

Imperfection in adverse event detection: is this the opportunity to mature our focus on preventing harm in paediatrics?

Chris Wong,^{1,2,3} Charles Macias,^{1,2} Marlene Miller ^{1,2}

¹UH Rainbow Babies & Children's Hospital, Cleveland, Ohio, USA

²Department of Pediatrics, Case Western Reserve University School of Medicine, Cleveland, Ohio, USA

³University Hospitals Seidman Cancer Center, Cleveland, Ohio, USA

Correspondence to

Dr Marlene Miller, Pediatrics, UH Rainbow Babies & Children's Hospital, Cleveland, OH 44103, USA; Marlene.Miller@UHhospitals.org

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In a recent issue of *BMJ Quality and Safety*, Dillner and colleagues aim to estimate the incidence of paediatric adverse events (AEs).¹ The authors provide a thorough examination of inpatient paediatric AEs through a much-needed systematic review and meta-analysis to characterise the incidence rate. A previous systematic review was published more than 10 years ago and reported a surprisingly low AE incidence but was based on only nine studies with samples of at least 1000 patients.² Dillner and colleagues included studies regardless of sample size and identified more than 30 000 paediatric admissions and 8000 AEs from 32 studies: 22 for general inpatient paediatric care and 11 for intensive care populations. The rates of AEs between studies were, not surprisingly, heterogeneous. The authors approached this work with solid scientific rigour, using prediction intervals (PIs) rather than CIs to characterise the variability of the rate estimates and quantify in which range of estimates future studies are expected to be. PIs better allow for conclusions to be drawn and applied in individual settings, as compared with CIs in meta-analysis with expected rate heterogeneity.³ Pooled estimates for the primary outcome on the percentage of admissions with at least one AE in the general inpatient paediatric population were significantly different between methodologies and each estimate had a wide PI: 17.7% (95% PI 3.8–53.8%) for trigger tool methodologies and 3.9% (95% PI 0.3–33.7%) for the Harvard Medical Practice Study (HMPS) method. Similarly wide PI estimates for AE rates per 1000 patient days and preventability of AEs were found. The authors conclude that it

is not possible to estimate a single reliable AE rate in paediatric inpatient care due to inherent methodological limitations and differences between studies. This conclusion is not unexpected, highlighting known limitations of AE detection methodologies drawn from previous studies.⁴ Until now, it had yet to be highlighted for the paediatric population, making the work by Dillner and colleagues pivotal in our growth for improving paediatric patient safety.

Perfecting methodologies for AE identification with a resulting 'true rate' of patient harm has been a priority since the start of the patient safety movement, although ever elusive.^{2,4,5} Yet, Shojania and Marang-van de Mheen likened AE detection as an omnibus metric in patient safety inherently limited by its heterogeneity as a composite indicator.⁴ They argued that limitations in the methodologies to detect AEs make it nearly impossible to define a true gold standard methodology or true rate of patient harm. In addition, tools for AE identification are predominantly retrospective tools, where patient harm has already occurred, been documented and therefore 'flagged' by the AE detection tool rather than proactively detecting hazards before the AE occurred. These approaches can limit our ability to identify the true set of conditions under which the AE occurred (ie, root causes of harm) particularly if they depend on completeness of hospital documentation or willingness/ability among healthcare workers to provide data on context, so that we can thoughtfully grow successful prevention strategies. In the earlier days of patient safety efforts, broad-based 'hammer' tools like AE detection methodologies were

needed to convince people that patient safety events do occur and occur too frequently. With the inherent intractable limitations of AE detection methodologies, the time is right to mature our focus on building the evidence base for paediatric patient safety interventions and on proactively preventing harm.

PAEDIATRIC PATIENT SAFETY AND AES: A DIFFERENT BEAST

Children and adults experience AEs distinctly due to differences in epidemiology, demography, developmental issues and dependencies.^{2 5-7} The first few days of a newborn's life offers a plethora of examples of these unique risks.⁶ Newborns are often identified with a temporary name in newborn care (eg, Baby Boy Smith) despite their parents (and healthcare staff) likely using the newborn's given name. This adds complexity to the use of patient identifiers for medication administration. Prescribing medications in children is performed using weight-based dosing, yet newborn weight is expected to change significantly for their first several weeks of life, making dose calculations a complex endeavour. A newborn cry due to an identifier band being too tight on a leg is almost impossible to differentiate from a cry of hunger, often depending on a parent who has just began to know their newborn child to advocate for them while at the same time potentially requiring medical care of their own. The vulnerabilities of children to medical harm are further exacerbated by the complexities of receiving a significant amount of medical care outside of the hospital setting, often in multiple ambulatory settings, where patient safety interventions and human factors engineering support is not as robust, or similarly applicable.⁷ Also, patient safety interventions, such as clinical decision support in Electronic Health Records (EHRs), have mostly been designed for adult populations which may limit their effectiveness due to not including all relevant variables for paediatric patients and add potential risks for children.⁸ A comprehensive review of evidence-based patient safety interventions, supported by the Agency for Healthcare Research and Quality in 2013 by its Evidence-based Practice Centres, found few such interventions specifically designed for paediatric populations, with much of the evidence for proven strategies relying on adult studies.⁹ So even though AEs in paediatric and adult patients may occur in the same hospital, they reflect different subsystems of care in terms of the variables that are relevant to understand why they occur and may reflect unique risks. Therefore, the approach to eliminating paediatric harm must address these differences rather than simply adopting adult practices that may not work in children.

Despite the limitations discussed by others and reconfirmed by Dillner and colleagues, AE detection tools may still have a valuable role in the patient safety toolbox when applied appropriately in paediatric

populations. The relative ease of applying these tools, particularly those automated into EHRs, makes AE detection tools a fast, although non-comprehensive approach to internally identify patient safety events. For example, the need to use naloxone or development of pressure ulcers in hospitalised patients are key events that may signify lapses in patient safety that need further investigation. The vulnerabilities of children and the rarity and potential severity of some events may necessitate that paediatric patient safety systems maintain AE detection tools regardless of these limitations. For example, tools that detect AEs resulting from an unnoticed 10 percent weight loss for a patient in a particular institution are important for children with a cancer diagnosis who receive weight-based dosing chemotherapy versus an adult who receives fixed dosing.

CREATING NEW EVIDENCE TO IMPROVE PAEDIATRIC PATIENT SAFETY

Historically, paediatric patient safety research has often taken the approach of adaptation from adult patient safety research, despite their differences. The science and history behind catheter-associated blood stream infection (CLABSI) efforts best exemplifies the limitations of only adopting adult patient safety practices to improve paediatric safety. The landmark study by Pronovost and colleagues demonstrated a dramatic impact on CLABSI reduction by an evidence-based intervention focused on central line insertion in adult intensive care units.¹⁰ Yet, despite years of efforts in paediatric intensive care units across the USA, CLABSI reductions were not replicated when focused solely on central line insertion efforts.¹¹ Unlike adult healthcare and due to inherent risks of inserting central lines in children (eg, physical size and sedation needs), most central lines in children are inserted by the most experienced paediatric care providers as opposed to trainees in adult care practices. This difference is likely one of many reasons why children's hospitals were unable to improve CLABSI rates focusing on central line insertion practices. Only with the creation of new evidence-based interventions, not derived from adult studies and focused on the day to day 'maintenance' care of the central line, were paediatric intensive care units able to achieve significant CLABSI reductions and thereby to add evidence-based practices validated in paediatric populations.¹¹

As another example, paediatric sepsis is a leading cause of mortality worldwide. It differs significantly from adult sepsis as many of the symptoms are relatively common in other paediatric illnesses (such as fever) which makes diagnosis more complex and increases the risk of misdiagnosis and missed diagnosis. Advances in the diagnosis of paediatric sepsis over the last decade have not come from new laboratory diagnostics, but rather from quality improvement (QI) and safety strategies for systems-based workflow

enhancements to more safely and efficiently diagnose and begin management in the critical hour of presentation.¹² This success reflects the reality of the smaller number of paediatric patients as compared with adult patients. Paediatric patient safety evidence creation, therefore, will only come from collaboration among children's hospitals to quickly and robustly create high-quality evidence-based new interventions. With data for over 300 000 visits concerning for paediatric sepsis, the Improving Paediatric Sepsis Outcomes QI collaborative of the Children's Hospital Association has identified and implemented bundles shared in near-time by member institutions that have led to timely and accurate diagnosis, thus demonstrating decreases in sepsis-attributable mortality.¹³

RESILIENCE ENGINEERING AND PROACTIVE EFFORTS TO PREVENT PAEDIATRIC PATIENT SAFETY ISSUES

Inherently, AE detection focuses on what went wrong and why. Successful CLABSI strategies started from events that went wrong and then built evidence on how to prevent them. As another perspective, the Safety-II approach focuses on how things go right and how people can adjust their performance to the varying and uncertain conditions of work.¹⁴ Investigation of successful adaptation events through a Safety-II lens may increase our understanding of how things go right and AEs (ie, things going wrong) are prevented. With the burgeoning growth of healthcare analytics and the widespread sophistication of EHRs, healthcare institutions now have more data than ever to characterise, analyse and replicate improvement successes.¹⁵ By applying Safety-II concepts, large-scale or even national data could be used to develop predictive analytics that can identify opportunities to intervene early locally or suggest thresholds for tools such as trigger alerts for local populations. For example, if large datasets can be used to identify situations when patients with sepsis were recognised and intervened with rapidly, prior to the onset of sepsis, clinical decision support can be designed to prompt appropriate timely interventions (eg, automatic ordering and administration of an intravenous fluid bolus based on vital signs, without delaying the intervention until the provider has examined the patient and placed the order). This allows the use of early predictors and interventions for evolving sepsis that if insufficiently controlled might result in an AE.

But concerns about use of Safety-II in healthcare are real, particularly around the lack of tangible ways to operationalise Safety-II.¹⁶ Children's hospitals are leaders in safety collaboration, with compelling associations between participation in paediatric patient safety hospital network collaborations and harm reduction.¹⁷ Hospital networks that discuss and disseminate evidence-based practices, and also highlight adaptation and situational awareness, Safety-II

strategies can begin to shift the culture towards effective Safety-II implementation. Some proactive solutions to prevent patient harm such as standardised hand-off tools have their origins in paediatrics.¹⁸ Others such as early warning systems to identify patients prior to the evolution of clinical deterioration have been successfully adapted to paediatric settings.¹⁹ There are already signs that individual paediatric hospitals have begun to operationalise Safety-II with more practical tools that can be used based on Safety-II key competencies (monitor, anticipate, respond, learn).²⁰

In summary, the golden opportunity in paediatric patient safety is before us in collectively and cooperatively ensuring we have a wide set of tools and approaches in our patient safety tool box and that these tools and efforts are appropriately used and supported. The work of Dillner *et al* shines a spotlight on paediatric safety measurement and exposes that AEs occur more than they should, with an opportune call for improvement in paediatric safety research. Children's hospitals and paediatric healthcare providers now have a stronger roadmap on tools and their uses as we all work together to make care safer for children.

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ORCID iD

Marlene Miller <http://orcid.org/0000-0002-9682-6266>

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