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Dose banding and dose rounding of antineoplastic agents

English summary

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Direction du médicament

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This is the English summary of the guidance entitled Standardisation (*banding*) et arrondissement (*rounding*) des doses d'agents antinéoplasiques published in August 2019.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

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SUMMARY

Introduction

Sizeable losses of antineoplastic agents intended for parenteral administration have been observed. These losses are largely attributed to unusable quantities of excess agent in partially used vials and unadministered preparations that are returned and not attributed to other patients.

Dose banding is a principle that aims to optimize the preparation of antineoplastic agents by reducing preparation time, minimizing wastage and mitigating the risk of error in preparation, as well as by increasing reattribution of returned preparations. In dose banding, when the calculated dose of antineoplastic agents falls within a certain range of values, it is adjusted according to a predetermined standard dose within this range in order to respect a maximum variation (e.g., ± 5%).

Dose rounding is a principle that aims to optimize the use of vials of antineoplastic agents by reducing wastage. This principle allows for a certain percentage of variation between the prescribed dose and the dose administered to the patient (e.g., ± 5%).

INESSS was mandated by the Direction générale de cancérologie of the Ministère de la Santé et des Services sociaux to assess whether Québec's health institutions should apply the principles of dose banding and dose rounding to antineoplastic agents intended for parenteral administration to adult cancer patients and, if so, to determine the terms and procedures for application and implementation.

Methods

To fulfill this mandate, 24 assessment questions were identified using the multi criterion CREDIS grid. The methodology used to answer these questions relied on the triangulation of three types of data: 1 – scientific data, obtained through a systematic review of scientific literature and good clinical practice guides; 2 – experiential knowledge gathered primarily from health professionals: representatives from professional orders, associations, organizations and federations and from patients; and 3 – contextual information sourced mainly from questionnaires completed by oncology care providers: pharmacy department heads and members of the Association des médecins hématologues et oncologues du Québec.

The data were compiled in the CREDIS multi-criterion grid, which served as an analytical framework, data collection tool and validation tool. The grid was used to formulate recommendations through a deliberative process that considered the full spectrum of criteria reflecting a range of worldviews and the associated ethical aspects. Only those recommendations that were supported by more than 80% of consultation committee members were retained.

Results

The results of the systematic review of the effects of dose banding and dose rounding of antineoplastic agents revealed limited evidence for the majority of the outcomes evaluated, including the efficacy and safety of treatments. More specifically, the data suggest that dose banding could reduce the preparation time for antineoplastic agents (low level of scientific evidence). For dose rounding, the data suggest that the principles could reduce wastage of antineoplastic agents (low level of scientific evidence) and acquisition costs (moderate level of scientific evidence).

In spite of the limited evidence on the topic, the stakeholders consulted believe that a variation of ± 5% between the dose administered to a patient and the calculated dose should not affect the efficacy or safety of treatment. This opinion is based on complementary information, such as inter-individual variation, National Cancer Institute assessment criteria and current tolerance in the network.

It was determined from the data triangulation that there is a single documented advantage to adopting the dose banding principle: reduced preparation time. Given the lack of pertinent data on antineoplastic agent wastage, the variation in the number of preparations and treatment types between Québec health care facilities and the potentially substantial treatment procedure reorganization required to adopt this principle, this single advantage does not constitute sufficient reason to recommend the adoption of dose banding for antineoplastic agents in all Québec health care facilities.

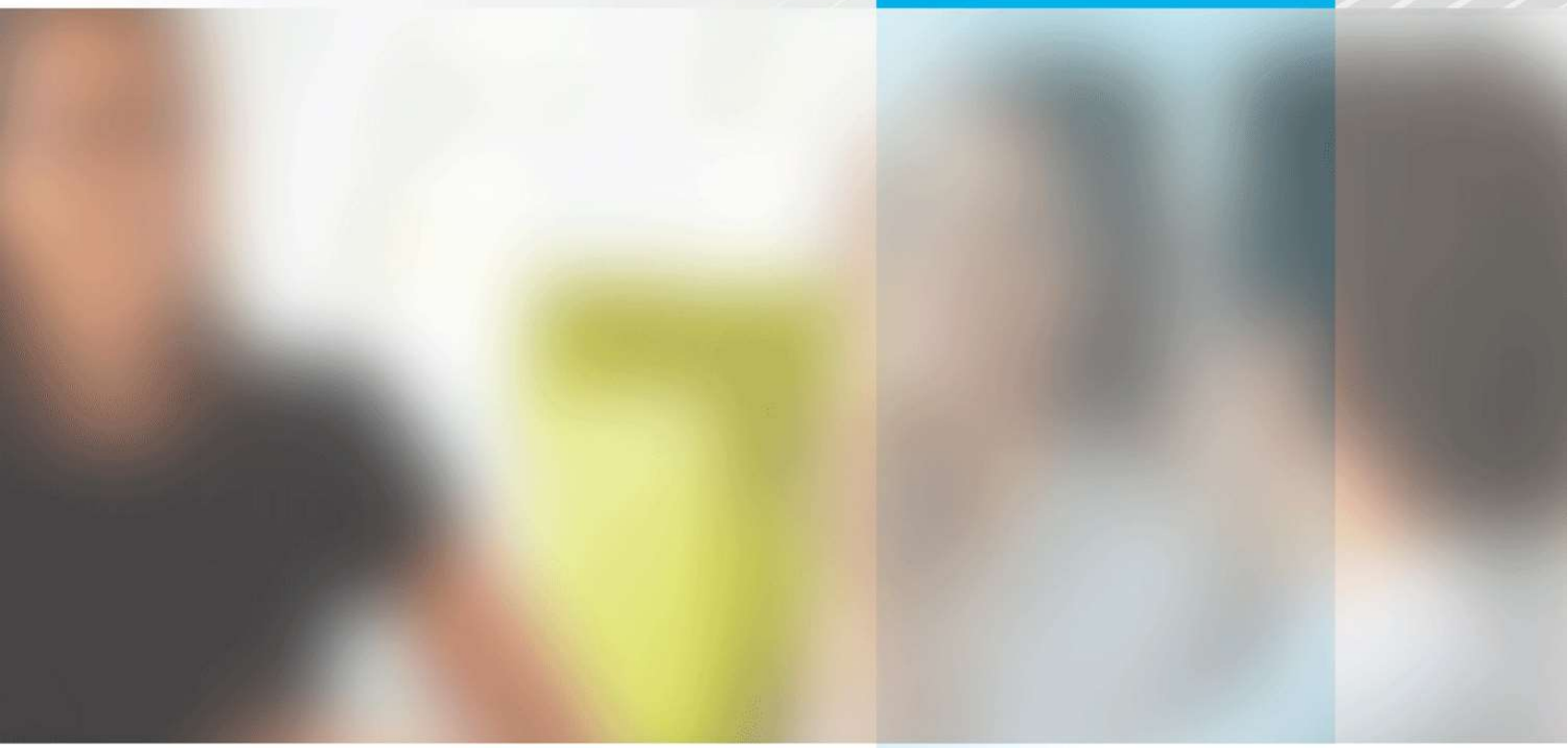
However, the application of dose rounding principle, which would require only a minor reorganization of the treatment procedure, could result in a reduction of antineoplastic agent wastage and acquisition costs. Therefore, the data triangulation supports the possibility of applying this principle in all Québec health care facilities, regardless of their disparities.

Conclusion

The recommendations in this notice should help to standardize practices pertaining to the preparation of antineoplastic agents, promote the reduction of agent wastage and optimize the treatment procedure, without compromising patient quality of life or treatment efficacy.

Recommendations

The recommendations formulated within the scope of this mandate are presented on pages 36 and 37 of this notice.



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