INESSS
LE SAVOIR PREND FORME

SEPTEMBER 2020

ENGLISH SUMMARY

Use of ulipristal acetate or levonorgestrel as oral emergency contraception

English summary

Une production de l'Institut national d'excellence en santé et en services sociaux (INESSS)

Direction de l'évaluation et de la pertinence des modes d'intervention en santé

Québec

SUMMARY

Use of ulipristal acetate or levonorgestrel as oral emergency contraception

Introduction

Emergency contraception is a complementary tool to the different regularly used contraceptive methods on the market and enables a woman who has had unprotected sexual intercourse (USI) to prevent, as far as possible, an unplanned and unwanted pregnancy. There are two types of emergency contraception: oral and intrauterine. In the case of oral emergency contraception (OEC), two drugs are recommended in the *Protocole de contraception du Québec* (Québec contraception protocol), which was published by the Institut national de santé publique du Québec (INSPQ), and they are covered by the public prescription drug insurance plan (RPAM): levonorgestrel (LNG) and ulipristal acetate (UPA).

To promote the optimal use of these drugs, the Ministère de la Santé et des Services sociaux (MSSS) asked INESSS to produce a clinical tool to guide health professionals in making the appropriate choice of an OEC, either LNG or UPA, based on the clinical situation of each requester and the different features of these contraceptives.

Methodology

The development of this clinical tool is based on the best available scientific data from a systematic review (SR) of primary studies and from clinical practice guidelines (CPGs), all of which was enhanced with legislative and organizational contextual elements specific to Québec, and with experiential knowledge provided by a number of Québec experts and clinicians who collaborated on this project.

The search for scientific information pertaining to all the research questions was conducted in several databases and was limited to certain types of publications in French or English. The literature search was conducted from each database's date of inception to September 2019 for primary studies and was limited to items published from January 2014 onwards for CPGs. A grey literature search was also conducted by consulting, among other things, the websites of the following organizations: the National Institute for Health and Care Excellence (NICE) in the United Kingdom, the Haute autorité de santé (HAS) in France, the Society of Obstetricians and Gynaecologists of Canada (SOGC), and the American College of Obstetricians and Gynecologists (ACOG). The official monographs for the oral

emergency contraceptives in question were consulted as well. Results were independently extracted by two reviewers using pre-established grids, and for each outcome examined in the SR, the quality of all the scientific evidence was assessed according to four predetermined criteria: methodological quality, consistency, clinical impact of the intervention, and generalizability.

Results

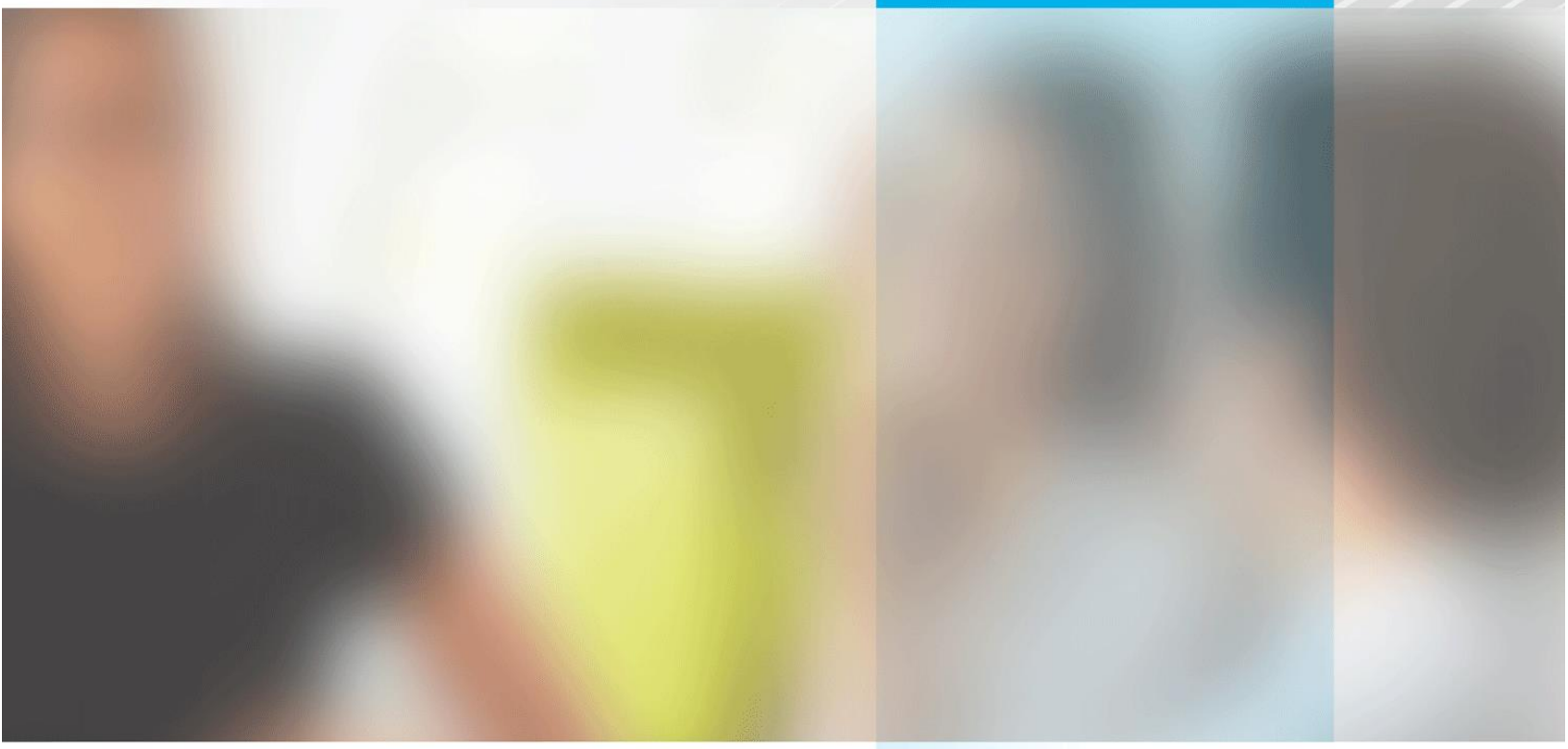
The search for scientific information yielded 2,331 publications, from which 20 primary studies and 8 items containing recommendations on the conditions of use were selected.

The data from the systematic review suggest that when compared, LNG and UPA have similar efficacy in terms of the pregnancy rate when administered within 72 hours of USI (level of evidence considered high) and that the efficacy of UPA is not affected by the USI-treatment interval if administered less than 120 hours after USI (level of evidence considered moderate). The data also suggest that the efficacy of LNG or UPA in terms of the pregnancy rate is not statistically significantly affected when administered to a woman with a BMI of 25 kg/m^2 to 30 kg/m^2 compared to a woman with a BMI of less than 25 kg/m^2 (level of evidence considered low), while the efficacy of LNG in terms of the pregnancy rate is statistically significantly decreased when administered to a woman with a BMI greater than or equal to 30 kg/m^2 (level of evidence considered low). In addition, the efficacy of UPA in terms of the pregnancy rate is not statistically significantly affected when administered to a woman with a BMI greater than or equal to 30 kg/m^2 compared to a BMI of less than 25 kg/m^2 (low level of evidence). With respect to the initiation or rapid resumption of hormonal contraception following the administration of UPA, the data suggest that hormonal contraception may statistically significantly decrease the efficacy of UPA in inhibiting follicular rupture (FR) (level of evidence considered moderate). Lastly, the data suggest that LNG and UPA have similar safety profiles (level of evidence considered high).

The conditions of use, specifically, the dosage, the USI-treatment interval, the influence of menstrual cycle phase or BMI, the precautions, the interactions, the mechanism of action, safety, and the resumption of regular hormonal contraception, in the publications containing recommendations were extracted, analyzed, and discussed with the members of the advisory committee according to their respective experiential knowledge and in light of contextual information specific to Québec. Subsequently, a clinical tool was developed.

Conclusions

OEC is, in all circumstances, an appropriate method to be used by a woman who has had USI within the past 5 days. Both LNG and UPA are approved for OEC by Health Canada and are covered by Québec's RPAM. However, their respective prices differ, the current price of the UPA being approximately three times that of LNG. Therefore, from an optimal drug use perspective, when the efficacy of two drugs is similar, LNG is considered, in the clinical tool, the preferred one. The proposed tool is intended to be updatable and will need to be adapted to new scientific data as they become available and in light of other drugs that might eventually receive the indication of OEC.



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