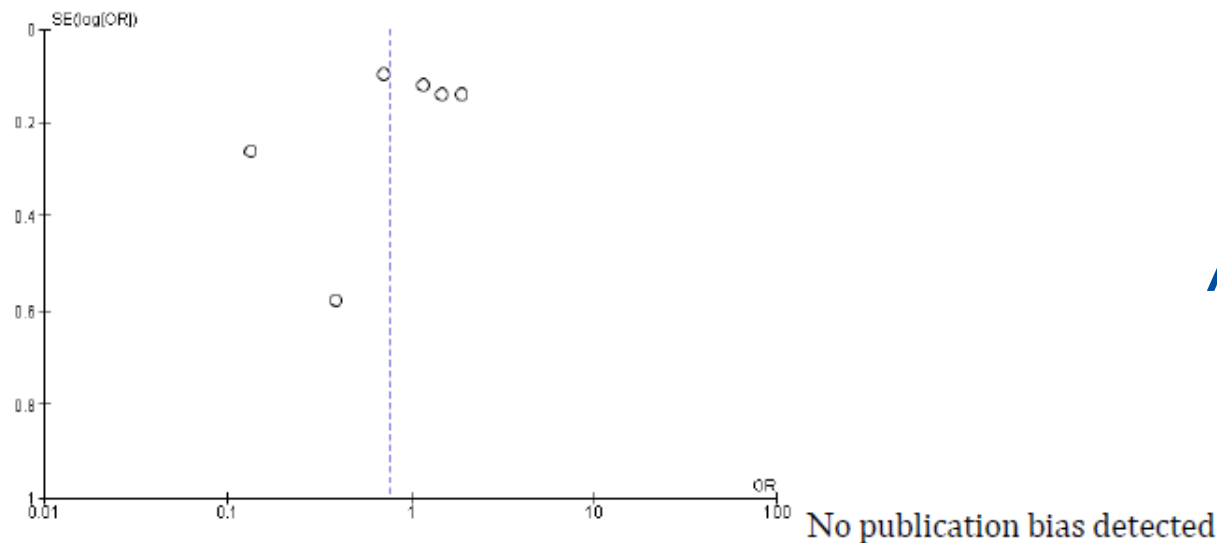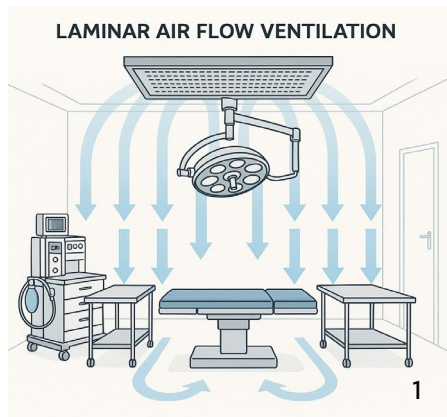
Abdominal and open vascular surgery

6

Apply the evidence to the problem: transferability / generalizability

CHARITÉ

Case Example

EbM

- As an hospital ventilation engineer you are consulted for the construction of a new operating theatre in the orthopedic department of a hospital

    → Which ventilation system (laminar air flow / conventional turbulent ventilation) do you recommend based on the effect on surgical site infections (SSI)

    → Which other factors should be taken into account?

LAMINAR AIR FLOW VENTILATION

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

[1] Generated with ChatpGPT, 19/06/2025, prompts: laminar air ventilation, operating theatre

Which ventilation system do you favor?

Using Evidence-based medicine (EbM) for clinical decision making☐ 549387

Which ventilation system (laminar air flow / conventional turbulent ventilation) do you recommend based on the effect on surgical site infections (SSI)? 💬

Dies ist eine Multiple-Choice-Umfrage.

Diese Umfrage läuft. Teilnahme ist über pingo.coactum.de/549387 möglich.
Ende der Abstimmzeit: Mittwoch, 02. Juli 2025, 13:53 Uhr.

Antwortmöglichkeiten:

0 Laminar air flow

0 Conventional turbulent ventilation

0 I do not know

QR Code #549387

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OR for SSI, LAF vs. turbulent ventilation:

- Total hip arthroplasty (8 cohort studies):   1.29 (95% CI 0.98 – 1.71)

- Total knee arthroplasty (6 cohort studies):   1.08 (95% CI 0.77 – 1.52)

- Abdominal and open vascular surgery (3 cohort studies):   0.75 (95% CI 0.43–1.33)

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➡ **Laminar airflow is no preventive measure to reduce the risk of SSIs**

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Limitations:

- Most data were obtained from national surveillance systems and registries, which were not designed to address whether laminar airflow systems decrease the risk of SSIs

- Surveillance databases and registries might not include data for possible confounders:
  - Smoking
  - Obesity
  - Intraoperative temperature
  - Glycaemia
  - Stopping bleeding using cautery

- Some studies did not provide information about the ventilation systems used in the ORs without LAF
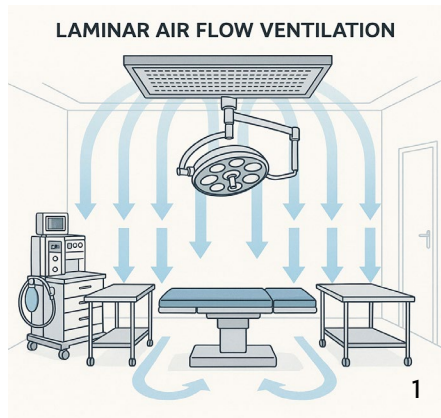
More meta-analyses:

1. Lv et al.
    The possible effect of different types of ventilation on reducing operation theatre infections:
    A metaanalysis.
    Ann R Coll Surg Engl (2021) 103: 145.

2. Bao J, Li J.
    The effect of type of ventilation used in the operating room and surgical site infection:
    A meta-analysis.
    Infect Control Hosp Epidemiol. (2021) 43: 1316.

3. Ouyang et al.
    Laminar airflow ventilation systems in orthopaedic operating room do not prevent surgical site
    infections: a systematic review and meta-analysis.
    Journal of Orthopaedic Surgery and Research (2023) 18: 572.

➜ **Laminar airflow is no preventive measure to reduce the risk of SSIs**

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Thank you

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