Reviewer's report

Title: Enhancing an adult-based computerized provider order entry system to meet the unique needs of children: description of an advanced dosing model

Version: 2 Date: 26 August 2010

Reviewer: Lemuel Waitman

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Major Compulsory Revisions:
This a very well written manuscript of the technical characteristics of pediatric dosing decision support in an order entry system. It also provides wonderful context for the need for pediatric decision support relative to adults. Because of Duke University’s pioneering role in advancing adverse drug event measurement and surveillance, the authors have an excellent opportunity to evaluate the impact of such technology on patient care.

The challenge for me as a reviewer with the manuscript in its current form is twofold:
A. the study design is weak for determining impact on the primary outcome
B. if the paper is considered a technical advance, it makes no mention of prior decision support methods developed academically or available commercially. Thus, it is difficult to determine the magnitude of the advance.

My sense is that with additional data analysis from their rich environment, they could reposition the paper as an evaluation of pediatric dosing decision support even as a pre post study and make a significant contribution to the field. I will make suggestions in section A below. If they wish to describe their work as a technical advance, the need to accurately represent the advances provided by this system relative to prior art either commercially or academically. I will elaborate upon that point in section B below.

A. Contribution as an evaluation/outcomes trial
The primary outcome of this paper was a greater than 40% reduction in the incidence of adverse drug events as measured by a voluntary safety reporting system. As the authors acknowledge the challenges of using voluntary reporting system as an outcome but do not make attempts to control for confounding factors in their study design which weakens the study. I think there are two avenues to addressing this which could significantly improve the manuscript. The first option is probably the strongest while the second may still strengthen the conclusions of their work but would benefit from additional statistical review.

1. If they preserved medication orders, they might repeat the methodology described by Potts et al 2004 in the 14th citation. While in a different organization, they could evaluate the added safety gains from advanced decision support relative to an organization. The Potts article noted that CPOE alone led
to very large reductions in rule violations and medication prescribing errors and a significant but less dramatic reduction in potential adverse drug events. Since they deferred CPOE until their advanced decision support was completed, they may still measure the impact of CPOE plus their model and detect if the advanced methods significantly increased ADE reductions relative to the prior Potts publication. This may be considered a strong comparison since the Potts manuscript analyzed data prior to the incorporation of the advanced dosing decision support described in the 22nd citation and the underlying CPOE technology is the same between the two organizations.

2. The other approach would be to still use the voluntary reporting data but confounding factors in their study design to strengthen their conclusions. The reader cannot conclude that the > 40% reduction was due to the decision support or other confounding factors such as:
   a. Was there an overall decline in the rate of adverse event reporting at Duke during the study period?
   b. A decline in reporting pediatric units at Duke during the study period?
   c. There is no discussion regarding what type of errors were reduced post intervention and were they related to the medications which utilized advanced dosing or other factors.
   d. There is no discussion of other safety interventions which may have occurred during the study period. Ex: perhaps during the study period the institution implemented improved decision support for infusion pumps and most of the reduction in adverse drug events was seen in over sedation using narcotics that are to be titrated by the nurse per protocol?
   e. Additionally, the authors should consider reporting the impact of the intervention on the general pediatric units which were implemented in January 2007 and the other critical care locations in 2007 and 2009. The absence of such data raises questions for the reader. If possible, presenting results in Table 4 which align with the implemented in Table 1 would be very informative for understanding which kinds of decision support yield benefit in clinical settings.

In addition to addressing these points, the authors may seek a statistical collaborator to evaluate if they could use adult units or pediatric units not yet implemented as controls for their use of voluntary ADE reporting. Since the deployment throughout pediatrics occurred over a two year period there may be enough statistical power to use a non-implemented unit as a control. They might also provide baseline data regarding overall ADE reporting to establish that the culture of safety reporting was consistent across the study period. Or, even if the rate was changing, an interrupted time series analysis may control for an overall rate reduction.

B. Contribution as a technical advance

1. Many of the components of the advanced dosing model were present in the predecessor “WizOrder” system from Vanderbilt in 2003. The novelty from the authors in light of the prior Vanderbilt system was explicitly requiring indication
and location.

2. Other academic institutions and commercial vendors of both clinical systems and drug content systems (such as Zynx, First Databank “FDB”, and Lexicon-Multum) provide advanced dosing decision support frameworks. The authors do not describe any of the prior literature in this area or review the available descriptions of commercial frameworks. This makes it difficult to understand which components of the described work are technical advances versus a description of the current art.

3. Since Horizon Expert Orders usually utilizes First Databank as a source of medication decision support content, as a starting point the authors might be in a position to strengthen their description of the technical advance by describing the deficiencies in the current FDB framework with a level of detail in concordance with the described approach. Such a comparison would be very informative to other organizations adopting systems that depend on such frameworks for their decision support.

Minor Essential Revisions:

Discretionary Revisions:

Vanderbilt noted indication in the instructions in the dosing region and would provide a different menu option aligned with each indication. Vanderbilt also decided that they were able to use consistent dosing regions across all locations in the children’s hospital. That’s actually an interesting point for discussion as to why the author’s institution considered location AND indication a necessary mechanism for differentiating dosing decision support. One might assume that indication and patient characteristics should drive decision support and not necessarily the location performing care. This is an important topic for discussion because if decision support can be derived based on patient characteristics alone, the knowledge can be generalized and shared amongst other institutions; especially from academic centers to small community hospitals. If instead, decision support is dependent on knowledge of specific clinical locations, generalization is reduced and requires customization by local institutions which may lack such expertise.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing financial interests of any kind. My non-financial interest would be a prior abstract of mine was cited.