inclusIV® compounding portfolio

TECHNICAL NOTE

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PRODUCTIVITY EVALUATION OF KIRO® ONCOLOGY

Dr. Gerardo Cajaraville,[1] Head of Pharmacy, Fundación Onkologikoa
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Introduction

During routine production of compounded sterile preparations (CSPs) using KIRO Oncology, the Pharmacy Department at Fundación Onkologikoa, a mid-size organization in the specialty hospitals industry located in San Sebastián, Spain, observed the variability of the time needed to complete preparations, depending on order types and ways in which the system is configured and used.

This study aimed to identify factors that contribute to optimal productivity when using KIRO Oncology by analyzing preparation times for **576 preparations**, including **11 drugs** and **110 compounding cycles**, that were completed in KIRO Oncology in our facility.

DRUGS	TOTAL		MEAN VOLUME (ml)	SD	AVERAGE ACCURACY (%)	SD
Flourouracil	103	17%	13.8	13.5	-0.72	1.91
Calcium Folinate	84	14%	49.1	27.4	-0.26	2.24
Paclitaxel	82	14%	24.8	7.9	0.74	1.75
Trastuzumab	79	13%	17.7	5.9	-1.93	3.91
Cyclophosphamide	54	9%	49.4	5.6	2.01	1.15
Doxorubicin	51	9%	48.6	7.4	1.23	1.19
Oxaliplatin	36	6%	27.2	7.4	2.42	1.42
Irinotecan	35	6%	14.1	2.8	-0.77	1.90
Cisplatin	19	3%	117.2	38.1	0.52	0.74
Carboplatin	17	3%	39.6	17.9	-0.83	3.06
Gemcitabine	16	3%	42.2	11.8	0.30	2.78
TOTAL	576		33.1	26.2	-0.03	2.69

The **table on the left** lists the number of preparations completed per drug, along with the mean and standard deviation (SD) of the volumes dosed into infusion bags, along with the corresponding dosing accuracy mean and SD determined by KIRO Oncology gravimetric control.

Accuracy

Ninety-nine percent (99%) of the preparations were released for patient administration:

- 96% were released automatically (dosing accuracy within ±5%).
- 3% were released after validation by a pharmacist (dosing accuracy within ±10%).

Five preparations (1%) were rejected because they were outside the ±10% acceptable dosing accuracy range.

Cycle Times

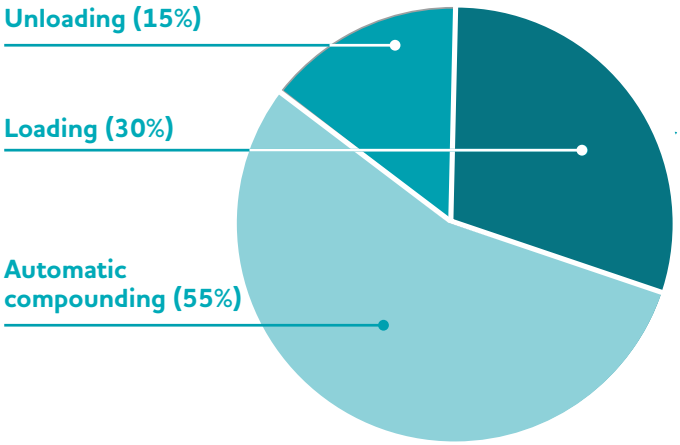
Compounding cycle times automatically registered by KIRO Oncology were analyzed for 576 preparations.

- Cycle time was considered started when the user selected and launched the preparations for 1 cycle.
- Cycle time was considered ended when the final product label of the cycle was printed.
- User time devoted to loading and unloading materials and completed preparations, per cycle, was recorded.
- Time, per cycle, during which the automatic compounding process took place and system autonomy was achieved, allowing the user to perform other tasks, was also recorded.

1. Dr. Cajaraville reported no relevant financial relationships with Grifols or KIRO Grifols.

GRIFOLS

KIRO Oncology Cycle Time



As presented in the **pie chart on the left**, the automatic compounding process accounted for an average of 55% of the cycle time, while the loading and unloading tasks accounted for an average of 30% and 15% of the cycle time respectively.

Productivity

To optimize the pharmacy production workflow in KIRO Oncology, the following configuration and device use conditions were taken into consideration in our facility:

- **Avoiding unnecesary operations such as filling and emptying diluent in infusion bags whenever possible**
  Although the KIRO Oncology system is capable of filling and/or emptying diluent when needed to meet specific clinical needs, volume adjustment operations will decrease preparation speed.

- **Minimizing manual tasks and user interventions via strategic configuration and use**

- **Reusing syringes in the same working cycle for each diluent or drug**
  KIRO Oncology software will manage the reuse of a syringe for the withdrawal and injection of each drug or diluent and replace it before proceeding with a different one, thereby reducing manual loading time and automatic process time needed to replace the syringe between preparations.

- **Avoiding visual checks requiring user intervention**
  Once optimal mixing parameters have been defined for reconstituted drugs, confirmation by the user of the drug being correctly dissolved can be averted.

- **Avoiding pharmacist supervision of preparation reports when dosing is accurate**
  Configure the system to automatically release preparations whenever gravimetric control determines that the preparation is within the established clinical standards for acceptable dosing accuracy to avoid the need for supervising preparation reports before releasing them.

- **Optimizing efficient use of KIRO Oncology as well as users**
  Although KIRO Oncology has the flexibility to prepare urgent individual preparations and combine up to 8 bag preparations of different drugs in one compounding cycle, these cycle types reduce efficiency of the system and are suboptimal uses of loading time and capacity.

  To improve efficiency of the manual and automatic tasks in KIRO Oncology preparation cycles, the number of drugs per cycle should be minimized and the number of preparations per cycle maximized.

- **Aligning schedules with production work loads to optimize productivity**
  A trained and qualified user should be assigned to operate KIRO Oncology during each production day/shift.

  Defining tasks that users can perform in the same room or in nearby hoods during the automated compounding process optimizes overall productivity of both users and the KIRO Oncology system.

Time per Preparation

Data was analyzed to evaluate the impact of specific preparation features on the production speed of KIRO Oncology, focusing on the following factors that could be analyzed retrospectively:

Number of preparations per cycle

The mean number of preparations per cycle was 5.8 (SD 2.1)

Number of different drugs per cycle

The mean number of different drugs per cycle was 2.9 (SD 1.2)

Number of vials required for each preparation

The mean number of vials per preparation was 1.1 (SD 0.6)

Need to reconstitute vials for the preparation

Two of the 11 drugs usually prepared in KIRO Oncology (or approximately 18%) are reconstituted during the compounding process. Of the 110 preparation cycles included in this study, 22 (20%) of them included cyclophosphamide, with a mean of 2.4 (SD 1.2) cyclophosphamide preparations per cycle.

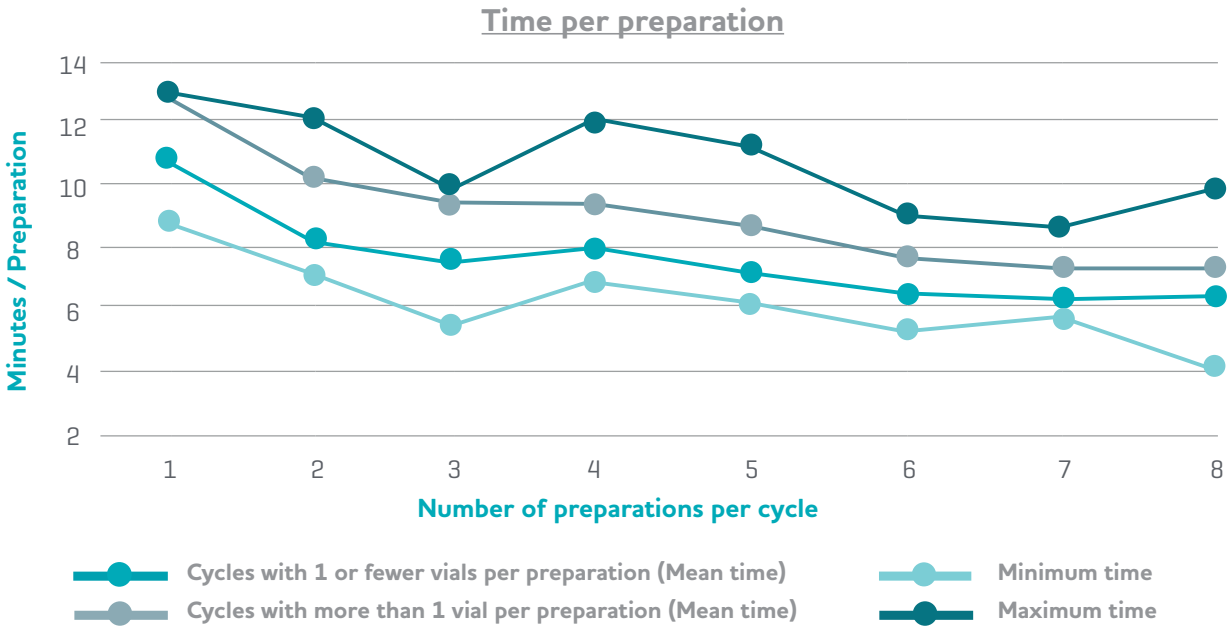
The minimum preparation time calculated for this series of preparations was 4.3 minutes per preparation and corresponded to cycles using 8 preparations (mean volume of 20 mL per preparation) with no more than 2 different drugs. In more complex cycles using 6 preparations (mean volume of 10 mL per preparation) and up to 4 different drugs in a cycle, the minimum preparation time was 5.2 minutes per preparation.

Under sub-optimal conditions, selected cycles containing 5 or fewer preparations and more than 4 drugs in a cycle, or more than 1 vial per preparation in the cycle, the mean preparation time was 8.6 minutes per preparation.

As shown in the **graph below**:

- Preparation time decreases significantly for cycles with a minimum of 6 preparations per cycle when the total number of vials per cycle does not exceed the total number of preparations in the cycle (blue line), with a mean time of 6.5 minutes per preparation.
- Preparation times are slightly increased if the number of vials in the cycle is higher than the number of preparations in the cycle, but preparation time is also reduced for cycles with a minimum of 6 preparations per cycle (orange line).

For cycles including up to 5 cyclophosphamide preparations, an oncology drug that is typically hard to fully dissolve during manual compounding, the mean preparation time was 6.5 minutes per preparation, indicating that preparation speed in KIRO Oncology is not significantly increased for drugs that are reconstituted during the compounding process.



Conclusions

Based on this analysis, we have concluded that by optimizing the pharmacy workflow with the use of KIRO Oncology, **an approximate mean outcome of 9 preparations per hour can be achieved in KIRO Oncology for common oncology preparations.**

It is to be noted that **preparing the device for daily operations requires an average of 15 minutes.**

Preparation for the self-cleaning process at the end of each production day, **involves an average of 25 minutes** with no other manual cleaning or maintenance tasks required.

An **8-hour production day** provides a minimum of **7 hours of compounding cycle** operations in KIRO Oncology with a **mean outcome of 63 preparations per day.**

Additionally, **55% of the operational time is automatic compounding that does not involve the user,** leaving more than 3.5 hours per day for the user to perform other tasks.

ABOUT THE PORTFOLIO

inclusiv is a comprehensive IV compounding portfolio of integrated technology, software, and service solutions designed to support your needs for sterile compounding from the design and building of your sterile compounding environment, to the preparation and verification of your products, through the ongoing management and optimization of your pharmacy operation.

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GRIFOLS

Grifols International, S.A.
Parc empresarial Can Sant Joan, Av. de la Generalitat, 152-158
08174 Sant Cugat del Vallès, Barcelona - SPAIN
Tel. +34 935 710 500
hospital.division@grifols.com
www.grifols.com

GNL-KOC-2500009