

"Making Pediatric Patients Safer: Developing an Automated Detection Program at Cincinnati Children's"

Stephen E. Muething, MD

September 18, 2008

Background

- **3.7% of hospitalized patients experience an adverse event (AE)**
Brennan and Leape: NEJM 1991;324:370-376
- **2.3% AE rate in children**
Kaushal, et al: JAMA 2001;285:2114-2120
- **In Neonates, 0.74 AE/patient**
Sharek et al: Peds 2006;118:1332-1340
- **Voluntary reporting systems have been shown to detect 1-10% of AE's.**

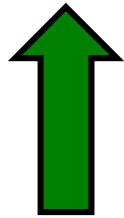
Strategic Priority to Reduce All Safety Events

- Plan to reduce Serious Safety Events involves error prevention program, redesign patient safety governance, new approach to cause analysis and response to SSE, transparency and other tactical interventions
- Plan to reduce Adverse Events involves specific process improvements in addition to overall culture change
- Need to detect and understand all safety events in order to improve.
- Current detection system felt to be inadequate

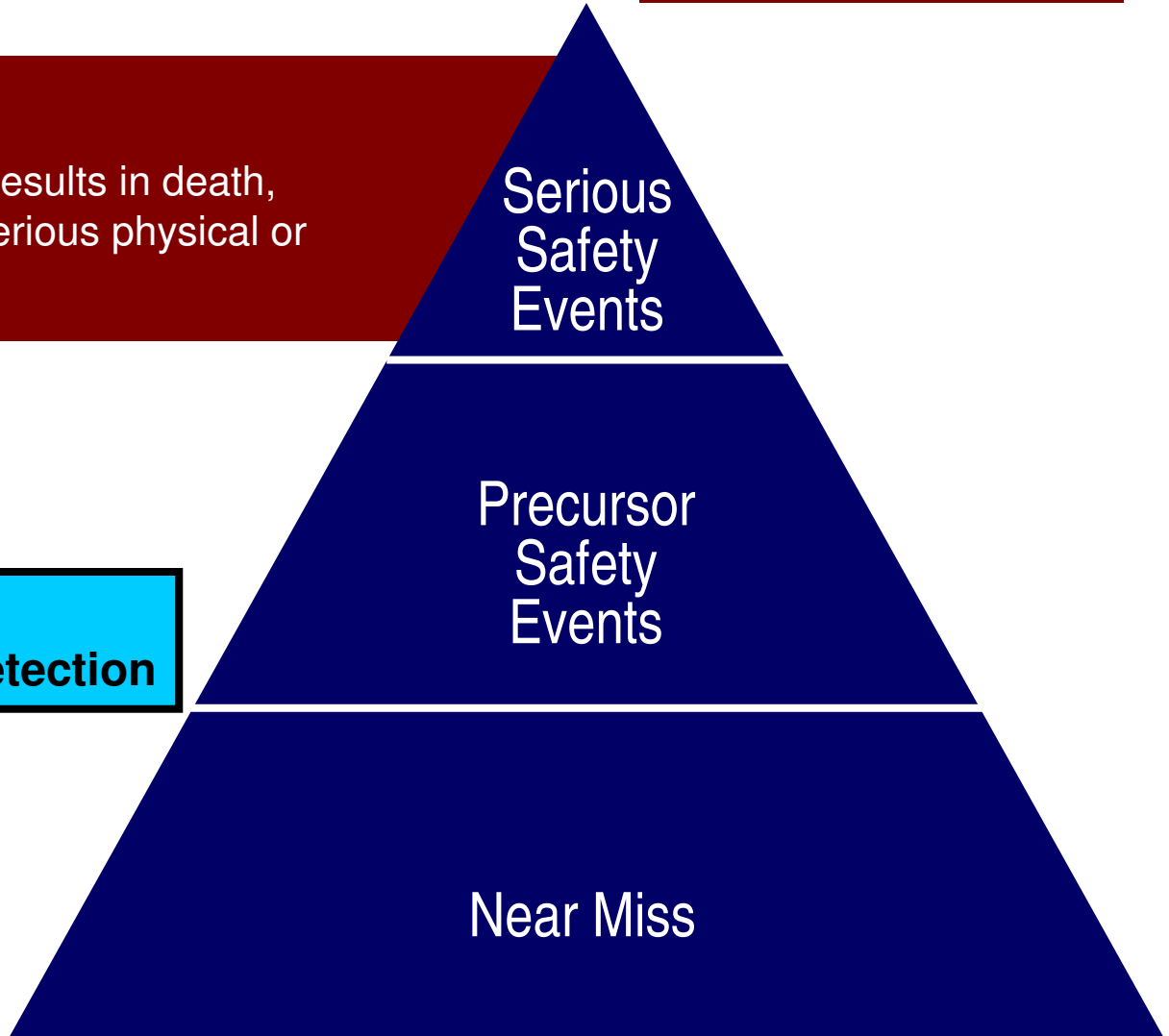
*Variation from standard of care
that results in:*

Serious Safety Event

Event that reaches the patient and results in death, life-threatening consequences, or serious physical or psychological injury



**Culture of safety has resulted
in a extremely high rate of detection**



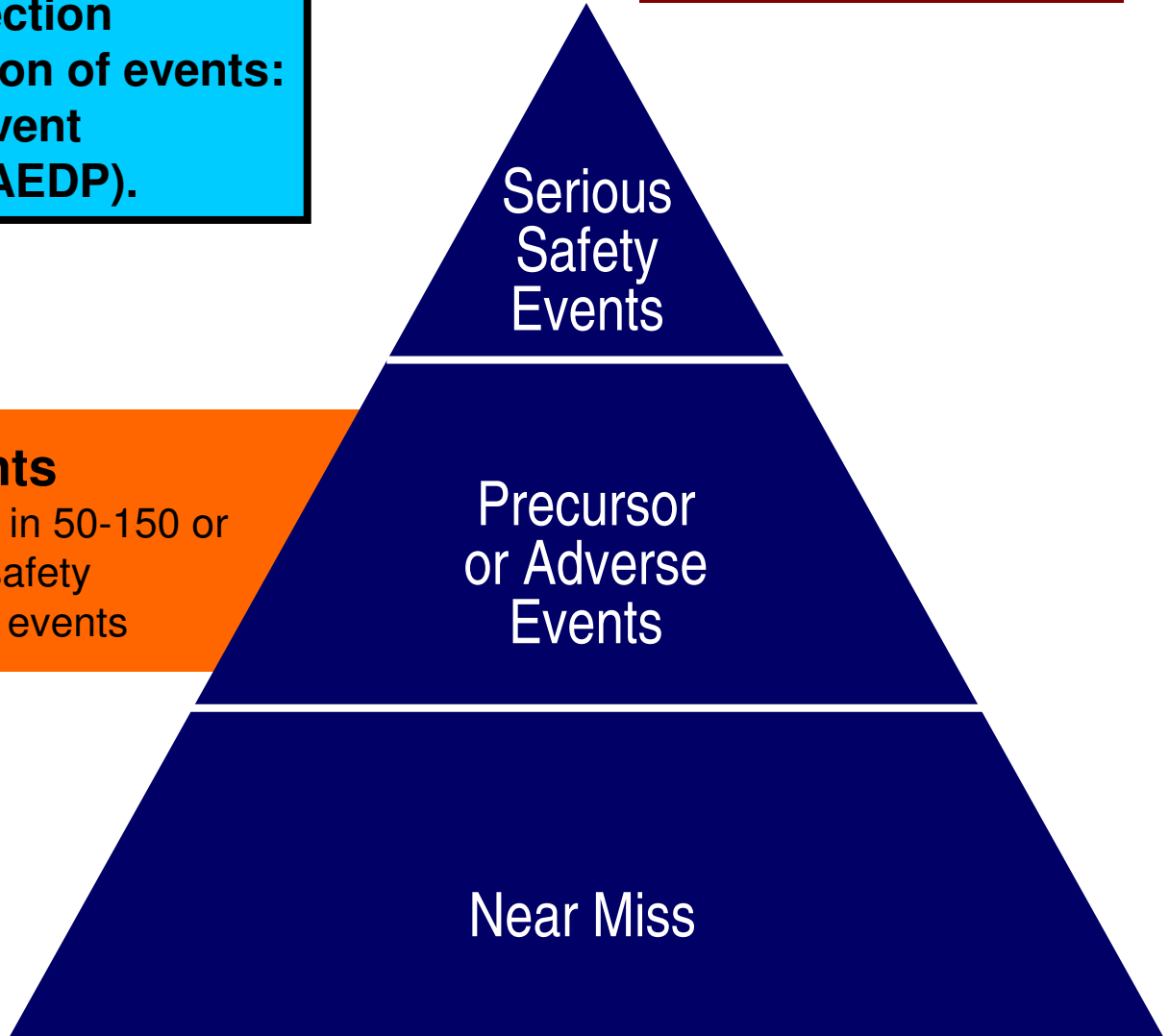
Serious Safety Event

Serious Safety Event	Death	Death attributed to deviation in care
	Severe permanent harm	Detectable harm, not expecting change in clinical status, and causing great discomfort, injury, and/or distress (included permanent loss of organ function)
	Moderate permanent harm	Detectable harm, not expecting change in clinical status, and is greater than minimal harm but less than severe harm (e.g. chronic renal insufficiency post acute renal failure)
	Severe temporary harm	Detectable harm, lasting for a limited time only, resulting in no permanent injury, yet causing great discomfort, injury, distress, and/or additional procedure, surgery, or resuscitation.

Need for increase detection as step toward reduction of events: Automated Adverse Event Detection Program (AAEDP).



Precursor or Adverse Events
Believe currently our system results in 50-150 or more events each month. Believe safety reporting system detects 10-15% of events



Precursor or Adverse Event

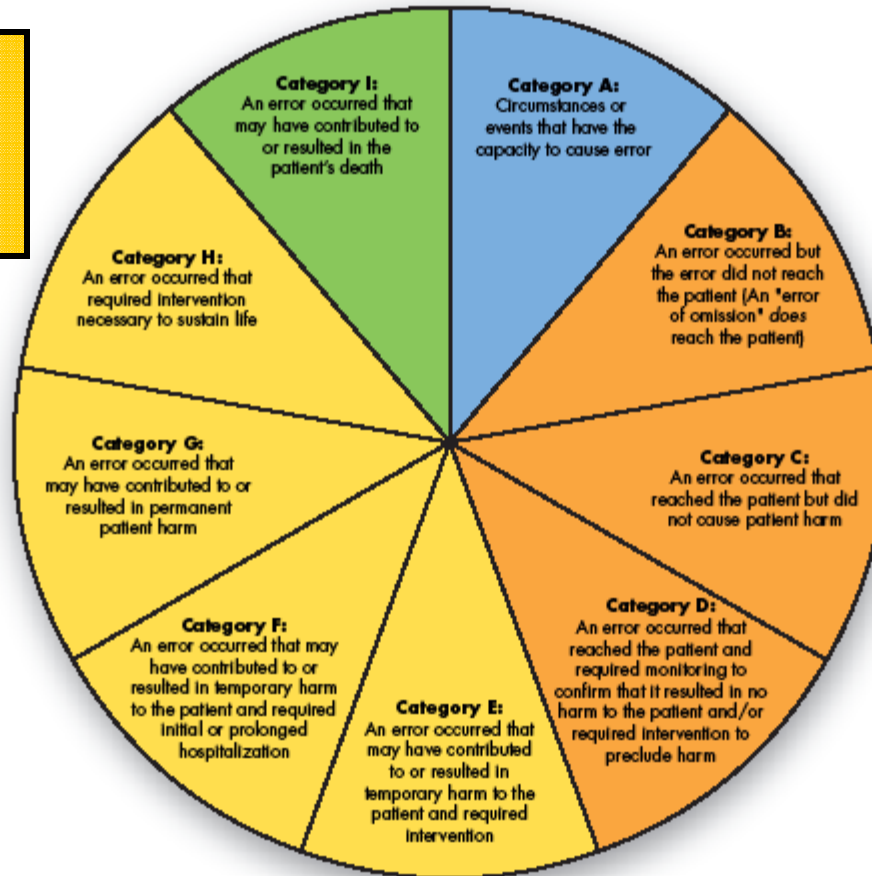
Precursor Safety Event Or Adverse Event	Moderate temporary harm	Detectable harm, lasting for a limited time only, resulting in no permanent injury, and is greater than minimal harm, but less than severe harm (e.g. does not require additional surgery, procedure or resuscitation measures)
	Minimal permanent harm	Detectable harm, not expecting change in clinical status, and is minimal in severity (e.g. scar from laceration).
	Minimal temporary harm	Detectable harm, lasting for a limited time only, resulting in no permanent injury, and is minimal in severity; requires little or no intervention.

Definitions of Harm

NCC MERP Index for Categorizing Medication Errors

**SSE
Category G-I**

- No Error
- Error, No Harm
- Error, Harm
- Error, Death



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

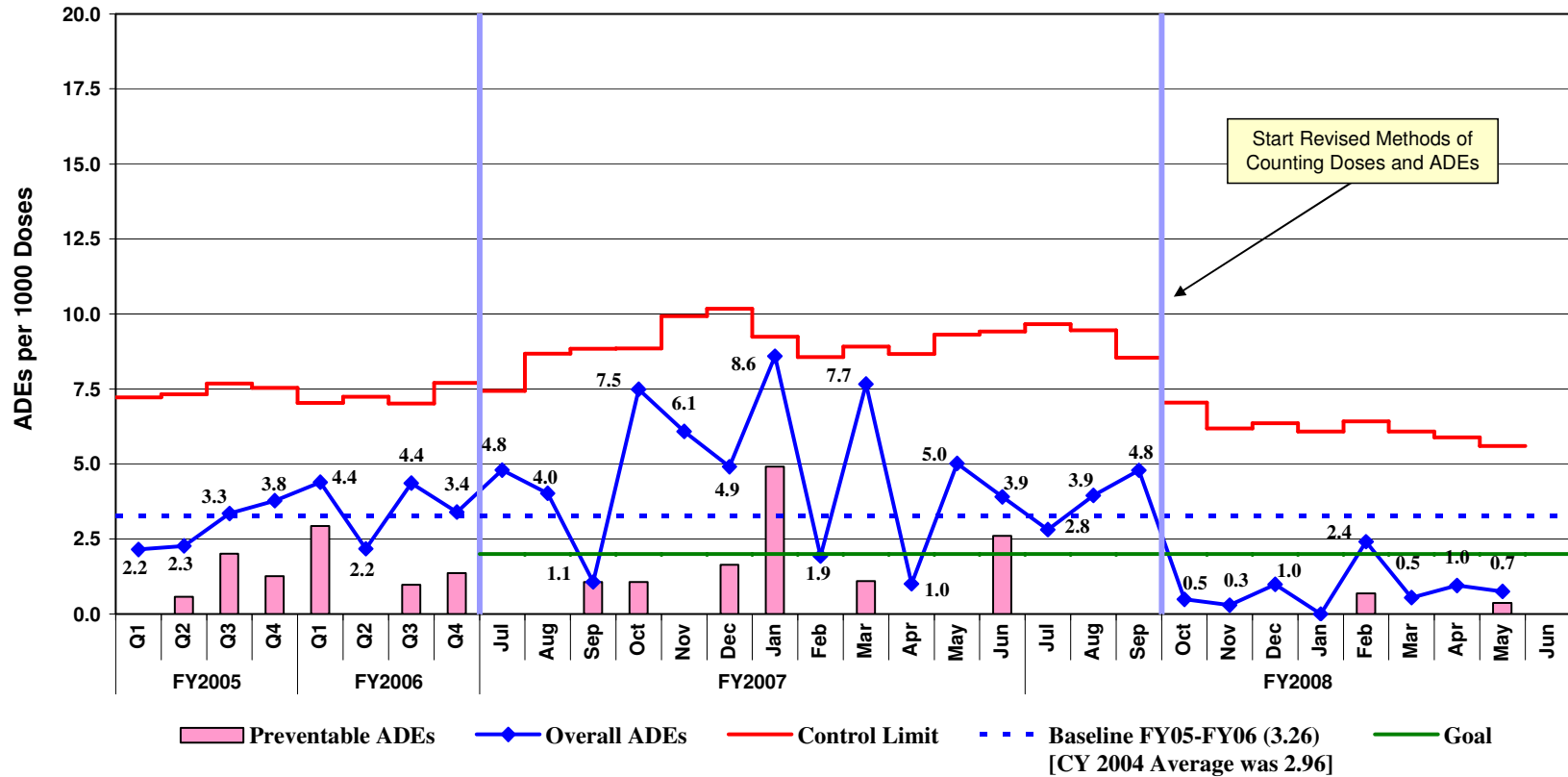
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

**Precursor or Adverse Event
Category D-F**

© 2001 National Coordinating Council for Medication Error Reporting and Prevention. All Rights Reserved.

* Permission is hereby granted to reproduce information contained herein provided that such reproduction shall not modify the text and shall include the copyright notice appearing on the pages from which it was copied.

Adverse Drug Events

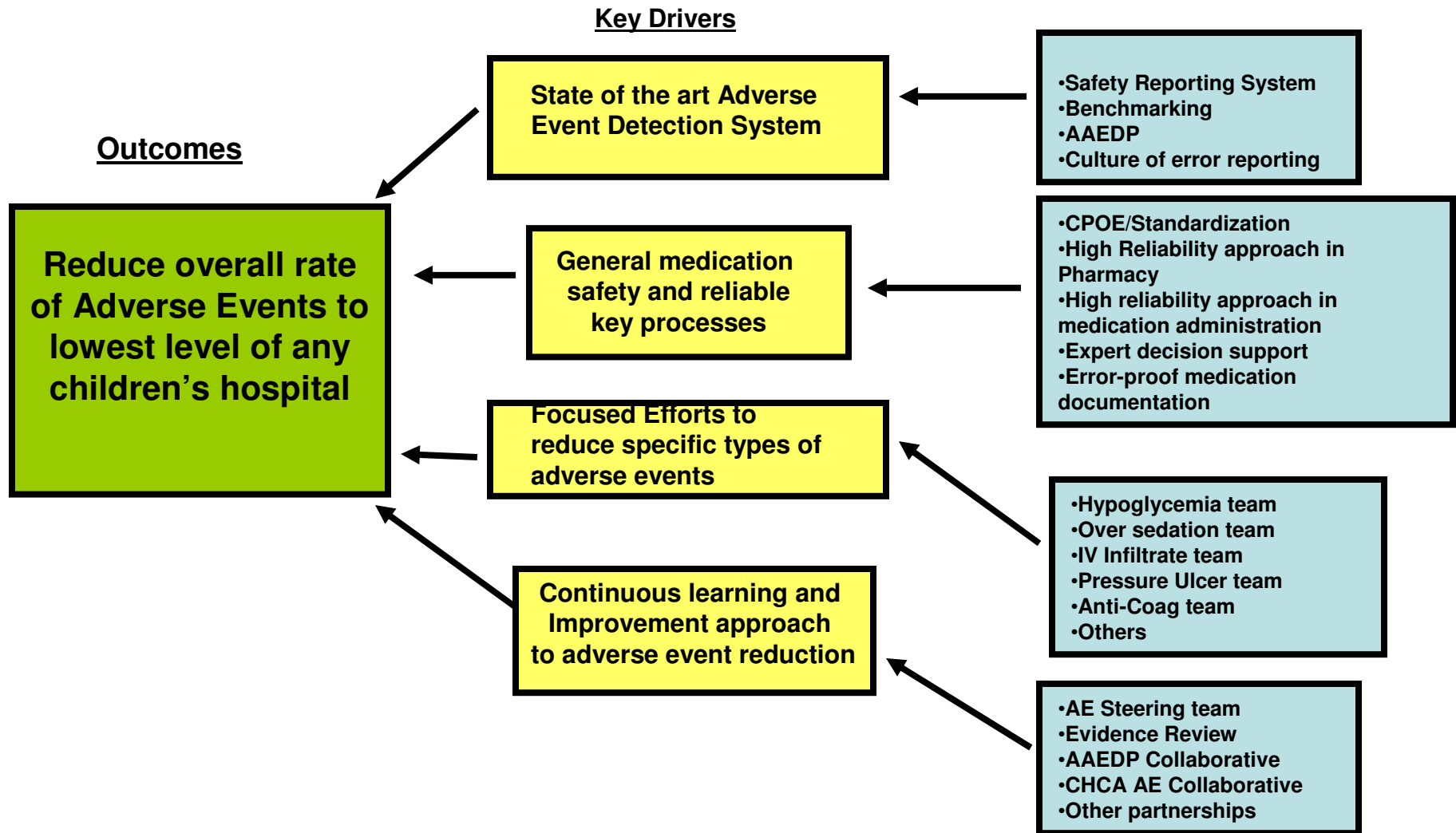


ADEs	4	4	5	6	9	4	9	5	8	4	1	7	4	3	7	2	7	1	4	3	2	3	5	1	1	3	0	7	2	4	4	
Preventable	0	1	3	2	6	0	2	2	0	0	1	1	0	1	4	0	1	0	0	2	0	0	0	0	0	0	0	2	0	0	2	
Doses	1859	1764	1493	1589	2047	1844	2063	1473	1668	994	936	934	657	611	815	1036	913	1000	797	768	711	760	1045	2028	3408	3048	3670	2907	3649	4206	5341	

Chart Updated Through 31May08 by Art Wheeler, Legal/HPCE Depts.

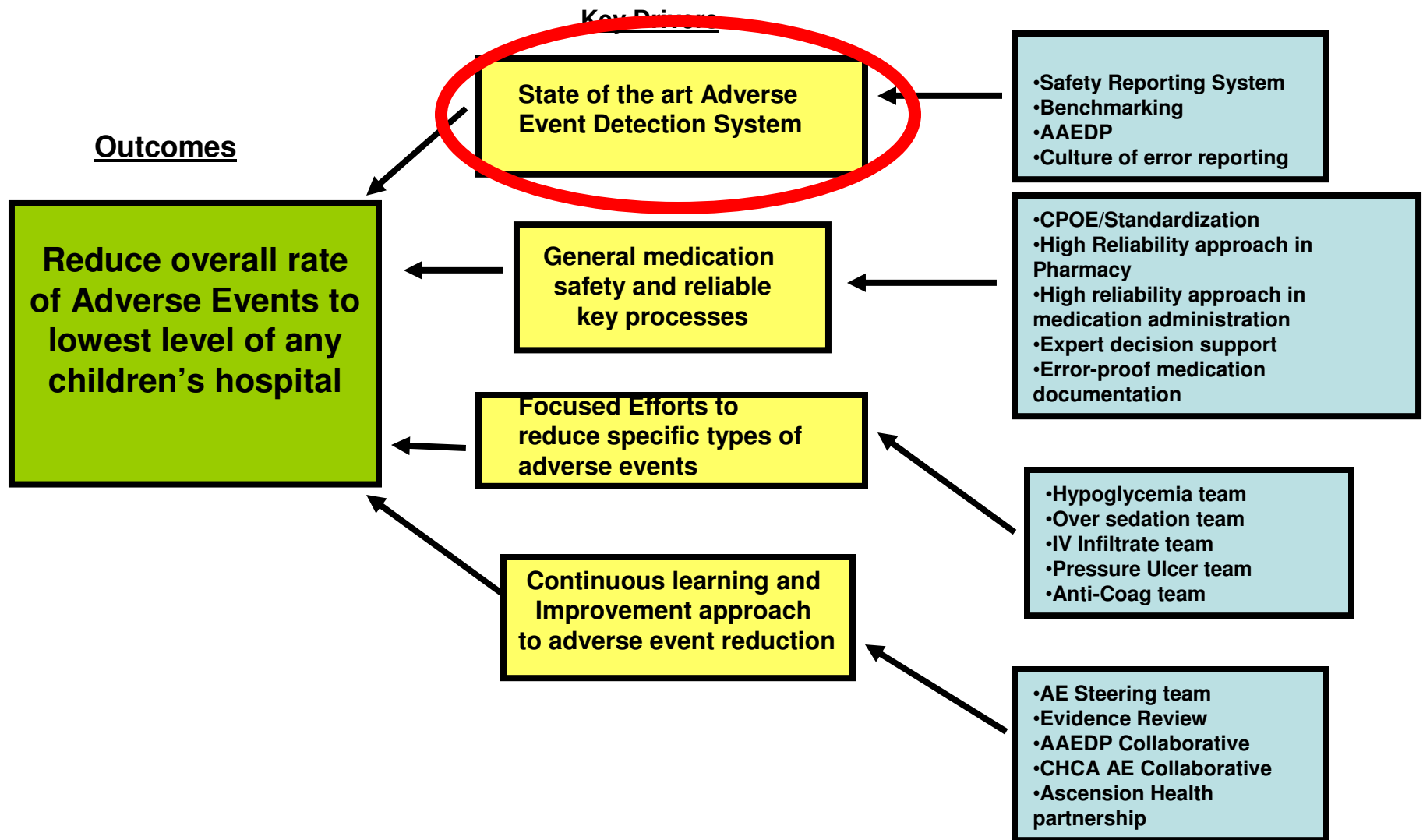
Source: Chart Review of Random Sample (20 Charts)

Reduction of Adverse Events Intervention/Change Concepts

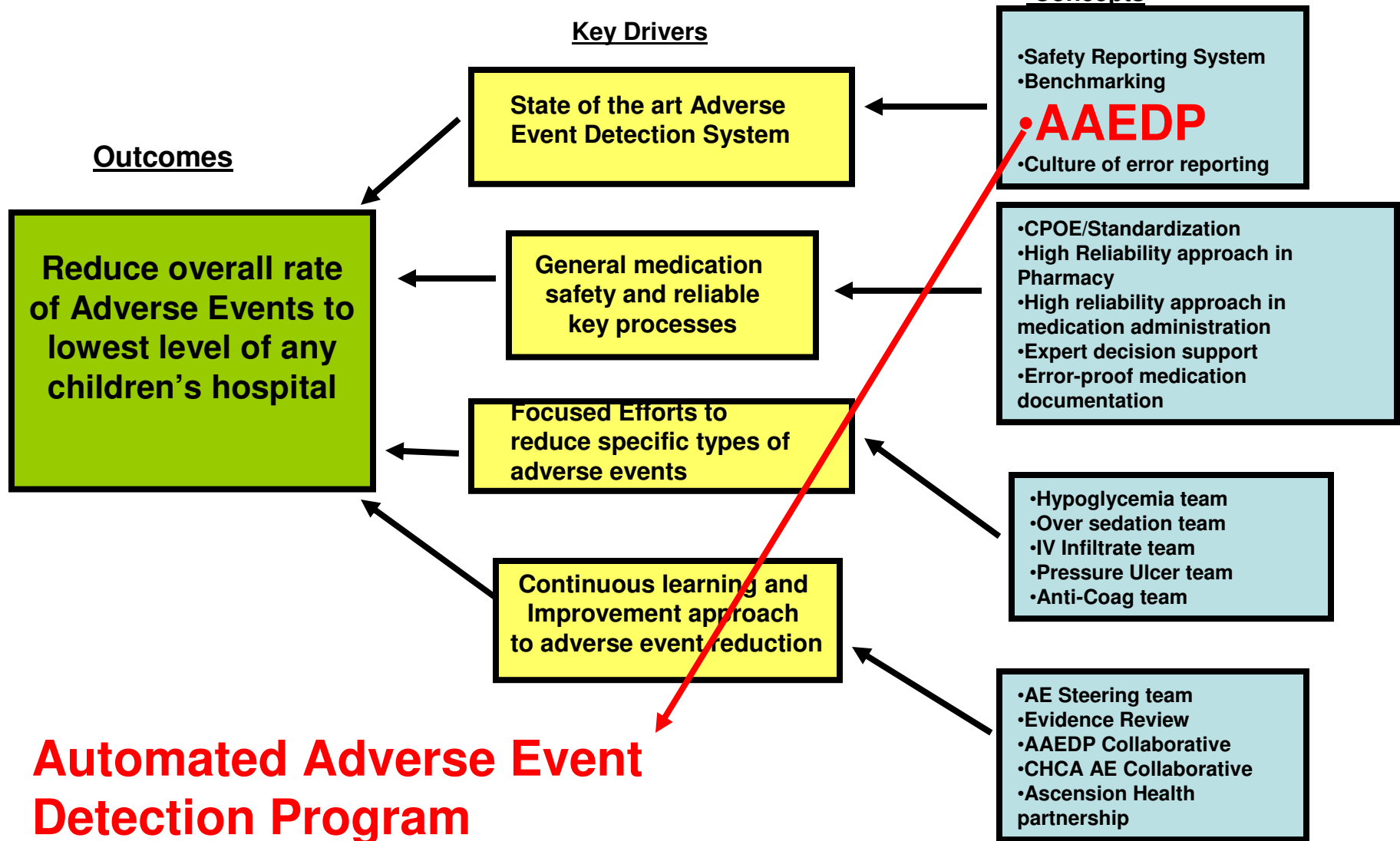


June, 2008

Reduction of Adverse Events Intervention/Change Concepts



Reduction of Adverse Events Intervention/Change Concepts



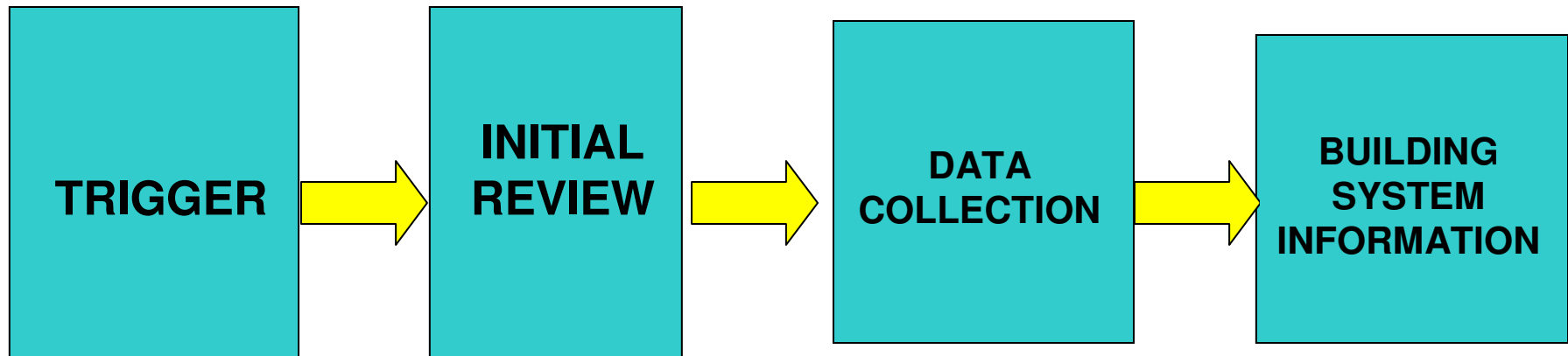
Reasoning for Developing **AAEDP**

- Need to significantly increase detection of Adverse Events.
- Chart review sample using trigger tool is helpful for benchmarking, but does not yield data essential for further improvement.
- Near real-time detection allows for effective apparent cause analysis/failure analysis.

AAEDP Methodology

- Uses structured flags such as medications, lab values or clinical symptoms to identify possible Adverse Events (AE's)
- Uses Electronic Health Record to allow for daily search of all encounters
- Review of all triggers to determine if AE occurred
- Analysis of all AE's for characteristics

Automated Event Detection Work Flow



Morning Trigger Report

Alerts Project Manager to potential Adverse Event

Project Manager (RN)

Reviews:

- Patient's chart electronically
- Paper chart (if necessary)
- Speaks to Care Team (if necessary)

To determine if Adverse Event occurred

Project Manager

Collects system information by completing Apparent Cause Form. E-mails form to Care Team and follows-up in person as necessary.

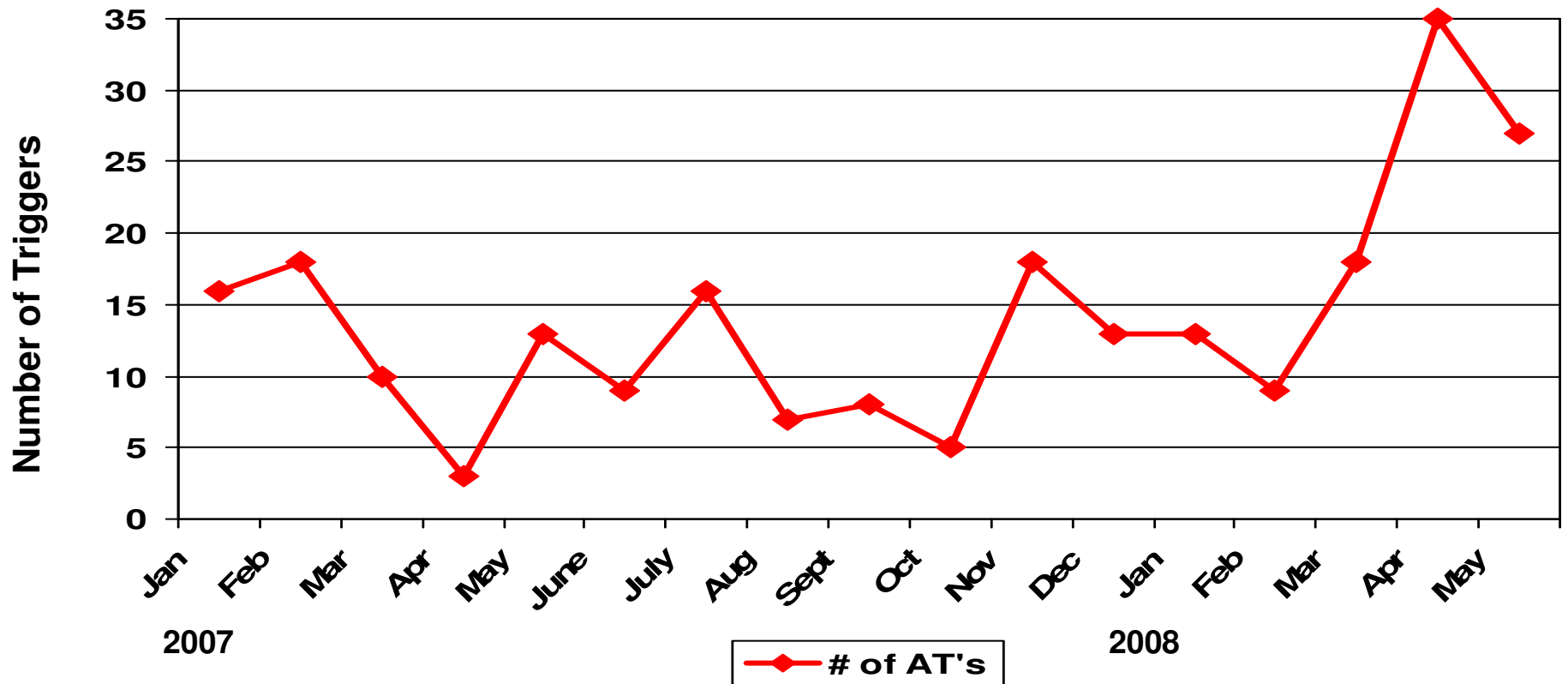
Project Manager

Adds information to data base, builds reports on trends and rates. Shares information with teams

Results of Automated Trigger System

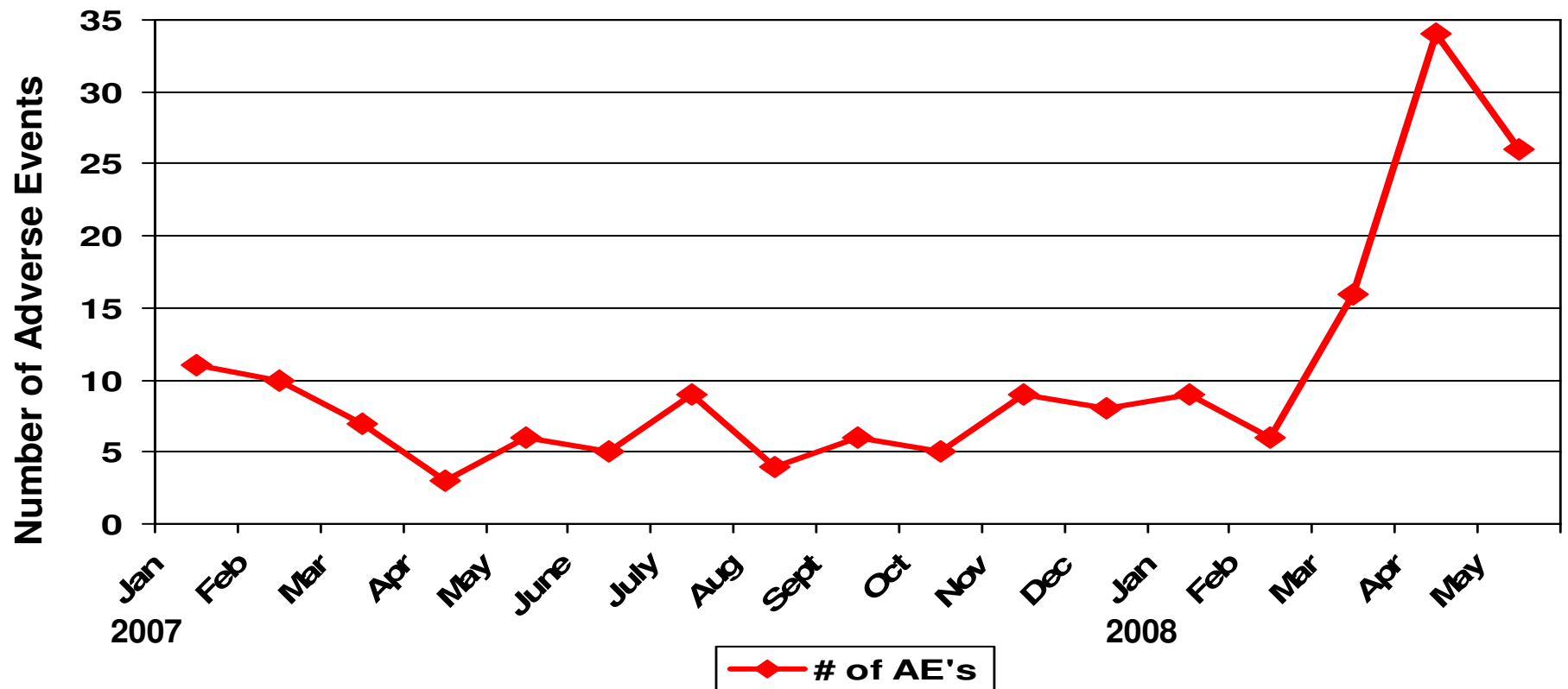
Adverse Event	Trigger	# of Triggers	# of Adverse Events (AE)	Predictability of Trigger	Approx n AE/month	Level of Severity			Incident Report Completed by On Adverse Event
						Level 5	Level 6	Level 7-9	
Acetaminophen Overdose	Acetylcysteine	14	0	0%	0	0	0	0	0
Benzodiazepene Oversedation	Flumazenil	5	4	80%	0.25	4	0	0	1
Hypoglycemia	Glucose Bolus while on Insulin	40	29	72.5%	3	26	3	0	4
IV Infiltrate	Hyaluronidase	9	9	100%	3	9	0	0	5
Opiate Oversedation	Naloxone	54	29	59%	2	27	2	0	6
Diagonstic or Treatment error	Readmission <24 hrs	57	21	47%	1.5	0	20	0	0
Warfarin overdose	Vitamin K	4	2	50%	0.1	2	0	0	0
	TOTALS	181	95	52%	6	70 (71%)	25 (26%)	0	16 (17%)

Number of Triggers Investigated Each Month



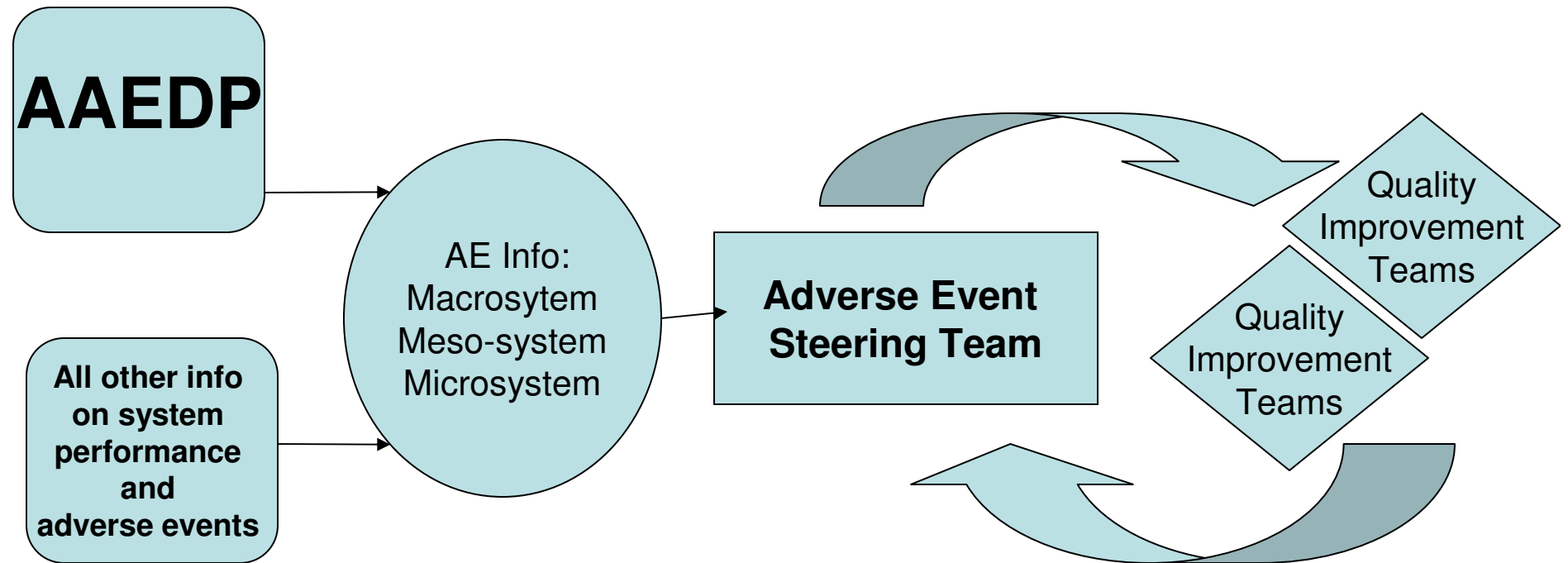
Number of Adverse Events Detected Each Month

(Level 5 severity or greater)



Adverse Event Name	Start Date	Report Date	# Adverse Events	# Triggers	Predictive Performance	Safety Report Filing Status			
						None Filed	Filed by ASE or >72 hrs.	<24 hrs.	24-72 hrs.
Insulin-Related Hypoglycemia	12/8/2006	3/31/2008	30	50	60.0%	23	5	2	0
Opiate-Related Over-sedation	7/8/2006	3/31/2008	35	59	59.3%	10	17	4	4
Total			65	109	60%	33	22	6	4

Adverse Event Reduction Design at CCHMC



Adverse Event Steering Team

Steering team reviews data on system performance monthly.
Reviews monthly updates from QI teams.
Supports and charters QI teams.
Suggests and oversees development of new triggers.

Quality Improvement Teams

QI teams chartered for 90-180 days to reduce specific Adverse Events.
They are given QI and data support. Baseline data and system performance info ready for team and allows move to action faster.

Hypoglycemia Adverse Events Associated Factors

- Too much insulin given day of event? (% yes)
- Blood glucose levels checked as ordered? (% yes)
- Patient NPO (% yes)
- Patient receiving tube feedings (% yes)
- Patient receiving parental nutrition (% yes)
- Patients receiving other IV fluid containing carbohydrates (% yes)
- Did hypoglycemia follow a decrease or discontinuation of glucose infusion. (% yes)
- Did hypoglycemia follow a decrease or discontinuation of tube feedings. (%yes)
- Primary failure mode of event (NEED TO DEFINE/EXPLAIN THESE)
- Was there an order error (%yes)%
- Does patient have Diabetes Mellitus (% yes)

Over sedation Adverse Events Associated Factors

- Event occurred within 48 hours of surgery (% yes)
- Category of surgical procedure
- Order error/Overdose? (%yes)
- Pain team involved in patient's care (% yes)
- Additional service order narcotics also (%yes)
- PCA system used (% yes)
- Additional sedative medications given the day of the event (% yes)
- Additional analgesia given the day of the event (% yes)
- Does patient have underlying chronic condition (%yes)
- Was patient extubated in last 4 hours (%yes)
- Failure mode: Dose-related, Handoff-related, Communication-related, Monitoring related.

Improvement Teams

- Reduction of Opiate-related Oversedations (goal 50% reduction)
- Reduction of Insulin-related Hypoglycemia (goal 50% reduction)

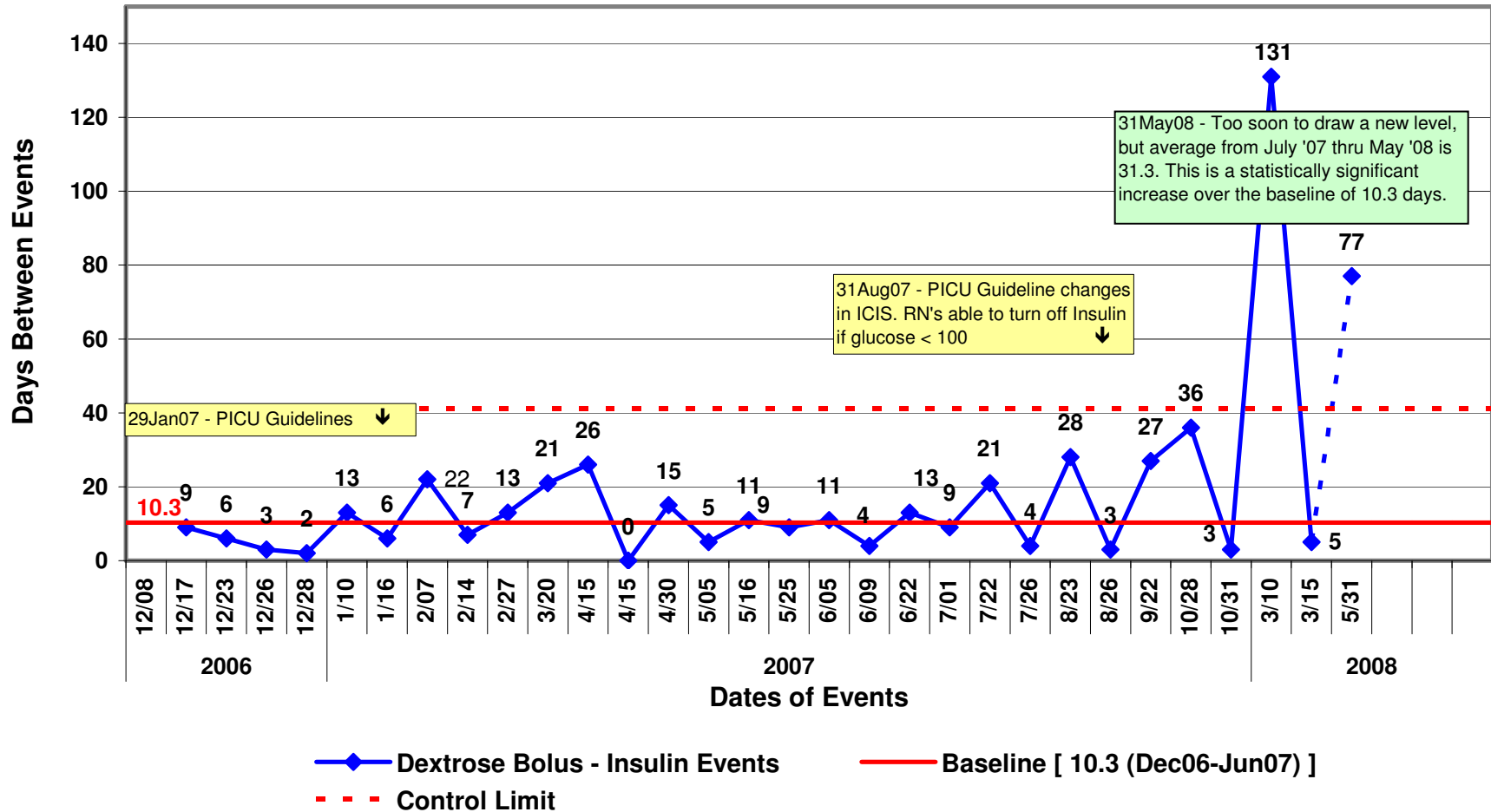
Insulin-Related Hypoglycemia Change Concepts

- Develop Insulin Protocol in PICU
- Revise and spread protocol to other key microsystems
- Add reminders linking insulin drip rate changes to TPN rate changes



Administrations of Dextrose Bolus to Patients on Insulin December 2006 thru May 2008

Chart Type: t-chart



Current as of 31May08 (Art Wheeler, Legal/HPCE Depts.)

Source: Automated Triggers & Associated Event Reviews

Opiate-Related Over-sedations

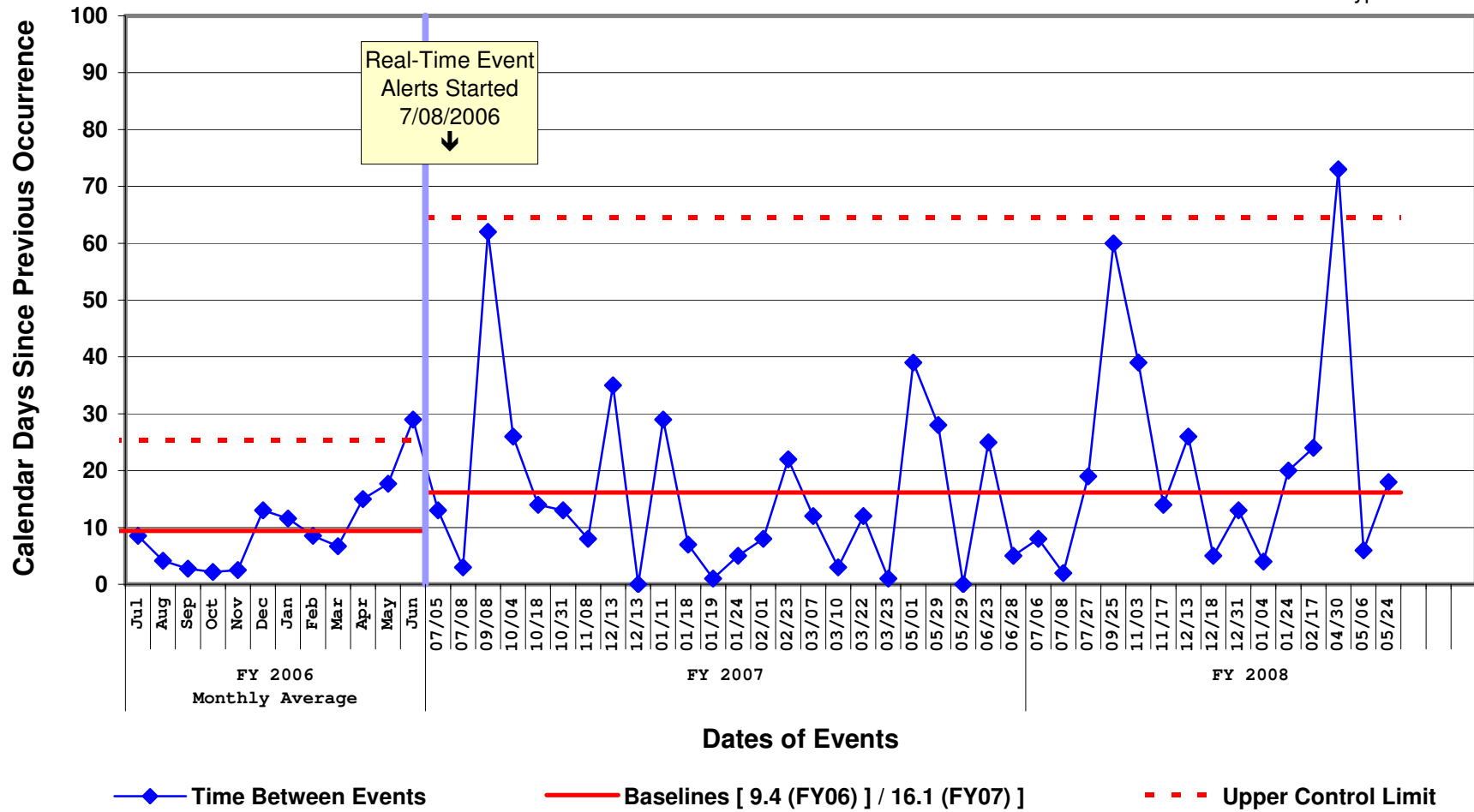
Change Concepts

- Standardize opiate orders in the PACU with limited choices
- Develop simple sedation assessment in PACU as basis for redosing
- Spread sedation scale to key microsystems
- Refine decision making with PCA's by limiting decisions to Pain MD and use SBAR.



Time Between Opiate-Related Oversedations July 2005 thru May 2008

Chart Type: t-chart



Current as of 31May08 (Art Wheeler, Legal/HPCE Depts.)

Source: Automated Triggers & Associated Event Reviews

Next Triggers to Investigate

- Panel of Experts
- Evaluate lists of potential adverse events and triggers
- Lists developed from literature and local expertise
- Use modified delphi method to develop list of top 10 adverse events/triggers to investigate.

Developing New Triggers: Selection Criteria

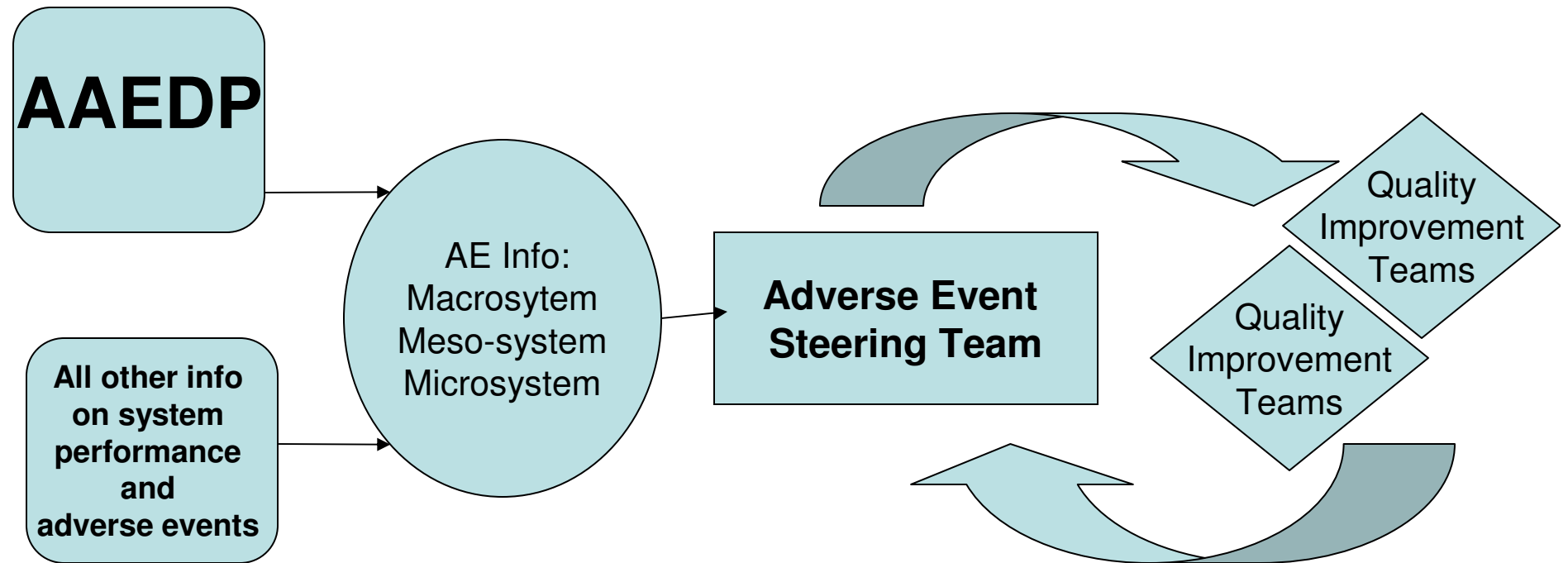
- 1) Frequency**
- 2) Degree of Harm (Level 5 through 9)**
- 3) Positive Predictive value of trigger
for detecting an AE**
- 4) means to identify trigger**
- 5) AE not already being
addressed/detected**

4 Categories of Triggers

- ✓ **Antidotes** – e.g. Naloxone administration
- ✓ **Lab Based** – e.g. glucose < 50 mg/dl
- ✓ **Process Based** – e.g. Transfer to a Higher Level of Care
- ✓ **Clinical indicators** – e.g. Vital sign abnormality

IV Infiltrations/ Extravasations	"In Depth" Hourly IV Reports
IV Infiltrations/ Extravasations	Hyaluronidase
Dopamine, Epi and Norepi IV Infiltration	Phentolamine
Digitalis Toxicity	Digibind
Opiate Over-sedation	Naloxone
Benzodiazepine Over-sedation	Flumazenil
Warfarin/ Coumadin Overuse	Vit K after Warfarin
Hypoglycemia	Glu bolus/Insulin
Hypoglycemia	Glucagon
Inadequate Monitoring or Response	Same Day Transfer to ICU
Unrecognized Clinical Signs of severity of illness	Return Visit to ED within 24 hours and admission to Medical Center (excluding Psyche cases)
Hyperkalemia	*Events where glucose bolus and insulin were used to treat hyperkalemia
Acetaminophen Overdose	Acetylcysteine
Unrecognized Clinical Signs of severity of illness	Re-Admissions < 1 calendar day
Hypoglycemia	Glucose Bolus - no Insulin
Heparin Overdose	Protamine Administration (not in OR - ECHMO)
Unrecognized Clinical Deterioration	Death
Harm from a Surgical Procedure	Unplanned Return to Surgery within 48 hours
Inadequate Acuity Assessment	PACU → PICU Transfers
Inadequate Monitoring	Attempted Suicide and Admission to Medical Center
Hemorrhage	Abrupt drop in Hg > 4 gms (or drop of 25% or greater)

Adverse Event Reduction Design at CCHMC



Adverse Event Steering Team

Steering team reviews data on system performance monthly.
Reviews monthly updates from QI teams.
Supports and charters QI teams.
Suggests and oversees development of new triggers.

Quality Improvement Teams

QI teams chartered for 90-180 days to reduce specific Adverse Events.
They are given QI and data support. Baseline data and system performance info ready for team and allows move to action faster.

2008-09 Adverse Events planned for Improvement

- **Anti-Coagulation AE's**

Potential Triggers: Abnormal lab values, protamine, Failure to obtain scheduled screening labs, diagnostic categories

- **IV Infiltrates**

Potential triggers: Hyaluronidase, Abnormal site check in EHR

- **Opiates**

Trigger: Naloxone

Making Pediatric Patients Safer: Developing an Automated Detection Program at Cincinnati Children's"

Questions? Feedback?

Stephen E. Muething, MD

September 18, 2008

