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THERAPEUTIC AND ECONOMIC BENEFITS OF A CENTRALIZED UNIT FOR CYTOSTATIC DRUGS PROCESSING

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Therapeutic Benefit, Economic Benefit, Centralized Unit, Cytostatic Drug Processing, Drug Traceability.

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ABSTRACT: Cancer is a global problem. However, in low-income and developing countries, the expenditures associated with its treatment are increasing disproportionately with resources available. Hence, reducing the drug wastage and financial burden placed on patients, family and society in general is becoming imperative. Our aim was to calculate therapeutic and economic benefits derived by the use of a centralized unit, which allows residual amounts of unused drugs to be reused by patients whose treatments are elaborated in the same working day. We calculated in a comprehensive manner the number of spared vials (flasks) for seven drugs generated from residual amounts of the same working day and, its consequent therapeutic and/or economic benefits. We did not take into account prescribed drug dosages that fitted exactly with doses contained in a vial. Over a six month period, there were: a total of 1524. 07 saved vials with an approximate consequent therapeutic benefit of 123.57 patients and, considering the price of the centralized unit**,** a total economic benefit of approximately 134, 348 (€), for a total of 6558 prescriptions and a total of 1180 patients. The economic benefit represents 6.2 percent of the cytostatic drugs budget for 2015. Our analysis confirms that how a relatively simple policy of drug waste reduction, due to a centralized unit of cytostatic drugs processing, gives consequent therapeutic and economic benefits. The centralized unit increases also the drug traceability from preparation to patient.

INTRODUCTION: Current knowledge in the field of Medical Oncology is greater than ever before, but the number and cost of new anticancer drugs are higher than the available resources. This financial burden of cancer [1] represents a moral as well as an economic challenge, especially in developing countries and emerging economies in which health care budget is limited [2].

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Furthermore, recent date demonstrates that the growing cost of cancer treatment will accelerate in the coming years due to the development of new, more expensive treatments [3], the ageing of the world's population, the increased life expectancy by improvements in therapeutic outcome, and more effective diagnostic procedures.

The cost of one cycle of chemotherapy may range from 330 euro for doxorubicin 50 milligram (mg) to 13116 euro for trastuzumab 150 mg, both delivered every three weeks. Several strategies have been suggested to contain the increasing expenditures and improving efficiency, such as the use of generic and biosimilar molecules [4], the outpatient management of cancer patients, and

optimizing treatment selection based on pharmacogenetics.

Some other strategies proposed to reduce cancer treatment expenditures using the rational application of personalized dose principle, dose rounding to the nearest vial size [5, 6], dose standardization [7] of anticancer drugs and, selecting the most convenient vial size [8].

The Service of Oncology in University Hospital Centre "Mother Teresa" of Tirana is the only public health structure that offers multidisciplinary treatments for cancer patients in Albania.

Cancer is becoming a major priority for health policies in Albania for three major reasons: the increase of mortality and morbidity rates for a number of cancers, the delays in diagnosis and high costs of its treatment.

In this framework, a project of drug waste reduction was designed and launched at the end of 2014. The project aimed at: estimating the resulting therapeutic and economic benefit of reused leftovers of the same working day while respecting drug stability.

MATERIALS AND METHODS:

The material for the study of this topic has been collected, over a period of six months (October 2014 – April 2015), from Day Hospital and the Chemotherapy Ward of Oncology Department, in University Hospital Center "Mother Teresa", Tirana, Albania where data like patient generalities, record number, diagnosis and chemotherapy regimens can be found. In order to protect the patient's privacy the patient's name has not been shown. As a study material, charts and medical prescriptions of seven drugs selected by us were used (**Table1**).

TABLE 1: LIST OF DRUGS INCLUDED IN THE STUDY

Generic Name	Commercial Name	Quantity Contained in a Vial (mg)	Price in Euro (€)
Doxorubicin	Adriamycin	50	12.92
Docetaxel	Taxotere	80	29.10
Trastuzumab	Herceptin	150	512.35
Gemcitabin	Gemzar	1000	22.07
Rituximab	Mabthera	500	1042.76
Cisplatin	Platinol	50	5.60
Bevacizumab	Avastin	400	1041.70

The Hospital Pharmacy calculated the number of different vials needed to prepare the prescribed dose if vials are shared by patients whose treatments are elaborated in the same working day. Knowing most commonly used dosage of each drug, we converted the number of spared vials in approximate number of new patients that would be included in the treatment plan (therapeutic benefit) or its consequent economic benefit for other scenario. Below we show a calculation sample for doxorubicine (**Table 2**).

TABLE 2: SIX MONTH THERAPEUTIC AND/OR ECONOMIC BENEFIT EVALUATION FOR DOXORUBICINE

Chemotherapy Ward	The amount of drug used during a cycle	Number of patients	The amount of drug saved in six months	Economic benefit (€)
	30 mg	1	120 mg or 2.4 fl.	30.36
	40 mg	7	420 mg or 8.4 fl.	108.52
	45 mg	3	90 mg or 1.8 fl.	23.256
	50 mg	25	0 mg or fl.	0
	60mg	1	240 mg or 4.8 fl.	60.72
	65 mg	1	0 mg or fl.	0
	70 mg	5	900 mg or 6 fl.	77.52
	75 mg	6	900 mg or 6fl.	77.52
	80 mg	56	6720 mg or 134.4 fl.	1700.16
	85 mg	5	450 mg or 4 fl.	113.85
	90 mg	21	540 mg or 3.6 fl.	46.512
	95 mg	1	30 mg or 0.6 fl.	17.59
Day Hospital	30 mg	0	0 mg or fl.	0

40 mg	2	120 mg or 2.4 fl.	30.36
45 mg	0	0 mg or fl.	0
50 mg	2	0 mg or fl.	0
60 mg	0	0 mg or fl.	0
70 mg	2	360 mg or 7.2 fl.	93.024
75 mg	0	0 mg or fl.	0
80 mg	8	960 mg or 6.4 fl.	242.88
85 mg	2	180 mg or 3.6 fl.	45.54
90 mg	39	2340 mg or 15.6 fl.	592.02 €
95 mg	2	60 mg or 1.2 fl.	15.18 €
100 mg	122	0 mg or fl.	0
110 mg	0	0 mg or fl.	0
Total savings for Doxorubicine		**213.2 fl.**	**2754.54**

In **Table 3** we are representing the number of patients, number of vials spared and consequent therapeutic and/or economic benefits for each drug selected over a six months period.

TABLE 3: THE FINAL RESULTS

Generic Name of Drug	Number of patients for each drug	Number of spared vials (flasks)	Approximate therapeutic benefit	Economic benefit (€)
Trastuzumab	942	135.18 fl	7.5	2754.54
Doxorubicine	2370	213.20 fl	17.7	22486.15
Docetaxel	1770	772.72 fl	85.85	69259.40
Gemcitabine	750	257.7 fl	26.84	5687.43
Rituximab	168	30.6 fl	5.1	31908.45
Cisplatin	1080	105.36	8.78	590.01
Bevacuzimab	78	9.31	1.5	9698.22

RESULTS: During the study period, vial consumption data were obtained, number of saved vials (flasks) for each drug and, the consequent therapeutic and/or economic benefits are also indicated using the Doxorubicine sample calculations. The total number of saved vials were 1524.07, which means that the total number of new patients who might be included in treatment plan (therapeutic benefit) was, approximately 123.57. The total savings for seven drugs were 134,348 (€), which represents 6.2 percent of the cytostatic drugs budget for 2015.

DISCUSSION: Our Department of Medical Oncology is a research-oriented academic unit with an admission capacity around 3.500 new patients every year. The Facilities include a ten-bed day-hospital service and a forty-bed- ward. On September 2014 we installed a reconstitution unit for the preparation of intravenous cytotoxic drugs, but the pharmacy is not yet equipped with a computerized physician order entry (CPOE) system.

Before the installation of the centralized unit, the prescriptions of the chemotherapeutic agents were written in mg/kg/m^2 and number of vials correspondent to the dose needed, respectively in patient's record and pharmacist's chart. The remaining residual amounts of each vials were disposed immediately, causing a significant economic loss. On the other hand, the patient or his/her family members followed a path of taking the vials in the pharmacy room according to the physician prescription and following the pharmacist's orders. The dosage administration took place in the chemotherapy ward, day hospital or in an outpatient settings. Drug traceability was unfavorable in the last option.

It has been previously demonstrated that inefficiency of drug waste minimization may produce a considerable economic loss, though experiences are limited and most studies are dated or focused on other therapeutic areas [9, 10, 11].

The results of our research have confirmed that the use of the residual amounts of the vials while the drug remains stable decreases drug loss and represents a considerable reduction in cancer treatment budget [12]. Therefore, a change in the management process would minimize the overall

health expenditure without adversely impacting patient's health outcomes. This is one of the biggest future challenges of health care systems in the current economic environment.

The leftover amount of the used drug depends on the number of patients attended, anthropometric characteristics, the time between patients who receive the same drug and the marketed vials.

In our study, results imply an overall cost savings for seven drugs around 6.2% of the cytostatic drugs budget, almost approximate with those previously described, who estimated potential savings around 7% and 15%. These findings demonstrate that this practice is economically advantageous, especially in large hospital centers. However, this process could be hindered because of the available drug stock in the hospital pharmacy, treatment delays due to adverse effects and the fact that in some patients a delay in treatment could adversely affect the outcomes.

Finally, we think that after the installation of the centralized unit, new working habits have been developed. The benefits of this change in paradigms into cooperation could be defined as a combination of reaching the goal of giving the right drug, with the right dosage, to the right patient, at the right time, at a more cost-efficient level.

CONCLUSION: Our experience confirms how a relatively simple policy of drug loss reduction due to a centralized unit of cytostatic drugs processing, gives consequent therapeutic and economic benefits, especially when used in large centers. The centralized unit also increases the drug traceability from preparation to patient. We recommend to extend this approach toward Pediatric Onco-Haematologic Service and to initiate a centralization project at least in three other national urban centers.

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