ASCO's Quality Training Program

Project Title: Improvement of Treatment Toxicity Grading According to the Common Terminology Criteria for Adverse Events (CTCAE)

Presenters: George Rigakos, MD
Effrosyni Vlachou, RN
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Institution: Contemporary Oncology Team, Athens, Greece

Date: January 26, 2017

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Institutional Overview

- The Contemporary Oncology Team (COT) is a private practice located in Athens, Greece.
- COT is a team of 3 Medical Oncologists, 2 Internists, 5 junior doctors, RNs and administrative staff.
- Each Medical Oncologist in COT has his own patients as the Primary Physician and also supports the other Oncologists of the team as an Attending Physician.
- COT achieved QOPI® Certification during 2016 and was the first practice in the world to attain certification outside the USA.

Problem Statement

During the evaluation for QOPI® Certification in Spring 2016 it was noted that toxicity assessment was rarely graded according to the Common Terminology Criteria for Adverse Events (CTCAE) in the files of patients receiving treatment and this could hinder appropriate treatment dose modification.

After collecting baseline data we determined that toxicity was graded according to CTCAE only in **26%** of the patients receiving chemotherapy with epirubicin/cyclophosphamide and nab-paclitaxel and immunotherapy with nivolumab*.

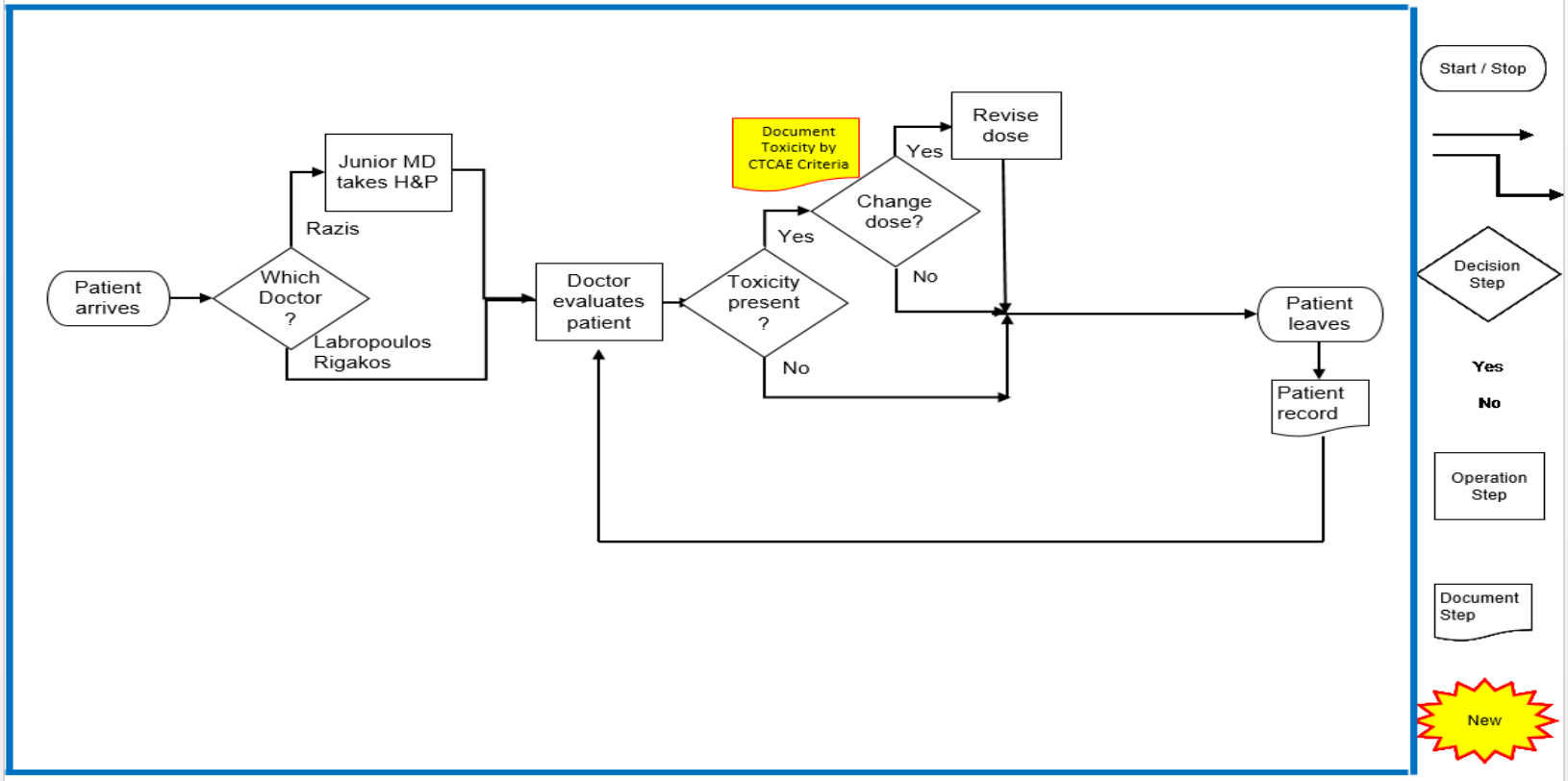
*Represents approximately 5-7% of the COT patient population under iv treatment.

Team Members

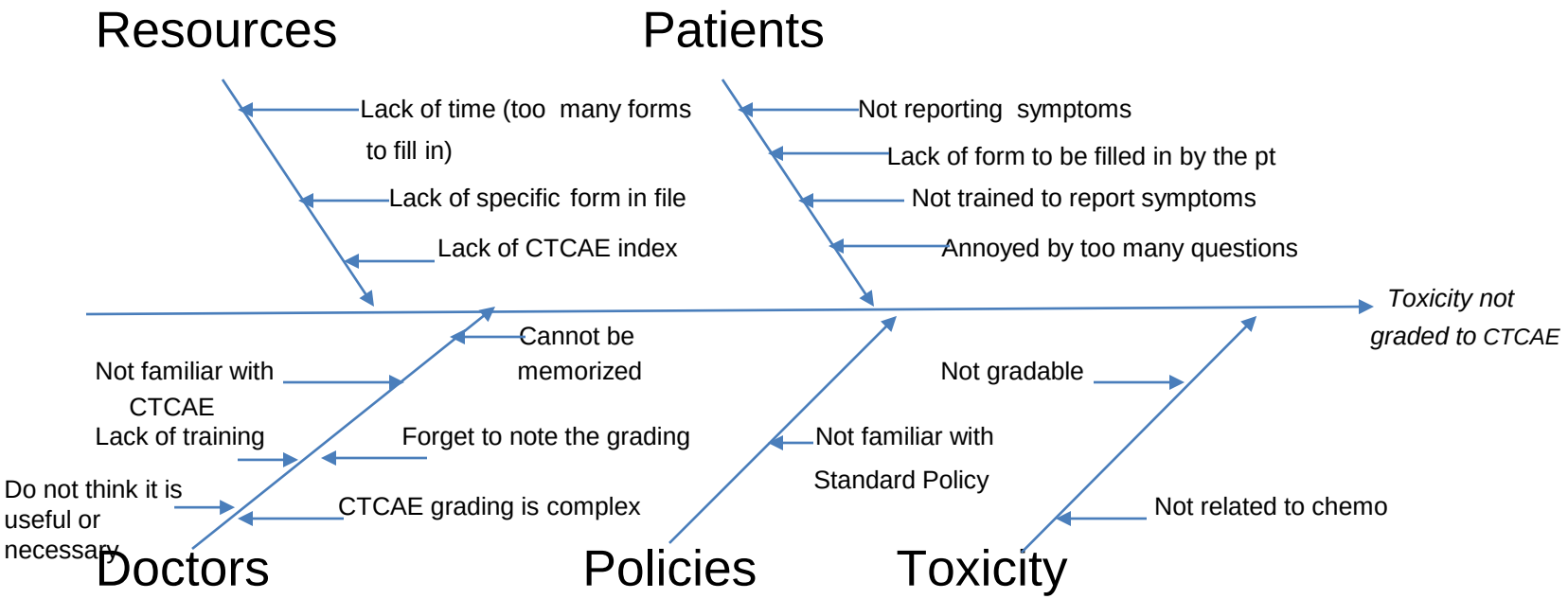
ROLE	NAME	JOB FUNCTION
Project Sponsor	Evangelia Razis, MD, Ph.D	Practice Director
Team Leader	George Rigakos, MD	Attending Physician
Core Team Member #1	Frosso Vlachou, RN	Oncology Nurse
Core Team Member #2	Ioanna Theodorakopoulou	Practice Administrator
Other Team Member #1	Stefanos Labropoulos, MD	Associate Director
Other Team Member #2	Olympia Spyri, RN, Msc	Oncology Nurse
Other Team Member #3	Kallia Stathaki, RN	Oncology Nurse
QTP Improvement Coach	Barbara Corning-Davis, MS, CPHQ	

Process Map

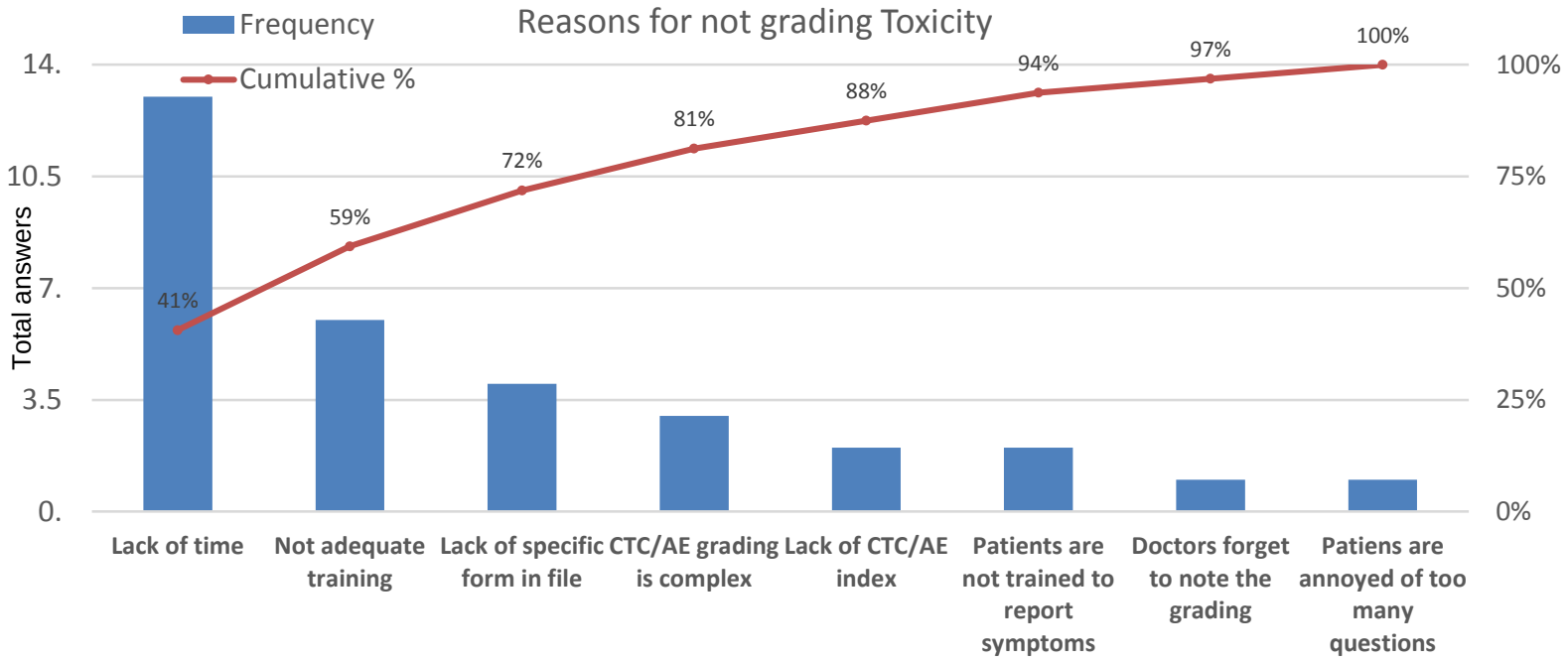
Process Name:	**Evaluating patients toxicity**				
Date Created:	1 September 2016	**Start Step:**	Patient Arrives	**End Step:**	Patient Leaves



Cause & Effect Diagram



Diagnostic Data



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Aim Statement

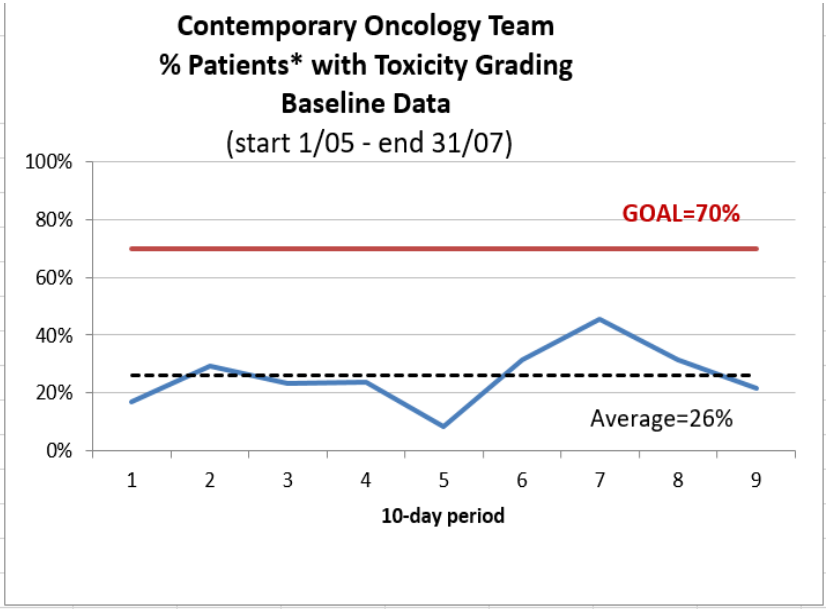
As a pilot, by January 2017, toxicity for at least **70%** of all COT patients who receive chemotherapy with epirubicin/cyclophosphamide or nab-paclitaxel and immunotherapy with nivolumab at COT will be graded by the CTCAE criteria and appropriate dose modification will be documented.

Baseline Data/Process Measure:
% COT patient visits with documented toxicity CTCAE grading

Sample baseline data collection for Contemporary Oncology Team

10-day period	Total pts*	# pts w/ toxicity grading	% pts w/ toxicity grading	Goal	Average
1	12	2	17%	70%	26%
2	17	5	29%	70%	26%
3	13	3	23%	70%	26%
4	21	5	24%	70%	26%
5	12	1	8%	70%	26%
6	16	5	31%	70%	26%
7	11	5	45%	70%	26%
8	16	5	31%	70%	26%
9	14	3	21%	70%	26%
Average:	**15**	**4**	**26%**		

*Number of COT patients who receive chemotherapy with epirubicin/cyclophosphamide and nab-paclitaxel and immunotherapy with nivolumab



Patients receiving epirubicin/cyclophosphamide and nab-paclitaxel and immunotherapy with nivolumab

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Baseline Data - Outcome Measure: *Dose modification*

10-day period	Total pts*	# pts w/ dose modification due to toxicity grading	% pts w/ toxicity grading
1	12	0	0%
2	17	0	0%
3	13	0	0%
4	21	1	5%
5	12	1	8%
6	16	0	0%
7	11	0	0%
8	16	0	0%
9	14	1	7%
Average	15	0	2.25%

* Number of COT patients who receive chemotherapy with epirubicin/cyclophosphamide and nab-paclitaxel and immunotherapy with nivolumab

** As noted by Dr.Razis and the team the most preferred outcome measure would be patient outcome but this cannot be properly assessed within 6 months.

Baseline Data - Balance Measure:
Average total time of patient visit for patients who receive reviewed treatment in COT Practice

AVERAGE TOTAL TIME OF PATIENT VISIT FOR PATIENTS WHO RECEIVE CHEMOTHERAPY IN COT PRACTICE INCLUDING INFUSION TIME.		
Time Period	**May 1-July 31**	
Therapy Clinic	**Average Time**	**(min-max)**
Razis	121'	(70' - 191')
Labropoulos	144'	(68' - 288')
Rigakos	124'	(43' - 195')

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Prioritized List of Changes (Priority/Pay –Off Matrix)

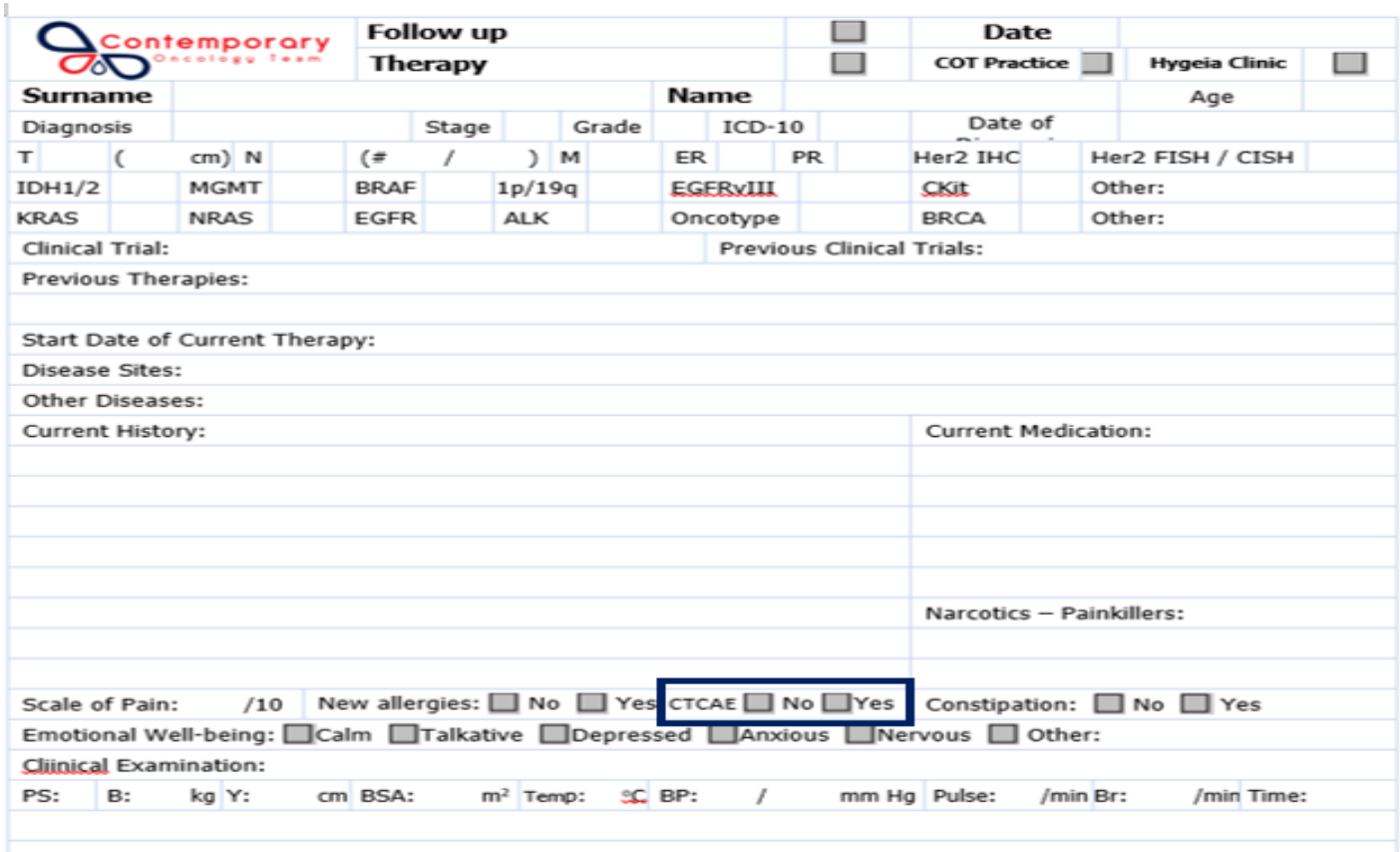
Impact	Easy	Difficult
High	**Insert CTCAE field to chemo checklist to identify new patients that start on these regimens.** **Insert CTCAE field to chemotherapy and follow-up forms with hard-stop for CTCAE grading.**	**Educate and sensitize staff on CTCAE grading**
Low	Label files of patients that receive Tx with EC, Abraxane and Nivo with a blue sticker, “CTCAE grading”	Dedicate employee to apply CTCAE criteria for the toxicity grading

Ease of Implementation

PDSA Plan (Test of Change)

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
17-31/10/16	Define CTCAE toxicity grading. Educate medical staff on CTCAE procedures	Practice staff alerted to importance of CTCAE toxicity grading	Proceed to obtain materials and optimize patient visit procedure
17-31/10/16	Provide paper CTCAE paper index in all examination rooms Upload CTCAE e book in PCs of examination rooms	CTCAE index made available to physicians	Apply measures Collect data from 1/11/2016 - 31/12/2016 Interim check on December 1st
17-31/10/16	Label files of pts that receive Tx with EC, Abraxane and Nivo with blue sticker Insert "CTCAE sticker " field in chemo check list to identify new pts that start on these regimens	Eligible patients were identified	
17-31/10/16	Insert "CTCAE " filed chemotherapy form and follow-up form requiring CTCAE grading (hard stop)	Ensure patient treatment is administered only upon completion of CTCAE toxicity grading	
1/11-31/12/16	Collect data on CTCAE grading and dose modification	74% of patient files have completed CTCAE grading toxicity Dose modification was necessary for 1.4% of patients	Evaluation of benefit of CTCAE grading to long term patient outcome If positive, expansion to other treatment regimens Random evaluation of 10 patient charts every 2 months for CTCAE grading
1/11-31/12/16	Collect data on patient visit times		

Materials Developed



Contemporary Oncology Team

Follow up ☐														Date					
Therapy ☐														COT Practice ☐		Hygeia Clinic ☐			
Surname								Name										Age	
Diagnosis				Stage		Grade		ICD-10						Date of					
T		(	cm) N		(#	/	) M		ER		PR			Her2 IHC		Her2 FISH / CISH			
IDH1/2		MGMT		BRAF		1p/19q			EGFRvIII					CKit		Other:			
KRAS		NRAS		EGFR		ALK			Oncotype					BRCA		Other:			
Clinical Trial:											Previous Clinical Trials:								
Previous Therapies:																			
Start Date of Current Therapy:																			
Disease Sites:																			
Other Diseases:																			
Current History:														Current Medication:					
														Narcotics – Painkillers:					
Scale of Pain: /10				New allergies: ☐ No ☐ Yes				CTCAE ☐ No ☐ Yes						Constipation: ☐ No ☐ Yes					
Emotional Well-being: ☐ Calm ☐ Talkative ☐ Depressed ☐ Anxious ☐ Nervous ☐ Other:																			
Cliinical Examination:																			
PS:	B:	kg	Y:	cm	BSA:	m^2	Temp:	°C	BP:	/	mm Hg			Pulse:	/min	Br:	/min	Time:	

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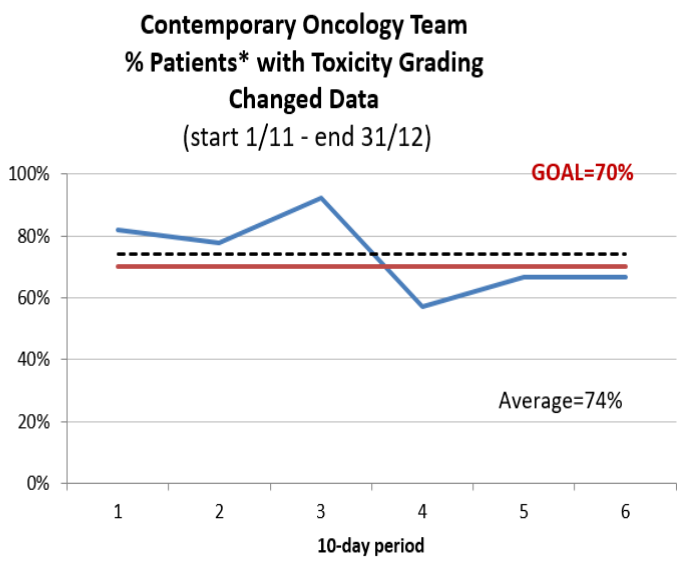
Changed Data/Process Measure:
% COT patient visits with documented toxicity CTCAE grading

Changed data collection for Contemporary Oncology Team

10-day period	Total pts*	# pts w/ toxicity grading	% pts w/ toxicity grading	Goal	Average
1	11	9	82%	70%	74%
2	9	7	78%	70%	74%
3	13	12	92%	70%	74%
4	7	4	57%	70%	74%
5	12	8	67%	70%	74%
6	9	6	67%	70%	74%
Average:	**10**	**8**	**74%**		

*Number of COT patients who receive chemotherapy with epirubicin/cyclophosphamide and nab-paclitaxel and immunotherapy with nivolumab



*Patients receiving epirubicin/cyclophosphamide and nab-paclitaxel chemotherapy and immunotherapy with nivolumab

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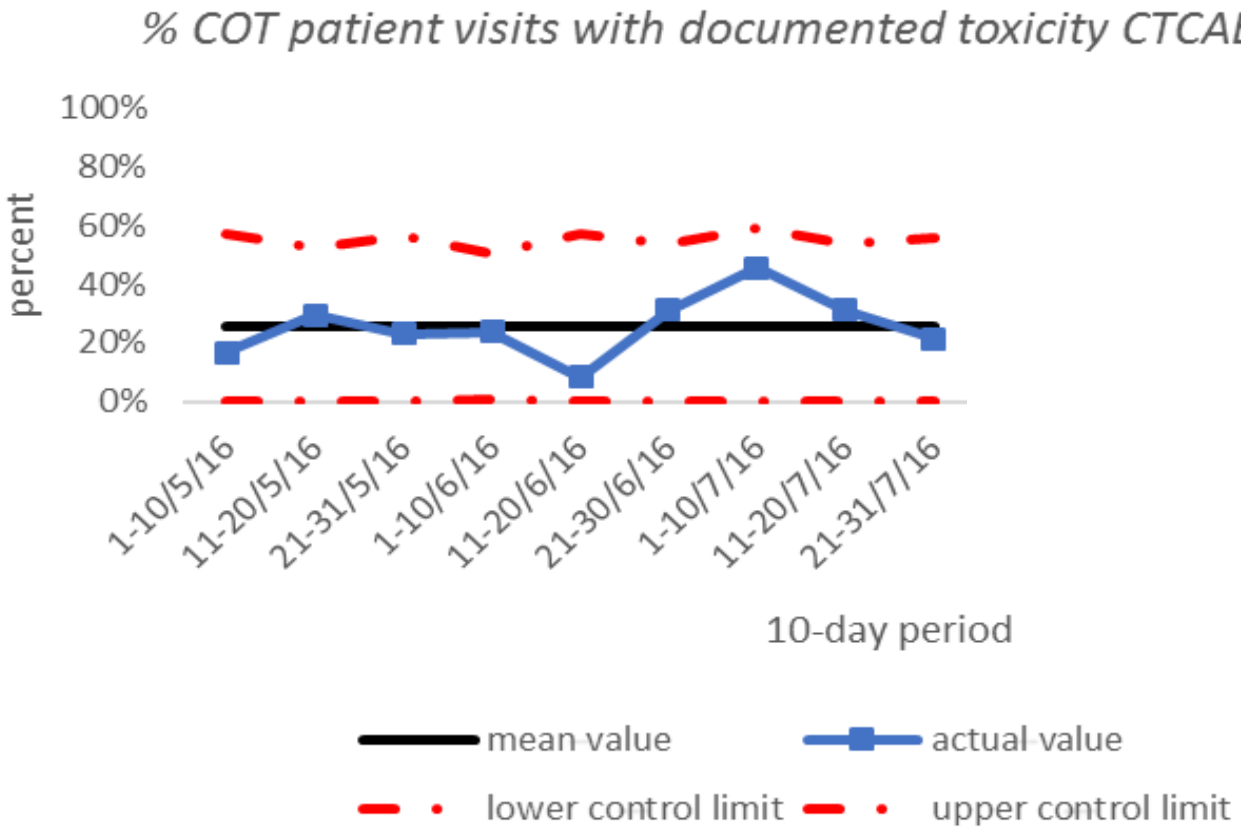

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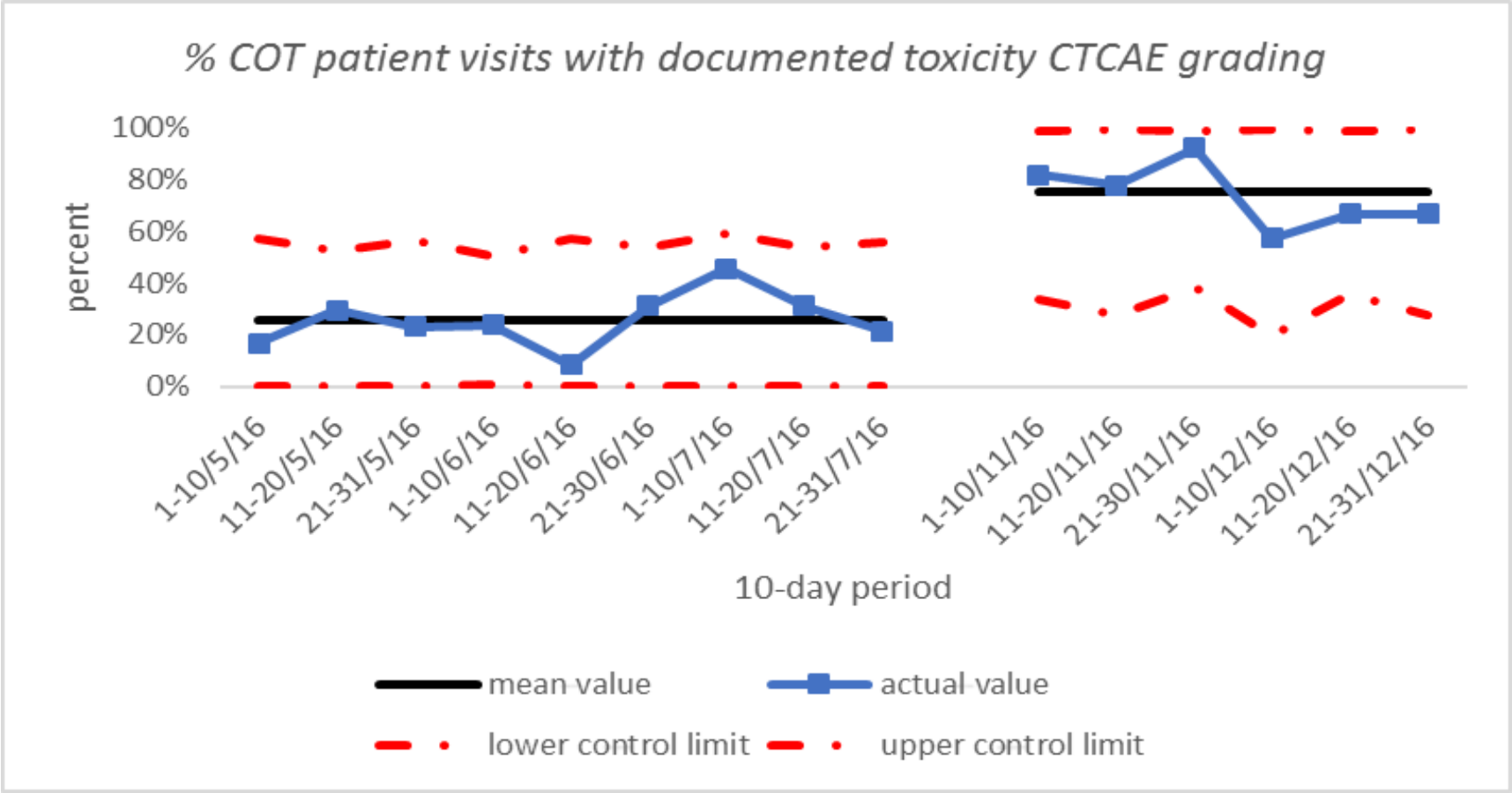

Changed Data - Outcome Measure: *Dose modification*

10-day period (1/5-31/7)	Total pts*	# pts w/ dose modification due to toxicity grading	% pts w/ toxicity grading	10-day period (1/11-31/12)	Total pts*	# pts w/ dose modification due to toxicity grading	% pts w/ toxicity grading
1	12	0	0%	1	11	0	0%
2	17	0	0%	2	9	0	0%
3	13	0	0%	3	13	0	0%
4	21	1	5%	4	7	0	0%
5	12	1	8%	5	12	1	8%
6	16	0	0%	6	9	0	0%
7	11	0	0%				
8	16	0	0%				
9	14	1	7%				
Average	15	0	**2.25%**		10	0	**1.39%**

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Changed Data - Balance Measure:
Average total time of patient visit for patients who receive reviewed treatment in COT Practice

AVERAGE TOTAL TIME OF PATIENT VISIT FOR PATIENTS WHO RECEIVE CHEMOTHERAPY IN COT PRACTICE INCLUDING INFUSION TIME				
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Conclusions

- Lack of toxicity grading in COT files was addressed through quality improvement interventions that were further evaluated with process, outcome and balance measures
- Educating the team about CTCAE, using proper file labeling and modified follow up and chemotherapy forms with hard-stops, we were able to increase the frequency of CTCAE Toxicity grading and documentation from 26% to 74% of COT sessions with epirubicin/cyclophosphamide or nab-paclitaxel chemotherapy and immunotherapy with nivolumab
- Dose modification was necessary for 1.39% of treated patients compared to 2.25 in the baseline period. The significance of this result is not certain and validity of clinical benefit from CTCAE grading remains to be proven with long term patient follow up
- Average visit time was not prolonged for any physician from implementation of CTCAE grading procedures

Next Steps/Plan for Sustainability

- Assess long term outcome benefit for patients assessed with the use of CTCAE grading
- If proven beneficial (either because of less toxicity or because of few dose reductions leading to better cancer outcomes), we will expand CTCAE grading to patients receiving other regimens
- Sustain intervention efficacy with periodical random check of 10 patient file every 2 months