Reviewer’s report

Title: Study protocol: The Labor Progression Study, LAPS - Does the use of a dynamic progression guideline in labor reduce the rate of intrapartum cesarean sections in nulliparous women? A multicenter, cluster randomized trial in Norway

Version: 1 Date: 07 Mar 2017

Reviewer: Jeremy L. Neal

Reviewer's report:

Dr. Stine Bernitz and colleagues submitted a well-written research protocol (e.g., a protocol and hypotheses without results/findings). Although physiologic (or ‘dynamic’) partographs with broadly suggested protocols have been previously published [Neal JL, Lowe NK. Medical Hypotheses. 2012;78(2):319-326.] and pilot results of physiologic partograph studies have been published previously [Neal JL, Lowe NK, Nacht AS, Koschoreck K, Anderson J. Journal of Midwifery & Women’s Health, 2016;61(2):235-241.], introduction of this work is new in Norway and most countries. While the true novel value of the Bernitz et al study will be through eventual publication of their findings/results, some readers may be interested in the published protocol.

In the Zhang figure, inclusion of P1 and P2+ curves are not necessary since this is a protocol for nulliparous women. Are there figure legend.

Better Friedman figures are available. The authors used one that calls out a particular case wherein Demerol and Scopolamine is given and one point, and only Demerol and another point. Friedman presents aggregate labors curves for nulliparous women in 1955 and 1978 – these would be better for use.

Are the methods appropriate and well described?  
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?  
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?  
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I have potential 'non-financial competing interests' in relation to this paper that follows the chain of events outlined below.

1) In 2012, my research team has published a paper introducing the physiological partograph ('dynamic' as described by Bernitz et al) and suggestions for testing the instrument in clinical settings. We suggested a protocol similar to that being conducted in this study.

2) My research team has published pilot work findings regarding use of a 'dynamic' (largely Zhang et al based) physiologic partograph (conducted in the United States approx. 2013).


3) My research team has been pursuing extramural National Institutes of Health funding (U.S. government funding) for physiologic (computerized software) partograph vs. usual labor assessment testing since 2015 (based on our 2012 publication). Our proposed research aims are, in many ways, similar to those in the protocol submitted by Bernitz and colleagues and their background/introduction (and citations) is similar to ours, perhaps simply due to limited available literature in this area. We have submitted 3 NIH applications for this work. In our study applications, we propose implementing computerized-partograph software during our work. Indeed, our team has already designed and developed partograph software which is a proposed next step by Bernitz and colleagues.

4) My research team (United States-based) has joined with an Australian-based research team to write research protocols for studying the physiologic Neal & Lowe partograph vs. the 4-hour action line partograph. This research team includes Dr. Jun Zhang who is also an author on the Bernitz et al. submission to BMC Pregnancy & Childbirth (reviewing this submission may, therefore, be considered a conflict of interest for me based on this connection alone). This team has been pursuing funding for this work since 2014 and based on the Neal & Lowe 2012 publication listed above. Australian government-funded pilot work has already been completed for this work. Publications for this work are also under review.

A pilot randomised controlled trial (RCT) to determine the effect of a physiological (step) versus a standard action (slope) labour progress line on the rate of spontaneous vaginal birth amongst low risk women in labour for the first time. Mater Health Services, South Brisbane, Queensland. (ACTRN12614000786695). (Jan 2015 - Jan 2016)

In summary, the Bernitz et al. protocol is not an original idea but their eventual findings may inform practice and research.
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