UT HEALTH SCIENCE CENTER SAN ANTONIO

CANCER THERAPY
& RESEARCH CENTER

AN NCI-DESIGNATED CANCER CENTER

CLINICAL SAFETY & EFFFECTIVENESS
Session #19

Improving Efficiency of Adverse Event
Documentation for Data Reporting

UT Health
San Antonio

- CS&E Participants
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- MD Team Member Advisor
  - Laura Tenner, MD
- Facilitator
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Aim Statement

Increase the accuracy of adverse event documentation in the patient population served by three physicians by 20% over baseline by December 2016.

Project Milestones

- Team Created   August 2016
- AIM Statement Created   August 2016
- Weekly Team Meetings   September – December 2016
- Background Data   September – October 2016
- Brainstorming Sessions   September – October 2016
- Workflow and Fishbone Analysis   September – October 2016
- Interventions Implemented   November – December 2016
- Data Analysis   December 2016
- CS&E Presentation   January 2016
- Future Interventions   December 2016 until complete

# What is the Issue and Why is it a Problem?

- **Patients report AEs** to different individuals:
  - Triage Medical Assistant
  - Clinic Nurse
  - Research Nurse or Study Coordinator
  - Physician during physical exam
  - Treatment Room Nurse

- Data Coordinators (DCs) **extract AE data from EPIC** in order to:
  - Fill out CRFs
  - **Report to the sponsor** or to the **CTRC DSMB** (as applicable)

- Not all AEs are graded, and **information about the AE may be missing** from the progress note.
  - <u>Missing documentation includes</u>:
    - Grading and attribution to the study drug
    - Conflicting data caused by cut and paste errors
    - Missing start and stop dates

What is the workflow for AE Collection?

- To determine the current state of AE collection, documentation and reporting we went to the clinic setting to do the following:
  - Shadowed a research subject through the following areas:
    - Signing in at front desk
    - Triage (VS, weight, blood draw, etc)
    - Physical exam with research physician
    - IND administration in the research treatment room

  - Observed how staff interacts with the subject, how they document their interactions and how they communicate information with other staff members.
    - Triage staff interaction with subject
    - Clinic Nurse interaction with subject
    - Research Nurse interaction with subject
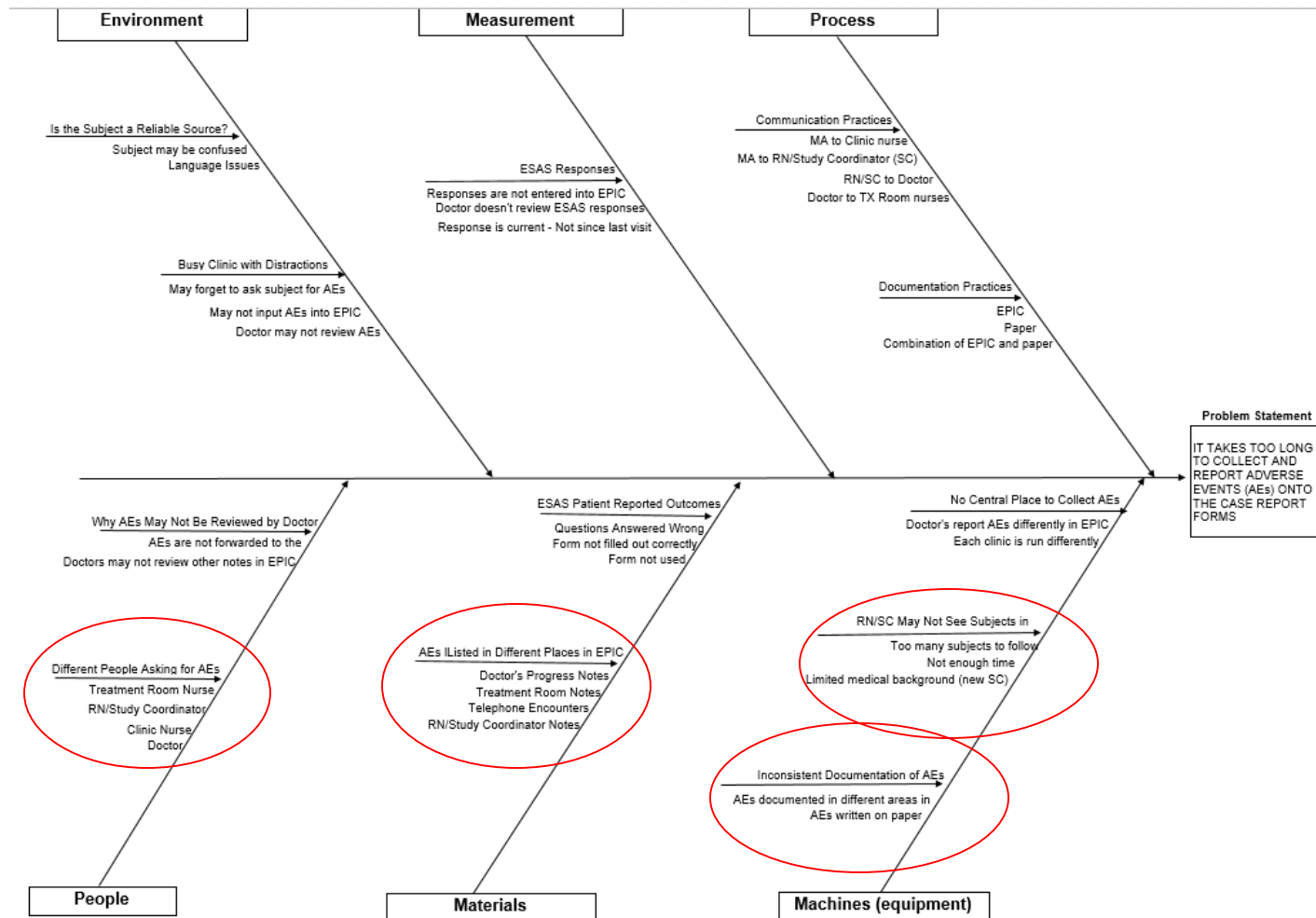   - Doctor interaction with subject

Process Flow Chart
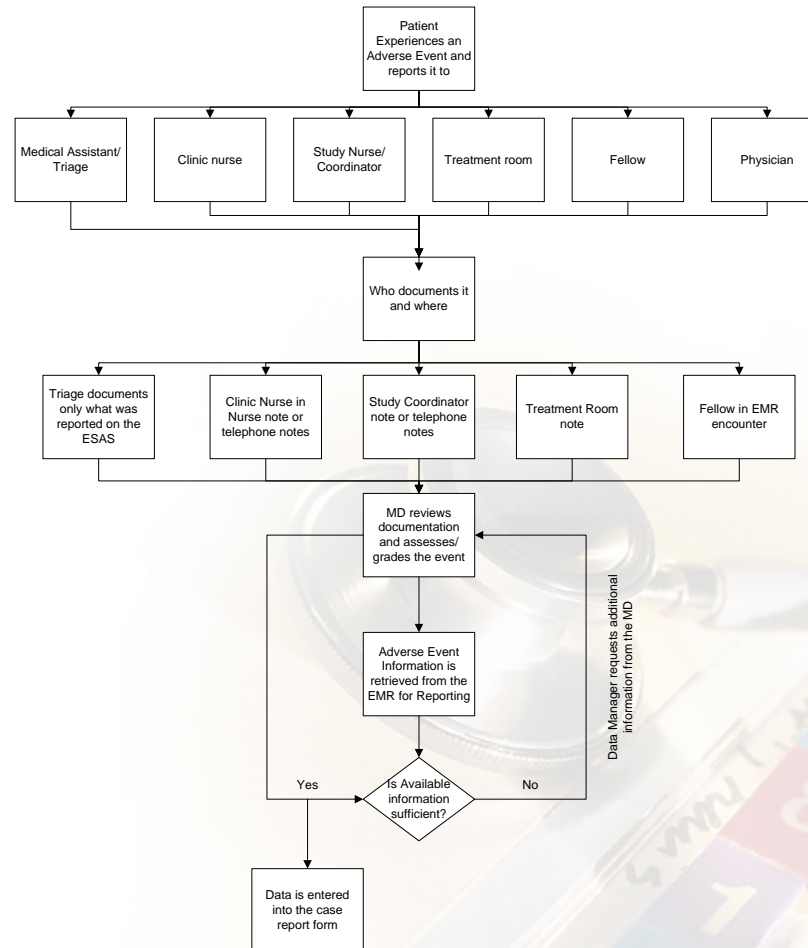
Variations in the Process

- Some coordinators meet with subjects before the MD to document adverse events

- Some PI's use a template for documentation

- Some clinics opt out of using ESAS tool that captures patient health status that day
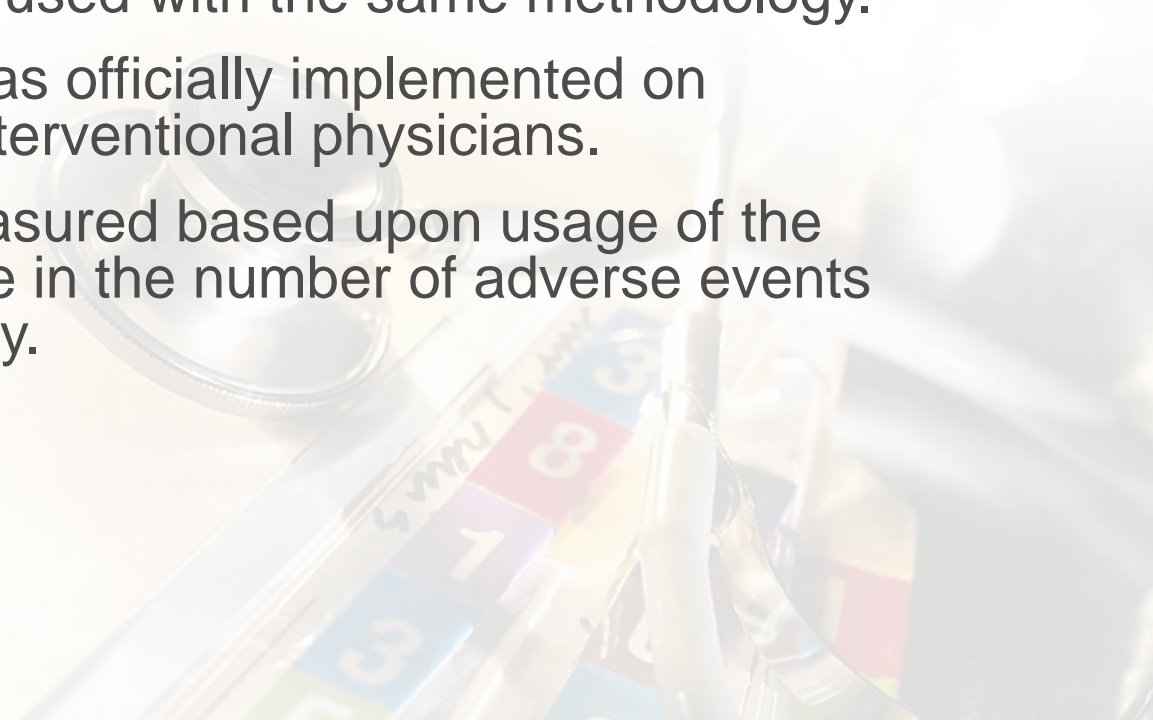
Fishbone Diagram

- If there is missing or conflicting information in the progress note:
  - The DC will email the physician asking him to provide the information requested.
    - Sometimes up to 3 - 4 weeks after the clinic visit.
    - Physician's memory of the AE may no longer be accurate

- AEs reported to the Treatment Room Nurse are typed up into the Treatment room visit summary or assessment document.
  - Physicians are not consistent in reviewing other notes or encounters found in EPIC
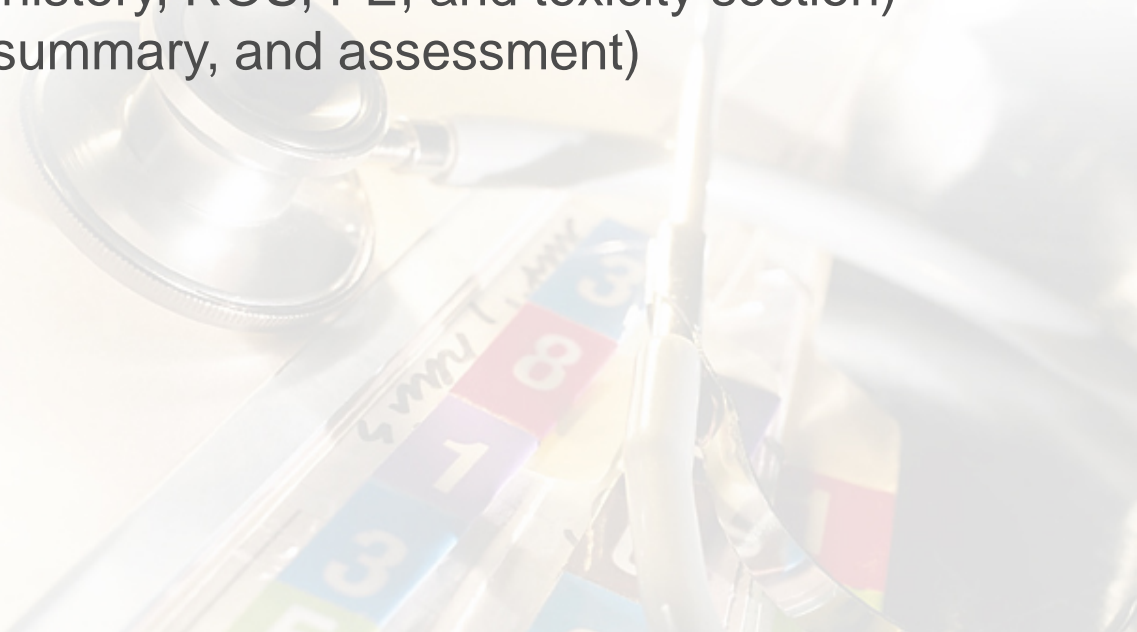 - AEs are missed, are not graded, and are not assessed for attribution

Plan for Data Collection to Quantify the Issue

- Audited a sample of research encounters of subjects on clinical trials for the month of September using the 10/7/2016 IDD Monday morning research report seen by the interventional physicians

- Post Intervention, the 12/2/2016 IDD Monday morning research report was used with the same methodology.

- The smart phrase was officially implemented on 11/11/2016 by the interventional physicians.

- Progress will be measured based upon usage of the template and change in the number of adverse events documented correctly.

How Chart Reviews were Performed

- <u>Subject Chart Reviews</u>:

  – Chart reviews were conducted in EPIC to look for AE documentation in order to determine if a request for additional information would be needed.

- <u>The following notes were reviewed in EPIC for documentation of AEs</u>:

  – Progress notes (interim history, ROS, PE, and toxicity section)
  – Treatment room notes (summary, and assessment)
  – Telephone notes
  – Message Encounters

- The errors in documenting AEs were categorized the following way:

    - Documentation Errors:

        - Conflicting grades (graded one way in one section, and then graded another way in a different section)

        - Missing Grades

        - Missing attribution to the study drug

        - Missing start and stop dates

    - Communication Errors:

        - Not all AEs that are recorded on the following notes are captured and graded in the doctor's progress note.

            - Treatment room notes

            - Telephone notes

            - Message encounters

Sample of Progress Notes Issues

- Example of Conflicting Grades:
  - Progress Note:
    - Review of Systems – Fatigue (Grade 2)
    - Toxicity AE Section – Fatigue (Grade 0)

- Other observations that were made during the chart review:
  - At least 1 AE documented in each progress note was not graded
  - Attribution to study drug was missing part of the time
  - Start/stop dates missing most of the time.

Sample of Communication Issues

- **Telephone Note (**dated 09/23/2016) (CTRC# 14-2015 Subject initials HF)
  - <u>Patient called to report</u>:
    - Nausea
    - Vomiting
    - Fatigue
    - Diarrhea
    - Abdominal bloating
    - Dysgeusia (impaired sense of taste)
  - <u>The doctor's progress note (dated 9/29/16) documented the following</u>:
    - Nausea (grade 2); disease related
    - Fatigue (grade 1); related to treatment
    - Diarrhea (grade 1); related to treatment
    - Abdominal bloating (grade 1); related to treatment
    - Vomiting was not mentioned in the progress note
    - Dysgeusia was not mentioned in the progress note

Sample of Communication Issues

- **Treatment Room Note** (dated 09/08/2016) CTRC# 14-0046 Subject Initials MS
  - <u>Summary</u>: No AE's were listed
  - <u>Assessment</u>: Documented the following AEs
    - Diarrhea
    - Moderate fatigue
    - Mild Shortness of breath (SOB)
    - Numbness: feet and fingers
  - <u>The doctor's progress note (dated 9/08/16) documented the following</u>:
    - Diarrhea (grade 2)
    - Fatigue (grade 1)
    - Mild SOB was not mentioned in the progress note
    - Numbness: feet and fingers was not mention in the progress note
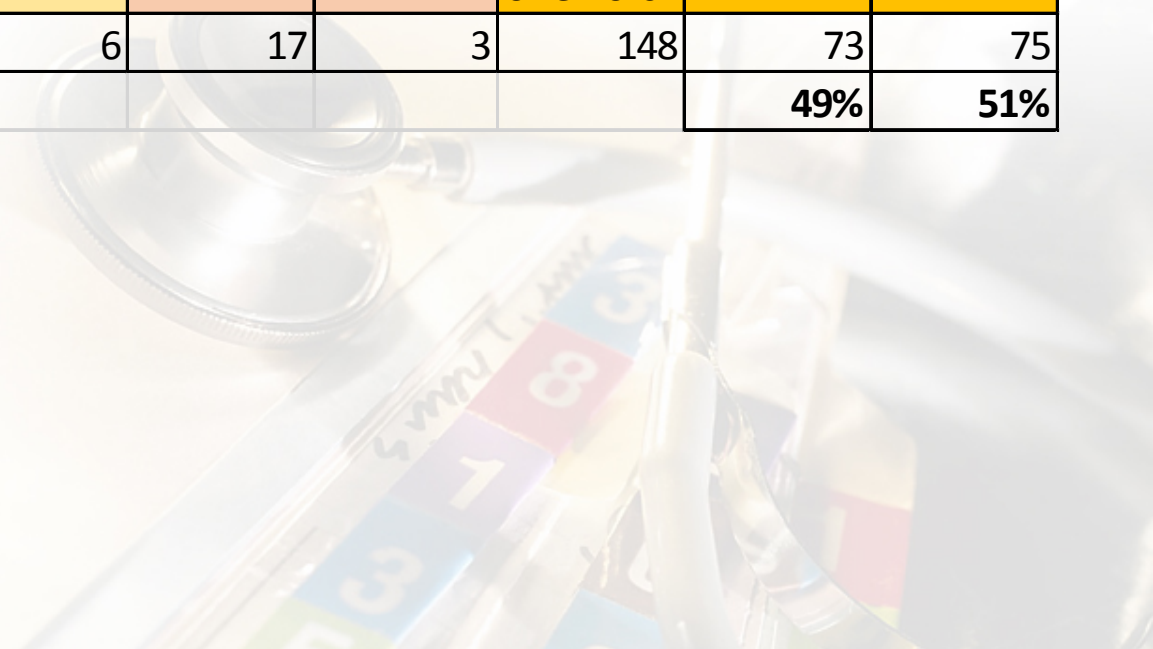
What does all of that data look like?

| Date of Visit/Cycle Period	Conflicting Documentation	Missing Grade	Lab AE	Communication - Infusion room	Communication Telephone note	# of AE/Potential number of errors	#Errors	#Correct
8/10/2016	0	3	0	0	0	8	3	5
8/11/2016	0	0	0	2	1	5	3	2
8/18/2016	0	0	0	0	0	3	0	3
8/23/2016	1	2	0	0	0	13	3	10
8/25/2016	0	0	0	0	0	3	0	3
8/31/2016	0	5	0	2	1	8	8	0
9/1/2016	0	0	0	2	0	2	2	0
9/6/2016	0	0	1	1	0	2	2	0
9/8/2016	0	0	0	0	1	1	1	0
9/8/2016	0	3	0	2	0	7	5	2
9/8/2016	0	3	0	0	0	7	3	4
9/9/2016	2	0	0	0	0	4	2	2
9/13/2016	1	0	2	3	0	13	6	7
9/15/2016	0	1	0	0	0	3	1	2
9/20/2016	1	0	0	0	0	3	1	2
9/27/2016	1	2	1	1	0	11	5	6
9/28/2016	0	4	0	2	0	6	6	0
9/29/2016	1	1	0	0	0	4	2	2
10/4/2016	1	0	2	0	0	11	3	8
10/5/2016	0	7	0	2	0	12	9	3
08/16/2016 - 09/06/2016	0	0	0	0	0	7	0	7
08/23/2016 - 09/20/2016	0	0	0	0	0	3	0	3
09/26/2016 - unknown	0	6	0	0	0	6	6	0
09/29/2016 - unknown	0	2	0	0	0	6	2	4
Totals	8	39	6	17	3	148	73	75

Detail of Pre-intervention Data

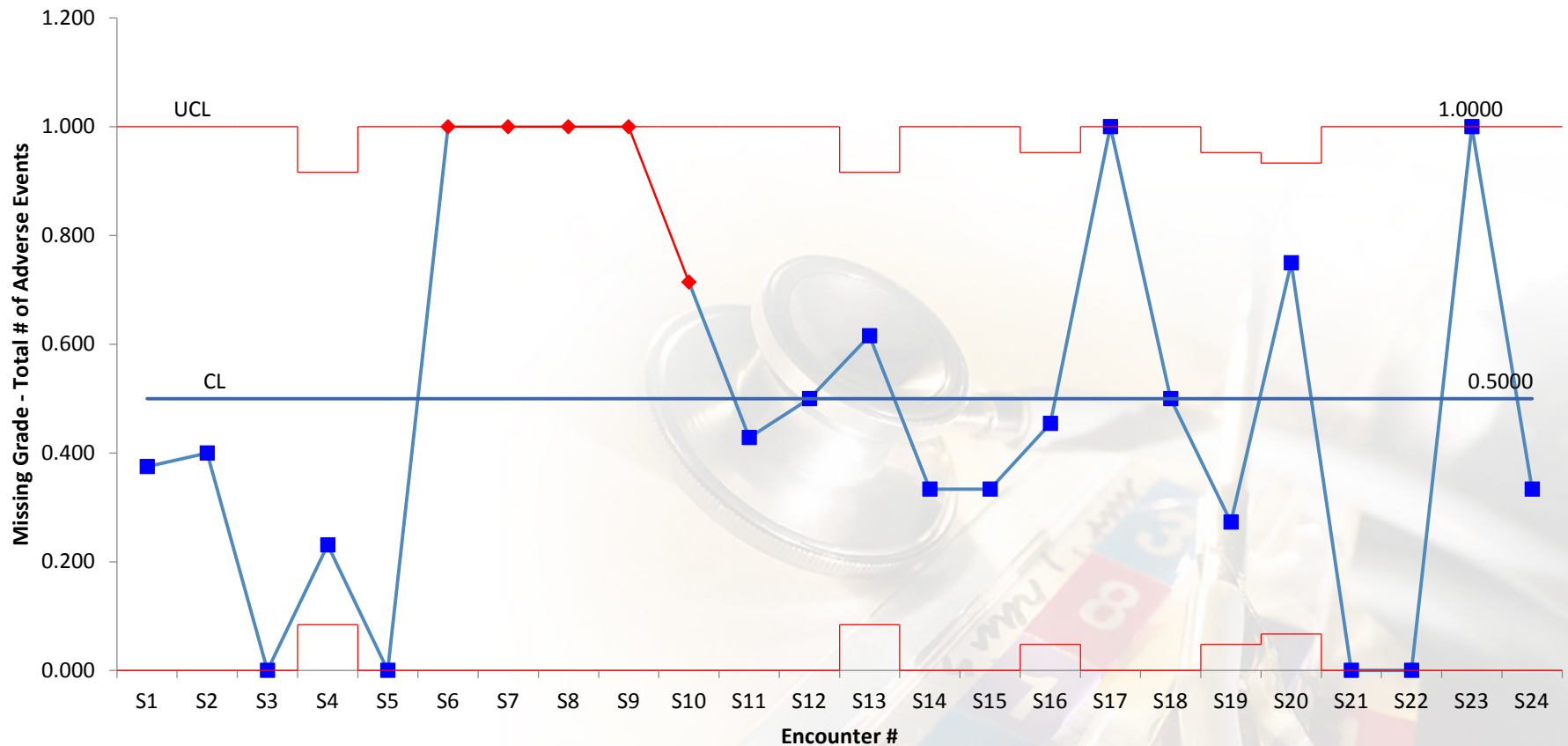| # of Encounters	Conflicting Documentation	Missing Grade	Lab AE	Communication - Infusion room	Communication Telephone note	# of AE/Potential number of errors	#Errors	#Correct
24	8	39	6	17	3	148	73	75
							49%	51%

Pareto Chart – Adverse Event Documentation Issues

Source of AE Queries
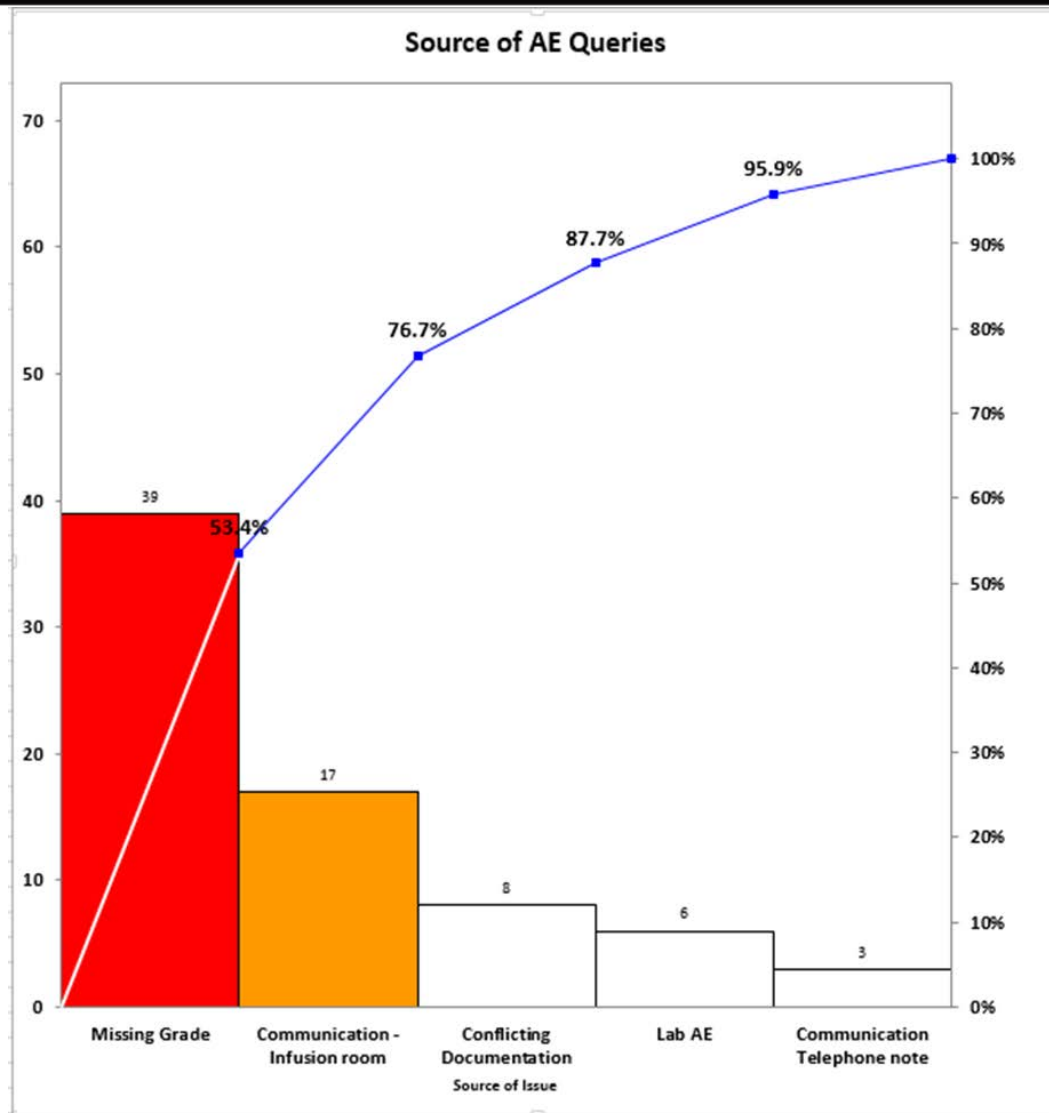
SPC Chart– Pre Intervention

Missing Grade / Total # of Adverse Events - Pre Intervention

Intervention

- Implementing usage of Dr. Kaklamani's **smart phrase** in EPIC with 3 physicians

- Upload CTCAE quick reference for mobile phones

- When creating a note – use

- the smart phrase: vkae

What did the post intervention data look like?

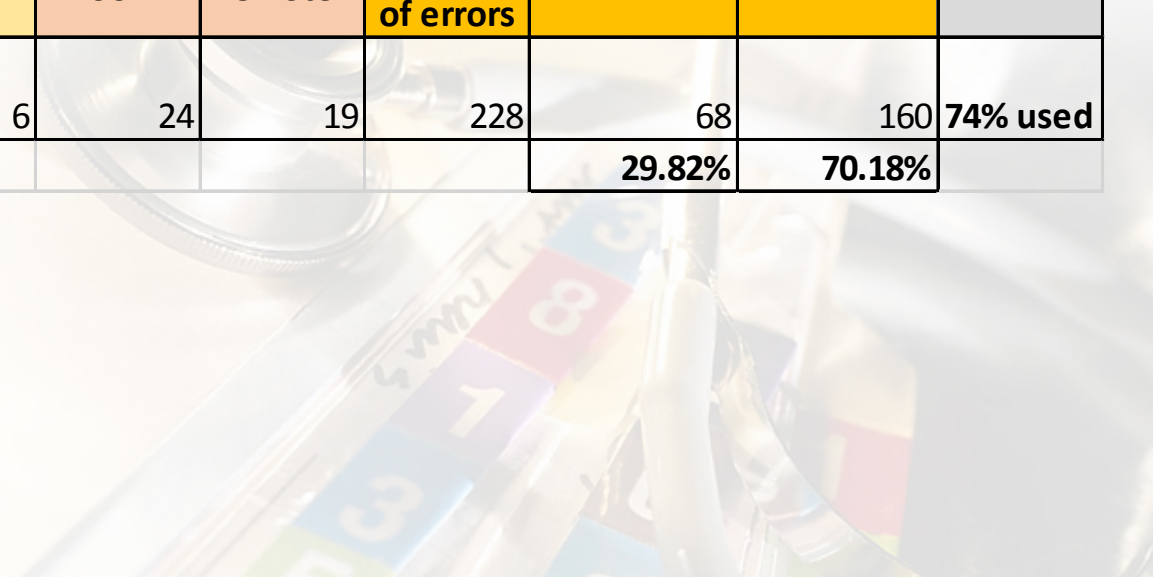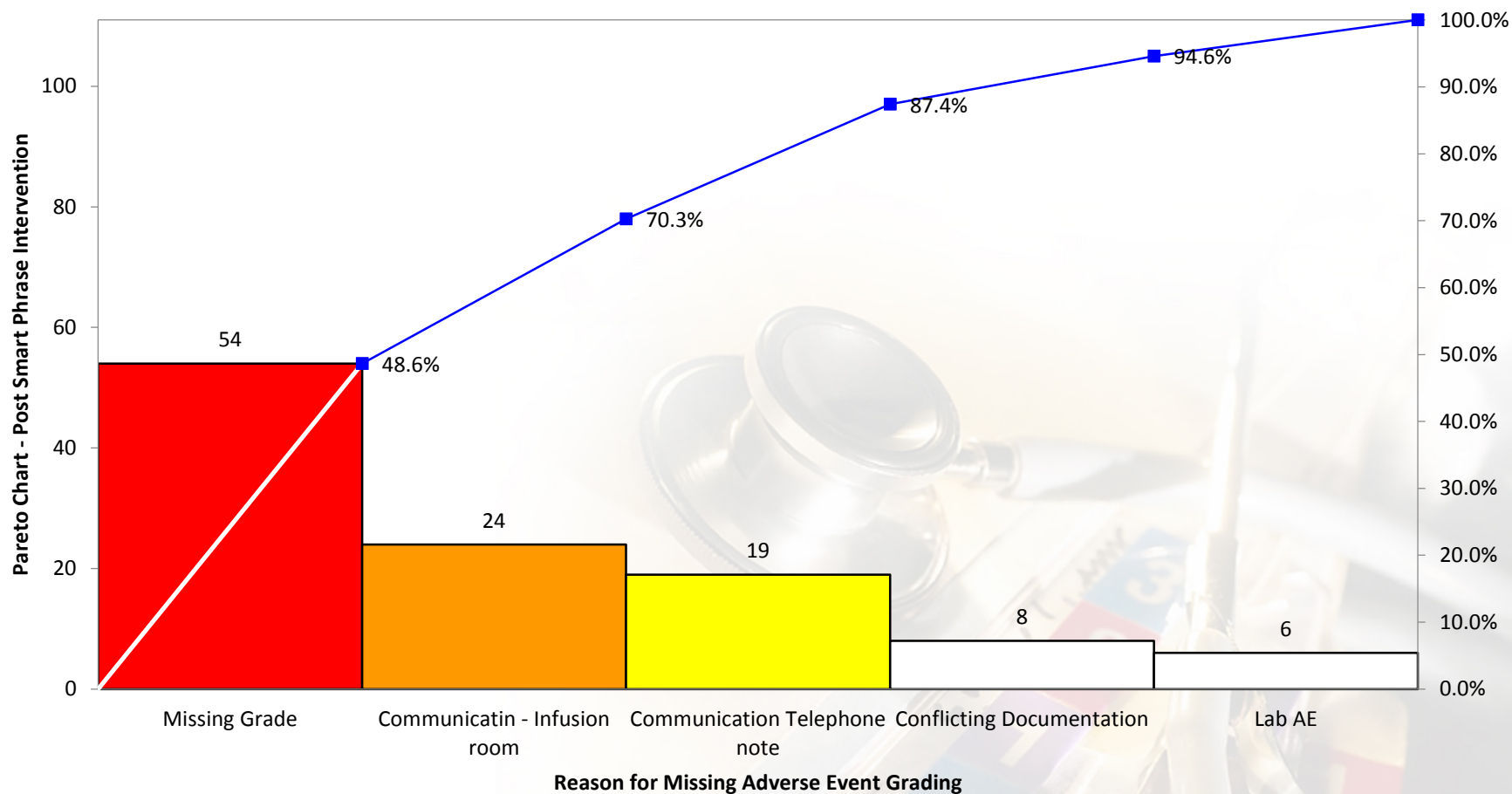| Date of Visit/Cycle Period	Adverse Event? Y or N	AE Reported to MD by Patient	Missing Info by PI in AE Assessment - Documentation	AE Reported by another route?	Error - Missed PI AE Documentation - Communication	DC would need to request additional info	Conflicting Documentation	Missing Grade	Lab AE	Missing start/stop date	Communicatin - Infusion room	Communication Telephone note	# of AE/Potential number of errors	#Errors	#Correct	Smart Phrase used?
11/29/2016	Y	Y	Y	Y	Y	Y	N	N	N	Y	0	3	8	4	4	n
11/29/2106	Y	Y	Y	N	N	Y	Y	N	N	Y	0	0	3	1	2	n
11/11/2016	y	N	N	Y	N	N	N	N	N	N	1	0	1	0	1	y
11/18/2016	Y	Y	N	N	N	Y	N	N	N	Y	0	0	3	0	3	Y
11/28/2016	Y	Y	N	Y	Y	Y	N	Y	N	Y	0	3	8	2	6	Y
12/9/2016	Y	Y	Y	N	N	Y	N	Y	N	Y	0	0	8	1	7	Y
12/13/2016	Y	Y	Y	N	N	Y	N	Y	N	Y	0	0	2	2	0	n
11/18/2016	Y	Y	N	Y	Y	Y	N	Y	N	Y	2	0	6	1	5	Y
12/2/2016	Y	Y	Y	Y	Y	Y	N	Y	N	Y	1	0	5	1	4	Y
11/15/2016	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	4	0	14	6	8	y
11/29/2016	Y	Y	Y	Y	N	Y	N	Y	Y	Y	2	0	11	3	8	y
12/6/2016	Y	Y	Y	Y	N	Y	N	Y	Y	Y	1	0	13	2	11	y
11/22/2016	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	3	2	9	3	6	y
11/29/2016	Y	Y	Y	Y	Y	Y	N	Y	N	Y	0	4	11	3	8	y
12/9/2016	Y	Y	Y	Y	N	Y	Y	Y	N	Y	0	1	6	2	4	N
12/13/2016	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	2	0	8	2	6	Y
11/18/2016	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	3	0	18	4	14	y
12/7/2016	y	Y	Y	Y	Y	Y	N	Y	N	Y	3	0	21	4	17	Y
11/4/2016	Y	Y	N	N	N	N	N	N	N	N	0	0	1	0	1	Y
11/10/2016	Y	Y	Y	Y	N	Y	Y	Y	N	Y	1	0	7	1	6	Y
11/15/2016	Y	Y	Y	N	N	Y	N	Y	N	Y	0	0	9	3	6	Y
11/22/2016	Y	Y	y	n	n	y	n	y	n	y	0	0	9	3	6	Y
11/29/2016	Y	Y	Y	Y	Y	Y	N	Y	N	Y	1	0	10	4	6	Y
11/15/2016	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	0	2	7	4	3	Y
11/29/2016	Y	Y	N	N	N	Y	Y	N	N	N	0	0	8	0	8	N
11/30/2016	Y	Y	Y	N	N	N	Y	Y	N	Y	0	0	12	6	6	N
11/22/2016	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	0	4	10	5	5	N

Detail of Post Interventional Data

# of Encounters	Conflicting Documentation	Missing Grade	Lab AE	Communicatin - Infusion room	Communication Telephone note	# of AE/Potential number of errors	#Errors	#Correct	Smart Phrase used?
27	8	54	6	24	19	228	68	160	**74% used**
							29.82%	**70.18%**	

Post Intervention Pareto Chart

Pareto Chart - Post Smart Phrase Intervention

Y-axis (left): Pareto Chart - Post Smart Phrase Intervention

X-axis: Reason for Missing Adverse Event Grading

Reason	Count	Cumulative %
Missing Grade	54	48.6%
Communicatin - Infusion room	24	70.3%
Communication Telephone note	19	87.4%
Conflicting Documentation	8	94.6%
Lab AE	6	100.0%

SPC Chart Comparison

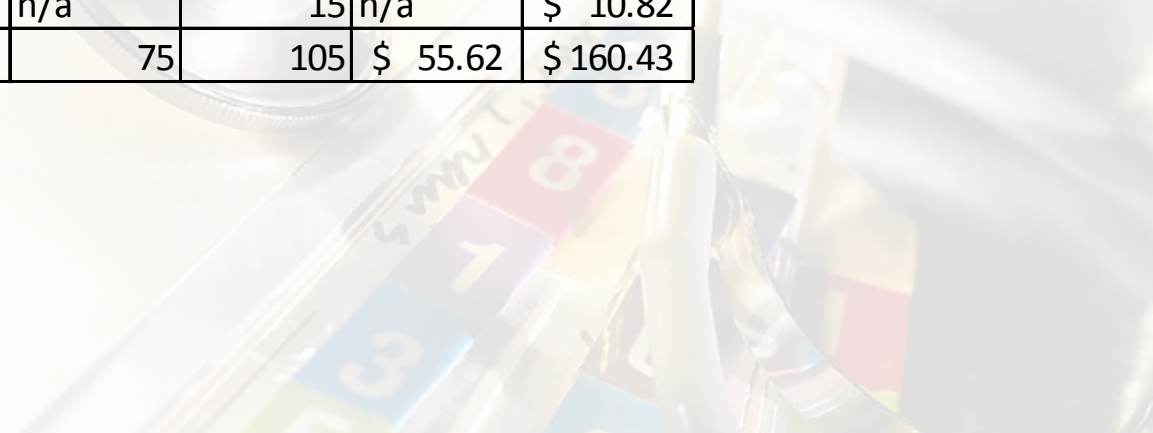Missing Grading in Adverse Events - Pre and Post Epic Smart Phrase Intervention
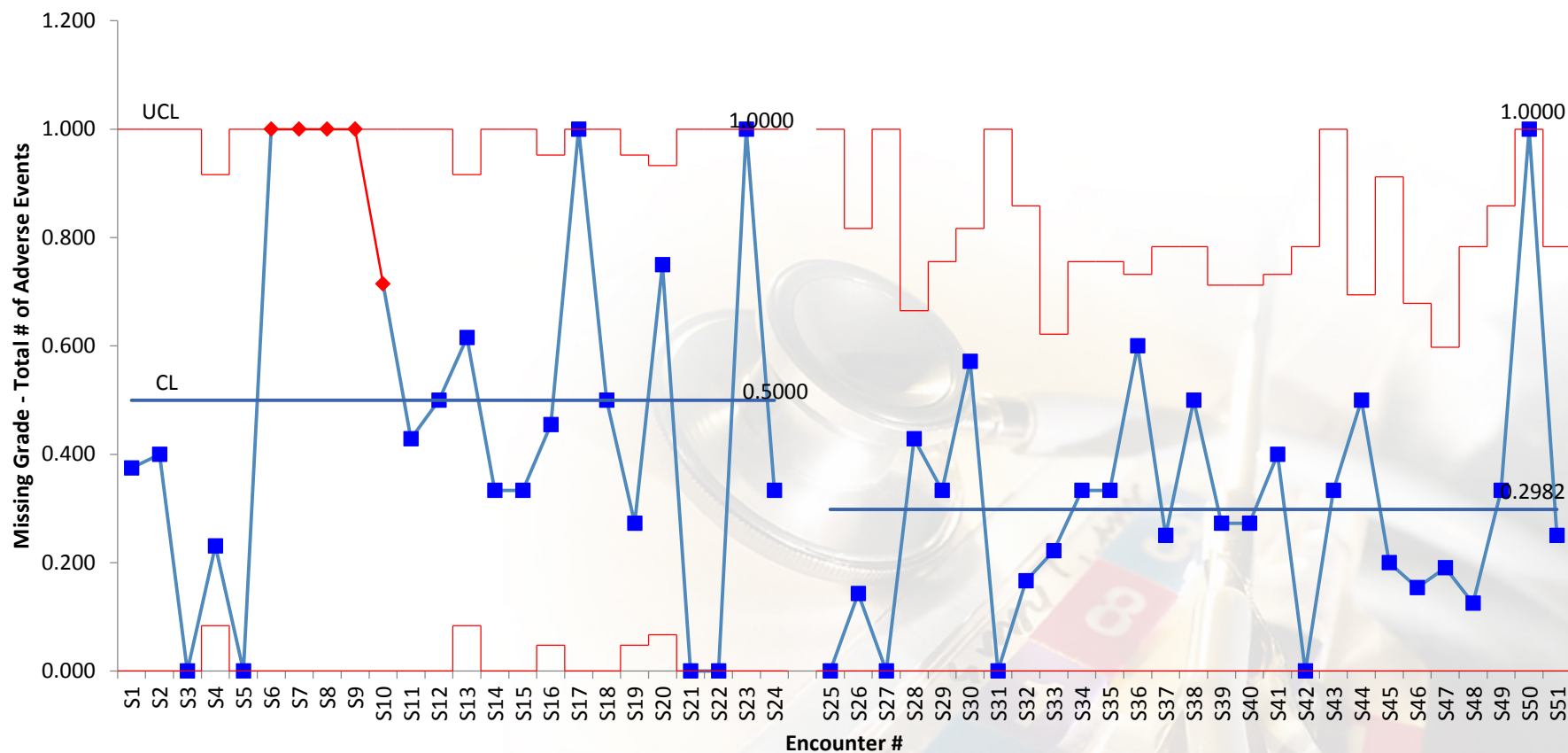
Estimated Return on Investment (per encounter)

Time to write the smart phrase
~ 30 minutes!

Cost Savings	Minutes		Dollars	
	Std	**IIS**	**Std**	**IIS**
Study Coordinator	15	15	$ 9.34	$ 9.34
Investigator	20	20	$ 28.01	$ 28.01
Data Coordinator	20	20	$ 7.33	$ 7.33
Monitor	20	20	$ 10.94	$ 10.94
DSMB	n/a	15	n/a	$ 94.00
QA Director	n/a	15	n/a	$ 10.82
Total	75	105	$ 55.62	$ 160.43

- AE Smart phrase should be used in all MD documentation sections that capture an Adverse event. Most commonly, missed AE grading occurred in the Review of Systems section.

- Consistent use of terminology to describe an adverse event. There was noted inconsistent usage of terms that were likely the same AE, but different words were used to describe the issue. Examples: 1 - one section noted "swelling" while another section listed "edema". 2 - Unsteady gait used by MD, nurse noted ataxia and balance issues 3 - Nurse noted numbness/tingling hands and feet, MD noted Neuropathy.

- Continued missing start and stop date of events, occasionally missing the relationship to the intervention

- Continued cut and paste errors

- Closing out telephone/infusion room reports of adverse events with grading, association and dates

Planned Future Intervention

- Implementing NCI's Patient Reported Outcomes – Common Terminology Criteria for Adverse Event

- Teleconference scheduled with Memorial-Sloan Kettering and University of North Carolina Lineberger January 9th

- UT Health EPIC team onboard

- May apply for grant funding if needed

PRO-CTCAE Measurement System

1. Symptom Library	2. System for Survey Administration
• 78 symptomatic adverse events drawn from CTCAE	• Web-based system to customize surveys and manage survey administration
• PRO-CTCAE questions evaluate symptom occurrence, frequency, severity, and interference	• Patient responds to surveys using web, tablet or interactive voice response (IVRS) telephone system
	• Conditional branching (skip patterns)
	• Write-ins with automatic mapping to standardized terminology

Sustainability

- This project is anticipated to have long term sustainability as a continuous quality improvement project in clinical trial documentation

- Results shared with CTRC Associate Director for Clinical Research

- May plan to expand pilot to require mandatory use of smart phrase for adverse event documentation

- Meeting planned January 12th to discuss results with data collection team and brainstorm on areas of improvement identified during the project

- Will spot check for template usage during routine audit