



REACH FOR THE STARS

An Event Reporting System Analysis

David M. Lang

NIH CC Office of Patient Safety and Clinical Quality

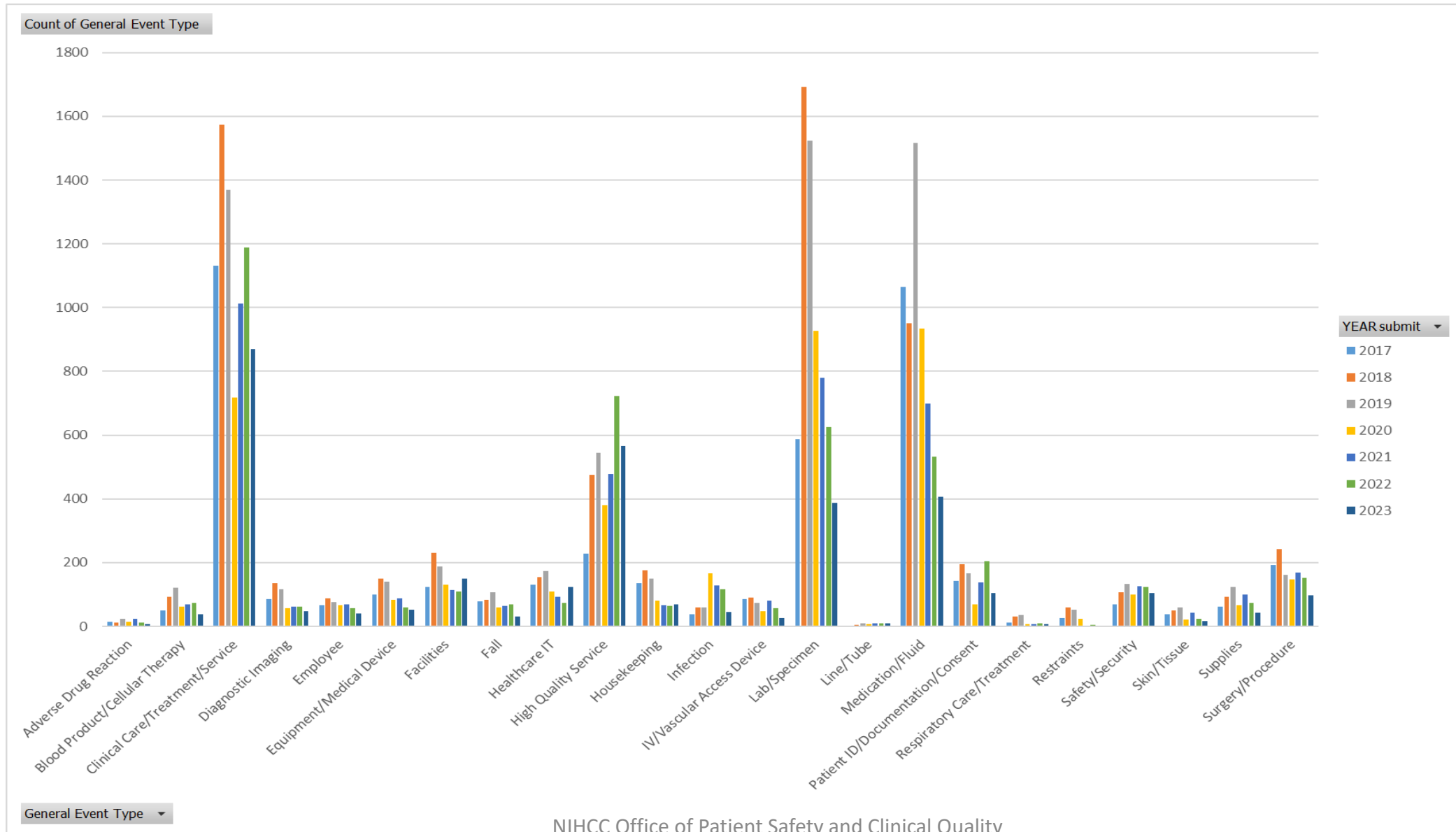
October 18, 2024



Safety Tracking and Reporting System

- Clinical Center's safety occurrence reporting system
- Went into service in April 2017
- RL Datix platform
- Voluntary web-based user-entry
- More than 35,000 entries at end of 2023

General Event Types, 2017-2023



STARS Process

- STARS are an initial report as stated by the reporter
- Each report is reviewed by OPSCQ and assigned to reviewers
- File managers in each relevant patient care area, department, or IC are scoped
- Information, analysis, summary, recommendations
- Additional steps as indicated

Opportunities and Goals

- Each event gets *individual attention*
- Some event types are trended to look for patterns

- Opportunity to look back at several years data
- Can a deeper dive into the aggregate provide useful information?
- Are there elements that can become standard data points?
- Are there common data elements in reports?

The project

- A proof of concept and a deep-dive into one event type cluster
- Are medication pump issues really pump issues?
- To capture possible pump issues- 2 General Event Types (GET) with 4 Specific Event Types (SET)
 - GET- Equipment/Medical Device; SET- IV Pump Malfunction
 - GET- Equipment/Medical Device; SET- PCA Pump Malfunction
 - GET- Medication/Fluid; SET- Incorrect Rate
 - GET- Medication/Fluid; SET- Pump Programming Issue
- Manual review of narratives and follow-up for additional data

Number of each STARS type

- Total of 269 reports reviewed from 2018-2023

STARS Type	2018	2019	2020	2021	2022	2023	Grand Total
Equipment/Medical Device	41	22	19	11	3	10	106
IV Pump Malfunction	28	15	13	9	2	7	74
PCA Pump Malfunction	13	7	6	2	1	3	32
Medication/Fluid	34	49	35	24	11	10	163
Incorrect Rate	17	36	29	14	7	6	109
Pump Programming Issue	17	13	6	10	4	4	54
Grand Total	75	71	54	35	14	20	269

Medications involved- Top 11 (N=106)

Medication	2018	2019	2020	2021	2022	2023	Grand Total
Potassium Chloride Infusion		10	7				17
Etoposide/Doxorubicin/Vincristine	2	3	1	2		4	12
Parenteral Nutrition	4	2	3	3			12
Magnesium Sulfate Infusion		6	1	2			9
Sodium Thiosulfate Infusion	9						9
Fat Emulsion Infusion 20%	2	1	2	4			9
IV PCA Hydromorphone	2	4	3				9
IV PCA Fentanyl	6	1					7
Epidural PCA Fentanyl	2	2	1	1			6
Hydromorphone	3	1		2			6
Parenteral nutrition (TPN)		2	1		1	1	5

Equipment Involved/Malfunctioned?

- Suspected in 82% of the “Equipment/Device” reports and 23% of the “Medication Fluid” reports

General Event Type	2018	2019	2020	2021	2022	2023	Grand Total
Equipment/Medical Device							
Yes	34	19	11	9	6	9	88
Unknown	8	3	4			1	16
No	1			2			3
Medication/Fluid							
Yes	10	6	9	7	3	3	38
Unknown	2	5	4			1	12
No	21	38	26	16	5	6	112

Device tested by Biomed?

Determined from follow-up narrative

- When “Equipment Involved/Malfunctioned” = Yes (N=126), testing by Biomed is entered in 60% of reports

General Event Type	2018	2019	2020	2021	2022	2023	Grand Total
Equipment/Medical Device							
Yes	22	10	9	8	6	5	60
No	11	9	2	1		4	27
Unknown	1						1
Medication/Fluid							
Yes	4	2	4	3	2	1	16
No	6	4	5	4	1	2	22

Was the pump faulty?

Determined from follow-up narrative

- When Biomed results are in narrative (N=76), a malfunctioning pump issue is identified in 20% of reports
- This represents 12% of all reports with “Equipment Involved/Malfunctioned”

General Event Type	2018	2019	2020	2021	2022	2023	Grand Total
Equipment/Medical Device							
Yes	3	3	5	1	1	1	14
No	15	4	3	6	5	3	36
Undetermined	4	3	1	1		1	10
Medication/Fluid							
Yes			1				1
No	3	1	2	3	2	1	12
Undetermined	1	1	1				3

“Equipment Involved/Malfunctioned” (N = 126)

Top 10 Medications Involved (N = 78)

Medication	2018	2019	2020	2021	2022	2023	Grand Total
Not selected	8	5	5	2	2	1	23
Etoposide/Doxorubicin/Vincristine	3	1	1	2	3	3	13
Sodium Thiosulfate Infusion	6						6
Hydromorphone	2	1		2		1	6
Parenteral Nutrition		1	3	1			5
IV PCA Hydromorphone Inj	2	3					5
IV PCA Fentanyl Inj	4	1					5
Fluorouracil Infusion for Portable		4					4
Fat Emulsion Infusion 20%		1	2	1			4
Epidural PCA Fentanyl Inj	1	2	1				4

Pump issues identified (N = 15)*

Medication	2018	2019	2020	2021	2022	2023	Grand Total
Not Selected	3	3	3		1		10
Etoposide/Doxorubicin/Vincristine				1		1	2
dexmedetomidine			1				1
Parenteral Nutrition			1				1
IL-15 Infusion			1				1
Grand Total	3	3	6	1	1	1	15

*One case where pump infusion rate was determined to be faulty

Pump issues identified (N = 15)

- Pump malfunction and infused at an incorrect rate- too fast (1)
- Batteries- malfunctioning, depleted, not fully charged (5)
- Error code, maintenance need, or other software (4)
- Door, latch, or door sensor broken (3)
- Other part broken or sensors dirty and not connecting (2)

Issues identified when pump was tested and not faulty- Examples (Total N = 48)

- One specific highly viscous medication repeatedly occluded tubing
- Tubing kinked or damaged
- Multiple interruptions or occlusions prolonged total time
- Tubing set-up incorrectly
- Programming error discovered on history
 - Incorrect rate entered
 - Miscalculation using mcg vs mL
 - Restarted infusion and cleared parameters
- Underdelivered but within 5% standard
- PCA- Misunderstanding of how lockout parameters work or documentation issue
- Could not be determined

Additional observations

- Some reports of error when there was none
- Fewer reports as familiarity with equipment increased vs. when new in 2018
 - “Equipment involved” and tested not faulty- 18 in 2018, 4 in 2023
- PCA reports reduced over time
- Instances where Biomed did not receive all of the parts needed for testing
- Biomed evaluation was able to provide information on programing and interruptions from pump history

Conclusions

- Systematic review of STARS over time did provide useful information.
- Binary fields in report help identify what was thought to contribute.
- “Equipment involved”- When pumps were tested, an incorrect infusion rate was discovered 1 time out of 76 tests (1.3%) and 126 “Equipment Malfunctioned” reports (<1%).
- Pump was tested by Biomed 60% of time that “Equipment Malfunctioned” was selected.
- User setup or programming errors contributed but decreased over time.
- With multiple STARS reports, medication specific issues could be identified.

Opportunities

- Clarification and messaging on what and how to send to Biomed
- Pump usage quick tips- cleaning, battery maintenance
- Identification of systematic ordering and labelling vulnerabilities that increase risk of errors.
- Alignment of education with identified repeated misunderstandings or user challenges.
- Identify additional frequently used specific event types for similar analyses