

Adverse Drug Event (ADE) Prevention Roadmap

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I. Background & Team

The ADE (Adverse Drug Events) Pioneer Cohort group was formed in June 2014 to determine key strategies and interventions for reducing ADEs given that ADE was the 8th largest contributor to harm caused across the SPS network.

Using analysis of the data obtained from the ADE Pioneer Cohort and available evidence from the medical literature synthesized by medication safety experts, the ADE team has developed a list of medication delivery system interventions that when implemented reliably, and carried out in the context of a comprehensive, integrated medication safety program committed to continuous learning and improvement are highly likely to result in decreased harm to hospitalized children. Reflecting the number and complexity of these system-wide interventions combined with the dependence of some interventions on capital investments which will happen at different times among member hospitals, the ADE reduction strategies are best understood as a Roadmap rather than a traditional "bundle."

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II. ADE Pioneer Cohort Data Analytic Summary

Objective

To identify the factors that, when reliably implemented, are likely to result in a reduction in adverse drug events in hospitalized children. This analysis utilizes: outcomes based on a standard operational definition, process, and survey data obtained from participating hospitals; input from cohort hospitals and clinical leaders; and external evidence from the medical literature.

Overview

The Pioneer cohort for ADE, which includes 20 hospitals, tested promising factors in an attempt to identify those factors most closely related to ADE rate reduction. Since the cohort began testing interventions in June 2014:

- The whole network has experienced a decline in ADE rates which likely reflects a secular trend in medication safety across network hospitals and important co-interventions such as SPS Culture Waves. However, the ADE cohort has achieved a both greater decrease and lower overall rates than non-cohort hospitals.
- The cohort has achieved and sustained an F-I rate (.022) which is 18% lower than the non-cohort hospitals' rate (0.026).
- The cohort experienced a decline in Level E rates of 43% (compared to 25% for network hospitals not in the cohort).

The analysis demonstrating the effectiveness of the interventions supports moving the ADE improvement work to the Aviator phase so that all network hospitals can access and implement a portfolio of factors associated with a safe medication delivery system, including ordering, dispensing, and administering medication. This portfolio of factors is called the ADE Prevention Roadmap.

Note: [Reference NCC MERP Index in the appendix](#)

Category E:	Category F:	Category G:	Category H:	Category I:
An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	An error occurred that may have contributed to or resulted in permanent patient harm	An error occurred that required intervention necessary to sustain life	An error occurred that may have contributed to or resulted in the patient's death

Data Collection and Preparation

- The cohort submitted retrospective outcomes data back to the beginning of 2012.
- Each participating hospital was expected to detect all level E-I events using their existing methods of detection. The proportion of the true number of events captured by voluntary reporting systems likely varies between hospitals. However, the assumption was made that individual hospitals were stable and consistent in their methods of detection, and therefore changes observed likely represented changes in the actual rate rather than changes in reporting behavior. The proportion of true events detected by voluntary reporting is likely higher for high harm events (F-I) than for lower harm events (E), but analysis was performed on level E events in order to have greater power to detect change.
- All data were checked for missing and erroneous data.
- The baseline period was defined as January 2013 to December 2013.
- In addition to monthly outcomes data, beginning in June 2014, the cohort submitted process reliability data for the intervention factors that they selected for implementation.

- In February 2016, 16 cohort hospitals completed a survey on how they implemented and measured individual factor elements.

Initial Data Review

During the study period, the ADE rates of the cohort dropped significantly. However, analysis with the purpose of determining which of the factors and sub-factors were responsible for this reduction was hampered.

The cohort design limited the analysis because of two issues:

1. Most hospitals reported that they had implemented several of the factors prior to beginning the ADE Pioneer work. This potentially blunted the impact of that factor's effect.
2. Hospitals did not declare which of the sub-factors they measured when reporting reliability to a factor. This confounded the attribution of the outcome effect to specific factors or sub-factors.

Survey

In order to address the design limitations, a survey was conducted asking cohort participants the following:

- Which sub-factors are you measuring?
- Which sub-factors had you implemented prior to the initiation of the pioneer cohort effort?

This survey showed that most of the hospitals had implemented certain factors prior to joining the cohort. Hereafter designated as *standard of care sub-factors*, these sub-factors were also supported by strong, pre-existing evidence in the medical literature. These *standard of care sub-factors* were subsequently excluded from the factorial analysis but considered for Roadmap inclusion.

Of note, hospitals did report which sub-factors they were measuring but did not discriminate among individual sub-factors when reporting reliability. For example, a hospital may report a single reliability value that reflects compliance with the collection of three unique sub-factors.

This information assisted the ADE leadership team by allowing them to focus subsequent factorial analysis on those sub-factors that were most likely to have made a contribution to the ADE rate reduction.

Honing the Sub-factors for Analysis

As stated, the standard of care sub-factors were ultimately considered for the bundle but were not further analyzed. To further narrow the number of sub-factors analyzed, the ADE leadership team identified the factors most commonly practiced by hospitals with rates lower than the pioneer cohort centerline and were also clinically and practically relevant. These sub-factors, designated as *INCLUDED sub-factors*, were included in the analysis. Another group of plus sub-factors were clinically relevant but had equivocal results. These sub-factors called *TEST sub-factors*, were also analyzed.

Factor Analysis

Analysis was completed on *plus sub-factors* within 4 of the original factor categories (ordering, administration, dispensing, and patient monitoring) as defined above.

For each factor category, tests of statistical significance were conducted assessing the effect of the identified *plus sub-factors*:

1. Something less than the all of the INCLUDED sub-factors
2. All of the INCLUDED sub-factors only
3. The INCLUDED sub-factors AND the TEST sub-factors.

Subsequently, ANCOVA analysis was conducted to statistically control for the initial rate of each group, and a p-value was determined.

***Level of SPS Evidence - Scenario Key:**

- **Scenario 1:** Hospitals that reliably implement an element show improvement
- **Scenario 2:** Hospitals that do not implement an element fail to improve when the system improves
- **Scenario 3:** When all hospitals implement an element, hospitals that implement an element without measuring reliability fail to improve when the system improves
- **Scenario 4:** Hospitals that reliably implement an element do not show improvement; however, relevant research literature supports adoption
- **Scenario 5:** Implementing an element is associated with improvement; however, the impact of reliability cannot be determined due to data or design factors

Criteria for Inclusion in ADE Prevention Roadmap

Using the resulting analysis as well as available information from the medical literature,* the ADE leadership team analyzed the strength of evidence for each sub-factor. Those that met the Scenario 5 were included in the Roadmap. In addition, some sub-factors with strong literature evidence were included in the Roadmap as well (Scenario 4).

Conclusion

Using both the results of the SPS Pioneer Cohort analysis and available medical literature synthesized by medication safety experts, an ADE Reduction Roadmap was developed to aid hospitals in significantly reducing pediatric adverse drug events.

****CDC Modified Recommendation Category¹¹³**

- **IA** - A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms
- **IB** - A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms or an accepted practice (e.g., aseptic technique) supported by low to very low quality evidence
- **IC** - A strong recommendation required by state or federal regulation
- **II** - A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harms

III. ADE Prevention Roadmap

Rationale

Preventing hospital-acquired conditions in children typically involves the reliable implementation of evidence based practices for one or a small number of processes. The development of a discrete bundle of 3-5 interventions is a highly effective strategy for reducing harm in these situations. In contrast, preventing pediatric adverse drug events involves many different processes and requires the coordinated interface of people, technology and processes, as well as a commitment to continuous learning and improvement over time. It takes time to establish, grow, and bring to maturity a comprehensive medication safety program that will achieve the best results for ADE prevention. Rather than considering this a “bundle,” we aim to provide a set of high-yield strategies, the application of which will be customized to hospital needs and technological capabilities and which will be intended to mature over time aided by access to expert guidance and longitudinal learning opportunities.

The SPS ADE Pioneer Cohort has developed evidence to support 13 system-level elements that are part of a highly effective pediatric medication delivery system. While SPS does not have the data to independently support the implementation of each of these elements in isolation, it does have clear evidence associating the implementation of the elements with decreased ADE rates and/or strong external evidence from the medical literature to support their implementation or in the case of the final two elements, expert opinion.

What is an ADE Prevention Roadmap?

To support the implementation of these critical system elements and thereby further decrease the rates of ADE across the SPS network, an ADE Prevention Roadmap has been developed. This Roadmap is designed as a reference for hospitals to use in order to assess and guide their implementation of key improvements to their medication delivery system. The elements, almost all of which are system-level interventions, are divided into the stages in the medication delivery process: ordering, dispensing and administering.

How to use the ADE Prevention Roadmap

SPS hospitals should begin by reviewing the roadmap and conducting a self-assessment of whether and how robustly they are approaching each of the elements. In consideration of the provided evidence as well as local hospital data (such as cause analysis), hospital leadership should develop a strategic plan for the implementation of all elements in the roadmap, acting with a sense of urgency to prevent harm but cognizant of the long-term capital investments that may be required. To chart SPS hospital progress toward this goal, SPS will conduct a network-wide survey to assess those elements that require the most collaboration and support for hospital implementation. Subsequently, SPS will repeat this survey annually to identify how to most effectively promote and support use of these best practice elements.

How SPS will help

To assist hospitals, SPS will use the survey results to design collaborative opportunities during webinars and at regional and national learning sessions to support the adoption of the Roadmap. These opportunities will include longitudinal access to and teaching by experts, guidance on customizing individual hospital roadmaps, and identifying and sharing the most effective and efficient way to implement, monitor, and continuously improve each element.

What you will report

Unlike HAC process bundles, measuring monthly reliability to many of the Roadmap elements at the network level may not be productive. For this reason, hospitals will simply complete the annual ADE Prevention Roadmap survey and will not report reliability data. Hospitals should strongly consider creating a customized plan to collect monthly reliability data to track adherence of key processes at the time of element implementation or based on gaps identified by local safety data, but this monthly data is not required at the network-level.

Summary of SPS Hospital Next Steps

1. Review the Roadmap and its supporting evidence with hospital key stakeholders.
2. Conduct a self-assessment that includes Roadmap and local hospital data.
3. Develop a strategic plan to implement all Roadmap elements with an individualized timeline
4. Complete the annual SPS ADE Prevention Roadmap survey.
5. Prioritize participation in SPS collaborative opportunities that will support effective implementation of improvements based on the Roadmap.
6. Reduce your pediatric ADE rate and help eliminate this serious harm across all children's hospitals

IV. ADE Prevention Roadmap Elements

a) Ordering Elements

Roadmap Element	Description	Level of Evidence: SPS Pioneer Analysis*	Level of Evidence: Medical Literature, CDC ** 113	Evidence Cited (Ref. No.)
Ordering: Medication reconciliation	Perform medication reconciliation within 24 hours of admission	Scenario 4	IA, IC	67-78
Ordering: Standard order sets	Utilize order sets, based on individual hospital preferences; audit strategies are used to determine how frequently they are used for eligible conditions or for specific high-risk medication	Scenario 4	IA	53-66
Ordering: Alert fatigue reduction	Monitor the number of alerts to reduce alert fatigue, i.e. decrease the volume of alerts and increase the proportion of alerts that are valuable and actionable	Scenario 5	IA	42-52
Ordering: Dose range checking	Use customized dose range checking with minimum and maximum range based on weight and surface area; alerted when outside of range	Scenario 5	IA	79-90
Ordering: Ordering through CPOE	Use CPOE, which means prescriber electronic order entry, using computerized decision support, direct to pharmacy electronic database	Scenario 5	IA	16-29
Ordering: Pharmacist on rounds	Include clinical pharmacists on inpatient rounds. For example on the following units: PICU, CICU, HEMONC, NICU, Transplant	Scenario 5	IA	91-99
Ordering: Pharmacy intervention database	Utilize pharmacists' intervention data and include it in hospital wide improvement program	Scenario 5	II	100-108
Ordering: Basic alerts	Utilize alerting intended to avoid common medication ordering issues, e.g. medication allergy checking and interactions	N/A	IA	30-41

b) Dispensing Elements

Roadmap Element	Description	Level of Evidence: SPS Pioneer Analysis*	Level of Evidence: Medical Literature, CDC ** 113	Evidence Cited (Ref. No.)
Dispensing: Independent verification	Perform independent double check before preparation of source/bulk containers (unless technology is used to validate) as well as for orders requiring pharmacy transcription for your individual hospital selected high risk medications (chemo, TPN, etc.)	Scenario 4	IB	16
Dispensing: Dispensing Cabinet/Omnice Overrides	Track and monitor medication overrides at least monthly with improvement efforts aimed at minimizing override lists	Scenario 5	IC	16

c) Administration Elements

Roadmap Element	Description	Level of Evidence: SPS Pioneer Analysis*	Level of Evidence: Medical Literature, CDC ** 113	Evidence Cited (Ref. No.)
Administration: Barcode assisted medication administration	Implement bar coding technology to match the patient identification information (ID band) to the correct medication (label information), confirmed by person administering (name badge); Verifies the right patient, drug, dose, and time. ADE Pioneer Cohort recommends monitoring compliance monthly over time and related improvement work to achieve high reliability	Scenario 5	IA	1-5
Administration: Smart pumps/guard rails	Use infusion pumps with a drug library and alert functionality	Scenario 4	IA	9-11
Administration: Smart pump data analysis	Analyze and take action on identified gaps from smart pump data to minimize use of basic mode and alert fatigue, at least quarterly	Scenario 5	IB	12

Roadmap Element	Description	Level of Evidence: SPS Pioneer Analysis*	Level of Evidence: Medical Literature, CDC ** 113	Evidence Cited (Ref. No.)
Administration: Standard medication hand- off process at shift change	Perform a handoff process with oncoming and off-going staff to verify that the medications being administered are correct compared to the order (medication administration record). This should entail a bedside check of the medications currently infusing to include pump settings and line tracing when applicable	Scenario 5	IB	
Administration: 5 Rights	Perform the 5 Rights on each patient and on each medication administration	N/A	IC	6-8, 16
Administration: Independent double check for high-risk medications	<ul style="list-style-type: none"> • Perform the double check process for your hospital-specific high risk medications: • Two individuals (RN, pharmacist, physician/provider as defined by the hospital) separately check for accuracy of the dose, the volume, and the preparation: <ul style="list-style-type: none"> – Confirm that the weight based dosing is accurate – Confirm that the volume needed to deliver the prescribed dose is accurately calculated – Confirm that the medication is accurately prepared/drawn up – Confirm that if a pump is used that the IV tubing is traced to the correct pumping channel – Confirm if a pump is used that it is programmed correctly 	N/A	II	13-16

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+ Indicates reference acknowledging pediatrics

VI. Revision History

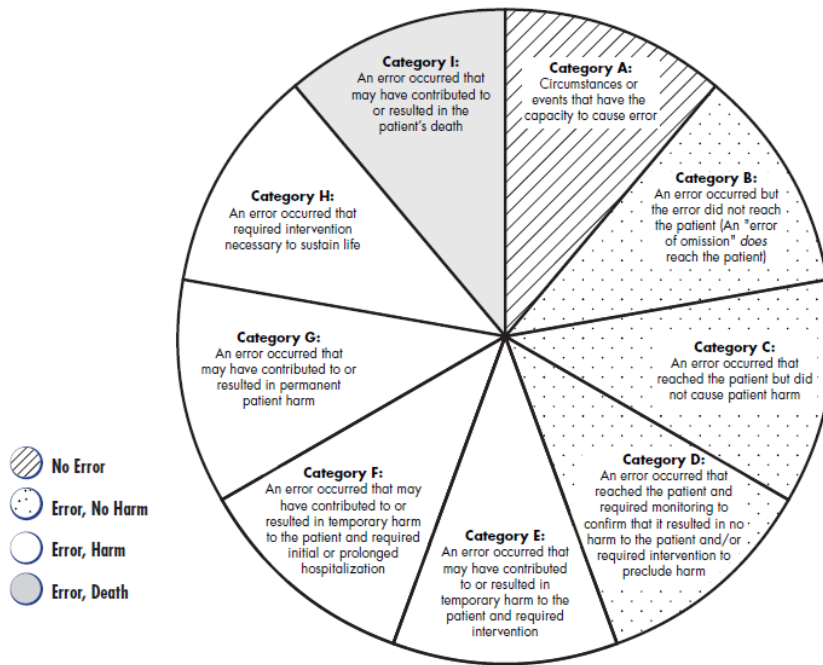
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VII. Appendix

NCC MERP Index for Categorizing Medication Errors



Definitions

Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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