Clinical Safety & Effectiveness
Cohort # 17

Chronic Opioid Therapy (COT) Safety Assessment

CENTER FOR PATIENT SAFETY & HEALTH POLICY

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The Team

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- Sponsor Department:
  - Division of Geriatrics, Gerontology, and Palliative Medicine

Special thanks to Dr. Sandra Sanchez-Reilly, Dr. Jennifer Healy, Dr. Jeanette Ross

AIM Statement

We aim to improve adherence (completion and appropriate chart documentation) to the *"Chronic Opioid Therapy (COT) Safety Assessment"* from 0% - 50% in patients receiving chronic opioid therapy (COT, current users or those newly initiated on therapy) seen in the UHS Palliative Care Fellows Clinic from October 2015 to January 2016.

- Chronic opioid therapy safety assessment includes COT appropriateness assessment, misuse risk assessment, informed consent and therapy contract, patient specific counseling and education
- Appropriate chart documentation includes completed smartphrase in the recommendations section of the Palliative Medicine outpatient clinic note

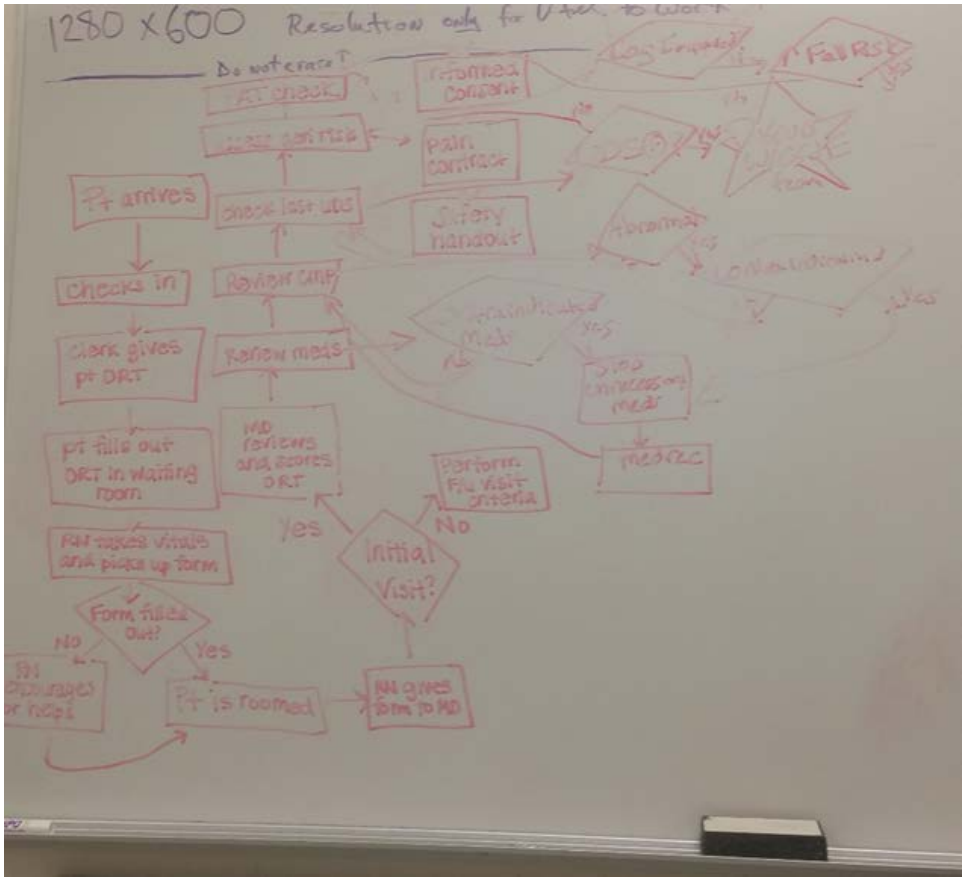
Project Milestones

• Team Created	July 2015
• AIM statement created	Aug. 2015
• Weekly Team Meetings	Aug 2015 – Oct 2015
• Background Data, Brainstorm Sessions, Workflow and Fishbone Analyses	Aug 2015 – Oct 2015
• Interventions Implemented	Oct 1st 2015
• Data Analysis	Sept 1st 2015 – Feb 29th 2016
• CS&E Presentation	Jan 15th 2016

Background

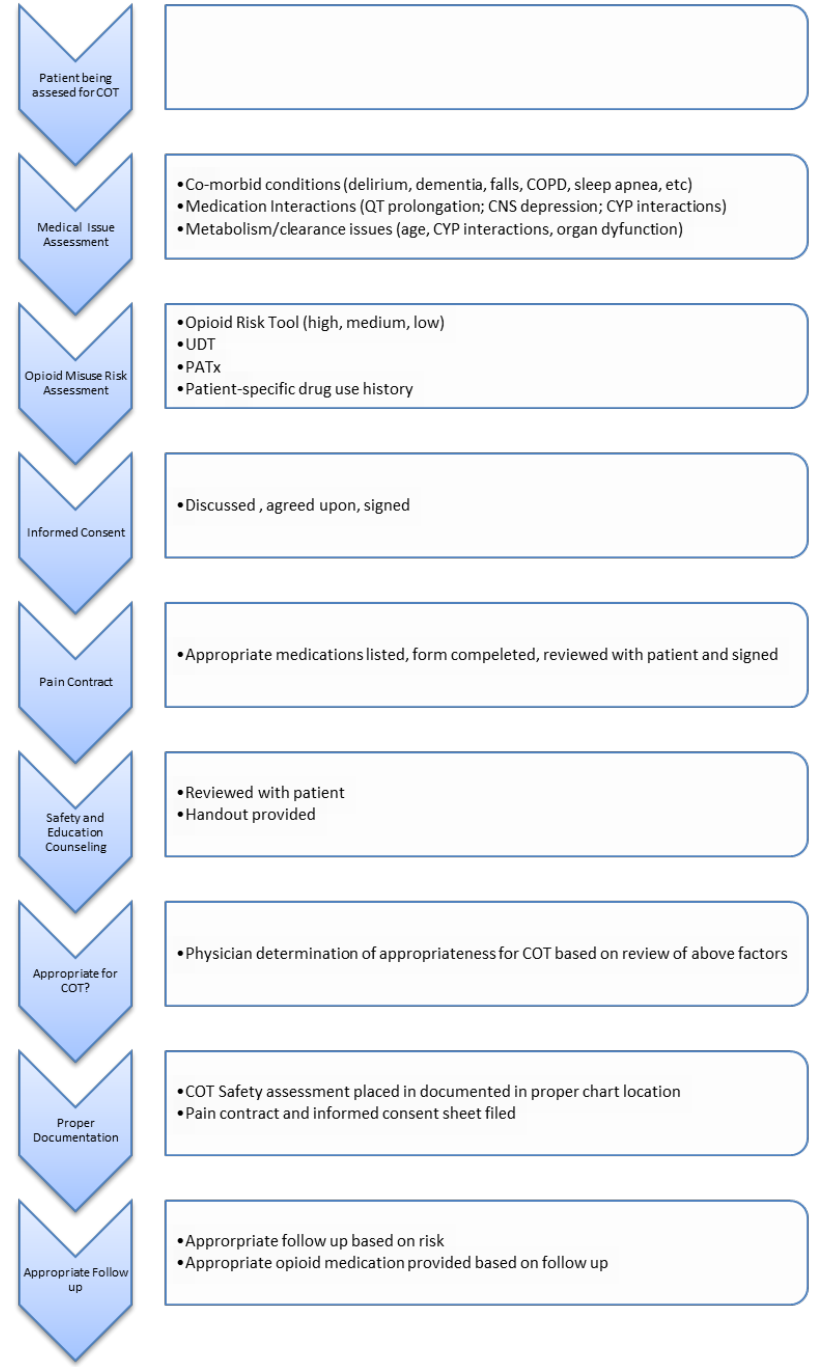
- Opioid Misuse: Deliberate use of opioids in way other than prescribed due to addiction, including diversion
- 4.9 million people misused opioids in 2012[1]
  - Complications from misuse on the rise[2]
- ***Nonmalignant*** pain guidelines:
  - Stress **screening** and **monitoring** for misuse[3,4]
- Palliative care patients also misuse opioids
  - 40% of palliative patients at risk
  - 60% of those eventually show evidence of misuse.[5]
- ***No formalized guidelines or management recommendations exist for the palliative care population***
- Our palliative care clinic is no exception

Planning



- Screening and Monitoring protocol development was more complex than anticipated
- Modified our plans for a smaller scale intervention
  - New patient screening
  - Plans to implement follow-up visit monitoring in the future

Chronic Opioid Therapy Safety Assessment Algorithm



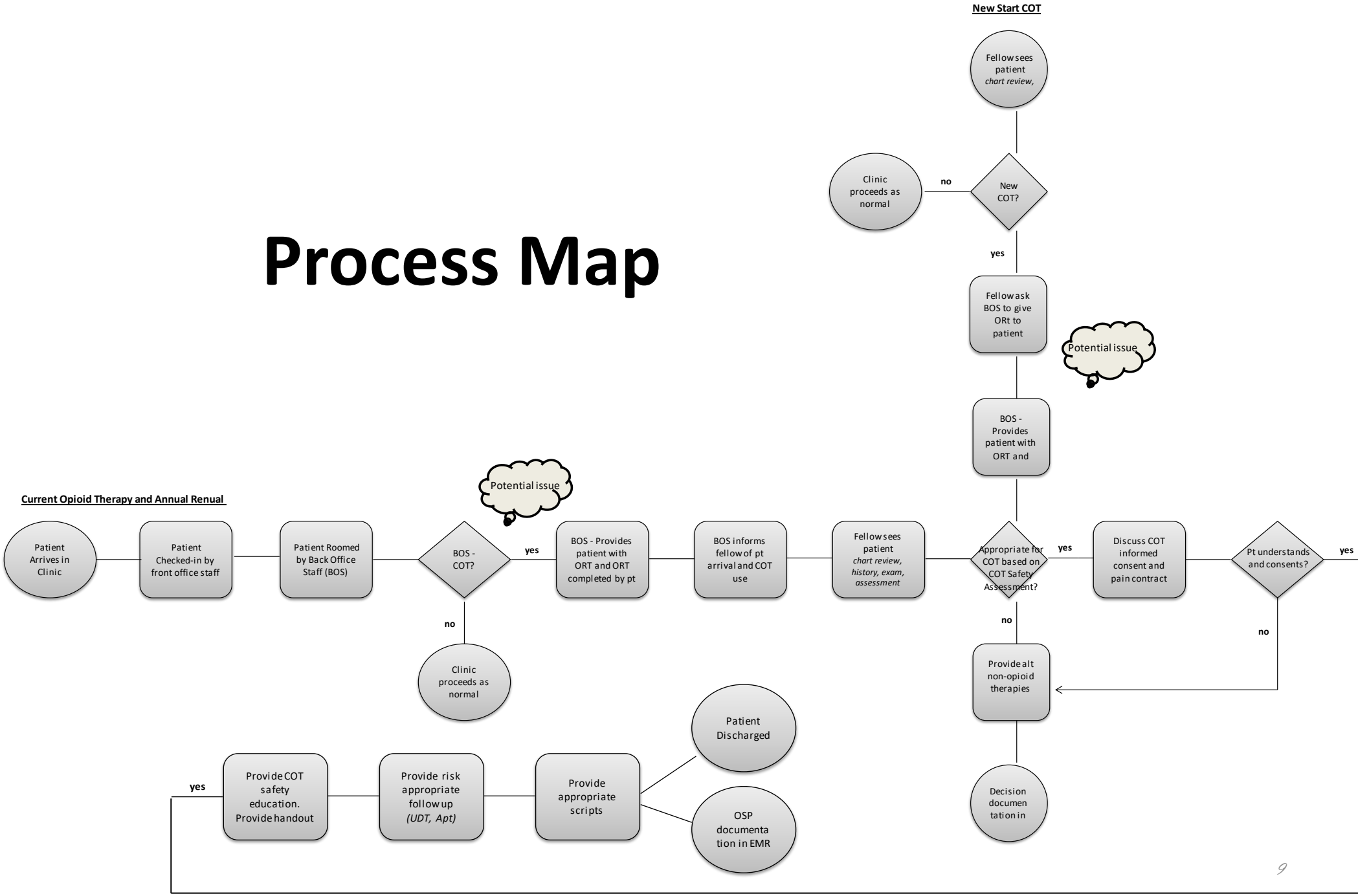
OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
	TOTAL		_____	_____

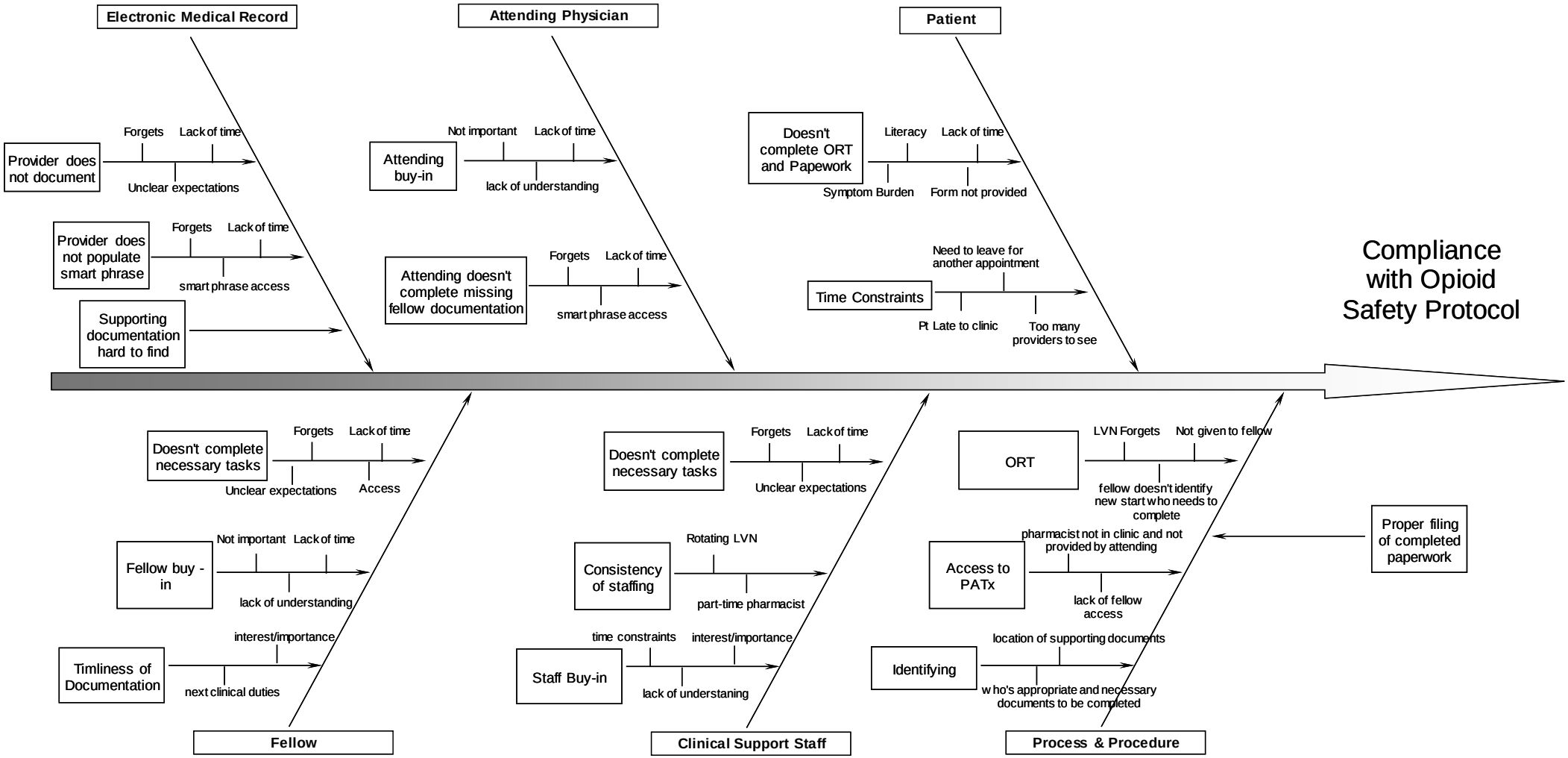
Total Score Risk Category
Low Risk 0 – 3
Moderate Risk 4 – 7
High Risk $\geq$ 8

Reference: Webster LR. Predicting aberrant behaviors in opioid-treated patients: Preliminary validation of the opioid risk tool. *Pain Medicine.* 2005;6(6):432-442. Used with permission.

Process Map


New Start COT
Fellow sees patient chart review,
Clinic proceeds as normal
no
New COT?
yes
Fellow ask BOS to give ORt to patient
Potential issue
BOS - Provides patient with ORT and
Current Opioid Therapy and Annual Renual
Potential issue
Patient Arrives in Clinic
Patient Checked-in by front office staff
Patient Roomed by Back Office Staff (BOS)
BOS - COT?
yes
BOS - Provides patient with ORT and ORT completed by pt
BOS informs fellow of pt arrival and COT use
Fellow sees patient chart review, history, exam, assessment
Appropriate for COT based on COT Safety Assessment?
yes
Discuss COT informed consent and pain contract
Pt understands and consents?
yes
no
Clinic proceeds as normal
no
no
Provide alt non-opioid therapies
Patient Discharged
yes
Provide COT safety education. Provide handout
Provide risk appropriate follow up (UDT, Apt)
Provide appropriate scripts
OSP documentation in EMR
Decision documentation in

Fishbone


Electronic Medical Record
Attending Physician
Patient
Provider does not document
Forgets
Lack of time
Unclear expectations
Provider does not populate smart phrase
Forgets
Lack of time
smart phrase access
Supporting documentation hard to find
Attending buy-in
Not important
Lack of time
lack of understanding
Attending doesn't complete missing fellow documentation
Forgets
Lack of time
smart phrase access
Doesn't complete ORT and Papework
Literacy
Lack of time
Symptom Burden
Form not provided
Time Constraints
Need to leave for another appointment
Pt Late to clinic
Too many providers to see
Compliance with Opioid Safety Protocol
Doesn't complete necessary tasks
Forgets
Lack of time
Unclear expectations
Access
Fellow buy - in
Not important
Lack of time
lack of understanding
Timliness of Documentation
interest/importance
next clinical duties
Fellow
Doesn't complete necessary tasks
Forgets
Lack of time
Unclear expectations
Consistency of staffing
Rotating LVN
part-time pharmacist
Staff Buy-in
time constraints
interest/importance
lack of understaning
Clinical Support Staff
ORT
LVN Forgets
Not given to fellow
fellow doesn't identify new start who needs to complete
Access to PATx
pharmacist not in clinic and not provided by attending
lack of fellow access
Identifying
location of supporting documents
w ho's appropriate and necessary documents to be completed
Proper filing of completed paperwork
Process & Procedure

Driver Diagram

Aim	Primary Drivers	Interventions
Improve compliance with *"Chronic Opioid Therapy Safety Assessment"* to 50% in patients receiving chronic opioid therapy seen in the UHS Palliative Care Fellows Clinic from October 2015 to February 2016.	**Provider Forgets to Document**	"Smart phrase" in EMR with uniform access by all providers
		Visual reminder in clinic to document
		Attending double-checks fellow documentation
		Weekly "follow up" with providers to 1) provide feedback on their documentation, and 2) determine barriers to documentation
		Incorporate smart phrase template into EMR (future)
	Difficulty Accessing Necessary Information	Pharmacist bring printed PATx report to clinic
		Attending access PATx database if pharmacist absent
		Nursing to determine presence and date of last pain contract prior to clinic
		Nursing to determine date of last UDT and print results prior to clinic
		Clearly marked location with appropriate documents needed to be completed
		Proper filing of completed documents so accessible at subsequent visit
	Time Constraints	Consistent clinic staffing for support staff so the process becomes streamlined
		Nursing provides ORT and helps complete
		Necessary documents identified and readily available, as above.

Data Collection Form

Clinic Date: Patient ID:

Data Collection Form

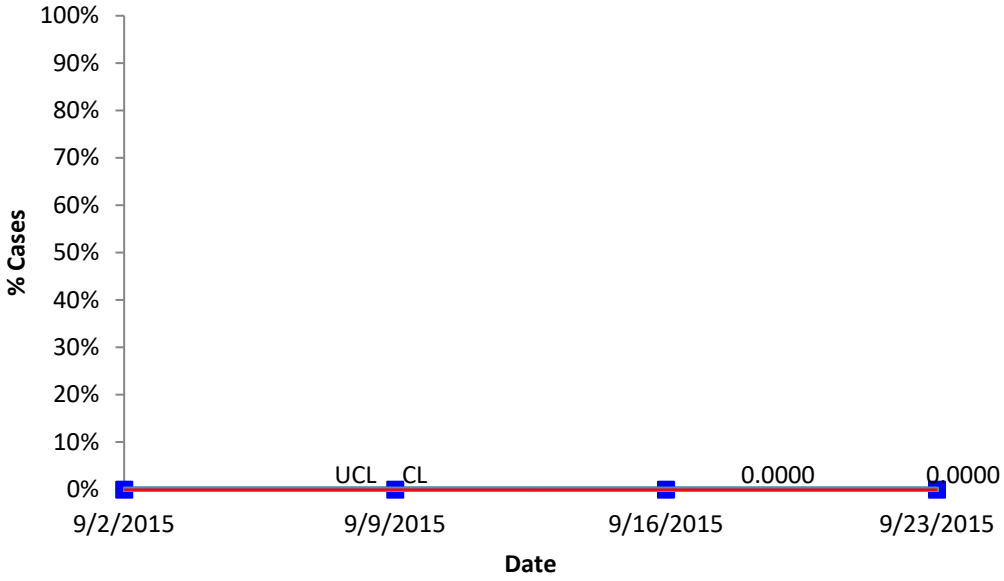
Data Label	Description	Possible Responses
Age	Patient's Age	
Sex	Patient's Sex	☐ Male [0] ☐ Female [1]
Race	Patient's Race	☐ Caucasian[1] ☐ African American[2] ☐ Asian[3] ☐ Native American[4] ☐ Other[5] ☐ Not Documented[6]
Ethnicity	Patient's Ethnicity	☐ Not Hispanic/Latino/Spanish[1] ☐ Hispanic/Latino/Spanish[2] ☐ Not Documented[3]
Fellow	Fellow who saw the patient	☐ Amdur [1] ☐ Mireles [7] ☐ Davila [2] ☐ Pagan [8] ☐ Frausto [3] ☐ Sawey [9] ☐ Kapp [4] ☐ Seetharma [10] ☐ LaCoss [5] ☐ Vandemeer [11] ☐ May [6] ☐ No Fellow [0]
Attending	Attending who cosigned the note	☐ Morrow [1] ☐ Healy [2] ☐ Stowers [3]
PallDx	Patient's Palliative Diagnosis	☐ Cancer [1] ☐ Pulm/COPD [5] ☐ ESRD [2] ☐ Dementia [6] ☐ Cardiac [3] ☐ Neurologic [7] ☐ HIV [4] ☐ End Stage Liver[8] ☐ Other [9]
OpioidDx	Patient's Diagnosis that Requires Opioids	☐ Terminal Diagnosis [1] ☐ Chronic (nonterminal) Pain [2] ☐ Both [3] ☐ Unknown [4]
AnyOpioid	Is the patient on opioids at all (from our clinic or other source)?	☐ No Opioid Naïve [0] ☐ Yes Currently on Opioids [1]
OnOpioids	Is the patient prescribed opioids by this clinic? (Old & New Starts)	☐ No [0] ☐ Yes [1]
OldOpioid	Has the patient previously been prescribed opioids by this clinic (Old)	☐ No [0] ☐ Yes [1]
NewOpioid	Is this visit the first time patient has been prescribed opioids by the clinic? (New Start)	☐ No [0] ☐ Yes [1]
LongAct	Is the patient prescribed long acting opioids?	☐ No [0] ☐ Yes [1]
PRN	Is the patient prescribed PRN opioids?	☐ No [0] ☐ Yes [1]
DocuComp	Is the entire Opioid Safety Protocol 100% complete in the chart?	☐ No [0] ☐ Yes [1]
Appropriate	Does provider document patient is appropriate for opioids in the chart	☐ No [0] ☐ Yes [1]
Concerns	Does the provider document whether or not there are concerns for the patient to take opioids?	☐ No [0] ☐ Yes [1]
TypeCon	Type of concern documented	☐ No documentation at all [1] ☐ Documented no concerns [2] ☐ Comorbid Conditions [3] ☐ Medication [4] ☐ Organ Function [5] ☐ Drug Abuse [6] ☐ Other [7] ☐ Multiple [8]

Clinic Date: Patient ID:

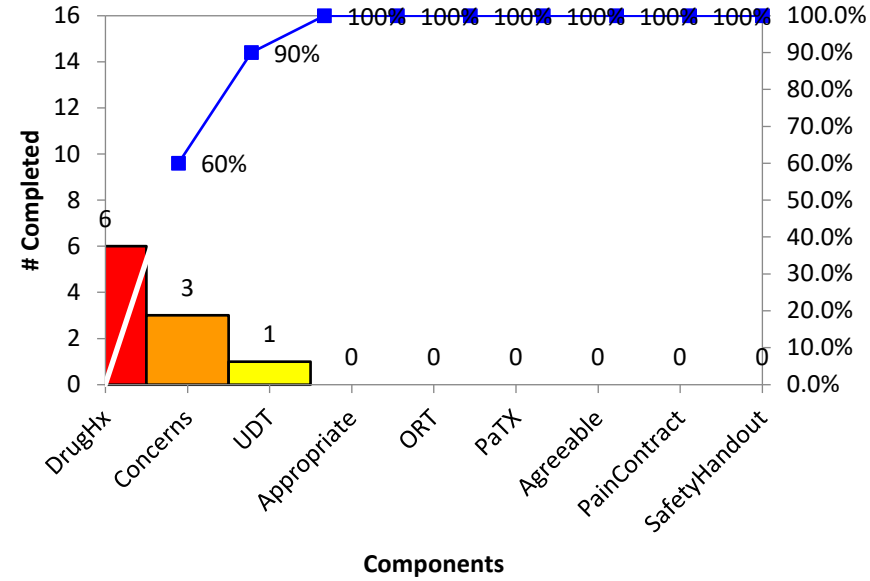
FTConcern	Type of concerns documented in free text format	☐ None Concerns:
ORT	Was ORT done/documented?	☐ No [0] ☐ Yes [1]
ORTDate	Date ORT was completed	☐ Not Done Date:
ORTScore	Raw ORT score	
ORTHML	Was ORT scored as High Medium or Low?	☐ ORT not done ☐ High [2] ☐ Medium [1] ☐ Low [0]
UDT	Was a UDT documented?	☐ No [0] ☐ Yes [1]
UDTDate	Date UDT was done	☐ Not Done Date:
UDTResult	Was the UDT negative or positive?	☐ No UDT done ☐ Negative [0] ☐ Positive [1]
UDTAppropriate	Was the UDT appropriately positive or negative for the patient's opioid status?	☐ No UDT Done ☐ Appropriately Positive [1] ☐ Inappropriately Positive [2] ☐ Inappropriately Negative [3] ☐ Appropriately Negative [4]
PaTx	Was the state screening documented?	☐ No [0] ☐ Yes [1]
PaTxDate	Date the PaTX database was searched	☐ Not Done Date:
PaTXResult	Were concerns identified on the PaTX?	☐ No PaTX Documented ☐ No [0] ☐ Yes [1]
DrugHx	Is there a history of drug use documented?	☐ No [0] ☐ Yes [1]
DrugHxDate	Date drug use history was assessed	☐ Not Done Date:
Drug Type	Type of drug use documented	☐ No Drug Use [0] ☐ Rx Opioids [6] ☐ Marijuana [1] ☐ Amphetamines[7] ☐ Cocaine [2] ☐ EtOH [8] ☐ Crack [3] ☐ Polysubstance[9] ☐ Heroin [4] ☐ Other Drugs [10] ☐ Benzos [5]
FTDrugHx	Details of drug use history	☐ Blank if no drug use history Details:
Agreeable	Is there documentation that the patient understands opioid risks/is agreeable to treatment?	☐ No [0] ☐ Yes [1]
PainContract	Was a pain contract signed?	☐ No [0] ☐ Yes [1]
PainConDate	Date Pain Contract was signed	☐ Not Done Date:
Counseling	Date counseling was performed	☐ Not Done Date:
SafetyHand	Is there documentation that a safety handout was given?	☐ No [0] ☐ Yes [1]

Baseline Data

p-Chart for % Cases with Completed Documentation



Pareto Chart of # Completed Documentation Components



No Patients Had Complete Documentation at Baseline

Only 3 of 9 Components Were (Inconsistently) Documented at Baseline

PLAN: Intervention

- Implement a standardized protocol for routine safety assessment in patients on chronic opioid therapy
- Changes
  - Add Risk Assessment Tool Screening (Opioid Risk Tool)
  - Add standardized chart documentation
  - Add Chronic Opioid Safety and Education Counseling
  - Reorganize assignment of responsibilities for the protocol
  - Reorganize clinic flow (storage/filing of documents, etc)
- Physician and Clinical Staff education/training on new protocol

Chronic Opioid Therapy Safety Assessment Documentation Template

.COTsafetyassessment

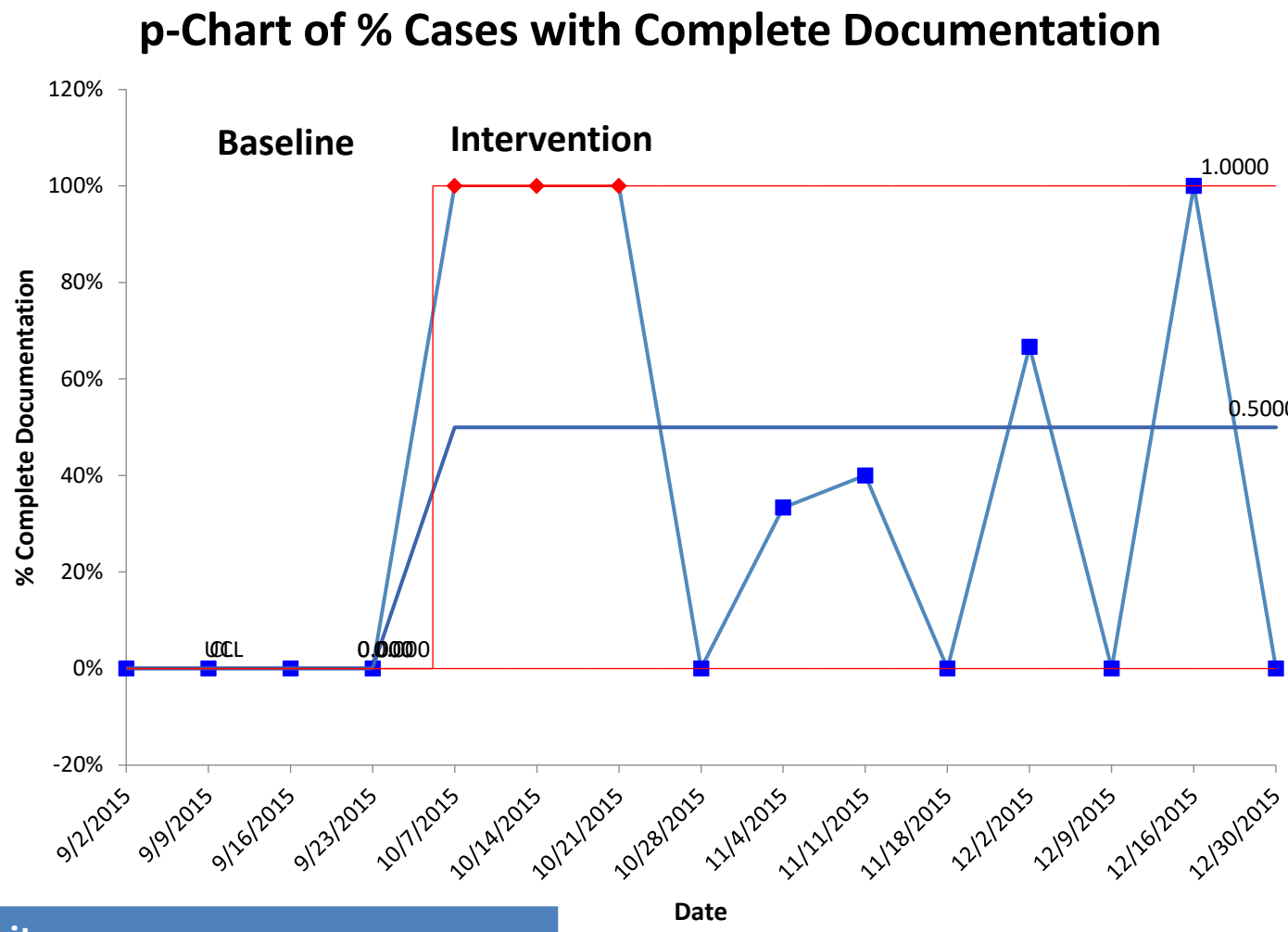
Chronic Opioid Therapy Safety Assessment

- This patient (is / is not) appropriate for chronic opioid therapy (COT)
- Patient-specific assessment of co-morbid conditions, medications, organ function reveal the following concerns for COT therapy: (none / free text)
- Opioid Misuse Screening: ORT results: (date, high / med / low); UDT: (date, results); PATx (date reviewed, results); Pertinent Drug use history: (none / free text)
- Pain Contract and Informed Consent: Patient understands the risks and benefits to COT and (is/is not) agreeable to therapy. Date signed: (date) Placed on File: (yes / no)
- COT Safety Education and Counseling performed on (date) and handout provided (yes / no)

DO: Implementing the Change

- Implementation Date: October 1st 2015
- Implementation Plan:
  - Physician and office staff training prior to implementation
  - One CS&E team member in clinic during first week
  - Qualitative and Quantitative data collected after each clinic
  - 4 clinics since implementation *(Oct 7th, 14th, 21st, 28th)*
- Lessons:
  - Clinical staff turnover disrupts flow
  - Helpful to have a physician leader who supports the project in clinic
  - Need handouts in English and Spanish
  - Burden and compliance may be improved by incorporating documentation into note template

CHECK: Results/Impact

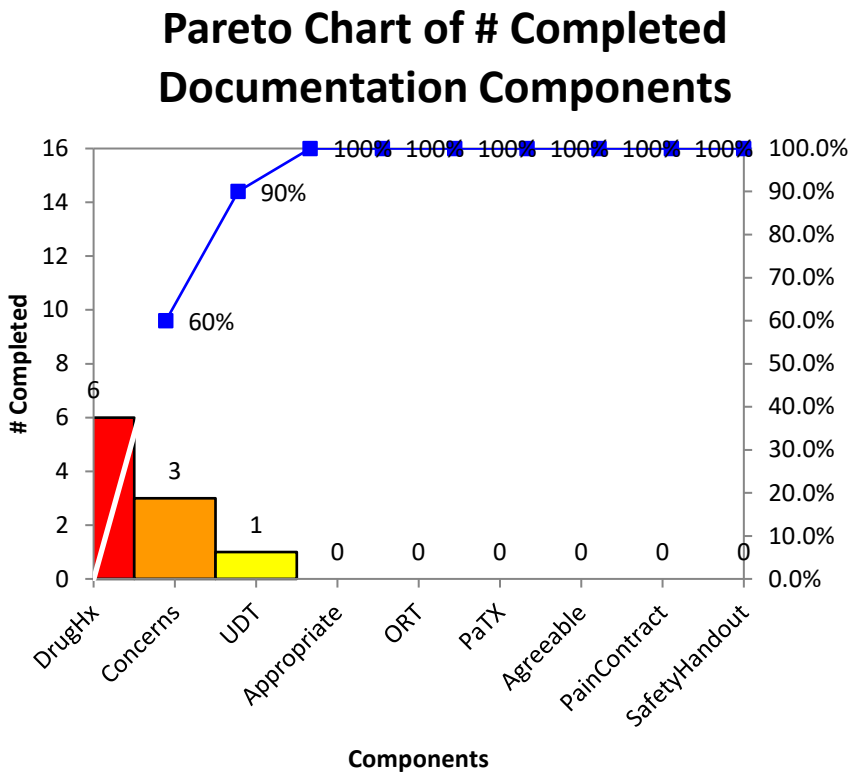


Phase Limits			
Phase	**LCL**	**UCL**	**Avg**
Baseline	0%	0%	0%
Intervention	0%	100%	**50%**

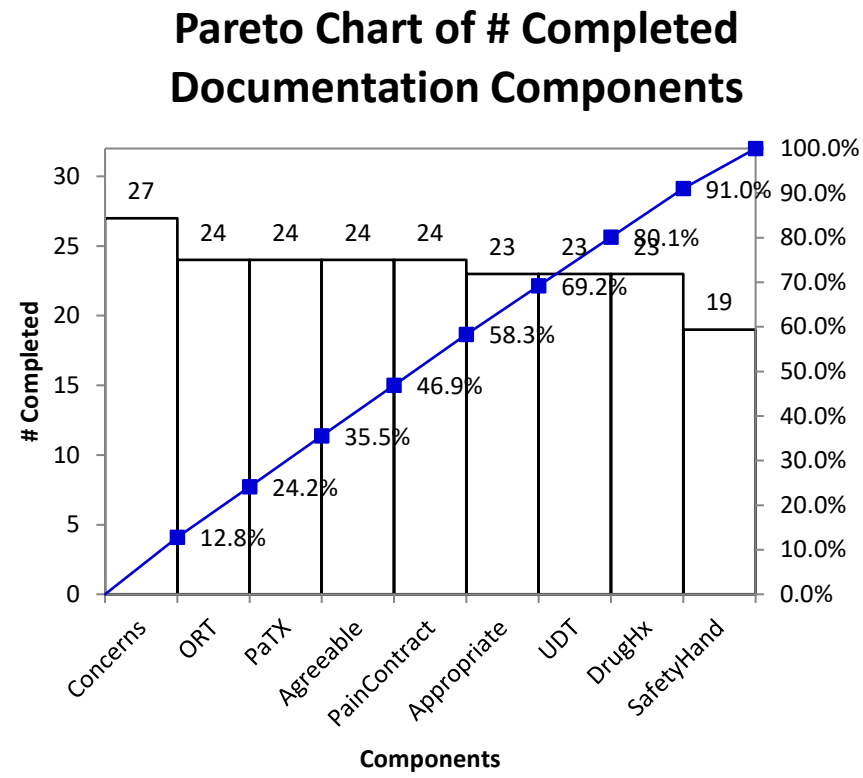
We Hit Our Goal!

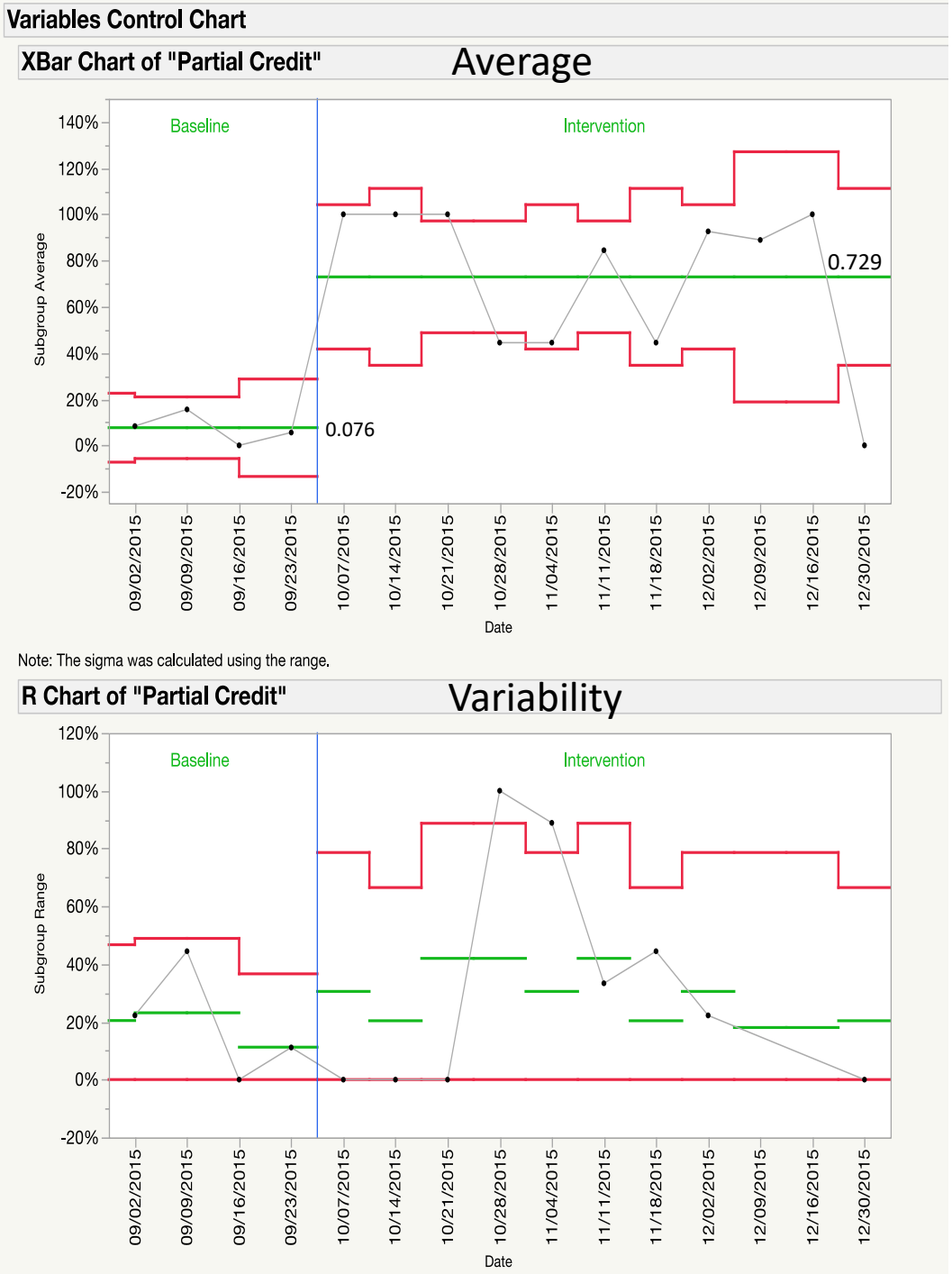
Improved Documentation

Baseline



Intervention





Partial Credit

- 9 points needed for complete documentation
  - Baseline: <1 point per encounter documented
  - Intervention: 6-7 points per encounter documented
- Personnel changes were main source of variability

Act: Sustaining the results

- Palliative Care Clinic will continue to implement protocol when prescribing opioids to patients
  - Staff will continue to hand out Opioid Risk Tool
  - Plan to incorporate acronym into note template
  - Opioid Education and Safety handout will continue

Act: Sustaining the results

- Fellowship will train new incoming fellows in protocol during orientation to promote sustainability
- Future QI projects will continue from protocol that fellows will be able to conduct and present at American Academy of Hospice and Palliative Medicine annual conference

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Return on Investment

- At University Hospital, the average cost per day of inpatient stay is $2,759
- During past year we had one adverse event involving clinic patient with drug overdose. He was admitted for four days at University Hospital.
- Total cost of hospital stay was $11,036
- We had no adverse events during QI
- We saved UHS at least $11,036!

Conclusions/What's Next!

- Successful QI projects involve collaboration and teamwork
  - Physicians, nurses, social work, chaplain, medical assistants all working together as a team
- Plan to continue project and gather more data regarding opioid safety and misuse
  - Consider obtaining feedback of patient attitudes towards protocol
  - Continue to tweak protocol

Conclusions/What's Next!

- Future benefits will include increased patient education and safety regarding opioid use
  - Increased education will potentially lead to less adverse events or side effects
  - Enhanced safety will hopefully make providers more comfortable with prescribing narcotics to adequately treat pain
- Future barriers will include incorporating new palliative care fellows and staff into QI project

Team Picture

Thank you!


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References

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