



**SDI Review Form 1.6**

**PART 1:**

Journal Name:	<b><u>British Journal of Medicine and Medical Research</u></b>
Manuscript Number:	<b>MS: 2013_BJMMR_3208</b>
Title of the Manuscript:	<b>The Necessity of Randomized Clinical Trials</b>

**General guideline for Peer Review process is available in this link:**  
**(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)**

- This form has total 9 parts. Kindly note that you should use all the parts of this review form.



**SDI Review Form 1.6**

**PART 2: Review Comments**

	<b>Reviewer's comment</b>	<b>Author's comment</b> <i>(if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)</i>
<b><u>Compulsory</u></b> REVISION comments	<p>The authors have presented an excellent case of necessity of randomized clinical trials. However, this may cause more disarray in the field of evidence-based medicine and comparative effectiveness research which continues to evolve based on the opinions of methodologists and requirements of policy-makers. This manuscript will empower methodologists to state that none of the treatments work. In essence, we do not need any medicine.</p> <p>While the authors properly describe the necessity of randomized clinical trials, they have not described what a randomized trial is. There are multiple types of randomized trials, i.e., placebo-control, active-control, placebo-and active-control, dose-response, and various other combinations.</p> <p>The authors also do not define the role of placebo. It includes pure placebo, impure placebo. Further, in the modern world, methodologists continue to claim all active-control trials are worthless because they construe one of the treatments as placebo, i.e., injection of local anesthetic versus steroids into epidural space or</p>	



**SDI Review Form 1.6**

	<p>over the nerves.</p> <p>Further, the authors also need to define what actual placebo is. Just because a placebo solution is injected into an active structure, it is not going to be inactive. There is substantial literature when sodium chloride solution or dextrose is injected into closed spaces, such as epidural space, discs over the nerve roots, facet joints, etc., they produce substantial response, leading to lack of understanding of actual placebo and misinterpretation of the evidence.</p> <p>The authors will do a great favor to the medical community even though they will not empower methodologists. If they clarify the role of placebo and necessity to design an appropriate placebo prior to embarking on placebo trials.</p> <p>Basically, the authors should describe what they mean by randomized trial. It is extremely important that they show the potential, advantages, as well as disadvantages and facts and fallacies of each randomized type of controlled trial prior to embarking on the decision.</p> <p>The authors may want to expand the text further, along with the boxes explaining more practical scenarios rather than examples such as tracheostomy.</p>	
--	--	--



**SDI Review Form 1.6**

<p><b><u>Minor</u></b> REVISION comments</p>	<p>The authors may want to expand the text overall and also describe the differences between evidence-based medicine and comparative effectiveness research. The authors in the discussion section describe about the Patient-Centered Outcomes Research Institute (PCORI). Obviously they are mixing evidence-based medicine with comparative effectiveness research. In comparative effectiveness research, mainly it is active-controlled trials rather than placebo-controlled trials. Methodologists tend to state that active-controlled trials are worthless, since basic treatment has not been proven in a randomized placebo-controlled trial.</p>	
<p><b><u>Optional/General</u></b> comments</p>	<p>None</p>	

**PART 3:**



**SDI Review Form 1.6**

**Reviewer Details:**

Name:	<b>Dr. Laxmaiah Manchikanti.</b>
Department, University & Country	<b>Anesthesiology and Perioperative Medicine, University of Louisville, Kentucky</b>