Developing a Good Research Question and Study Design

Dr. Julia Wytsma and Dr. Temesgen Beyene and Dr. Victoria Myers August 2023



Outline

- Review the 'anatomy and physiology' of a good research question
- Apply these principles to example questions
- Question workshop of second year residents' proposed questions

A Trip Back In Time...

Clinical Epidemiology 1

Introduction

Written by: Jennifer Bryan, MD, MA, FRCP With course and slide contributions by: Drs. Cheryl Hunchak, Lisa Puchalski-Ritchie, Nazanin Meshkat, Anne Aspler University of Toronto, Division of Emergency Medicine

How to Develop a Research Plan

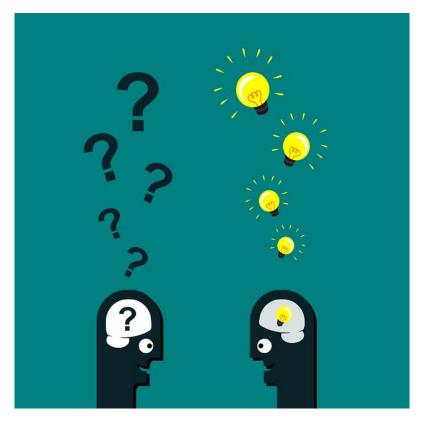
- Research Question question addressed
- Background and significance why is the question important?
- Design time frame, epidemiologic design
- Subjects who? selection criteria and method
- Variables what will be measured? predictors, outcomes, confounds
- Analysis how will data be analyzed? sample size?

How to Develop a Research Plan

Research Question

- Background and significance
- Design
- Subjects
- Variables
- Analysis

Where do research questions come from?



Origins of a Question

- Curiosity
- Patient care
- Speaking to experts
- Conferences

•

• Skeptical attitude

- Teaching juniors
- Reading journals
- Mentors
- Systematic review
- Answering a question

Develop a curious, questioning and critical approach to delivery of Emergency Medicine care – recurrently question current practice!

Curiosity – "I wonder"

•I wonder....

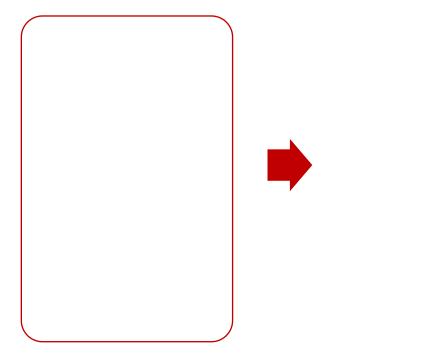
If we could treat hospital acquired pneumonia with a shorter duration of antibiotics?

Whether workers from certain industries are at greater risk of covid-19 infection?

If delayed presentation to hospital affects outcome of patients presenting with STEMI?

If ED POCUS availability affects time to OR in trauma patients?

Origins of a Question



Narrowing down a concern to a question

Should people drink more coffee?

How often do EM residents drink coffee? Does drinking coffee lower the risk of developing diabetes? Is there an increased risk of high cholesterol from excess caffeine?

Does caffeine in tea have the same effect on risk of developing diabetes as coffee?

Do people with a family history of type 2 diabetes who drink a lot of coffee have a lower risk of developing diabetes than those who rarely drink coffee?

Narrowing down a concern to a question

Should people drink more coffee?

How often do EM residents drink coffee? Does drinking coffee lower the risk of developing diabetes? Is there a risk of increased cholesterol from excess caffeine? Does drinking caffeine in tea have the same effect on risk of developing diabetes as coffee?

> Among a sample of patients seen in TASH ED what proportion of patients with and without a diagnosis of DM report drinking more than 3 servings of coffee a day when interviewed?

Master the literature

- Literature review provides context and rationale
 - What do we already know?
 - What studies have been done? How?
 - Has the question been answered well? Read critically!
 - Who do results apply to? Do they apply to your population?
 - What is unknown?

Does the evidence apply in your setting?

AfJEM



Contents lists available at ScienceDirect

African Journal of Emergency Medicine

Research primer

Developing a research question: A research primer for low- and middleincome countries

Rob D. Mitchell^{a,b,*}, Gerard M. O'Reilly^{a,b}, Georgina A. Phillips^{b,c}, Trina Sale^d, Nobhojit Roy^{b,e,f}

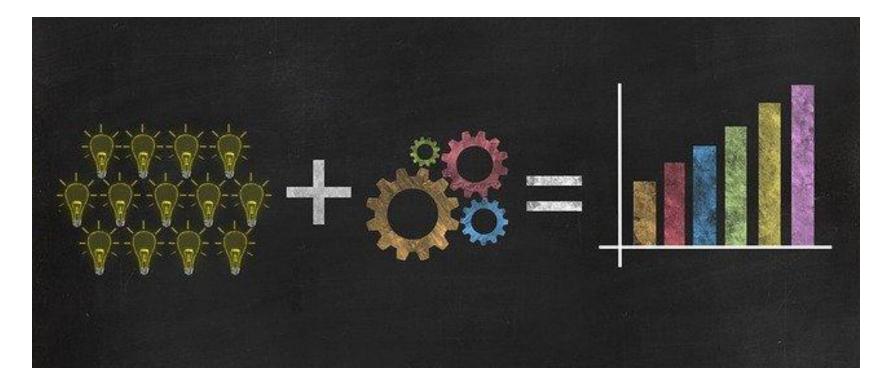
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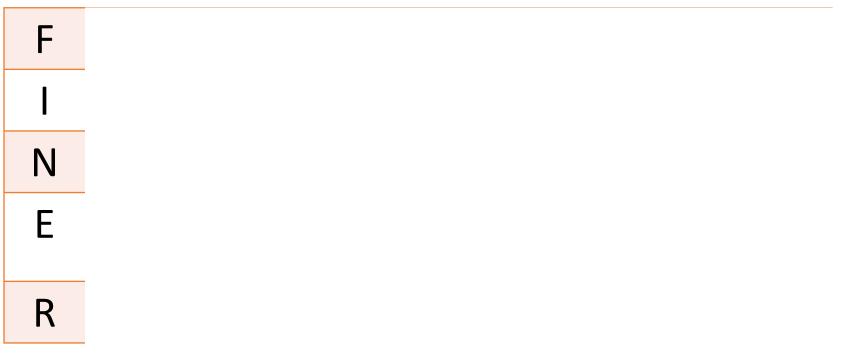
"Is this diagnostic or treatment approach, which is (or is not) supported by research in a well-resourced setting, ...

- 1. Relevant to my local epidemiology
- 2. Relevant to my emergency department
- 3. Available
- 4. Feasible
- 5. Safe
- 6. Effective
- 7. Good value for money
- 8. Culturally appropriate, and
- 9. Of a public health benefit
- ... in my resource-limited setting?"

What makes a good research question?



"FINER" criteria for a good research question



Source: "Designing Clinical Research 4th Ed." Hulley, S.B et al. 2013.

"FINER" criteria for a good research question

F	FEASIBLE Adequate subjects and expertise, affordable and fundable, manageable scope and time
I	INTERESTING Answering the question is interesting to investigator and colleagues
Ν	NOVEL Contributes new information, contributes/refutes/extends previous findings
Е	ETHICAL Should not pose unacceptable physical risk or invasion or privacy – must pass IRB
R	RELEVANT Impacts clinical practice, scientific knowledge, healthy policy, or future research
	Source: "Designing Clinical Research 4 th Ed." Hulley, S.B et al. 2013.

PICO: the anatomy of a clinical question

Population, patient, problem

- Precise and brief description of subjects
- Participants should be relevant to study's target population

Intervention (controlled) or exposure (not controlled)

- Therapy (medication, procedure), delivery of therapy (who, where)
- Risk factor, prognostic factor, etiology
- Diagnostic test or result

Comparison or control

• What is the alternative to the intervention?

Outcome

- A specific outcome at a point in time
- Should be something that matters to patients or clinicians

Source: The Centre for Evidence-Based Medicine https://www.cebm.ox.ac.uk/resources/ebm-tools/asking-focused-questions

Common Question Pitfalls

- Not clearly defined by PICO
- Not focused: pick one main PICO question
- Not feasible: scope too large, data difficult to retrieve
- Too many outcomes studied

In Summary...

- Be curious and read the literature around your interest area, discuss with mentors and experts
- Narrow you interest down to define a PICO question, then focus your literature search
- Decide how to best answer the question and write your proposal...

Now time for some practice....

Many of your patients with STEMI are brought by family or private taxi to your ED and seem to have long delays in their transport time. Some arrive via EMS.

You wonder if method of transport to hospital affects outcomes of STEMI patients.

What is your PICO question?

- P = patients with STEMI presenting to TASH ED
- I = arrival by ambulance
- C = arrival by other means
- O = survival to hospital discharge

For adult patients with STEMI presenting to TASH ED, are those arriving by ambulance, compared to those not arriving by ambulance, more likely to survive to hospital discharge?

Your patient had a falling down accident and has a small hemothorax. You wonder if it should be drained or managed conservatively. What is your PICO question?

- P = trauma patients with closed small volume hemothorax (<250ml)
- I = chest tube drainage
- C = conservative management
- O = hospital length of stay

For adult patients with chest wall trauma and a closed small volume hemothorax, does chest tube drainage, compared to conservative management, improve hospital length of stay?

Some of your own examples?

You notice many neurosurgical patients have prolonged ED stays prior to being transferred to the Neurosurgery service (admitted to the ward or brought to the OR).

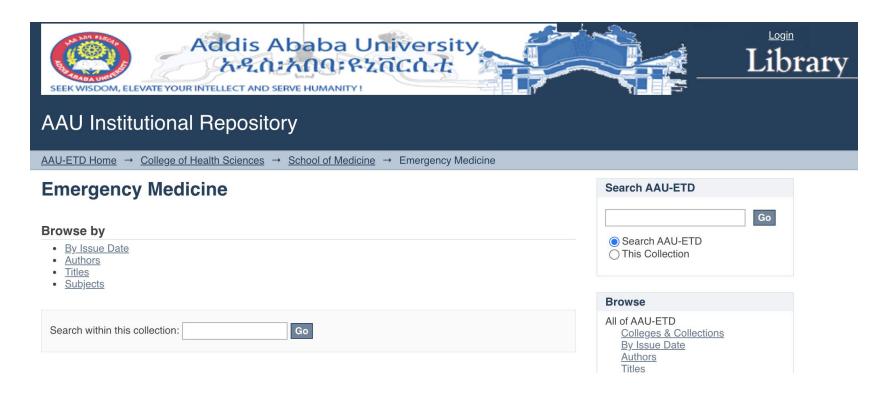
You wonder if this affects their outcome.

What is your PICO question?

- P = patients in the ED consulted to neurosurgery
- I = ED stay greater than 24 hours after consultation
- C = ED stay less than 24 hours after consultation
- O = disability score on discharge

Among neurosurgical patients kept in the ED, are those who spend over 24 hours in ED after consultation, when compared with those who spend less time, at greater risk of disability?

Inspiration from your predecessors...



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UTILIZATION OF DIAGNOSTIC FAST ULTRASOUND IN DETECTING INTRA-PERITONEAL FREE FLUID COLLECTION DONE IN TASH ED FOR ABDOMINAL TRAUMA PATIENTS

BY Dr. TINBIT YEHUALAESHET

EMERGENCY MEDICINE AND CRITICAL CARE RESIDENT

"OBJECTIVE- This study will generally assess the utilization of FAST in abdominal trauma patients and the diagnostic accuracy in intra-op findings and to validate the use of FAST US in all abdominal trauma patients.

METHODS AND MATERIALS- This is a prospective cross-sectional study to assess the utilization of bedside FAST US and the diagnostic accuracy of bedside FAST US in detecting intraperitoneal collection for patients presenting to the TASH FD with abdominal trauma and who are hemodynamically stable or unstable. FAST performed by emergency medicine senior (R3) residents or attending emergency physicians in the ED will be taken and compared with the results of formal ultrasound, CT scan or intra-op findings."

- P: Patients presenting to TASH ED with abdominal trauma
- I: FAST ultrasound scan by ED provider
- C: Ultrasound or CT with radiology, intra-operative findings
- O: Detection of intra-abdominal bleeding

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PAIN TREATMENT PRACTICE AND ITS IMPACT ON PATIENT SATISFACTION IN EMERGENCY DEPARTMENT: EXPERIENCE FROM TIKUR ANBESSA SPECIALIZED HOSPITAL, ETHIOPIA, 2019.

Principal Investigator

Demmelash Gezahegn Nigatu, MD

ADVISORS

Professor Aklilu Azazh (Internist, Professor of Emergency Medicine)

Dr. Tigist Zewdu (Assistant Professor of Emergency Medicine)

"Objective: The general objective of this study is to assess the pain treatment practice and its impact on patient satisfaction in the emergency department of Tikur Anbessa Specialized Hospital, July 15-19, 2019 Addis Ababa Ethiopia.

Methodology: Single centered, prospective, observational study for a continuous 24 hours of 5 days was conducted on total of 106 patients with history of recent pain. Numeric Rating Scale was used to assess patient's severity of pain. Each patient was evaluated twice, initially at triage and 2-4 hours after arrival. The desire for analgesics was assessed at triage and Patient's level of satisfaction was also assessed during the second evaluation."

- P: Patients presenting to TASH ED with recent pain
- I: Analgesia prescription
- C: No analgesia prescription
- O: Patient satisfaction, pain severity

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DEPARTMENT OF EMERGENCY AND CRITICAL CARE MEDICINE

Thesis on accuracy of emergency and critical care residents in interpreting emergency cranial CT scans as compared to neuroradiologist experience from two medical schools in Ethiopia

Nathan Muluberhan (MD, EMCC RIII)

"Objectives: was to determine competence of emergency medicine residents of TASH in the assessment of cranial CT scans, May 2019

Methodology: A prospective cross-sectional study employed on the EMCC residents of AAU, and St' Paul MMC. Data collected from May 2019-June 2019 by using structured questionnaires as well as through radiant view software by displaying the full slices of the cranial CT scans."

ADVISORS: Temesgen Beyene (MD, & Ass. Prof. of Emergency and Critical care)

- P: sample CT scans on computer
- I: ED resident interpretation of CT head
- C: neuroradiologist interpretation of CT head
- O: detection of correct pathology



COLLAGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE DEPARTMENT OF ANAESTHESIA

Prophylactic effect of sub hypnotic dose of propofol in the prevention of Intraoperative post-delivery nausea and vomiting in mothers undergoing elective caesarean section under spinal anaesthesia at ALERT referral hospital, Addis Ababa, Ethiopia, 2020, aprospective cohort study. "Objective: To assess the prophylactic effects of sub-hypnotic dose of propofol in preventing the occurrence and severity of post-delivery nausea and vomiting in parturients who underwent elective Caesarean Section under Spinal Anaesthesia

Methods: A prospective cohort study was done at Alert Referral hospital on 62 Parturients who came for elective caesarean section under spinal anaesthesia by using systematic random sampling method. Incidence of nausea and vomiting, severity of nausea and use of rescue anti emetic were assessed."

P: patients undergoing elective c/s with spinal anesthesia

- I: sub-hypnotic dose of propofol
- C: no propofol

O: incidence of nausea and vomiting, severity, use of rescue medication

Some more examples:

<u>Clinical profile of peripheral arterial disease at emergency department in Tikur Anbesa Specialized hospital,</u> <u>Addis Abeba, Ethiopia.</u> Tesfagabr, Shewit (Addis Abeba University, 2018-06)

<u>Clinical features and outcome of acute Coronary syndrome in patients presenting to the emergency</u> <u>departments in Addis Abeba, Ethiopia.</u> Dr.Wakwaya, Rediet (Addis Abeba University, 2019-08)

<u>Prevalence and risk factors of delirium in intensive care unit and, emergency department of Tikur Anbessa</u> <u>specialized university hospital.</u> Anteneh, Meron (Addis Abeba University, 2019-08)

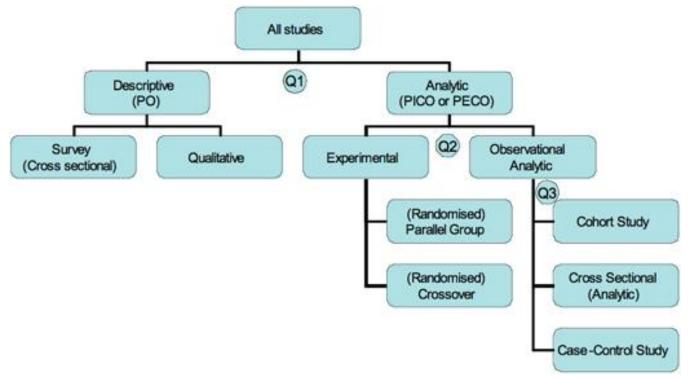
Pattern and outcome of Acute Kidney Injury in Tikur Anbessa specialized hospital Kefyalew, Merahi (Addis Abeba University, 2019-08)

From Dr. Merahi's report:

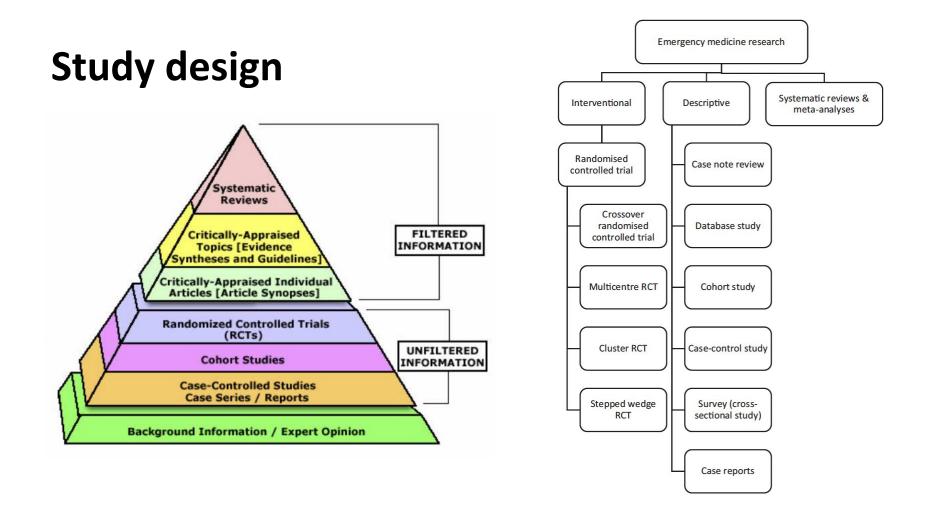
Result A total of 144 cases of AKI were included in the study...The most common causes of AKI were Sepsis (43.2%) ... Uremic encephalopathy, sepsis and hyperkalemia were factors that were identified as mortality predictors in overall AKI patients. AKI patients with sepsis were found to have lower hospital survival than those without sepsis. From the laboratory findings, there was significant difference between creatinine values on admission and discharge. Conclusion: As sepsis was the dominant cause of AKI as well as mortality predictor and cause of lower hospital survival, early initiation of antibiotics in the Emergency unit would be beneficial in order to improve the in-hospital outcome of patients with AKI.

There are many follow up PICO questions to develop!

PICO and study design



Source: The Centre for Evidence-Based Medicine https://www.cebm.ox.ac.uk/resources/ebm-tools/study-designs



Survey / Cross sectional

- Lowest level of clinical research
- Measures data, often population based, at a single point in time
- Benefits:
 - Inexpensive
 - Large amount of information can be collected in a short space of time from a variety of stakeholders
- Challenges:
 - Quality of information is variable- improved by using a validated tool or questionnaire
 - Biases
 - response bias
 - order of question bias
 - sampling bias
- <u>CROSS checklist</u> can assist in reporting survey data and <u>STROBE checklist</u> for cross-sectional studies



Research

Buprenorphine-naloxone practice and attitudes in 22 Canadian emergency physician groups: a cross-sectional survey

Andrew Kestler, Janusz Kaczorowski, Kathryn Dong, Aaron M. Orkin, Raoul Daoust, Jessica Moe, Kelsey Van Pelt, Gary Andolfatto, Michelle Klaiman, Justin Yan, Justin J. Koh, Kathryn Crowder, Devon Webster, Paul Atkinson, David Savage, James Stempien, Floyd Besserer, Jason Wale, Alice Lam and Frank Scheuermeyer September 21, 2021 9 (3) E864-E873; DOI: https://doi.org/10.9778/cmajo.20200190

Qualitative

- Types of qualitative research:
 - Ethnography
 - Focus groups
 - Semi-structured interviews
- Allows for exploration of why events are happening or barriers and facilitators to changing practice.
 - It focuses on understanding experiences attitudes, and behaviors.
- Analyzing qualitative work generally requires specific software to track themes/patterns in interviews
- <u>SRQR guidelines</u> or <u>COREQ checklist</u> assist with reporting qualitative research

Original Research | Published: 07 January 2021

A qualitative study to identify factors that influence patients' decisions to call Emergency Medical Services for syncope

Tamara M. Williamson, Mary Runte, Tigana Runte, Satish R. Raj, Ian E. Blanchard, Robert S. Sheldon, Tavis Campbell ⊠, Kathryn King-Shier & the Community Alternatives to Syncope Management in the Emergency Room (CASMER) Executive Committee

Canadian Journal of Emergency Medicine 23, 195–205 (2021) Cite this article

716 Accesses 3 Altmetric Metrics

Descriptive Studies: Case Note Reviews

• Retrospective

- Identify a condition or presentation and retrieve charts of patients that fit this definition
- Review charts for clinical data to answer pre-specified question
 - CAREFULLY define data and have a data collection sheet
- Downsides often include missing data, data that is poorly documented
- <u>STROBE statement</u> assists with case note review design, can also be thought of as a *retrospective* cohort design

> Ann Emerg Med. 2023 Apr 5;S0196-0644(23)00123-3. doi: 10.1016/j.annemergmed.2023.02.014. Online ahead of print.

Bilateral Emboli and Highest Heart Rate Predict Hospitalization of Emergency Department Patients With Acute, Low-Risk Pulmonary Embolism

Scott D Casey ¹, Lara Zekar ², Madeline J Somers ³, Lauren M Westafer ⁴, Mary E Reed ³, David R Vinson ⁵

Affiliations + expand

PMID: 37028997 DOI: 10.1016/j.annemergmed.2023.02.014

Descriptive Studies: Prospective Cohort

• Prospective

- Identify a condition or presentation ahead of time and then collect data on these patients when they are seen in the emergency department
- Improves data collection as data points pre-defined and data collection sheets can be followed as the data is collected in real time
- Typically requires research support staff
- <u>STROBE statement</u> assists with cohort study design

> Ann Emerg Med. 2023 Mar 22;S0196-0644(23)00117-8. doi: 10.1016/j.annemergmed.2023.02.009. Online ahead of print.

Frailty and Neurologic Outcomes of Patients Resuscitated From Nontraumatic Out-of-Hospital Cardiac Arrest: A Prospective Observational Study

Ryo Yamamoto ¹, Tomoyoshi Tamura ², Akina Haiden ², Jo Yoshizawa ², Koichiro Homma ², Nobuya Kitamura ³, Kazuhiro Sugiyama ⁴, Takashi Tagami ⁵, Hideo Yasunaga ⁶, Shotaro Aso ⁷, Munekazu Takeda ⁸, Junichi Sasaki ²; SOS-KANTO 2017 Study Group

Affiliations + expand

PMID: 36964008 DOI: 10.1016/j.annemergmed.2023.02.009

Descriptive studies: Case control study

- Retrospective
- Identify associations between the condition of interest and possible epidemiological or causative factors
- Compares people with a disease or condition and a group of people who do not have the disease or condition
- <u>STROBE checklist</u> can be used to help with case control study design

Research | Open Access | Published: 12 May 2023

Effect of emergency physician-operated emergency short-stay ward on emergency department stay length and clinical outcomes: a case-control study

Sean Moon, Taegyun Kim 🖂, Heesu Park 🖂, Hayoung Kim, Jieun Shin, Yun Seong Park & Gaonsorae Wang

BMC Emergency Medicine 23, Article number: 47 (2023) Cite this article

281 Accesses Metrics

Case Reports

- Single patients who present with unusual or unique clinical presentations or undergo unique course of illness or management plan
- Good for gaining experience in writing and publishing brief papers
- Does not change practice but may disseminate knowledge
- <u>CARE checklist</u> assists with writing a case report

> CJEM. 2023 May 11. doi: 10.1007/s43678-023-00523-0. Online ahead of print.

Marine envenomation by a Pacific red octopus in Vancouver, British Columbia

Matthew B Douglas-Vail ¹, William N Morley ², Jan Hajek ³

Affiliations + expand

PMID: 37166680 DOI: 10.1007/s43678-023-00523-0

Double blind randomized control trial

- Gold standard study design for comparing a new intervention to the current standard
- Double blind: both the participants and the researchers are not able to tell what treatment/intervention the participant is receiving
 - Minimizes risk of bias
- Different types of randomization:
 - Cluster, crossover, stepped wedge
- Multi-center studies improve generalizability but add cost/logistical complications
- <u>CONSORT guidelines</u> assist in reporting randomized trials



Annals of Emergency Medicine Volume 68, Issue 5, November 2016, Pages 574-582.e1

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Pain management and sedation/original research

Propofol or Ketofol for Procedural Sedation and Analgesia in Emergency Medicine—The POKER Study: A Randomized Double-Blind Clinical Trial

<u>Ian Ferguson MBChB, FACEM</u>^{a b} ∩ ⊠ ⊕, <u>Anthony Bell MBBS, FACEM</u>^{c d}, <u>Greg Treston MBBS, FACEM</u>^e, <u>Lisa New MBChB</u>^d, <u>Mingshuang Ding RN, PhD</u>^c, <u>Anna Holdgate MBBS, FACEM</u>^{a b}

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https://doi.org/10.1016/j.annemergmed.2016.05.024 A

Systematic Reviews & Meta-analysis

- **Systematic review:** bring together the various papers in an organized systematic manner to ensure that no important studies are omitted
 - <u>PRISMA 2020 statement</u> can be followed for conducting and reporting a systematic review
- **Meta-analysis:** when the results of a multiple studies are pooled, and new analysis is run. The goal is to give stronger evidence for or against an intervention or treatment if the sample size is large enough.
 - Requires specialist expertise and statistical skills

 Meta-Analysis
 > Am J Emerg Med. 2022 Jan;51:169-175. doi: 10.1016/j.ajem.2021.10.043.

 Epub 2021 Nov 1.

Efficacy of topical tranexamic acid in epistaxis: A systematic review and meta-analysis

Rajesh Naidu Janapala¹, Quincy K Tran², Jigar Patel¹, Esha Mehta¹, Ali Pourmand³

Affiliations + expand

PMID: 34763235 DOI: 10.1016/j.ajem.2021.10.043

Study Design

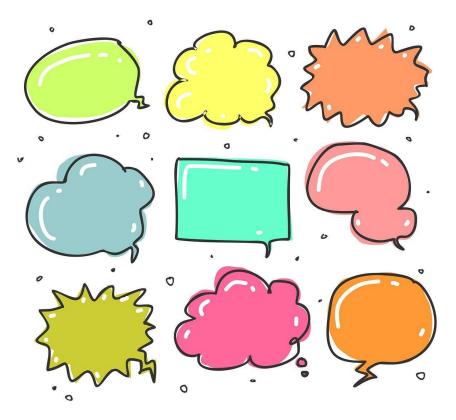


Table 1

Direction, strengths, weaknesses, potential biases, utility in emergency care research and level of evidence generated of various study designs.

Design	Direction	Strengths	Weaknesses	Potential biases	Utility in emergency care research	Level of evidence generated
Randomised controlled trial (RCT)	Prospective	Less bias overall; high quality design; minimises differences at baseline; answers single important question.	Answers single important question; costly; difficult to perform, especially in multiple centres; consent difficult in emergency patients.	Selection bias; performance bias; attritionbias; detection bias; reporting bias; measurement bias.	****	High
Case note reviews	Retrospective	Clinical records readily available; consent generally not required.	Data often not reliable; interrater reliability not reported; lack of data abstractor training; lack of	Reporting bias; information bias; loss of data bias	***	Low to medium
	n		standardised data collection forms; lack of definitions.			
Database studies	Prospective	Data quality usually high; prospective data collection	Costly and labour intensive	Systematic data bias; inclusion bias; selection bias	****	Medium to high
Cohort studies	Prospective	Data quality high; follow up can be planned and high quality.	Expensive; long-term; costly; difficult to perform in the emergency setting	Loss to follow up bias.	**	Medium to high
Case-control studies	Retrospective	Limited	Limited applicability in the emergency setting	Inclusion bias; lack of follow up bias		Medium to high
Surveys	Cross-sectional/	Cheap; usually quick; give almost real-	Data quality is low; limited response rates are common	Selection bias; inclusion bias; response	***	Low
	prospective	time information		bias		
Sys tematic reviews & meta-analyses	Retrosp ective	High quality; reliable data; high level of evidence impacts practice	Expensive; time-consuming; needs special skills and training	Minimal	*****	High

Workshop: R2 Research Proposals



Current R2's Research Proposals Workshop

Current R2's Research Proposals Workshop

Current R2's Research Proposals Workshop

Resources

- Hulley, S.B. et al. 2013. *Designing Clinical Research (4th Ed)*. Philadelphia, USA: Lipincott Williams and Wilkins.
- Rob D. Mitchell, et al., African Journal of Emergency Medicine, <u>https://doi.org/10.1016/j.afjem.2020.05.004</u>
- University of Oxford, Centre for Evidence-Based Medicine. Asking focused questions:

https://www.cebm.ox.ac.uk/resources/ebm-tools/asking-focused-qu estions (Accessed online Oct 2020) and Study Designs: https://www.cebm.ox.ac.uk/resources/ebm-tools/study-designs (Accessed online Oct 2020)

Extra Question Examples

You notice several medication errors related to improperly labelled syringes of medications drawn up in the ED.

You wonder if producing standard medication labels would reduce these errors.

What is your PICO question?

- P = medications used in the ED
- I = standardized medication labels with name, concentration, dose
- C = usual practice (tape or no label)
- O = medication errors

For commonly used ED medications, does use of standardized labels, compared to tape (or no label,) produce less medication errors?

You assess a 40-year-old patient with fever and a new heart murmur.

Your senior performs a bedside ultrasound and does not see any vegetations.

You wonder how good POCUS is at detecting vegetations compared to a formal echo.

What is your PICO question?

- P= patients with suspected endocarditis
- I = POCUS performed by ED clinician
- C = trans-esophageal echo performed by cardiology
- O = detection of vegetations

In adults with suspected endocarditis, is bedside ultrasound, when compared with TEE performed by cardiology, as good at detecting vegetations ?