

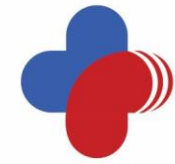
# SVT 2023 webinar series

## **#1 When is my research, actually research?**



Led by Osian Llwyd

Oxford University Hospitals, University of Oxford



# SVT Quarterly Newsletter



1. A Road map to Research
2. Identify and define the research questions
3. Literature Reviews
4. Research Questions and Hypothesis

**June 7<sup>th</sup> - 2<sup>nd</sup> Webinar**  
**Clinical Research Methodology and Types of Study Design**



# Road map to Research





# Identify and define the research questions

*“A journey of a thousand miles begins with a single step”*



# Identify and define the research questions

*"A journey of a thousand miles begins with a single step"*



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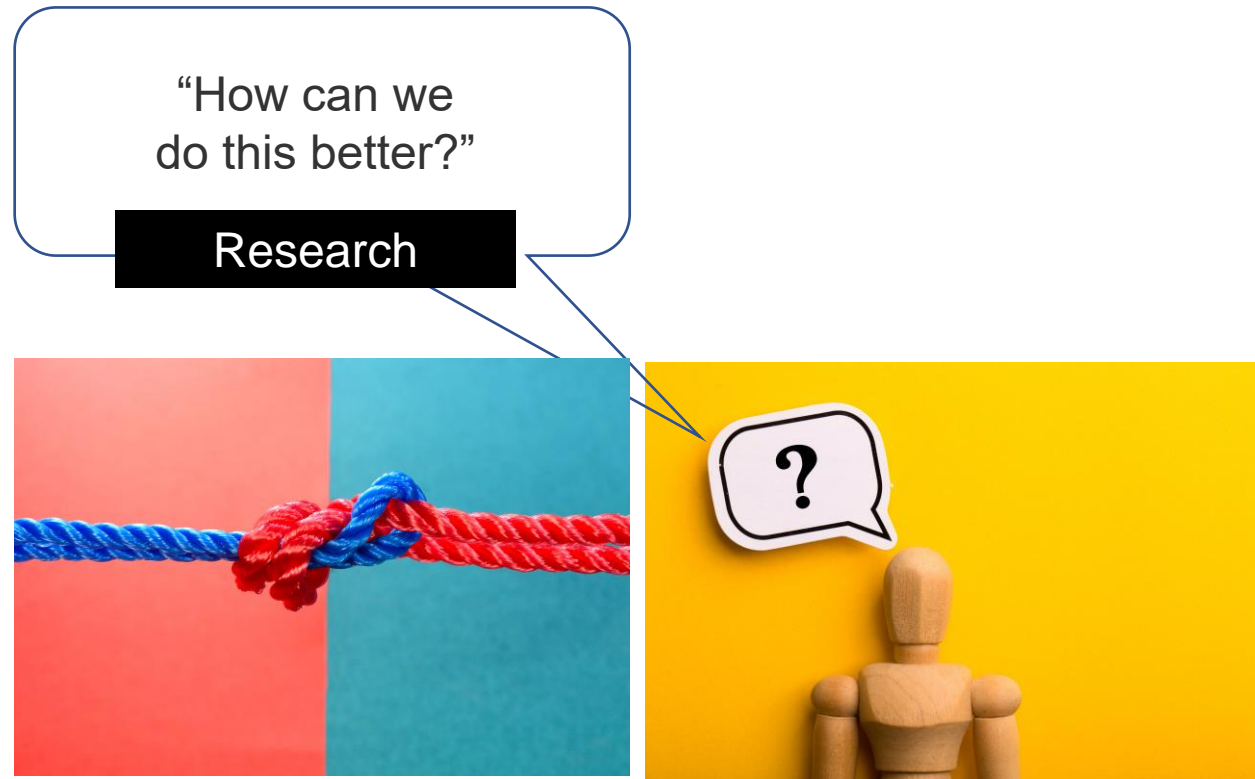


**3<sup>rd</sup> Webinar - September 6<sup>th</sup> on Training and Approvals**



# Research

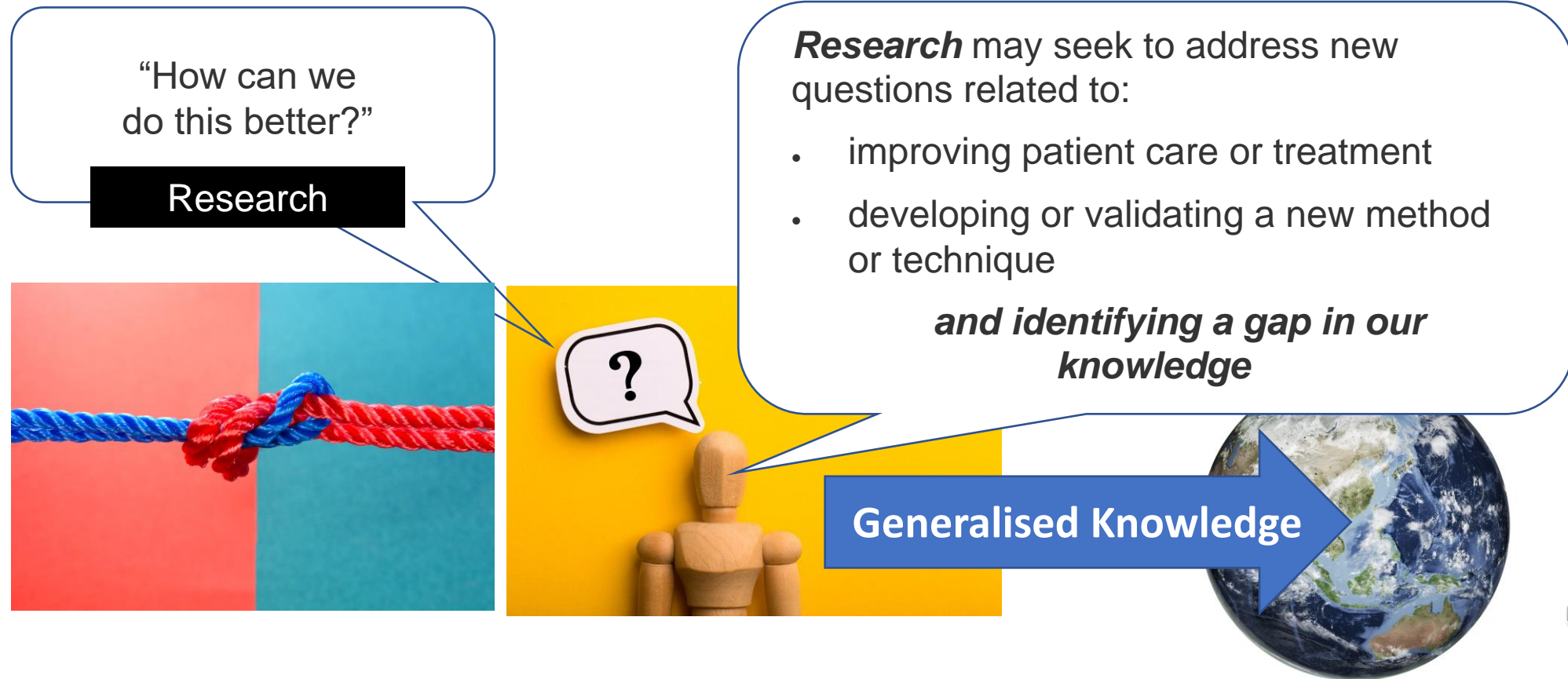
*“Challenging current scientific opinion”*





# Research

*“Challenging current scientific opinion”*



# Service Evaluation

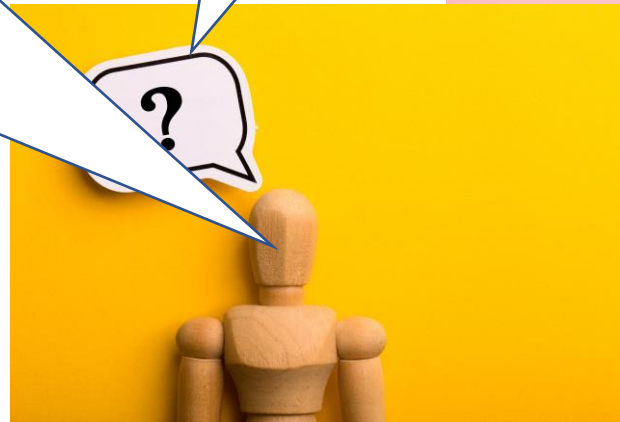
*“Evaluation assesses the worth or value of something”*

**A Service Evaluation** may seek to generate knowledge about:

- making use of resources
- meeting the needs of patients
- patient experience and satisfaction etc.

“How good is our current practice?”

**Service  
Evaluation**



# Service Evaluation

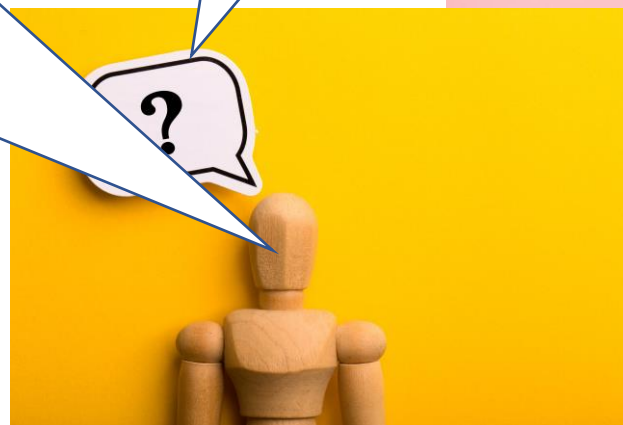
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“How good is our current practice?”

Service  
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**Within your  
department**



# Audit

*“Audit comes from the verb Audio - Latin word for hear”*

**An audit** may seek to address whether the standards are what it can be?

- Quality improvement process
- Against well defined standards
- vs. evidence-based practice

“Does it meet the  
**standards** set?”

Audit



# Audit

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Audit

**Evidence-Based  
Medicine**

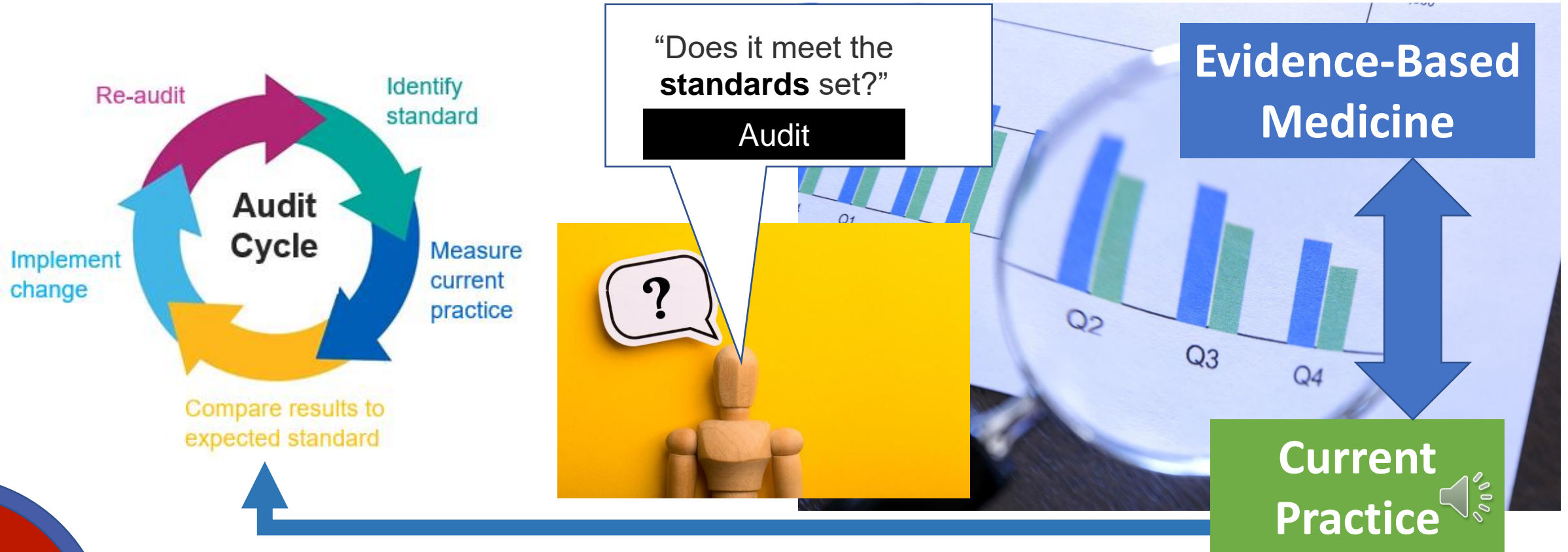
**Current  
Practice**

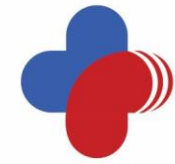




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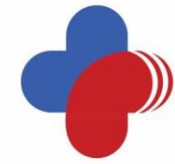
# Literature Reviews

***“Has the Question been asked before?”***

- Defining the Question
  - Aim
  - Objectives
  - Hypothesis
- Introduction/Background/Discussion/  
Limitations in scientific articles








# Literature Reviews

## ***“Has the Question been asked before?”***

- Defining the Question
  - Aim
  - Objectives
  - Hypothesis
- Introduction/Background/Discussion/Limitations in scientific articles
- Informal literature search
- A formal ***systematic review***
  - ***‘Secondary research’*** that provides a summary of the available primary research to a specific research question

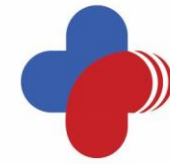


PubMed®

Advanced

PubMed® comprises more than 35 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full text content from PubMed Central and publisher web sites.


- Does this study address a clearly focused question?
- Did the study use valid methods to address this question?
- Are the valid results of this study important?
- Are these valid, important results applicable to my patient or population?



# Literature Reviews

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# Literature Review

Alannah Morley-Brown – Royal Derby Hospital

PGDip – Derby University

- How did you identify and define your research question?
- Why and how did you write a Literature Review?
- What would you do differently?



# Literature Review

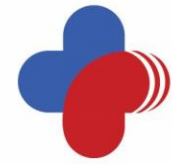
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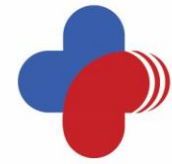
# How did you identify and define your research question?



- Is there anything that interests you?
- Is there anything you've noticed that could be improved?



# How did you identify and define your research question?

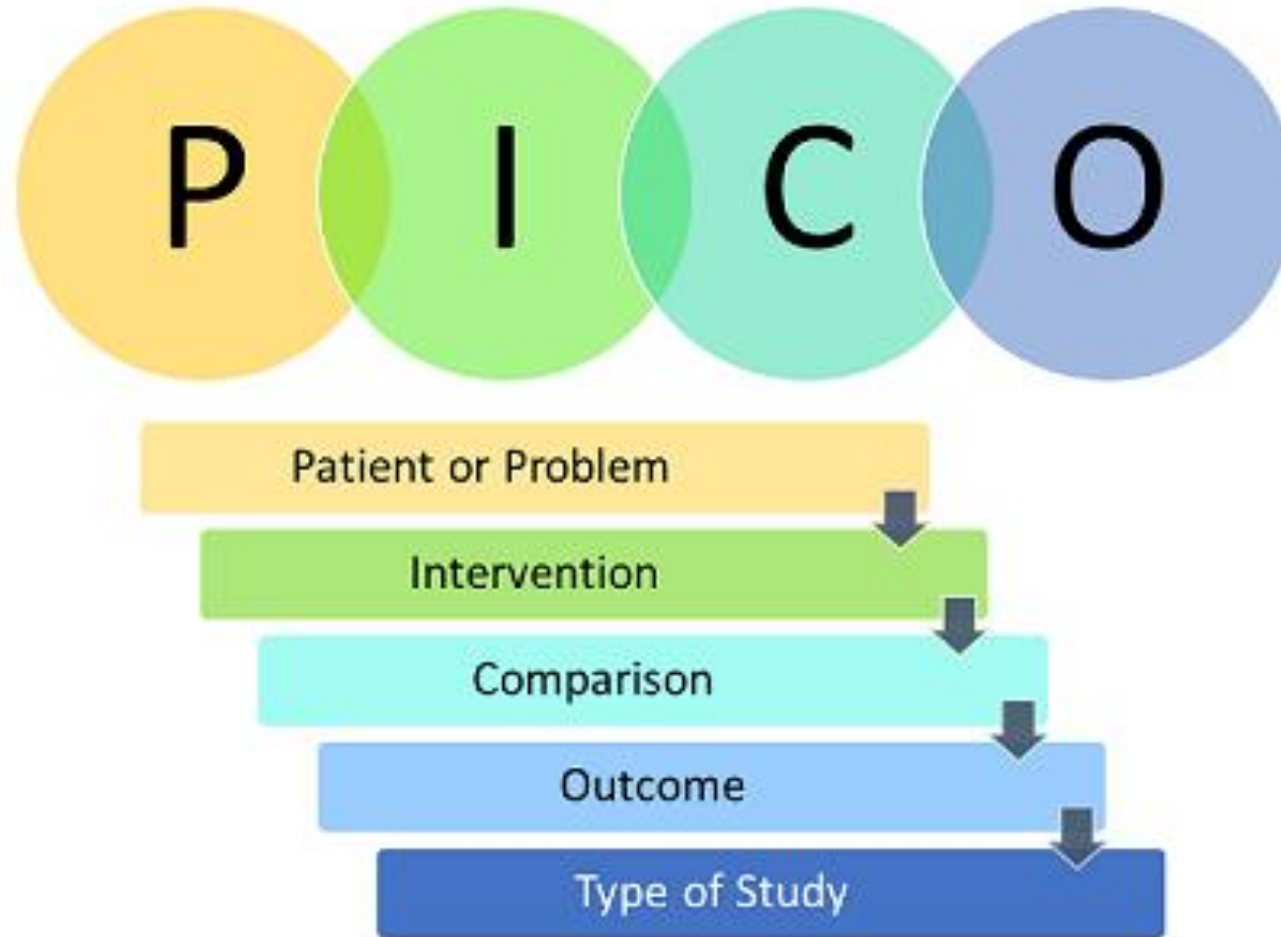


- PICO model
- Identifying synonyms
- Refer to relevant literature e.g., protocols to identify alternative words.



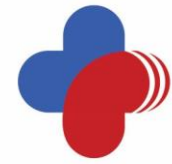
# How did you identify and define your research question?

- 
- 
- 





# Why and how did you write a Literature Review?

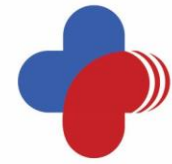


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- Provides an assessment of the current research about a topic.
- May identify key questions that need further research.
- Can evaluate methodologies used in previous topics.
- *It was part of an assignment...*



# Why and how did you write a Literature Review?

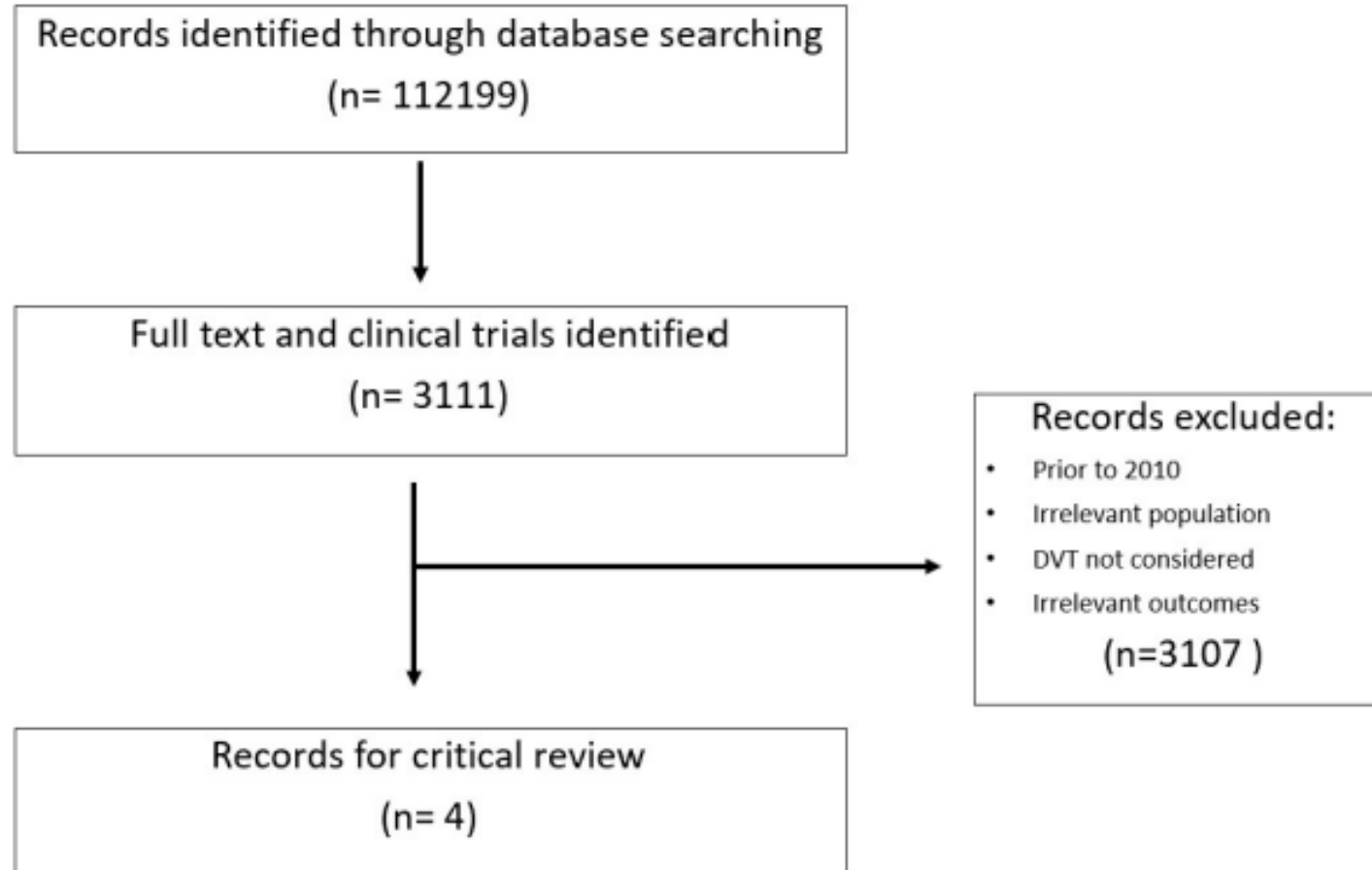


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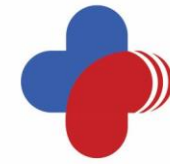
- Identify databases e.g., PubMed, Sciencedirect etc.
- Utilise Boolean operators – ‘AND’, ‘OR’, ‘NOT’, ‘AND NOT’
- Refine search to reduce number of articles
- Develop inclusion/exclusion criteria



# Why and how did you write a Literature Review?



# Why and how did you write a Literature Review?



Author	Title	Year	Sample	Findings	Conclusion
Chan, W-S. et. al	Safety of withholding anticoagulation in pregnant women with suspected deep vein thrombosis following negative serial compression ultrasound and iliac vein imaging	2013	221 pregnant women with suspected DVT.	16 patients were positive for DVT during initial scan. 1 patient with negative serial testing results had PE 7 weeks later.	Serial compression ultrasound and imaging of iliac veins excludes DVT in symptomatic pregnant women over a 7-day period.
Le Gal, G. et. al	Diagnostic value of single complete compression ultrasonography in pregnant and postpartum women with suspected deep vein thrombosis: prospective study	2012	210 pregnant and postpartum women with suspected DVT.	16 excluded due to suspected PE. 22 women identified with DVT. 2 out of the 177 negative scans were later confirmed to have DVT.	A negative, single complete compression ultrasound scan can safely exclude the diagnosis of DVT.
Ratiu, A. et. al	Diagnostic value of a negative single color duplex ultrasound in deep vein thrombosis suspicion during pregnancy.	2010	87 pregnant women with clinical suspicion of DVT.	30 patients were positive for DVT. 55 patients were negative and remained negative after follow up scan.	A single complete colour duplex ultrasound of lower limbs veins can safely rule out deep vein thrombosis.
Le Moigne, E. et. al	Validation of the LEft score, a newly proposed diagnostic tool for deep vein thrombosis in pregnant women.	2014	96 pregnant women with suspected DVT.	3% of patients with no LEft score, 9% with 1 point, 10% with 2 points and 75% with 3 points were positive for DVT.	LEft rule can be used to estimate probability of DVT.



# What would you do differently?



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- Less restrictive approach.
- Larger samples.
- Considered more databases.

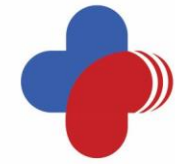


# Thank you for listening



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# Research Questions and Hypothesis

**Population** - Who the study is relevant to.

e.g. *patients with cerebral small vessel disease (CSVD)*

**Intervention** - Typically what your main variable of interest will be.

e.g. *whether a new vasoactive compound could improve cerebral circulation would be the intervention.*

**Control/comparator** - Try and use matching factors age/disease

e.g. *the effectiveness of the drug in different severity of CSVD*

**Outcome** - The main focus of the study and will decide whether the research worked.

e.g. *middle cerebral arterial pulsatility index after three weeks treatment*

***Being ambiguous about the factor that is being used to link the exposure and outcome is one of the most common errors in formulating a research question***







# Starting a project within the Vascular Sciences

- How did you identify and define your research question?
- Why and how did you decide to do a specific project?
- What would you do differently?



# Audit

## Emily Alderson – Cambridge University Hospitals Scientist Training Programme



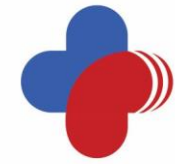
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### European Society for Vascular Surgery pre-carotid endarterectomy imaging guideline:

- 'When carotid endarterectomy is being considered, it is recommended that Duplex ultrasound stenosis estimation be corroborated by computed tomographic angiography or magnetic resonance angiography, or by a repeat Duplex ultrasound performed by a second operator'.
- **Aims:**
  - To determine compliance with the ESVS pre-CEA imaging guideline at Cambridge University Hospitals (CUH) between 1<sup>st</sup> January 2019 and 31<sup>st</sup> December 2021.
  - To identify reasons for non-compliance.
  - To develop and implement strategies to improve compliance.
  - To re-audit conduct a re-audit between 1<sup>st</sup> July 2022 – 31<sup>st</sup> December 2022 to determine the efficacy of interventions to improve compliance.



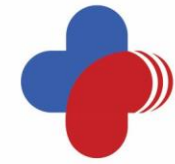


# Service Evaluation

Anna Corby – Oxford University Hospitals  
Scientist Training Programme

***“Exploring patients’ perceptions of care after elective endovascular or surgical repair of an Abdominal Aortic Aneurysm (AAA) at OUH”***





# How did you identify and define your research question?

- What am I interested in?
- What topics fit in with work being done at OUH?
- What work has not been done before?
- What is logistically possible for a MSc project?



# Why and how did you decide to do a Service Evaluation?

- Differentiating between a service evaluation and an audit
- HRA 'Is my study research?' tool (<https://www.hra-decisiontools.org.uk/research/>).
  - 1) Are participants randomised to a group?
  - 2) Does your study protocol demand changing treatment/care from accepted standards for any of the patients?
  - 3) Is your study designed to produce generalisable or transferable findings?
- Speak to R&D department to confirm decision
- Obtain local approvals from R&D, departmental leads
- Register service evaluation on our audit software 'Ulysses'

# What would you do differently?

- Carefully think about the size of the project and the amount of data generated.
- Plan how you recruit patients to ensure you have as much flexibility as possible.

# Service Evaluation

‘A local service evaluation of manual and automated ABPI methods used within the VSU’

Manual



Automated



Connor  
Hiscocks



Oxford University  
Hospitals  
Scientist Training  
Programme





# Why and how did you decide to do a Service Evaluation?

- My MSc project had to be a **service evaluation** or **audit** due to COVID.
- I wanted to select a project which could improve the department.
- Could the ABPI service be improved by evaluating the two methods?
  - Manual ABPI
  - Automated ABPI



# How did you identify and define your research question?

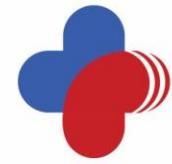
- Initial research title:
  - *'Locally validating the Dopplex ABility automatic ABPI system: a comparison of automated and manual ABPI methods in patients with known or suspected lower-limb arterial disease'.*
- Updated research title:
  - *'A local evaluation of automated and manual Ankle Brachial Pressure Index (ABPI) techniques currently available within the Vascular Studies Unit (VSU)'.*



# What would you do differently?

- Use the HRA study classification checklist from the start
- Use other similar studies as supporting evidence.
- Contact local R&D department as early as you can





# Research

Rhodri Furlong – St Georges University Hospitals  
MSc & Scientist Training Programme

*Cerebral haemodynamics and neurotrophic factor responses are dependent on the type of exercise*



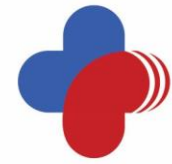
- How did you identify and define your research questions?
- Why and how did you decide to do research?
- What would you do differently?



# How did you identify and define your research question?

- Joined an established research group
  - My research question was already defined from previous work the group had completed
- Pro's: Worked with experienced researchers + plenty of learning opportunities
- Con's: I was not the principle investigator so had less autonomy





# Why and how did you decide to do research?

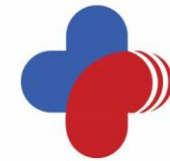
- The relationship between cerebral blood flow and exercise was for the most part unknown, so the collection of prospective data was required to answer the research question
- The project:
  - Created new knowledge
  - Tested a hypothesis
  - Was experimental



# What would you do differently?


- Apply for ethical approval as early as possible
- Ensure consumables, lab space, equipment hire etc. is in place so you can begin data collection once you have ethical approval






# Research, Service Evaluation or Audit?

← → ↻ 🏠 [hra-decisiontools.org.uk/research/](https://hra-decisiontools.org.uk/research/) 🔒 ⌂ ☆

**Medical  
Research  
Council**

**Health Research  
Authority**

## Is my study research?

Welcome. The aim of this decision tool is to help you decide whether or not your study is research as defined by the UK Policy Framework for Health and Social Care Research. It is based on the **Defining Research** table produced by the Research Ethics Service.

You will be presented with a short series of **YES** or **NO** questions. Take your time to consider the wording carefully. Once you have answered these questions the tool will let you know if your study is research.

To help you with terminology, a **GLOSSARY** button is available on every page. All links to individual glossary items or other websites appear in purple text and open in a new window.

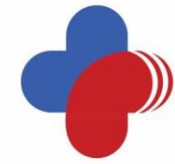
**Post Market Surveillance** is NOT usually considered research. However, there are some circumstances where NHS REC review may be required. Return to the **Do I need NHS REC review?** tool to determine if your post market surveillance requires NHS REC review.

[Follow this link to begin.](#)

[About this tool](#) [Feedback](#) [Contact](#) [Glossary](#) [Accessibility](#)



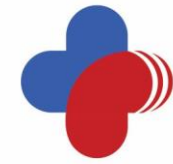




# Local Trust R&D office

- Contact your local NHS R&D office as soon as you can
- Send your PICO answers/2 page summary of intentions
  - Research > Audit
  - Audit > Research
  - Audit > Service Evaluation
  - Service Evaluation > Audit
- Can take some time to decide
- Contact them the earlier the better!





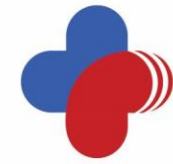
# Research, Service Evaluation or Audit?

- To decide you can find further guidance by using the HRA **Defining Research Table**.

<https://nspccro.nihr.ac.uk/working-with-us/research-service-evaluation-or-audit>

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (in public health including health protection)
The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to investigate the health issues in a population in order to improve population health Designed to investigate an outbreak or incident to help in disease control and prevention
Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.	Designed to answer: “What standard does this service achieve?”	Designed to answer: “Does this service reach a predetermined standard?”	Designed to answer: “What are the health issues in this population and how do we address them?” Designed to answer: “What is the cause of this outbreak or incident and how do we manage it?”
Quantitative research - addresses clearly defined questions, aims and objectives. Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, quantitative or qualitative methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Involves an intervention in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.





# Research, Service Evaluation or Audit?

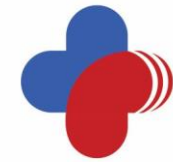
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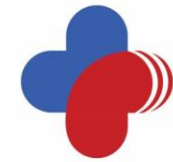




# To generalise or not to generalise

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Quantitative research – may involve evaluation of	Interventions or interventions in use only	Interventions or interventions in use only



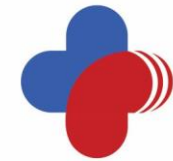


# In comparison to what?

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT
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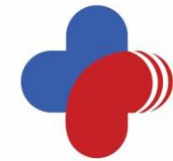




# To intervene more?

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.
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Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention. Qualitative research – does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.
May involve randomisation.	No randomisation.	No randomisation.
Normally requires REC review but not always. Refer to <a href="http://hra-decisiontools.org.uk/ethics/">http://hra-decisiontools.org.uk/ethics/</a> for more information.	Does not require REC review.	Does not require REC review.



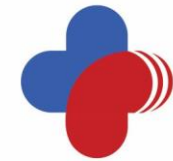


# Data, data and more data

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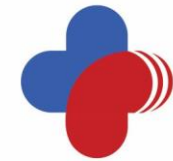


# Intervention and Randomisation

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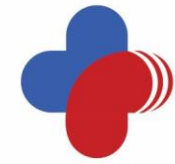




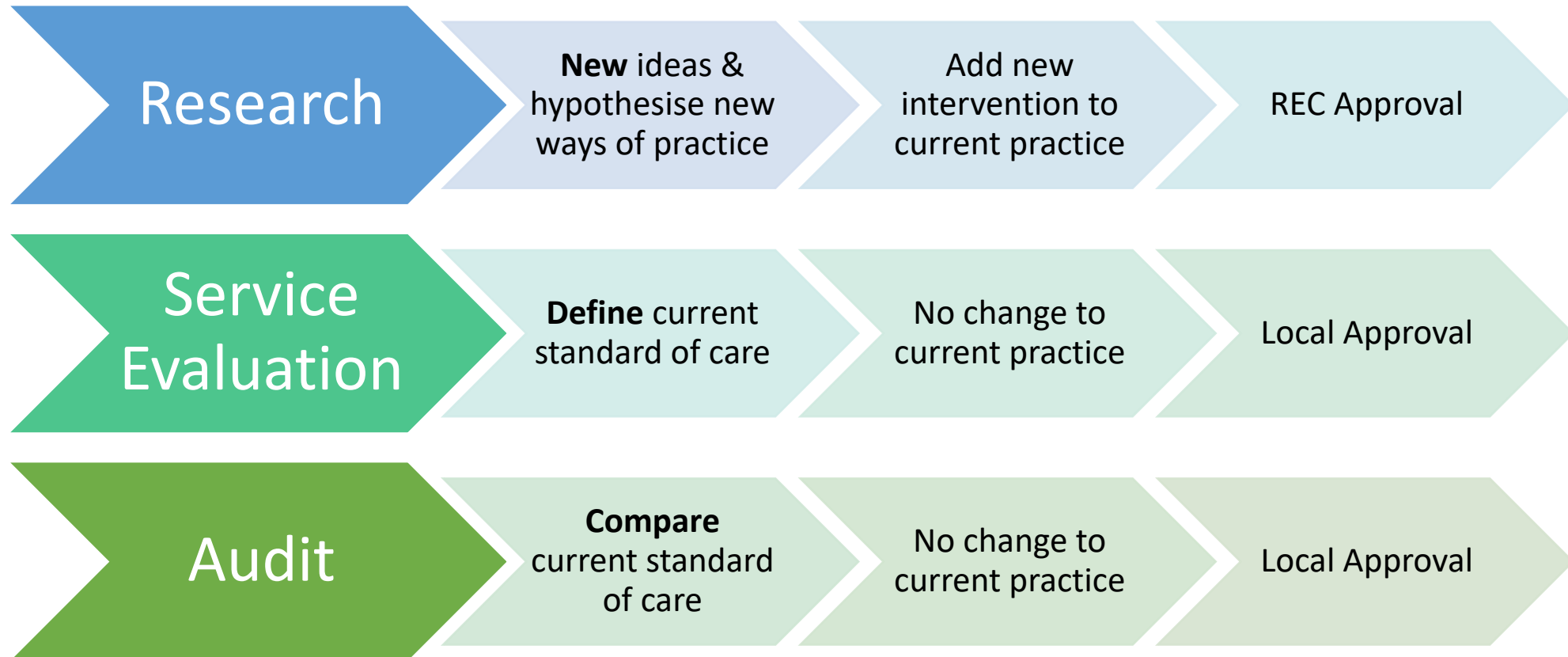
# Research Ethics Committee Review?

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# Summary



# To conclude

- ✓ Choose a project that you are interested in
- ✓ Review the literature, use the PICO model
- ✓ Communicate with colleagues within the department
- ✓ Use the HRA decision tool website
- ✓ Contact R&D ASAP!
- ✓ Consider carefully the scope and size of the project/data collection



***Aim for the stars to  
reach the moon***

