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Patient Safety (P Lachman, Section Editor)

Top 10 Interventions in Paediatric Patient Safety

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Opinion statement

Patient safety is at the core of modern healthcare. The concept of harm caused by the processes of healthcare is evolving, and injuries once seen as unavoidable are now seen as preventable and open to mitigation. There is growing evidence of safety interventions that can influence harm. In paediatrics, much of this evidence has been extrapolated from adult studies and the questions that must be asked are as follows: Do these interventions address the major harms seen in paediatrics? And will they work in paediatric populations? Equally important is being able to differentiate between the effect of the intervention and that of the context in which it is to be implemented; what are the foundational elements of patient safety that improve the chances of successful implementation and how do we promote the use improvement science as a means to change behaviour and embed best practice? Separating these features is complex and often leaves questions about what the key components of safety interventions are. An understanding of safety theory and improvement science is required if we are to make progress in the application of complex interventions across multiple care environments. We must find ways to share learning and collaborate with the purpose of accelerating the discovery, spread and application of top safety interventions in what is truly a global challenge.

Introduction

Patient safety has been marked as a key priority of healthcare in recent decades not only because of the recognition of the extent and severity of the problem but equally because of the demonstration that successful interventions can reduce, mitigate or prevent known harm [1]. The challenge for healthcare

professionals and organizations is how to best match, prioritize and implement safety interventions that provide effective, evidence-based, relevant, achievable, measurable and best value protection from harm across the care spectrum. It is widely accepted that all healthcare staff have a professional and ethical obligation to ensure they provide the safest and highest quality care; what is less frequently acknowledged is that there is a similar ethical onus upon them to ensure that they implement safe practice on a foundation that maximizes the likelihood of success. Hence, it is important not just to identify those practices that will likely have a substantial impact but also to identify the other critical success factors and ensure they are also considered and put in place.

In 2013, the Agency for Healthcare Research and Quality (AHRQ) published a critical analysis of patient safety strategies (PSS) [2••], an update on the 2001 report, "Making Health Care Safer: A Critical Analysis of Patient Safety Practices" [3]. The report defines a PSS as a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the healthcare system across a range of diseases and procedures. The report, compiled by a panel of 20 safety experts, asked important questions to evaluate PSS including the burden of the problem, the nature and theory behind the intervention, potential benefits and harms, costs, ease of implementation and the impact of context. The authors conclude the report and an accompanying publication in the *Annals of Internal Medicine* with a suggested list of 22 PSS that are strongly encouraged or encouraged for implementation today [4]—Table 1. While the report evaluates many paediatric studies and addresses problems relevant to paediatrics safety, it did not make specific paediatric recommendations.

The AHRQ report and other such evaluations of PSS are helpful in ensuring that interventions are evidence based. The AHRQ evaluation was also very mindful of the importance of context and other supporting elements; however, these may be overshadowed by the focus on the process and the pursuit of reliability of the PSS. Finally, when interventions are described as "top safety strategies" or "strongly encouraged", there is a suggestion that these practices should be prioritized above others.

So, how do we choose what our top paediatric patient safety interventions should be? We believe that there are three key drivers (Fig. 1) that successful safety interventions require and, like a bundle, all elements are required to accrue the benefit.

- First, we need to understand the need and the problems we seek to address.
- Second, there are foundational drivers, not specific to any safety intervention, but without them, it is likely that successful implementation, spread and sustainability will fail.
- Third, we must use knowledge of patient safety and quality improvement effectively and learn how to adapt the evidence into our particular context.

In this article, we will examine these drivers and their role in the generation of safety. We will also review the list of 22 PSS and their use from the point of view of relevance, paediatric evidence base and implementation challenges with a survey of members of the Pediatric International Patient Safety and Quality Community (PIPSQC).

Measure and learn about harm and safe practice

First do; know harm.

Identifying and understanding the nature of harm caused by healthcare provides the purpose for patient safety interventions [5]. The act of measuring and sharing data is in itself an important intervention if used to support safety behaviours. There are many methods used to measure harm and at their core are tradeoffs between the ease and the detail of data gathered.

Local data on harm

Trigger tools are a rapid and informing method to measure harm and have recently been adapted for use in paediatrics. Some have been adapted to specific paediatric settings and patient groups while others have focused on general (global) care. Trigger tools are designed and weighted towards the identification of common causes of harm, but they may also pick up other causes when broad definitions of harm are used [6]. What is emerging from the application of trigger tools is how frequently harm occurs in the paediatric inpatient hospital setting. Despite an increasing awareness of and focus on the need to improve safety, many experts remain concerned at what appears to be unacceptably slow progress in reducing preventable harm [7]. Recent publications have estimated that as many as one in four children

Table 1. List of 22 patient safety practices from AHRQ report that can be strongly encouraged or encouraged because of supporting evidence

Strongly encouraged
1. Preoperative checklists and anaesthesia checklists
2. Bundles to prevent central line-associated bloodstream infections
3. Interventions to reduce urinary catheter use, including catheter reminders, stop orders or nurse-initiated removal protocols
4. Bundles to prevent ventilator-associated pneumonia
5. Hand hygiene
6. The do-not-use list for hazardous abbreviations
7. Multicomponent interventions to reduce pressure ulcers
8. Barrier precautions to prevent health care-associated infections
9. Use of real-time ultrasonography for central line placement
10. Interventions to improve prophylaxis for venous thromboembolisms
Encouraged
11. Multicomponent interventions to reduce falls
12. Use of clinical pharmacists to reduce adverse drug events
13. Documentation of patient preferences for life-sustaining treatment
14. Obtaining informed consent to improve patients' understanding of the potential risks of procedures
15. Team training
16. Medication reconciliation
17. Practices to reduce radiation exposure from fluoroscopy and CT
18. The use of surgical outcome measurements and report cards, such as those from ACS NSQIP
19. Rapid-response systems
20. Use of complementary methods for detecting adverse events or medical errors to monitor for patient safety problems
21. Computerized provider order entry
22. Use of simulation exercises in patient safety efforts

experience at least one episode of harm during hospitalization [8••, 9].

Trigger tool studies have also provided insights into the specific causes of harm. Studies of medication adverse events have identified recurrent themes such as harm related to the administration of opiates, insulin and antibiotics [10, 11]. A trigger tool designed specifically for general paediatrics identified tissue injury related to intravenous cannulas as the most common cause of harm in hospitalized children, responsible for almost one in five harm events [8••].

System-wide data on harm

Measuring harm locally is important so that improvement efforts to reduce it can be guided and verified; however, these data can also be pooled to create a big picture view [6]. Other sources of big data include collaborative improvement networks that use multisite data to drive state-wide safety initiatives [12•].

A different kind of system-wide view comes from the UK's Confidential Enquiry into Maternal and Child Health (CEMACH) [13]. The 2008 report of a sample of child deaths identified failures in a child's direct care in almost a quarter of all deaths, and potentially avoidable factors in up to half of in-hospital deaths. Of particular concern in this report was the failure to recognize deteriorating children, with the report calling for the development of paediatric early warning systems.

Finally, national or state safety bodies that evaluate reports of harm provide an important opportunity to learn about infrequent but definite harms (such as hyponatraemia caused by the use of 0.18 % saline solution) and provide safety recommendations [14].

Combining different types of data across sites and even nations provides a greater understanding of harm that allows for consensus on what the most prevalent and unwanted adverse events are in paediatric practice. This could also highlight events that are agreed to be preventable [15]. Table 2 includes a selection of features that could be considered as the goals of harm-free paediatrics.

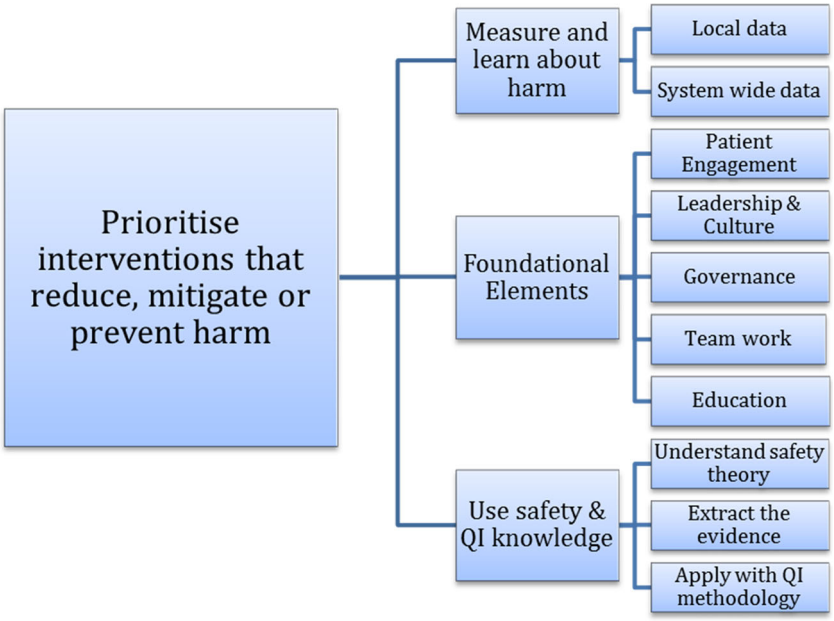

Fig. 1. Drivers to prioritize inventions that reduce, mitigate or prevent harm.

Foundational elements of safety

The foundational elements of patient safety are, we believe, those features that are responsible for what is collectively described as context when evaluating PSS. Context may been defined as "everything that is not the intervention" [16]. These are the factors that are responsible for the engagement, belief, effort and support required for successful implementation and sustainability. Focusing on internal factors only, we chose five important elements although it may be argued that there are many others [17].

Table 2. The goals of harm-free paediatrics

10 suggestions for harm-free paediatrics
1. No or minimal pain and distress
2. No tissue injury—extravasation, pressure ulcer or other tissue injury
3. No hospital-acquired infections
4. No medication or fluid injuries
5. Early recognition and management of procedural or surgical complications
6. Early recognition and management of sepsis or other life-threatening illnesses
7. Early recognition and management of in-hospital deterioration
8. Early recognition and management of safeguarding concerns
9. No unnecessary admissions, investigations, procedures or treatments
10. No psychological harm—provide a positive experience

- Patient engagement
- Leadership and culture
- Governance
- Teamwork
- Education

Bohmer emphasizes the interdependency of these elements in creating purpose for change when he describes what it is medical leaders need to communicate, "It is the value of patient benefit, patient autonomy and professional excellence that must serve as the compass of healthcare reform" [18]. The interaction between genuine patient engagement and strong clinical leadership is a key factor in the generation of a culture of patient safety.

Less commonly stressed is the importance of good governance, both at the macrosystem and microsystem levels. Good governance ensures that management systems, structures and processes are in place to provide accountability and assure the delivery of safe and high-quality care [19]. It also needs to challenge the blind pursuit of, sometimes counter-productive, externally imposed targets or assurance mechanisms from regulators and payers. [20].

Teamwork and education may be seen as traditional factors; however, the complexity and rate of change in modern healthcare mean they must evolve rapidly. Advances in human factors psychology, simulation and information technology provide opportunities to match training and teaching experiences to the needs of today.

We believe that resourcing these five foundational elements addresses many of the enablers and barriers of context in the successful implementation of patient safety practices. In fact, it is likely that these must be in place and functional in advance of any successful and sustainable safety intervention.

There remains a final foundational element that we have chosen to examine as a separate driver, one that helps to understand context but that may also compensate for and support the creation of positive context. Knowledge of patient safety and quality improvement can be used to learn much about what some authors consider a more useful definition of context, "the complex nature of local care settings—their processes, habits, and traditions" [21]

Use safety and quality improvement knowledge and capability

At the heart of choosing paediatric patient safety interventions is the question of what constitutes evidence. Is it simply evidence of efficacy? That the intervention can work. Or is evidence of reliable application and error-free implementation also required? That the proven intervention can be applied appropriately, in real world settings, and implemented flawlessly. Disentangling the practice from the system is a complex task [22].

While some of the effects of context can be addressed when assessing PSS, many remain and must be acknowledged. This is especially true when evaluating interventions in paediatrics as appraisals of safety interventions may include, but are rarely exclusive to, paediatric studies. Therefore, judgement is required about whether the intervention addresses a significant problem in paediatric care. Does it need a paediatric evidence base because of differences in physiology or pathology? And are the contextual factors different if applied in a

paediatric setting? Generating evidence that can address all of these uncertainties is a tall order and only ever likely for a very select number of problems. It is possible, however, to compensate for many of these deficits by using knowledge and expertise of patient safety and quality improvement to assess and apply existing evidence. Investing in these skills is also likely to improve the quality of new evidence as research and quality improvement knowledge combines [23].

The understanding of the theory behind harm and safety provides a significant benefit to those evaluating interventions. Patient safety theory (the concepts and models explaining the cause of harm and the source of safety) is evolving with inputs from many disciplines from within and outside of medicine. This evolution has seen a change in views of how harm occurs, in particular from harm being attributed to an individual's actions to harm being seen as a system attribute [24]. This in turn has influenced new safety interventions and supporting practices (see Table 3).

This has led to safety being seen as a continuum [25••]. Some authors have described the two ends of this continuum as safety I and safety II [26••]. The safety I end, familiar to most practitioners, portrays harm as a clear cause and effect relationship with interventions targeted at easily identified defects. The safety II end is focused on recognizing the adaptability that practitioners apply to allow everyday work to happen successfully. Many of the ideas of safety II are shared with resilience engineering, and while they have been used to describe safe systems, their practical application is yet to be established [27]. In between, however, are a myriad of concepts and models that move from simple to complex interventions, including risk management, high-reliability organizations (HROs) and resilient teams. This does not mean an abandonment of safe practices that are proven to be effective; however, it does signal the need for more sophisticated means of evaluation for complex or whole system changes.

The importance of understanding context has been highlighted by a number of high-profile publications suggesting that proven safety interventions are less effective when implemented in other settings [28, 29]. This often leads to questions about the efficacy of the intervention in the first place and is usually matched with claims of poor compliance, leadership or organizational buy-in at new sites [29, 30]. An understanding of quality improvement methodology provides an insight into the implementation

Table 3. The safety continuum. Models and concepts

		◂ Safety continuum ▸			
Example safety interventions	Safety I	Remove KCl from fluids drawers	CVC bundles	Paediatric early warning system	Safety II
Design principles		Design out error	Design for reliability	Design in resilience	
Human factors		People are a safety risk	Train for safety	People generate safety	
Risk principles		Avoid risk	Manage risk	Embrace risk	
Leadership and governance		Authority and accountability		Engagement and learning	

strategies and the foundational elements that were mobilized to support the intervention.

Finally, quality improvement knowledge provides for the development and testing of new implementation strategies that might support an effective intervention. Understanding and applying design methods to reduce the burden of trying new interventions is likely to improve the chances of success [31].

Ask the experts

As part of this paper, we wanted to assess the usefulness of the AHRQ list of 22 PSS for use in a paediatric population. We had initially evaluated this list ourselves but believed a broader view was required so we consulted an "expert" panel. In June 2015, we conducted a non-targeted survey of members of the Pediatric International Patient Safety and Quality Community (PIPSQC) about their interpretation of the PSS included in the AHRQ report and what they regarded as the top patient safety interventions.

We asked participants three questions regarding the AHRQ list of PSS. Five options were provided for each question.

1. What is the relevance of the intervention in paediatrics? (Not relevant to relevant for most, 1–5)
2. How strong is the paediatric evidence base for the use of the intervention? (No evidence to good evidence, 1–5)
3. What is the degree of difficulty in implementing this intervention? (Easy to difficult, 1–5)

We also asked respondents to rank their top three paediatric patient safety interventions, which could include interventions from the AHRQ list of 22. We received 60 survey responses with respondents from six countries (USA, Canada, UK, Ireland, Australia and New Zealand). The majority of respondents were nurses or doctors (38 and 40 % respectively) with pharmacists, allied health and administrative staff making up the remainder.

The survey results summarized in Table 4 provide an interesting insight into PSS in paediatrics and support many of our observations.

- More than 50 % of respondents ranked 20 of the 22 PSS as relevant to many or most paediatric cases
- More than 75 % of respondents ranked half of PSS as relevant to many or most paediatric cases

Medication safety, not surprisingly, topped the list of freely chosen safety interventions reflecting its importance in paediatric patient safety. This covers a broad range of harm causes and a correspondingly broad number of interventions required to generate safety that goes beyond those evaluated on the AHRQ list. Access to clinical pharmacists ranked highly as a top intervention.

It is interesting that hand hygiene, possibly healthcare's original patient safety strategy, features so prominently. An intervention that is universally accepted, cheap and effective but seen as both easy and difficult to implement, highlights the challenges of all safety interventions.

Table 4. PIPSQC survey results

Relevant in most cases	Enough or good evidence in paediatrics
1. Hand hygiene	1. Hand hygiene
2. Team training	2. Central venous line (CVL) bundles
3. Clinical pharmacists	3. Infection barriers
4. Infection barriers	4. Clinical pharmacists
5. CVL bundles	5. Team training
6. Pre-op checklist	6. Pre-op checklists
7. Consent	7. Simulation
8. Do-not-use abbreviations	8. Ventilator-associated pneumonia bundles
9. Rapid-response teams	9. Rapid-response teams
10. Medication reconciliation	10. Complementary measures of patient safety
Least relevant	Little or no evidence
Falls prevention	Falls prevention
Venous thomboembolism prophylaxis	Venous thomboembolism prophylaxis
Pressure ulcers	Do-not-use abbreviations
Easy implementation	Difficult implementation
Do-not-use abbreviations	Computer physician order entry
Hand hygiene	Team training
Consent	Alternative measurement
Top 3 (including PSS)	
1. Medication safety (including availability of clinical pharmacists)	
2. Team training and communication	
3. Hand hygiene	

Conclusion

So what are the top 10 interventions in paediatric patient safety? Are they those that address the most common or most severe causes of injury that could lead to harm-free paediatrics? Are they the 10 drivers that lead to successful prioritization and implementation of safe practice? Or are they the 10 patient safety strategies adapted from evidence-based evaluation and selected by our paediatric safety experts?

How you answer this question is likely to depend on your context. There is no single right answer. In contrast to the adult interventions in the paper by Shekelle et al., we do not believe there exists a prescriptive list of interventions to be addressed. Even if such a list could be compiled, the danger is that payers, regulators and others will focus on these simple interventions to the exclusion of others and thus perpetuate the systems failings that contribute to the majority of harm and error. Many interventions are only applicable to hospital settings and then even in specialized sections of the hospital such as PICU. Others, such as hand hygiene, are relevant in all settings and are simply foundations of good practice.

It is important to acknowledge that there has been relatively little research into the burden of medical harm occurring in the community or at home; however, studies that have examined this have found comparable or higher levels than those found in studies of hospitalized patients [32]. This is an important area of study as more care moves to the community.

We believe paediatric safety advocates must be equipped to help them address this question adequately. It may be that they can pick from a list of tried and tested interventions that have been proven in similar and specific environments and adapt with minimal changes. Some interventions should be named as standards, globally accepted, expected and reliably implemented everywhere because not doing so would be medically negligent or ethically unacceptable. Practices such as the use of central venous line bundles have a sufficient evidence base to be seen in this light. Support from foundational elements and quality improvement methods are still required and need to be seen as part of the intervention "package" when being resourced.

Addressing the majority of hazards and known harms will require more tailored solutions; based on an understanding of the nature of the problem, the theory behind interventions and the ability to adapt to local context. As opposed to other areas of science or medicine where evidence may be seen as a recipe to generate a specific outcome, in safety and improvement, evidence of effect remains only an important ingredient.

A fundamental rule of improvement is that healthcare is a complex system; focusing on simple interventions and expecting that these will result in a transformation is not consistent with a true systems perspective. It is, however, essential that the international healthcare community continues to research and evaluate safety interventions to show that specific harms can be diminished but also that we develop better methods to understand why success occurs.

The importance of the foundational elements in all improvement activity, and the fact that they are responsible for many of the positive effects of context in the successful implementation of interventions, needs to be better recognized and studied. These foundational elements also contribute to why so much activity goes right without the need for specific safety interventions. Understanding these roles and identifying which other factors are responsible for things going right is likely to provide significant insights into the future direction of patient safety.

We must continue to learn how to extract and use the good ideas from existing studies beyond the reporting of effect alone while encouraging new studies to make the theories of success more explicit [33••]. This will require an investment in capability and capacity for improvement but one that will be returned many times with better quality and safety outcomes [34].

Finally, we must continue to measure and share our learning. Paediatric patient safety communities, networks and collaboratives are leading the way in how to work together to improve paediatric patient safety. The Pediatric International Patient Safety and Quality Community (PIPSQC, www.pipsqc.org) uses social media to connect like-minded clinicians around the globe, and groups such as the Children's Hospitals' Solutions for Patient Safety (www.solutionsforpatientsafety.org) Network in the USA or the Making It Safer Together (www.mistuk.org) paediatric patient safety collaborative between children's hospitals in the UK and Ireland are transforming and accelerating how we learn about harm and safety. Together, we can make harm-free paediatrics a real goal.

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Compliance with Ethical Standards

Conflict of Interest

John Fitzsimons declares that he has no conflict of interest.
David Vaughan declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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