Using the PICOTS Framework to Strengthen Evidence Gathered in Clinical Trials—Guidance from the AHRQ's Evidence-based Practice Centers Program

P: Patient population
Define the patient population that will be studied in the trial and consider how it compares to the general affected population. Consider patient baseline sociodemographic (e.g., age, race, socioeconomic status) and clinical characteristics (e.g., severity of condition, comorbidities) that may contribute to differences in treatment outcomes or treatment preferences. Define the selection criteria and consider how patients in the study may be diagnosed or treated differently in usual clinical care. Consider biases that may be introduced by the selection of patients or attrition of patients.

I: Intervention
Define the intervention, including all of its components. Consider contextual factors, such as prior, concurrent, post-treatments, or specialized training of the provider, which may affect the safety and/or effectiveness of the intervention.

C: Comparator
Define whether there is a placebo or active control comparator. Consider blinding. For placebo-controlled studies, consider the risk and benefit of using sham comparators. An active comparator should be relevant to current practice. If the comparator is "usual care," define the components of the "usual care" clearly. Do not select an active comparator that has known poor effectiveness in specific subgroup populations.

O: Outcome
Define the safety and effectiveness outcomes that matter to patients and which predict long-term successful results. If surrogate outcomes, such as biochemical or physiological measures, are used, they should be clinically relevant. Consider the validity and reliability of outcome measures, including composite measures. Define the planned outcome measures and analyses in the protocol. Pre-specify subgroup analyses. Report all findings as defined in the protocol. Note any post hoc analyses.

T: Timing
Define the duration of treatment and the follow-up schedule that matter to patients. Consider both long- and short-term outcomes.

S: Setting
Define the setting (primary, specialty, inpatient, nursing homes, or other long-term care setting) where the study is implemented and the relevance of the study setting to real world use.

In summary, trials that provide high strength of evidence:
- Study patients who are likely to be offered the intervention in everyday practice.

- Examine clinical strategies and complexities that are more likely to be replicated in practice.

- Measure the most relevant set of benefits and harms.

- Have low risk of bias.

- Have adequate power to address subgroups.

- Directly compare interventions.

- Include all important intended and unintended effects including adherence and tolerability.

Consider how to [minimize the risk of bias](#) from confounding by indication and other threats to internal validity.

Consider following [CONSORT guidelines](#) when reporting the results of the study.