PEER REVIEW HISTORY

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ARTICLE DETAILS

| TITLE (PROVISIONAL) | Rapid Paediatric Fluid Resuscitation: A Randomized Controlled Trial Comparing the Efficiency of Two Provider-Endorsed Manual Paediatric Fluid Resuscitation Techniques in a Simulated Setting |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AUTHORS            | Cole, Evan; Harvey, Greg; Urbanski, Sara; Foster, Gary; Thabane, Lehana; Parker, Melissa |

VERSION 1 - REVIEW

| REVIEWER | Joelle Simpson  
Joelle N. Simpson MD, MPH  
Assistant Professor of Pediatrics and Emergency Medicine  
The George Washington University School of Medicine and Health Sciences  
Emergency Medicine and Trauma Center  
Children's National Medical Center |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| REVIEW RETURNED | 07-Apr-2014 |

GENERAL COMMENTS

The strength of this paper is the honest discussion on the limitations and relevance of these findings on real-life scenarios. However, these findings can be relevant to build future studies that address the limitations discussed. There are some minor grammatical edits that I would recommend. Otherwise well written.

| REVIEWER | Claudio Flauzino de Oliveira  
Hospital Israelita Albert Einstein  
Sao Paulo  
Brazil |
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| REVIEW RETURNED | 08-Apr-2014 |

GENERAL COMMENTS

1- although participants self-reported fatigue did not differ between the two groups, the result of fluid infusion rate by bolus is significantly lower for bolus 2 (PPT group), raising the question whether one health care provider can get tired or distracted the question is: would the result be different if PPT resuscitation had been performed by two health care providers (alternating turns)? is this point worth mentioning in the discussion?

2- it is not clear for me if all syringes were already ready and prepared before commencing resuscitation (DRT technique) it is important to be clarified as, if it was the case, this clearly do not reflect what happens in real clinical situation

3- although statistically significant, the difference in overall fluid infusion rate, when converted to minutes and seconds, is really
therefore, it seems to me that the main conclusion could be: prefer DRT when multiple health care providers are available; choose PPT when there is shortage of personnel, physical space or resources (number of syringes)

| REVIEWER       | Katie Saunders          |
|----------------|-------------------------|
| Cambridge Centre for Health Services Research, UK | |
| REVIEW RETURNED | 11-Apr-2014            |
| GENERAL COMMENTS |                         |
| • The statistical methods used in this study are appropriate throughout |
| • The title of the study should be emended to clarify that this is a non-clinical study. This should be also be re-stated in the study objective at the start of the abstract, in the key messages in the article summary and in the introduction to the study. |
| • I am uncertain about the registration and classification of this work as a clinical trial (p5 line 45). The subjects are not receiving interventions; they are health professionals participating in a research experiment, testing their clinical skills in a non-clinical setting. |
| • The observed difference in rates of 0.15 ml/s is less than the 0.2 ml/s that the investigators deemed clinically relevant in the power calculation p8 line 53. This should be commented on in the discussion |
| • Blinding. (p7) The DRT technique requires 2 people (table 3 page 16) and the research assistant gave start and stop signals (p8 line 13) which were used by the raters. Neither research assistant nor participant were blind to the technique and so I do not think that this study can be classified as single blind. |
| • “Outcome assessors were blind to the purpose of the study” (page 7 line 19) Does this mean that the video assessors of volume / rates / time were blind to the infusion strategy for each experiment rated? This should be clarified (also see p8 lines 1-15) |
| • Table 2 (footnote), the p-value for the comparison in infusion rates between boluses 1 and 2 for PPT should be stated, if tested, even if non-significant |

| REVIEWER       | Lee, Kyeong Ryong |
|----------------|------------------|
| South Korea    |                  |
Figures look like 30 ml syringes. Model setup is 60 ml syringes, isn't it? How about double PPT? I think it's more effective than DRT or single PPT.

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**VERSION 1 — AUTHOR RESPONSE**

**Joelle Simpson**

The strength of this paper is the honest discussion on the limitations and relevance of these findings on real-life scenarios. However, these findings can be relevant to build future studies that address the limitations discussed. There are some minor grammatical edits that I would recommend. Otherwise well written.

Thank you for the complimentary appraisal of our paper. The manuscript has been reviewed for grammar.

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**Claudio Flauzino de Oliveira**

Although participants self-reported fatigue did not differ between the two groups, the result of fluid infusion rate by bolus is significantly lower for bolus 2 (PPT group), raising the question whether one health care provider can get tired or distracted the question is: would the result be different if PPT resuscitation had been performed by two health care providers (alternating turns)? Is this point worth mentioning in the discussion?

The fluid infusion rate for PPT bolus 2 was actually not statistically significantly different from the rate of bolus 1 (See Table 2; page 13, line 3) and this is also explained in the Results and Discussion sections. Data from our previous work did suggest that progressive provider fatigue occurs with ongoing manual fluid administration (page 13, line 13). While it is possible that provider switches could mitigate provider fatigue, such a recommendation is not supported by our data and in fact participants' fluid administration rate actually increased over time. (See Table 2 and footnotes) We agree that the issue of provider fatigability is important and requires further study, recognizing that provider switches could also introduce procedural delay.

It is not clear for me if all syringes were already ready and prepared before commencing resuscitation (DRT technique) it is important to be clarified as, if it was the case, this clearly do not reflect what happens in real clinical situation

Syringes were not prepared for participants prior to commencing resuscitation with either technique. This has been clarified in the Model Setup (page 5, lines 12 and 14). More details of the model setup and intervention can be found in the published protocol (See reference 21).

Although statistically significant, the difference in overall fluid infusion rate, when converted to minutes and seconds, is really small
therefore, it seems to me that the main conclusion could be: prefer DRT when multiple health care providers are available; choose PPT when there is shortage of personnel, physical space or resources (number or syringes).

The 95% CI [0.055 mL/s, 0.251 mL/s] for the mean difference in rates did contain the value that we had specified a priori to be clinically significant in powering this study (0.2 mL/s). The issue of clinical relevance is discussed within the manuscript and we agree that this is as of yet this unclear. We leave this to readers to consider. The Conclusion has been reworded (page 16, line 21) to highlight the other considerations important in the selection of a manual fluid resuscitation technique.

Katie Saunders

The statistical methods used in this study are appropriate throughout.

The title of the study should be emended to clarify that this is a non-clinical study. This should also be re-stated in the study objective at the start of the abstract, in the key messages in the article summary and in the introduction to the study.

I am uncertain about the registration and classification of this work as a clinical trial (p5 line 45). The subjects are not receiving interventions; they are health professionals participating in a research experiment, testing their clinical skills in a non-clinical setting.

The observed difference in rates of 0.15 ml/s is less than the 0.2 ml/s that the investigators deemed clinically relevant in the power calculation p8 line 53. This should be commented on in the discussion.

Although the point estimate of the mean difference observed in this study was 0.15 mL/s, the 95% CI [0.055 mL/s, 0.251 mL/s].

Blinding. (p7) The DRT technique
| requires 2 people (table 3 page 16) and the research assistant gave start and stop signals (p8 line 13) which were used by the raters. Neither research assistant nor participant were blind to the technique and so I do not think that this study can be classified as single blind. | did contain the value that we deemed clinically significant a priori and used in our power calculation (0.2mL/s). This has been noted in the Discussion (page 16, line 13), and the question of its clinical relevance discussed. |
| “Outcome assessors were blind to the purpose of the study” (page 7 line 19) Does this mean that the video assessors of volume / rates / time were blind to the infusion strategy for each experiment rated? This should be clarified (also see p8 lines 1-15) | We have edited the Blinding section of the manuscript which now provides additional detail and highlights the efforts undertaken to minimize risk of bias. Please see this section (page 6). |
| Table 2 (footnote), the p-value for the comparison in infusion rates between boluses 1 and 2 for PPT should be stated, if tested, even if non-significant | The outcome (video) assessors were blind to the objectives of the trial and extracted time data from videos that showed only the graduated cylinder collecting the administered fluid. Paired videos with different a viewing angle were used to extract data related to technical errors. The Blinding section (page 6) has been edited for clarity. |
| This data has been added to the footnote of Table 2 (pages 12 and 13). |

**KR Lee**

| Figures look like 30 ml syringes. Model setup is 60 ml syringes, isn't it? | Figures 1 and 2 serve to illustrate the techniques under study and the steps required to perform these. The reviewer is correct that 30 mL syringes are depicted in the Figures, however we feel that these suit the required purpose. Our methods clearly state that 60 mL syringes are used in this study. |
| How about double PPT? I think it's more effective than DRT or single PPT. | The reviewer raises an interesting point. This form of PPT is not used in our hospital, to our knowledge, and it was not investigated in the current study. It would be interesting to evaluate this alternate form of PPT in future research. |