



PICUTS FRAMEWORK

OUTCOMES

PCORI-izing your Study Design

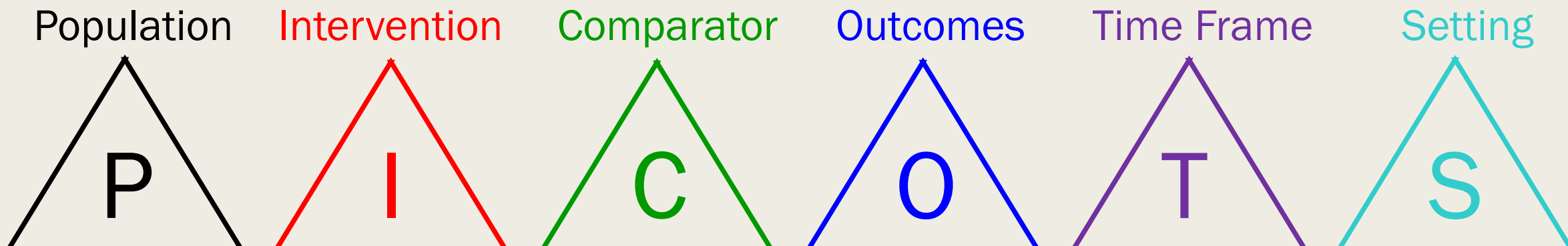


PICOTS Framework and CER

- Previous presentation defined overall PICOTS Framework, Population, and Intervention

Example:

Is **robotic assistance knee surgery** more effective than **conventional knee surgery** in achieving **mobility** for middle age men in **rural communities** during the **first six months** following surgery?



Objectives

- In-depth look at “Outcomes” aspect of the PICOTS framework
- Describing outcomes in your PCORI applications

Outcomes



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PCORI Definition of Outcomes

- PCORI Methodology Standards: Formulating Research Questions (RQ-6)

Identify and **include outcomes the population of interest notices and cares about** (e.g., survival, function, symptoms, health-related quality of life) **and that inform an identified health decision**. Define outcomes clearly, especially for complex conditions or outcomes that may not have established clinical criteria. Provide information that supports the selection of outcomes as meeting the criteria of “patient-centered” and “relevant to decision makers,” such as patient and decision-maker input from meetings, surveys, or published studies. Select outcomes based on input directly elicited from patient informants and people representative of the population of interest, either in previous studies or in the proposed research.

Health Outcome Examples

Measure	Example
Mortality	Infant death rate
Physiologic measures	Blood pressure
Clinical events	Stroke
Symptoms	Difficulty breathing
Functional measures	Ability to communicate clearly
Patients' Experiences with care	Consumer assessment of treatment

Types of Outcomes

- Primary Outcomes (mobility)
- Secondary Outcomes (recovery time, adverse events, length of hospital stay)

Example:

Is **robotic assistance knee surgery** more effective than **conventional knee surgery** in achieving **mobility** for middle age men in **rural communities** during the **first six months** following surgery?

Tell Your Outcome Story

- Outcomes are why you built a partnership and did this work
- Your Patient Voice makes outcomes meaningful
- Your Stakeholder Voice makes outcomes feasible
- Your Researcher Voice makes outcomes measureable
- This all impacts study design, IRB, recruitment strategies, and more.

Conclusions

- Outcomes should be important to patients and clinicians
- Outcomes inform the study design and require extensive researcher input
- Outcomes must be able to be measured
- Outcomes must be interesting to your funder
 - Contact sciencequestions@pcori.org

Questions or Comments?

Thanks for watching!

