**University of Utah Internal Medicine Journal Club Template:**

Updated: Brian Locke 2/25/2020

**Non-inferiority Randomized Controlled Trial:**

Goal: “Our aim [is] to distill an article down to its core while systematically reviewing its validity and telling a compelling story” Similar to case presentations, “the goal is to communicate the

essential information [..] in a mostly standardized format that is easily digested by the listener”

“Improving journal club presentations, or, I can present that paper in under 10 minutes” DOI: [10.1136/ebm.12.3.66-a](https://doi.org/10.1136/ebm.12.3.66-a)

Article Title

Study question and design: What is the null hypothesis?

Why did the trialists perform a non-inferiority trial instead of a superiority trial? What was their non-inferiority margin, and is it justified? If the intervention is found non-inferior to the control, what advantages would result? Does this benefit outweigh the possible inferiority margin?

Patients included: (where and how were patients enrolled? How did the trialists determine their sample size? What were the inclusion/exclusion criteria? Does this represent the population you’re interested in? Flow diagram and table 1 may be helpful)

Intervention: (What was the experimental intervention? Aside from the intervention, were patients treated equally - follow-up schedule, permitted additional treatments etc? Does this reflect current practice? Is the intervention realistic in our setting?)

Outcomes: (Focus on primary outcome. Is this an outcome important to patients, or a surrogate? Is it a composite? Appropriate duration of follow-up? Was there blinding, and of who? Were patients analyzed by the treatment they were assigned to, or the treatment they received? Were the secondary outcomes prespecified or post-hoc?)

Results: How large was the treatment effect, and what was the precision in the estimate (e.g. confidence interval, P-value)? Was there significant loss to follow-up or crossover between groups? Were the secondary analyses prespecified, or post-hoc? What were the primary adverse events, and how common were they in each group?

Critique: Are there threats to the internal validity (such as bias or chance) or external validity, aka generalizability? Relevant conflicts of interests?

Can I apply the results to my patient? How?