Author’s response to reviews

Title: Smart Pumps and Random Safety Audits in a Neonatal Intensive Care Unit: a new challenge for patient safety

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Author’s response to reviews: see over
Dear David A Paul,

Please find below our comments regarding the suggested corrections to the paper.

REFEREE 1:
Overall, I have concerns about the design of the study. This seems to be a pre and post intervention study of the implementation of new pump software and training to accompany it. However, the authors claim that the improvement seen is a result of Random Safety Audits (RSA). I believe that RSAs can be used to identify quality problems and implement change resulting in improvement, however, it seems the authors used them to take a measurement of the pre and post-implementation phase of a project. This is not in the spirit of how RSAs are intended to be used. Furthermore, for this to be a quality improvement publication, the data presentation should be such to see improvement over time (run charts or control charts). In my opinion, the authors should consider rewriting this paper to decide if they are doing a pre/post analysis of one intervention (which is legitimate but not in the spirit of RSAs and therefore can use the current type of analysis) or continue to track data over time and use the RSAs as originally intended to show continuous improvement and express their data over time with weekly/monthly measurements. In this way, I believe further review of the specific details of this manuscript can be postponed until the authors resolve the design issue above.

Dear Michael Posencheg, as you say, RSAs are tools to detect errors and potential risks, and are basically intended for the continuous monitoring of certain procedures. However, although they have traditionally been used for monitoring purposes, another possible use would be to consistently detect weaknesses and subsequently apply corrections. These procedures can continue to be evaluated after the change through monitoring. Error identification through audits maintained over time can be useful, as repeated weaknesses in the system are identified that do not depend on the professionals involved or the circumstances. These concepts have been described both in the introduction and the discussion Lines 87-92; 298-302.

REFEREE 2
LINN BAYNE

Title of Manuscript: Smart Pumps and Random Safety Audits in a Neonatal Intensive Care Unit: A New Challenge for Patient Safety
Summary Comments: I am unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions. However, the work has merit and is of concern to the global NICU community—physicians and nurses. These major compulsory revisions are offered in order to enhance the manuscript's readability and strengthen the scientific merit of its body of work. An improvement opportunity exists to show that the results of the random safety audits (RSAs) actually decreased the number of safety events that the unit experienced in terms of reduced medication errors and/or reduced infiltrates/extravasations. RSAs are most useful to develop and to identify compliance with a clinician unit's guidelines and manufacturer's intended product use. I would probably explain RSAs a little more in the “introduction” section of the paper. In its current format, the report shows that the pumps were working as the company intends them to work but the true patient safety impact data is still soft. My global comments re: the article is as follows:
1. It would be good to define what a random safety audit is and why it is useful in healthcare setting as a means to promote safety for bedside clinician.

A definition of RSA has been included in lines 76-82 of the paper.

2. A brief overview of Delphi technique including who participated in the exercises, how it was conducted, and what the exact derived checklist was for infusion pump. The mention of the other 22 technologies that were also being evaluated (device/procedures) concurrently with this performance improvement report was somewhat distracting. I would have confined the manuscript to focus solely on this product and safety features.
The Delphi model is described and the participants in the meetings are mentioned in lines 110-112 of the paper. The pump variables audited are described in lines 138-143.

**Abstract/Methods:** Were both time periods truly prospective? If so, why were they of differing lengths? Why wasn’t there a stronger consistent sampling plan for audits during both periods so that the audits were 24 x 7 (after all safety events happen at night)? Because the first phase covered so many devices/procedures, I do think there was chance that bias may have impacted the findings. Why wouldn’t the number of measurements be the same in both phases? What was the definition of a measurement? Is it the completion of an audit card on a single patient using a single pump? What was the definition of their shifting patterns? Were they 8 hours or 12 hours?

The two periods were prospective, lines 115-123; 133-137 and 159-163. In the first period (1 January 2012 to 31 December 2012) RSAs were performed on 23 different resources and procedures, one of which was the medication pumps. The data from this first period was analysed in 2013, when it was discovered that the use of the pumps was inappropriate in most cases. The program was immediately installed and theoretical and practical training was provided in workshops for doctors and nurses. After a period of adaptation to the program, all the information stored in the pumps in 2014 (shown on figure 2) was downloaded. In the second period (1 November 2014 to 31 January 2015), there were more RSAs, in this case only affecting the medication pumps, so a large number of data were collected in only three months. The data presented correspond to the first and second period, plus the downloaded information stored in the pumps throughout 2014. This is explained in lines 115-123 of the paper. This is why the number of measurements was different, and much larger in the second period, as the pumps were audited each time a RSA was performed.

Audits were conducted every day of the week, including weekends, and the shift was chosen at random. The night shift was not audited as the investigators were not available, and we realise that this is a limitation to the study. The lengths of the shifts are also given in these lines. In the second period, we focused solely on the RSAs of the pumps, which were the only reaudited devices, so the other procedures had no impact on the results.

**Abstract/Results:** As the authors started talking about the first period with 52 measurements (on how many different patients?), then shifting to the second period, I found it confusing that they presented the second period data first. Be consistent in presentation of data. Also, that seems like a LOT of infusions for 500 annual admissions when the second period audit only covered 3 months. It was not clear if that was the total number of infusions over the second period only or over both time periods.

**Introduction:** This was actually a performance improvement initiative rather than a research study. Again, you might consider a table to illustrate the derived audited variables. It also seems that the determination of which variables were to be audited was developed during this baseline. Were the pumps in use at this time and had people been trained to fully use the features of the device?

The number of patients affected by the audit in the first period was 32, followed by 83 in the second; this has been included in lines 199-200.

An explanation of the different study phases has been added to the methods section. Lines 115-123. As described in lines 138-143 and shown in Tables 1 and 2, the audited variables were: line type (central/peripheral), pressure alarm programmed (yes/no), appropriate pressure alarm (yes/no) (it was considered appropriate when programmed to 30–50 mmHg above the working pressure), volume to infuse programmed (yes/no), correct programming for volume to infuse (yes/no), correct infusion rate (yes/no). In addition, an outcome variable called appropriate use was defined. In this variable, the overall outcome was very demanding since the outcome appropriate use was only assigned when all the evaluated items were completely correct for a same device.

**Materials and Methods:** I would also like to see a clear explanation of the timeline of the project: 1. What were the unit’s baseline practices relative to infusions prior to use of these pumps? Before the start of the study, Alaris pumps were used without the program, which was installed later, with standard training provided to nurses joining the unit. As the study describes, their use was inappropriate as, for instance, alarms were not correctly programmed.

2. When were the pumps acquired?
2005.

3. How the pumps were installed?
   The new ones were installed in 2013.

4. Was there a discussion of the possible errors that caused the team to look at the pumps through RSA eyes?
   The data were analysed after the first period, and presented in meetings with doctors and nurses for discussion and suggestions for improvement.

5. When the 1st round of audits were done—this may merely be confirmation of the 1st round timeline from 1 January 2012 to 31 January 2012?
   Sorry but, we don’t understand this question.
6. What was the exact bundle of behaviors that were derived from this 1st round audit including retraining and software installation? There is a brief discussion of a unit based safety program having ended in June 2013. So what did the monthly data look like across the entire time of the study (phase I and phase II).

Meetings were held to discuss the results. The Guardrails CQI Event Reporter® program (CareFusion) was installed, and theoretical and practical workshops were given to doctors and nurses in the team and to all those who joined later. The drug library was reviewed and a detailed written protocol was drawn up for its use. This is described in the paragraph from lines 144-158.

7. Why the time lag until 1 November 2014 through 31 January 2015 for phase II audits from the phase I audits? Why 12 months for the 1st phase and 3 months for the 2nd phase? The time between the two phases was spent on data analysis, detection of weaknesses, introduction of the program, drafting of the protocol and drug library and training of the unit’s doctors and nurses, as well as a period of adaptation to the changes introduced.

8. Why the difference in number of audits between the two periods? The difference is explained in lines 115-123; 133-137 and 159-163 of the manuscript. The number of measurements was different – much higher in the second period – because during the second period the pumps were audited each time an RSA was performed.

9. How were the audits done—individually or together as a team? For example, when a day and shift were randomly selected (e.g. by a random number generator, etc.)? were all babies using an infusion pump in the NICU audited? The day and shift on which an audit was performed were chosen by drawing lots, not automatically. During the first period, the devices/procedures to be audited were also chosen at random. Two observers (EBS and MCPG) took part in the study; they recorded the data independently (one of the two for each day). The degree of agreement between the two observers, as measured by the kappa coefficient, was 0.93.

10. Did the staff realize that they were being audited? The NICU staff did not know the purpose of the audit but if an error was detected that might have involved a potential danger to the patient, the caregivers were immediately informed. Lines 133-137.

11. What specific baby data was collected? Any information about patient acuity? Are sicker babies in the larger room? Is there anything different about nursing expertise between the rooms? The following data was recorded, which is detailed in lines 167-170. The large area, NICU-A, receives at-term newborns, surgical cases and patients who have been transferred from another hospital. The other two areas, NICU-B and -C, receive newborns of less than 30 weeks. Therefore, there are no differences in terms of severity, but there are differences in the characteristics of the patients. In all areas the nurses have varying levels of experience. Lines 103-107.

12. Were any unit specific guidelines generated from the 1st round audit? As explained in question 6 and in lines 144-158.

13. When did the infusion pump auditing software get installed? The program was installed in 2013.

14. If the pumps were there in phase #1, what was the content of any re-training? Up until 2013, standard training was carried out on arrival in the unit. After that date, training was carried out in small groups, with 2-4 hours for each group, and for each shift, that was repeated to ensure the training of all staff.

Analysis plan: You also appear to use run control methods in Figure 2. However, the data presented in 2014 data yet your audit periods were different and not presented. This is explained in lines 117-123.

Results/Random Safety Audits: I believe that is you had had a stronger sampling plan for the
audits, and then you would have had a nice variation of working days versus weekends/holiday as well as day versus nights. This might have happened with use of a random number generator to select the day of the month as well as the shift. The days and shifts were chosen at random by drawing lots on the first day of each week; the devices/techniques to be audited were chosen in the same way. We do not have a random number generator. The night shift was not audited due to the lack of availability of the investigators; we understand that this could be taken to be a limitation in our study. See lines 126-133.

**Results:** This may have been an issue of translation from Spanish to English but the work perfusion started to find its way into the manuscript at this time. According to my medical dictionary, infusion is the act of introducing a substance into the vein, artery, or tissue while perfusion means nutrition delivery of arterial blood to tissues, organs. Technically, I believe these are classified as infusion pumps.

I would have likes to see data that the number of infiltrations/extravasations was different, that the number of children who received excess volume was reduced, or that the number of patient reported side effects from too fast infusion rates was reduced, as direct evidence that this initiative increased safety. If the 1st phase was evidence that they clinicians were not using the pumps as designed and intended, one would or could have done a chart review under IRB permission to demonstrate that drug overdoses were reduced.

We have changed all instances of "perfusion" in the manuscript to "infusion". We consider this suggestion to be both relevant and interesting, and we accept that this could be considered to be a limitation in our study, but we do not have this data available. We already had a suggestions box, which could be used to report errors and we analysed the reports; however, this of course does not indicate the number of errors, but rather the willingness of healthcare professionals to report them.

It has attempted to revise the English used in the manuscript for improvement.