PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	USE OF FMEA TO REDUCE RISK OF ERRORS IN PRESCRIBING AND ADMINISTERING DRUGS IN PEDIATRIC WARDS: A QUALITY IMPROVEMENT REPORT.
AUTHORS	Lago, Paola; Bizzarri, Giancarlo; Scalzotto, Francesca; Parpaiola, Antonella; Amigoni, Angela; Putoto, Giovanni; Perilongo, Giorgio

VERSION 1 - REVIEW

REVIEWER	Casper Bollen, MD, PhD Pediatric Intensivist Epidemiologist Department of Pediatric Intensive Care University Medical Center, Utrecht The Netherlands c.w.bollen@umcutrecht.nl I declare no competing interests
REVIEW RETURNED	18-May-2012

THE STUDY	Is the research question clearly defined? The authors state: 'This report describes our experience with FMEA'. Which is not a clear research question. Yet, in their conclusion they claim: 'FMEA is an effective proactive tool for enhancing the safety of drug delivery to children' implying that use of the the tool has an effect on safety of drug delivery. Therefore, the implicit question is an intervention question. Is the overall study design appropriate to answer the research question? When restricted to the descriptive nature of the study, the design seems adequate, however, as mentioned, some implicit research questions invalidate the design. Are participants etc.. clearly described? No, it is unclear what the exact composition was of the teams performing the risk analysis. It is merely mentioned that 'Each team consisted of eight members, including doctors, residents, nurses and quality managers'. The main outcome measure was not clear, relating to the vague nature of the research question. Overall, it seems that the authors wanted to show a reduction in the 'RPN' score after implementing measures to reduce this score. The abstract/summary/key messages/limitations are not accurate enough. The main objection can be posed to the statement that 'Its relevance to clinical practice is therefore not supported primarily by performance data. There is nonetheless a strong conviction that

	analyses are needed to correlate changes in RPN with actual improvements in performance'. I.e., you just have to believe that FMEA works. But what about reproducibility of the analyses, and what about before after measurements in drug errors/complications? These could be very valid research questions to investigate the benefits of FMEA.
RESULTS & CONCLUSIONS	When the research question is not clearly defined (unfortunately a very common problem) it is very difficult to provide a good answer to the implicit research questions. Basically, two questions could be raised (but are not answered): 1. FMEA is a classification tool and, therefore, raises a diagnostic question of how well and reliable can FMEA detect potential risks? 2. What is the effect of FMEA as an intervention on clinical outcome (patient safety, complications)? A big problem in the results is that a 'dramatic reduction' is reported in decline in RPN, but these results seemed to have been produced, unblinded, by the same teams that calculated the original RPNS. This introduces a substantial observer bias, i.e. misclassification of RPNS. It almost sounds like a self fulfilling prophecy. To conclude that FMEA is an effective tool without measuring a clinically relevant effect is not the conclusion that could be drawn from the current presented data.
REPORTING & ETHICS	It is difficult to determine which reporting statement or checklist could be applied to this study. However, given the diagnostic nature of the FMEA too, I feel that the application of the STARD statement could be applied. When FMEA is used as an intervention to change clinical practice, probably the STROBE statement would be the most appropriate.
GENERAL COMMENTS	Although I sympathize with the conviction of the authors that FMEA is an effective tool to improve complex processes like drug prescription in children, as a researcher I should question this conviction. And that is my major concern with the present manuscript, it lacks scientific value as it is not critical and does not question or evaluate the conviction that FMEA is of benefit.

REVIEWER	Kathleen E Walsh, MD, MSc Associate Professor of Pediatrics University of Massachusetts United States
REVIEW RETURNED	10-Jul-2012

THE STUDY	This is the report of a quality improvement project at a single institution. Such a report is valuable, at least in part, because it describes an approach taht may be used at other institutions. Some of the above questions don't seem relevant. The English could use a bit of cleaning up.
GENERAL COMMENTS	This is a generally well written article describing the use of FMEAs in quality improvement at a single hospital. My main concern is that the presentation of the results in primarily a table form is a bit confusing and could be improved upon. I though Saul Weingart did a good job publishing his FMEAs in Journal of Oncology Practice- you could look there to see how he describes his results. It might be interesting to compare the FMEAs you performed in different settings of the hospital- were there important differences between the NICU and other units? What about hem/onc and general pediatrics?

	There were some minor problems with the English used in the paper. Specific comments: Under key messages: it would be opportunities for error (not of) - Either FMEAs provide or FMEA provides Under strength and limitations - the work "per se" in the second bullet doesn't really make sense. You could remove it entirely and the sentence would make a little more sense In the abstract: double checking "inter-pares" I am not sure what you mean by that. The introduction is well written and clear. Methods are also generally clear. I would remove the word medical from "All medical prescription". In the same sentence there is a typographical error- with a space before the period. The next sentence would make more sense if you remove "and administered" from the part that says "prepared and administered by registered nurses" because you discuss administration in the next part of the sentence. Regarding the team- it seems a bit narrow- are there other people who should have been involved. Our FMEA teams typically include the unit secretary, the housekeeper (when needed), the pharmacist, sometimes a patient or parent. It would be helpful to describe any training that was given to the group before they began the FMEA. Regarding the results- see above. The tables contain too much information and there are too many of them- it is hard to find the important information here. I would suggest reducing the number of tables and including more information in the text. The text that is included is well written. I have not seen anyone repeat an fmea to compare results. Was their some prior study that the authors could cite here? If not, could the authors justify this a bit more in the methods? The discussion describes speed as an advantage to the FMEA. In addition to this, by including the front-line team and describing the process, the FMEA gives different information than one can garner from incident reporting or other sources. It is often used in conjunction with these other sources of information. I think the primary advantage is probably the unique information gathered rather than the speed. In any case, there is some literature about the strength and weaknesses of fmea and other methods (Frank Rath, Int J Rad Oncol Bio Phys; also literature from the American VA) that should be sited in a discussion of the strengths and weaknesses of the FMEA. The discussion of the health IT seems a bit tangential given that the setting does not have health IT. Perhaps I would shorten that section or link it more closely to the results of your FMEA.

	Overall this is an interesting article which would be useful to other institutions implementing fmeas to improve the safety of medication use.

VERSION 1 – AUTHOR RESPONSE

oWe have clarified the research question in the abstract and in the introduction.
oWe have better defined the composition of each team involved in the FMEA.
oWe have elucidated the main outcome measure, as reported in the abstract and methods.
oThe abstract/summary/key message/limitations have been reworded because the redefined main goal of the proactive risk analysis was to "identify the higher risk failures in the process of drug delivery to children and prioritize corrective actions to reduce the risk of error and enhance patient safety".
oRegarding the validity of FMEA and the impact of improvement efforts on clinical practice, we have added some comments in the discussion. Our goal in this study, however, was to show a reduction in the risk of drug delivery errors achieved by introducing changes in the process relating to the higher-priority failure modes.
oThe goal of FMEA is to reduce identified risks and it has the potential for increasing patient safety by means of specific actions: the efficacy of our corrective actions was demonstrated by the new, lower RPNs and validated by our outside consultant with extensive experience of proactive risk assessments, who guided the whole FMEA procedure in accordance with international standards. In our setting, FMEA really was a valid improvement opportunity.
oThe conclusion has been changed as requested, mitigating our optimism concerning our results in terms of the clinical validity of the revised process, which needs to be demonstrated by other indicators.

As for the comments from the second reviewer:

oThe revised paper has now been thoroughly checked by an English mother-tongue professional translator.
oWe have changed the presentation of the results as suggested, replacing Tables 2 and 3, and Figure 2, with the new Tables 2, 3 and 4 and describing the differences emerging from the FMEA in the different settings.
oWe have inserted all the corrections requested in the reviewer's "specific comments".
oWe have better explained the composition of the team and the training the team members received before starting the FMEA.
oRegarding the comment, "I have not seen anyone repeat an FMEA to compare results", other authors have reported recalculating RPNs to measure the reduction in the risk of failure modes occurring after making changes to the process concerned (and the author cited by the reviewer - Frank Rath - is among them) (Apkon M et al. Qual Saf Health Care 2004 and Bonfanti G. J Nephrol 2010).
oThe discussion has been modified as suggested, and completed with details on the strengths and weaknesses of FMEA. The discussion of the health IT has been abbreviated.

VERSION 2 – REVIEW

REVIEWER	Casper Bollen MD PhD Pediatrician Intensivist Department of Pediatric Intensive Care University Medical Center Utrecht The Netherlands No competing interests to declare.

REVIEW RETURNED	06-Sep-2012

THE STUDY	The research question seems clear. It is a descriptive qualitative study. Description of statistical methods are not applicable. Consort statement is not applicable to this study. In the methods section the authors describe their reevaluation of RPN's as follows: After taking any corrective action, its efficacy was evaluated by means of tests conducted in the wards and supervised by the consultant in accordance with international standards: these activities enabled us to estimate new occurrence, severity and detection scores for the drug delivery process and thus ascertain the efficacy of the corrective action and calculate the new RPN. I do not understand this, what is meant with tests conducted in the wards. Do the authors mean they reevaluated using FMEA the potential for errors to happen?
RESULTS & CONCLUSIONS	The study aims to identify and understand failure modes associated with drug delivery by means of FMEA. Yet, their main conclusion is that FMEA is an effective tool to enhance safety of drug delivery to children. There is a mismatch between the question and the answer/conclusion. In the last sentence of the study the authors claim that they were able to demonstrate a reduction in the risk of drug delivery errors. Again, the results do not support this, they show a reduction in the potential risk. So, I would suggest just to add the word potential, as that is exactly what a FMEA aims to do, reducing the potential for risk.
GENERAL COMMENTS	In in all this is a valuable descriptive study of use of FMEA in a clinical setting. However, I think that the current document is too long (3369 words). I would advice to shorten the introduction and the discussion, specifically by leaving out descriptions of reported literature and use of CPOE as they are not directly relevant to the objective of the study.

REVIEWER	Kathleen E Walsh, MD, MSc Associate Professor of Pediatrics University of Massachusetts United States
REVIEW RETURNED	25-Sep-2012

THE STUDY	It could use a good read through before publication- the writing still needs a bit of cleaning up.
GENERAL COMMENTS	This version of the paper is much improved. The paper is important to others interested in implementing a similar approach to qualtiy improvement

VERSION 2 – AUTHOR RESPONSE

oWe have clarified the comment about the tests being conducted in each ward together with the consultant, in order to show that the organizational and clinical changes introduced after applying FMEA to the pharmacological process were effective in reducing the risk of errors. In other words, we checked, in a statistically significant sample, whether the new activities were implemented in routine practice during an internal audit. For instance, we checked the evidence of doctors/nurses double-checking prescriptions and the preparation of drugs in a statistically significant sample of medical records. We have added a further explanation of this on page 8.
o We have added the word “potential” in the last sentence of the study.
oWe have shortened the introduction and the discussion sections, omitting the description of the literature listed in the references and the explanation of the use of CPOE as suggested (see pages 4,14,15).

VERSION 3 - REVIEW

REVIEWER	Casper W Bollen MD PhD MSc Pediatric Intensivist Pediatric Intensive Care Unit University Medical Center, Utrecht, the Netherlands
REVIEW RETURNED	03-Nov-2012

GENERAL COMMENTS	Well written and concise report highlighting potential sources of error in the drug treatment process.