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Global Initiative to Establish and Implement Dose Rounding Policy for Expensive Cancer Therapy

Ibrahim N*

Prince Sultan Military Medical City, Riyadh, Saudi Arabia

***Corresponding author:** Ibrahim N, Clinical Pharmacist Specialist, Prince Sultan Military Medical City, Riyadh, Saudi Arabia, E-mail: nag_ibrahim@hotmail.com

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Introduction

Cancer is one of the top leading causes of death worldwide. In the last few decades many new highly expensive novel agents have been developed and approved by the national and international regulatory bodies for the treatment of cancer such as monoclonal antibodies and immunotherapy. At the same time there are much more oncology drugs in the pipeline.

The cost of oncology products is considered as one of the fastest growing costs in healthcare. In 2020 the cost of cancer care is expected to exceed $170 bilion [1].

Dose rounding initiative indicates rounding the prescribed dose to the nearest vial available while maintaining optimal therapeutic response. Cancer drugs are supplied either as single use vials in a preservative free formulation or in a multi dose vials in a preservative formulation. This initiative is relevant to drugs supplied in single use vials.

The rationales of this initiative are to:

- Decrease the risk of dose calculation error
- Decrease the risk of preparation error
- Decrease the time per prescription in pharmacy
- Decrease pharmacy workload
- Decrease the risk of contamination
- Avoid wastage of unstable medications
- Improve stock balance
- Significantly reduce oncology prescription cost

As a result of the above mentioned rationales, potential improvement in pharmaceutical care and patient outcome are expected.

Questions that might arise:

1. Some of healthcare professionals might ask the following questions:
2. Is it ethical to round the dose of cancer therapy?
3. Does rounding the dose affect the clinical outcome of patients with cancer?
4. Do we have evidence to answer these questions?

Available evidence:

Actually there are no studies about the impact of dose rounding on patient clinical outcome. But the available studies have been conducted to assess significant cost saving by applying the dose rounding policy [2-5].

In my opinion the best evidence that support dose rounding policy without affecting the patient clinical outcome are the clinical studies that have been conducted to evaluate the impact of cancer therapy dose adjustment during treatment, due to development of side effects or intolerance, on patient clinical outcome. Authors from different studies reported a range of dose adjustment applied in their clinical trials that does not affect treatment outcome [6,7].

Based on the clinical outcome of these studies a limit for dose rounding was suggested as nearest vial size within 5% to 10% of the prescribed dose. The potential differences in dose rounding limits are depending on the intent of treatment. This is translated to dose rounding within 10% for palliative care therapy and within 5% for curative therapeutic goal.

The following are some examples for dose rounding calculation:

If we have a prescription for cyclophosphamide 1040 mg and the available vial size is 1000 mg, in this case we divide 1000 mg by 1040 mg and multiply result by 100=96%. This mean we give the patient 96% of the dose and dose reduction was 4% (100-96=4).

Another example, if we have a prescription for doxorubicin 110 mg and the available vial is 50 mg, in this case we round the dose to 100 mg (which mean we use 2 vials of 50 mg). In order to calculate the % of dose rounding divide 100 mg by 110 mg and multiply result by 100 (100/110) x 100=90.9%. This mean we give the patient 90.9% of the prescribed dose and dose reduction was by 9.1% (100–90.9=9.1).

Economic impact

We conducted a local study to assess the impact of dose rounding of cancer therapy on cost avoidance. The estimated annual cost saving to the nearest vial size within 5% to 10% of the prescribed dose was $192,800. Other studies have been conducted to prove cost saving while applying dose rounding for cancer treatment. Results were impressive and support our initiative [2-5].

Responsibilities

Clinical pharmacists are considered as gatekeepers and the frontline defenders for the effective medication utilization in compliance with the pharmacy and therapeutics (P&T) as well as formulary management. Dose rounding policy initiation and implementation is an oncology pharmacist responsibility. We implemented this initiative in the institution where I work since 2013 after the completion of our local study and the impressive cost saving expected [4-8].

Initiative of dose rounding policy taken by others

There is dose rounding policy has been developed by different societies and institutions such as Hematology/Oncology Pharmacy

Association "a position statement of the hematology/oncology pharmacy association" 8 and university of Toledo Medical Center.

Recommendations

Based on the above mentioned discussion I recommend the following:

Each institution has to develop local dose rounding policy for the expensive cancer therapy such as monoclonal antibodies, immunotherapy and chemotherapy. This will lead to potential improvement in pharmaceutical services. The recommended procedures are listed in (Table 1.)

	Recommendation	Responsibility	Approval
1	Identify and develop a list for high cost cancer therapy	Oncology pharmacist	
2	Develop a policy for dose rounding within 5% of the prescribed dose for curative intent and within 10% for palliative care setting.	Oncology pharmacist	P&T and end users (oncologists)
3	Ensure distribution of the expensive cancer therapy list and the approved policy of dose rounding in outpatient and inpatient oncology/hematology settings and any other locations dealing with oncology if available.	Oncology pharmacist	
4	Educate pharmacy staff and nurses.	Oncology pharmacist	
5	Assess the dose of the ordered cancer therapy for potential dose rounding.	Oncology pharmacist	
6	Prescribers should write "do not round the dose" in case they do not want the order to be assessed for potential dose rounding.		Prescriber
7	Calculate +/- 5% or +/- 10% of the written dose of cancer therapy according to the nearest vial size available, then round the dose if applicable. Pharmacist should document under comments that "dose rounded as per P&T approved policy".	Oncology pharmacist	
8	Notify the prescriber for potential rounding of doses greater than the agreed percentage.	Oncology Pharmacist	Prescriber
9	Document any dose rounding applied. Include the following information: drug name, % of rounding, if the dose is rounded up or down, strength of the available vial size, the prescriber name, the pharmacist name and signature. Keep the documentation record in pharmacy as well as patient file.	Oncology pharmacist	
10	Assess the dose rounding policy implementation periodically and report to P&T.	Oncology pharmacist	
11	Update the list of expensive cancer therapy periodically.	Oncology pharmacist	

Table 1: Dose rounding initiative recommended procedures.

Conclusion

Development of dose rounding policy in each institution dealing with oncology medications is warranted in order to reduce cost without affecting the patient clinical outcome. Implementation of such initiative will lead to improvement of pharmaceutical care and potential cost saving. This initiative could be applied to all expensive drugs in specialties other than oncology as well.

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