A Retrospective Analysis of Pharmacy Turnaround Times for Clinical Trial-associated vs Non-Clinical Trial Intravenous Anticancer Regimens

Maria Marchese[1,2]; Paul Grootendorst[1]; L Flay Charbonneau[1]; Jonathan J Shloush[1]; Christine Peragine[1]; Carlo DeAngelis[1,2]

[1]Sunnybrook Odette Cancer Centre, [2]University of Toronto, Leslie Dan Faculty of Pharmacy

Background

As research with anticancer drugs expands, there is a need to understand pharmacy service requirements for the preparation of sterile intravenous regimens.[1] The Odette Cancer Centre (OCC) pharmacy prepares approximately 100 IV anticancer regimens per workday; 5-10% of these are for clinical trials.

Pharmacy "turnaround time" (TAT)[2] is defined as the time required to prepare an intravenous anticancer regimen (containing 1-4 IV admixtures).

Objective

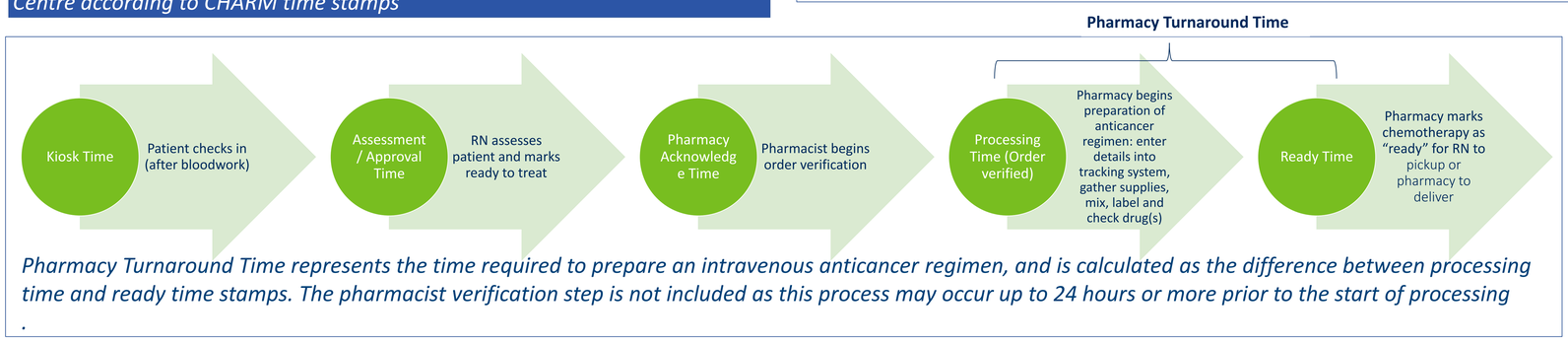
To determine whether the pharmacy turnaround time of IV anticancer regimens for clinical trials differs significantly from that of non-clinical trial regimens

- Hypothesis: pharmacy turnaround time is longer for clinical trial regimens than non-clinical trial regimens.

Methodology

- Data from July – December 2019 was extracted from the Patient Activity Report, CHARM patient management system (Figure 1)
- Pharmacy TAT was calculated using MS Excel for each anticancer regimen
  - Regimens prepared for a separate hematology unit were excluded due to a differing workflow (e.g. azacitidine)
- Multivariate linear regression model for Pharmacy TAT was estimated, dependent on regimen type (clinical trial, non-trial) and accounting for time of day (1130-1330 h lunch period, standard shift)
- Statistical analysis (two sample t-test and one-sided F test) was conducted at a significance level of 0.05 using Stata 16.0

Figure 1. Patient flow diagram for IV anticancer therapy at Odette Cancer Centre according to CHARM time stamps



Pharmacy Turnaround Time represents the time required to prepare an intravenous anticancer regimen, and is calculated as the difference between processing time and ready time stamps. The pharmacist verification step is not included as this process may occur up to 24 hours or more prior to the start of processing .

Results

Table 1: Breakdown of Regimens

Parameter	# (%)	Mean TAT, minutes (std. dev.)
Standard Regimen	8630 (89.12%)	56.79 (36.93)
Clinical Trial	1054 (10.88%)	68.88 (35.88)
	9684	
Standard Shift	5604 (57.87%)	49.30 (33.13)
Lunch Shift (1130-1330 h)	4080 (42.13%)	70.21 (38.60)
Total (All data)	9684	58.11 (37.00)

Table 1: Out of 9684 regimens, 1054 were clinical trials. Nearly half (42%) of the regimens prepared were either started or completed during the lunch shift period.

Figure 2: Distribution of TAT (All regimens) July-Dec 2019

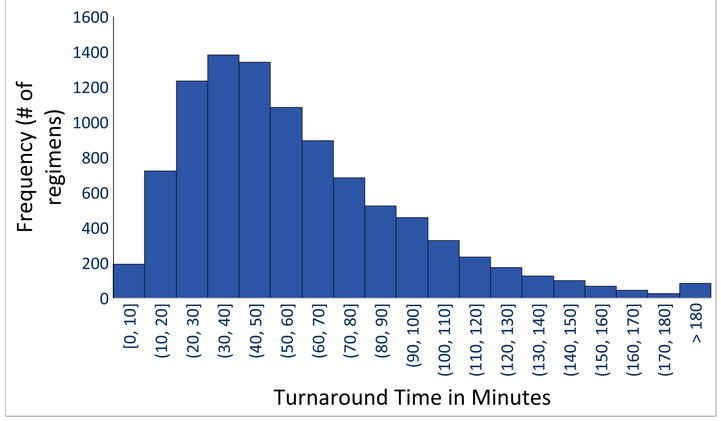


Figure 2: The data follows a skewed normal distribution with the presence of a few right outliers. Note that turnaround time estimates are based on surrogate measures of the preparatory steps and are subject to measurement bias

Figure 3: Boxplot - Distribution by Category

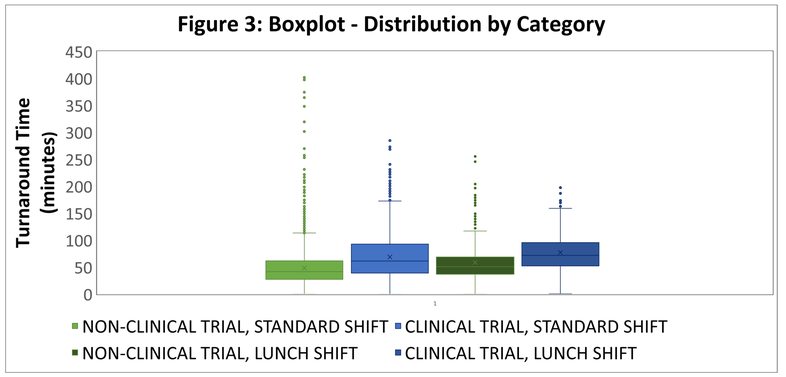


Figure 3. Boxplot visualizing mean and interquartile range for TAT according to variables. This verifies that the variance is consistent across the model. The F test demonstrated that the higher TAT for clinical trial regimens is not likely due to chance.

Table 2: Estimates of parameters of the linear regression model Outcome Variable: Pharmacy Turnaround Time

Parameter	Coefficient	95% C.I.	Standard error
Clinical Trial	9.25 ***	7.00-11.49	1.14
Lunch Shift	20.39 ***	18.91-21.87	0.75
Intercept of model	48.51		
Standard error of the regression	1254.72		

***$p<0.0001$; C.I. = confidence interval

Table 2: Clinical trial regimens took on average 9.25 minutes longer to prepare than non-trial regimens, even while holding the lunch variable constant (95% C.I. 7.00-11.49, p<0.0001).

Conclusion

- Clinical trial regimens were associated with longer processing times for pharmacy.
- Future research can investigate potential root causes for protracted TAT.
- Findings may be used to inform resource management for sterile compounding processes at outpatient cancer centres.
  - Preparing 10 clinical trials/day translates to approximately 1 FTE over the course of the week
- Limitations included obscure outliers and heterogeneity among different trial regimens.

Scan this QR code to download this and other Sunnybrook posters

References

1. Unger, J. M.; Cook, E.; Tai, E.; Bleyer, A. Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies. *Am. Soc. Clin. Oncol. Educ. Book Am. Soc. Clin. Oncol. Meet.* 2016, *35*, 185–198. https://doi.org/10.14694/EDBK_156686.
2. Naylor, H.; Woloschuk, D. M. M.; Fitch, P.; Miller, S. Retrospective Audit of Medication Order Turnaround Time after Implementation of Standardized Definitions. *Can. J. Hosp. Pharm.* 2011, *64* (5), 346–353. https://doi.org/10.4212/cjhp.v64i5.1070.

Disclosure Summary

Authors of this poster have the following to disclose concerning possible personal or financial relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Maria Marchese – Nothing to disclose
Paul Grootendorst– Nothing to disclose
Jonathan Shloush– Nothing to disclose
Carlo De Angelis– Nothing to disclose
L Flay Charbonneau– Nothing to disclose
Christine Peragine – Nothing to disclose