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CONSENSUS CONFERENCE - 2011

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# UPDATE ON THE CLINICAL MANAGEMENT OF HORMONAL, INTRAUTERINE AND EMERGENCY CONTRACEPTION

November 25th and 26th, 2011. MADRID

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SEC



SPANISH  
CONTRACEPTION  
SOCIETY

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# PRESENTATION

The Consensus Conferences of the Spanish Society of Contraception (SEC) are a major reference for the update of scientific evidence allowing for the correct management of the different contraceptive methods by health professionals.

This new Consensus Conference is the result of the experience acquired throughout the years in this type of conferences and of SEC's desire to remain in the scientific analysis line which enables the elaboration of practical recommendations for the development of our activity.

We must thank all participants for their efforts in order to obtain the results presented here, which involve the work of numerous professionals.

Prof. J. Calaf Alsina  
*President of Jury*

Dr. E. Pérez Campos  
*Coordinator of CC*

Dra. E. de la Viuda  
*President of SEC*

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# 1. PROPOSITIONS OF THE CONSENSUS CONFERENCE (CC)

The Management Board of the Spanish Contraception Society (SEC) detected the suitability of examining, in the light of Evidence- Based Medicine, the novelties arising in Hormonal Contraception since the last Consensus reached by the SEC in 2005.

To this end, it has once more resorted to the methodology of a Consensus Conference (CC) comprising, as is well known, the drafting of recommendations by a highly- qualified multidisciplinary Committee. The recommendations are drafted after listening to the opinions of Experts who have presented their reports summarizing the state of the art on the basis of an exhaustive examination of the best Scientific Evidence available.

The CC is a scientific conference at which experts set out their studies. This presentation is followed by a democratic discussion in which all the participants (experts, committee and invited guests) are able to express an opinion. It concludes with a “judicial” resolution in which the Committee, comprising multiple disciplines and professions, establishes its recommendations independently and objectively behind closed doors.

## 1.1. Objectives

The purpose of this CC was the updating of criteria for the clinical handling of hormonal contraceptives, examining the different forms of administration, routes for application and their new components.



It is necessary to update scientific knowledge and consensus on hormonal contraception

## 2. CONDUCT OF THE CC

### Promoter:

Spanish Society of Contraception

### Organizing Comitee:

Coordinator:  
Dr. Ezequiel Pérez Campos

### Directive Board:

Dr. Esther de la Viuda García  
Dr. Macarena Quesada  
Dr. M<sup>a</sup> J. Alonso Llamazares  
Dr. Nuria Parera Junyent  
Dr. José Vicente González Navarro  
Dr. José Ramón Serrano Navarro  
Dr. Mercedes Martínez Benavides  
Dr. M<sup>a</sup> Ángeles Gómez Martínez

### Jury:

President of the Jury:

Prof. Joaquim Calaf Alsina

### Jury

Dr. Mercedes Abizanda  
Dr. M<sup>a</sup> Jesús Alonso Llamazares  
Prof. Joaquim Calaf Alsina  
Dr. Carmen Coll Capdevila  
Dr. Esther de la Viuda García  
Dr. José Luis Doval Conde  
Dr. D. José Luis Dueñas Díez  
Dr. Iñaki Lete Lasa  
Dr. Eduardo A. López Arregui  
Dr. Javier Martínez Salmeán  
Dr. Francisca Martínez San Andrés  
Dr. Dolores Montero  
Dr. Javier Rodríguez Martorell  
Dr. Merce Roque Moreno  
Dr. Ana Saavedra Ruiz  
Dr. Luis Enrique Sánchez  
Dr. Isabel Serrano Fuster  
Dr. Jose R. Serrano Navarro

### Experts

Dr. M<sup>a</sup> Angels AVECILLA Palau  
Dr. Sergio Haimovich Segal  
Dr. Roberto Lertxundi Barañano  
Dr. M<sup>a</sup> Paloma Lobo Abascal  
Dr. Nicolás Mendoza Ladrón de Guevara  
Dr. Inmaculada Parra Ribes  
Dr. Isabel María Ramírez Polo  
Dr. Alberto Salamanca Ballesteros  
Dr. Ivan Solà

### Moderators:

Dr. Mercedes Martínez Benavides  
Dr. Nuria Parera Junyent  
Dr. Rafael Sánchez Borrego  
Dr. M<sup>a</sup> Jesús Cancelo Hidalgo

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### Bibliographic review team:

Iberoamerican Cochrane Centre

Director: Dr. Iván Solà

### Participating Audience

Dr. Magdalena Balaquer Fabuel  
Dr. Santiago Barambio Bermúdez  
Dr. Vicent Barragán Gómez Coronado  
Dr. Sergio Bernabeu Pérez  
Dr. Solina Bonacho Paniagua  
Dr. Ana Isabel Casasus Miér  
Dr. M<sup>a</sup> José Coco Alonso  
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Vigo

## 2.1. Function of the Jury

### Prior to the Conference:

- **Preparatory meeting** to establish the methodology of the group prior to, during and after the public meeting.
- **Individual work** based on the texts drafted by the bibliographical group and the experts.
- In accordance with the Organizing Committee, the **proposition of questions** and subjects for discussion to Experts.

### During public meeting:

- **Participate in the General Discussion**
- It establishes the **minimum degree of consensus** (on this occasion it was set at 75% of the members)
- It decides on its internal **modus operandi**.
- It indicates the level of agreement reached in the **final text of the recommendations**.
- It drafts the **Conclusions and Recommendations of the Conference**, in both full-text and summary versions.

The committee drafts the pertinent recommendations following the study of the scientific documentation and the evaluation of the presentations by experts and the participation of the members of the public

## 2.2. Function of Experts

- They are elected by the Organizing Committee on the basis of their skills in the subject matter.
- Each expert provides the Committee, 2 months prior to the Conference, a text containing the evidence-based information allowing the questions and subjects raised to be answered.
- They present their work at the public meeting, taking as their basis the selection made by the Bibliographical Group.

## 2.3. Programme of the Conference

The Conference takes place in Madrid, on November 25th and 26th, in accordance with the following Programme:

## Friday, November 25th, 2011

- 8,30h. Greeting. *Dr. Esther de la Viuda García. President of SEC. Guadalajara.*
- 8,35h. Presentation. *Dr. Ezequiel Pérez Campos. Consenses Conference Coordinator. Valencia.*
- 8,45h. Methodology for the grading of evidence. *Dr. Iván Solá Arnau. Cochrane Centre. Barcelona.*

### 9,00h. **Table 1: "Update on hormonal contraception management"**

Moderator: *Dr. Ma Jesús Cancelo Hidalgo. Guadalajara.*

- 9,00h. What are the prior requirements for the prescription of hormonal contraceptives?  
What are the necessary checks for the follow-up of hormonal contraceptives?

*Dr. Paloma Lobo Abascal. Madrid.*

- 9,30h. How should we handle cycle alterations caused by hormonal contraceptives?  
How should we handle forgetting combined pills and gestagen only pills?

*Dr. Nicolás Mendoza Ladrón de Guevara. Granada.*

- 10,00h. Until what age or circumstance should hormonal contraception be used?  
What is the right management of HC in cases of drug interaction?

*Dr. Inmaculada Parra Ribes. Valencia.*

- 10,30h. Discussion

### 11,45h. **Table 2: "Intrauterine Contraception Controversies"**

Moderator: *Dr. Mercedes Martínez Benavides. Sevilla.*

- 11,45h. Should antibiotic prophylaxis be used on any circumstance for a IUD insertion?  
Is misoprostol useful to facilitate IUD insertion?  
Is IUD insertion (Cu vs LNG) advisable among teenage population?

*Dr. Sergio Haimovich Segal. Barcelona.*

- 12,15h. Should LNG IUD be replaced after the age of forty?  
Does IUD (Cu) reduce the risk of cervix or endometrial cancer?

*Dr. Alberto Salamanca Ballesteros. Granada.*

- 12,45h. Discussion

### 16,00h. **Table 3: "Hormonal Contraception Controversies"**

Moderator: *Dr. Rafael Sánchez Borrego. Barcelona.*

- 16,00h. How efficient is each of the contraceptive methods available?  
Does HC diminish libido?  
What are the non-contraceptive proven benefits of the Gestagen Only Contraceptives?  
What pre-conceptional recommendations (advice) should be given in the contraception consultation?

*Dr. Roberto Lertxundi Barañano. Bilbao.*

## Friday, November 25th, 2011

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**16,45h.** Are there different risk levels of tromboembolism depending on the application and composition of CHCs?  
 Is obesity a risk factor in the use of CHCs?  
 Does a woman's weight decrease the efficiency of the hormonal contraceptive method?

*Dra. Isabel Ramírez Polo. Cádiz.*

**17,30h.** Discussion

**18,45h.** **Table 4: "Hormonal Emergency Contraception Controversies"**

*Moderator: Dr. Núria Parera Junyent. Barcelona*

**18,45h.** Are there efficiency differences between the use of levonorgestrel and ulipristal acetate as EC?

Are there any differences in terms of adverse effects between the use of levonorgestrel and ulipristal acetate as EC?

Does the free dispensation of LNG emergency contraception pills increase the incidence of STDs or the non-use of regular contraception?

*Dr. Àngels AVECILLA Palau. Barcelona.*

**19,15h.** Discussion

## Saturday, November 26th, 2011

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**9,00h.** Presentation of Jury agreements and y Preliminary Recommendations

*Moderator: Dr. Esther de la Viuda García. Guadalajara.*

*President: Prof. Joaquim Calaf Alsina. Barcelona.*

*Secretary: Dr. M<sup>a</sup> Jesús Alonso Llamazares. Málaga. (questions 1-10)*

*Secretary: Dr. José Ramón Serrano Navarro. Bilbao. (questions 11-21)*

**10,00h.** Discussion

**12,00h.** Presentation of Final Recommendations by the CC.

*Moderator: Dr. Ezequiel Pérez-Campos. Valencia.*

*President: Prof. Joaquim Calaf Alsina. Barcelona.*

*Secretary: Dra. M<sup>a</sup> Jesús Alonso Llamazares. Málaga. (questions 1-10)*

*Secretary: Dr. José Ramón Serrano Navarro. Bilbao. (questions 11-21)*

**12,30h.** Final nuances

**13,00h.** CC Closure. *Dr. Esther de la Viuda García. Guadalajara.*



The bibliographical review attempts to ensure objective scientific presentation of data for their interpretation

## 3. REPORT BY THE BIBLIOGRAPHICAL REVIEW GROUP

Iberoamerican Cochrane Centre. Institute of Biomedical Research.

***Critical review of the scientific literature for the elaboration of recommendations on intrauterine and hormonal contraception management.***

### 3.1. Methodology

#### **Search for scientific literature and eligibility of research studies**

From the scope established by the clinical questions formulated, and following a PICO structure (Patient - Intervention - Comparison - Outcome), a series of search strategies were designed with the aim of identifying the main systematic reviews and assessment reports of healthcare technologies on the formulated questions, and all those clinical tests which update the results of the relevant systematic reviews..

A specific search was performed (based on the term 'contraception') of general systematic reviews that could respond to any of the formulated questions at the following information sources:

- Cochrane Database of Systematic Reviews;
- Centre for Reviews and Dissemination Databases (DARE, HTA, NHS EED);
- TRIP Database, NHS Evidence y excelenciaclinica.net;
- EMBASE;
- MEDLINE through PubMed. On this database the applied search strategy was the following: Contraception[MH] OR "Contraceptive Agents"[MH] OR "Contraceptives, Oral"[MH] OR Contracepti\*[tiab] OR "Intrauterine Devices"[mh] OR Intrauterine Device\*[tiab]

Based on the results of this search, we determined the systematic reviews that could answer the different clinical questions of interest. We selected those systematic reviews and healthcare technology reports which, apart from being relevant for the formulated clinical questions, had some specific and explicit inclusion criteria based on an exhaustive database search, performing a quality assessment on the research studies included.

As from the search date of each selected systematic review, a new search for new revisions and clinical tests was performed at MEDLINE, EMBASE and CENTRAL.

Evidence-based medicine assesses the probatory power of scientific studies.



## 3.1. Methodology

### Critical review of scientific literature

The critical review was made in two stages: one stage describing the studies used to elaborate the critical review with its corresponding critical assessment, and a second stage of evidence review and grading according with the guidelines of the international workgroup Grading of Recommendations Assessment, Development and Evaluation (GRADE).

### Studies Descriptive Tables

The studies selected to answer the clinical questions are summarized into descriptive tables with their main features. These tables describe the main features in terms of design, patients, interventions and outcomes relevant to the systematic reviews and the clinical tests used in the development of the critical review. Besides, a formal evaluation of the main bias sources of the assessed studies was applied: for systematic reviews, the AMSTAR scale was applied, and for clinical tests we used the criteria accepted by the Cochrane Collaboration.

### Grading of evidence quality and summary of results

The review of scientific literature included the grading of the quality of evidence available for each assessed result variables following the method guidelines by the international workgroup Grading of Recommendations Assessment, Development and Evaluation (GRADE).

- Clinical question answered by evidence review, and the study contributing to the analysis (in most cases a systematic review).

- Assessment of modifying aspects of evidence quality: limitations, inconsistency, indirect evidence inaccuracy. The influence of these aspects on the quality of evidence is explained further on in this section. From the assessment of said aspects, the global quality is obtained for each outcome (high – moderate – low). Those aspects which help decrease evidence quality for each case are marked “-”. All relevant comments in connection with evidence quality grading are detailed at the bottom of the table.

### 3.1. Methodology

- Summary of the effect magnitude shown in the available studies in terms of: events in compared groups in the clinical trials available, and effect measure in relative and absolute terms (in this last case, when results present significant differences).

Quality assessment of evidence for each outcome of interest, which are graded by decision-making importance (key - important - not important). For each outcome it is recorded the number of studies in the literature which help analyze its design, the assessment of evidence quality modifying aspects and the results gathered from available studies..

#### **GRADE System for evidence grading**

The main goal of the GRADE system is to propose a transparent, explicit and structured process to develop critical reviews of scientific literature and to elaborate recommendations, a fact which makes it applicable both to the field of systematic reviews (and the rest critical reviews of literature) and to the clinical practice guides.

The system proposes a structured, systematized methodology to formulate clinical questions, select the outcomes of interest and establish their importance, assess the quality of the evidence available and include said assessment to the grading of a recommendation's strength, together with other factors. The system works on the basis of structured questions and the importance grading of the outcomes of interest (key - important - not important), with which the analysis of scientific evidence is then applied, resulting from an exhaustive search of literature.

In the GRADE system, the quality of evidence refers to the trust that may be given to the fact that the estimate of the effect magnitude of an intervention offered by the studies presented in the literature, is appropriate to support a recommendation. In the case of clinical trials, apart from the limitations in their design, one should assess the presence of inconsistencies or inaccuracies in the results, or of indirect estimations, before making any decisions. In the case of observational studies it is assessed whether they provide considerable effect estimates, or evidence a clear dose-response relationship. The GRADE system simplifies the grading of quality into three categories (high-moderate-low).

Clinical trials are considered to yield high quality. Their quality (trust in results) decreases if any of the aspects previously described is detected. Observational studies yield low quality, increasing their quality (trust in results) if any of the two specified aspects is detected.

### 3.1. Methodology

In brief, the aspects that may decrease trust in the results of clinical trials are the following:

- **Limitations in the design and execution of trials:** we analyze the main bias sources which may influence the effect estimate in a clinical trial: i) how the aleatorization sequence is created, ii) whether the aleatorization sequence is concealed iii) whether there is blinding in the trials iv) whether there has been considerable loss of patients that may affect results v) the use of composite outcomes, or vi) the interruption of trials before due time because of a benefit).
- **Inconsistent results:** if there are different estimates of a treatment's effect from studies being assessed on the same matter, one may reasonably suspect that there are considerable differences between these studies, which do not allow for the correct understanding of the effect magnitude of the assessed treatment.. In general, this aspect is evaluated by analyzing the variability between available studies, or by means of a formal heterogeneity test.
- **Lack of direct scientific literature:** this situation arises when i) there are no available direct comparisons between treatments (e.g., clinical trials have compared Alendronate against placebo and Risedronate against placebo, but there are no trials comparing these two bifosfonates with each other), or when ii) an extrapolation of results must be made from a study assessing certain aspects different to those in the clinical context where the recommendation should be elaborated.
- **Inaccuracy:** when studies include very few patients and results show few events of interest, the results from said studies will present a very wide confidence interval. The conclusion reached from these studies shall not be very reliable and, therefore, the corresponding evidence quality should be considered lower.

The GRADE system proposes to grade evidence quality in a separate way for each outcome previously defined and classified in accordance with their importance during the question stage.

For this reason, data is extracted into tables which summarize all available evidence for each outcome, with all quality-affecting factors and a summary of magnitude estimates reflected in the studies. This approach is important because sometimes, evidence grading may differ according with the outcome type (it should be much more important, for example, to have studies with proper blinding when measuring subjective outcomes such as pain, rather than in assessing more objective ones such as mortality).

### 3.1. Methodology

When formulating recommendations, evidence is graded jointly for the outcomes selected for each clinical question, so that evidence quality is conditioned by the lowest evidence quality level of key outcomes.

#### **Evidence Summaries**

For each clinical question formulated we summarized all the information obtained from literature and critical reviews, in order to create scientific evidence summaries. For each case we describe the systematic reviews assessed with a brief description of the clinical trials taken into consideration (and the new studies whenever relevant trials have been identified in search updates).

In the last section we describe the results of the assessed studies based on the outcomes of interest and the comparisons identified in the literature. On the right margin of this section one may find the grading of the available evidence for each outcome.

Each section ends with a summary of results and their corresponding evidence quality, apart from the bibliographic sources used for the analysis.

## 4. RECOMMENDATIONS

A- Regular hormonal contraception: Questions from **1 to 13**

B- Emergency contraception: Questions from **14 to 16**

C- Intrauterine contraception: Questions from **18 to 21**

### Regular hormonal contraception:

#### Final Recommendations 1.

##### **What are the prior requirements for the prescription of hormonal contraceptives?:**

A clinical record with a detailed anamnesis is recommended, in order to identify those women who present conditions that contraindicate contraception, according with categories 3 and 4 of the WHO, listed on the appendix.

In the case of gestagen only combined or injectable hormonal contraception, it is advised to measure blood pressure and calculate body mass index.

**Quality of evidence:** Good clinical practice.

#### Final Recommendations 2.

##### **What are the necessary checks for the follow-up of hormonal contraceptives?**

A follow-up visit is advised within 3 to 6 months after starting the use of contraceptives, in order to improve the adherence to the contraceptive treatment.

It is not necessary to perform specific periodical checks on women using hormonal contraceptives.

**Quality of evidence:** Good clinical practice.

#### Final Recommendations 3.

##### **a. How should we handle unexpected bleeding associated with the use of combined hormonal contraceptives?**

Oriented anamnesis is advised in cases of unexpected bleeding related to the use of combined hormonal contraceptives.

**Quality of evidence:** Good clinical practice

On women younger than 45 years old presenting unexpected bleeding resulting from the use of combined hormonal contraceptives, a watchful attitude is advised during the first three months. If bleeding persists after three months, the performance of specific analyses is recommended.

**Quality of evidence:** Low quality.

## 4. RECOMMENDATIONS

### **b. How should we handle unexpected bleeding associated with the use of gestagen only hormonal contraceptives?**

In case of unexpected bleeding related to the use of only gestagen hormonal contraceptives, an oriented anamnesis is advised, while reassuring and informing the patient.

**Quality of evidence:** Good clinical practice.

#### Final Recommendations 4

##### **a. How should we handle forgetting combined pills?**

If the patient forgets to take a combined contraceptive pill, they should take it immediately and continue taking the rest in the usual way, with no need for additional methods.

If the patient forgets twice or more to take a combined hormonal pill, it is advised to immediately take the last pill and continue to take the rest in the usual way. In this case we should advise the use of an additional barrier method (condom) for 7 days.

If oversights occur between the 1st and 7th pill, emergency contraception should be considered. Emergency contraception is not recommended if oversights occur between the 8th and 14th pill.

If oversights occur between the 15th and 21st pills, it is advised to skip the free interval and start with a new package.

**Quality of evidence:** Good clinical practice.

##### **b. How should we handle forgetting gestagen only pills?:**

If a patient forgets to take an only gestagen pill, it is advised to take the forgotten pill immediately and take emergency contraception if the oversight occurred over 12 hours ago and unprotected sex has taken place within said period. Additionally, we should recommend the use of an additional barrier method (condom) for 2 days.

**Quality of evidence:** Good clinical practice.

#### Final Recommendations 5

##### **Until what age or circumstance should hormonal contraception be used?**

It is not advised to contraindicate any hormonal contraceptive methods based on age only.

Decisions as to the interruption of hormonal contraception should be based on personalized advice, since there is currently no evidence which allows us to confirm the moment when the ovary function ceases and the fertility rate among women over 50 is extremely low.

**Quality of evidence:** Good clinical practice.

#### Final Recommendations 6

##### **What is the right management of HC in cases of drug interaction?**

Upon anamnesis it is advised to record any pharmacological treatment the woman may be undergoing and assess its potential interactions in accordance with the relevant updated technical files.

**Quality of evidence:** Good clinical practice.

## 4. RECOMMENDATIONS

### Final Recommendations 7.

#### How efficient is each of the contraceptive methods available?

Based on observational studies, contraception efficiency in Europe would have the following Pearl indexes:

- Combined Pill	2,1
- Gestagen only pill	0,41
- Transdermal Patch	1,24
- Vaginal ring	1,23
- Subcutaneous Patch	0,08
- IUD - LNG	0,1
- Depot Medroxyprogesterone acetate	3 *

**Quality of evidence:** Moderate quality.

\* USA data

### Final Recommendations 8.

#### Does the use of hormonal contraception diminish sexual desire?

The impact of hormonal contraception on sexual libido is unknown. It is not possible to assess the impact of any intervention, as several personal, psychological and social factors intervene on sexual desire.

**Quality of evidence:** Low quality.

### Final Recommendations 9.

#### What are the non-contraceptive proven benefits of gestagen only methods?

Gestagen only methods with non-contraceptive proven benefits are: levonorgestrel liberating device (IUD-LNG), the depot medroxyprogesterone acetate (AMPD) and the subdermal implants under the following indications:

Reduction of menorrhagia and hypermenorrhagia (DIU - LNG, AMPD, implant)

Endometrial protection in Hormonal Therapy (DIU-LNG)

Reduction of dysmenorrhea and pelvic pain in cases of endometriosis (DIU-LNG)

**Quality of evidence:** Moderate to low quality.

### Final Recommendations 10.

#### What preconceptional recommendations (advice) should be given in a contraception consultation?

Women who have used hormonal contraceptives do not require preconceptional recommendations different to those given to a woman who has never used hormonal contraception.

**Quality of evidence:** Good clinical practice.

## 4. RECOMMENDATIONS

Global pregnancy rates following the cease of hormonal contraception is comparable to that in the general population, and, after its interruption, there is no need for a posterior time interval before seeking gestation.

Only the medroxyprogesterone acetate has a longer fertility return period.

**Quality of evidence:** Low quality.

### Final Recomendations 11.

#### **Are there different risk levels of tromboembolism depending on the composition of combined hormonal contraceptives?**

The various combinations of oral contraceptives bear a different relative risk of venous tromboembolism, the latter being lower for combinations of levonorgestrel, norethisterone and norgestromine against the risk present in combinations of dienogest, gestodene, drospirenone or desogestrel, although the absolute risk is low.

The clinical relevance of such differences must be assessed while taking into consideration the low incidence of tromboembolic events on women in fertile ages.

The use of low estrogen contraceptives is advised (EE  $\leq 35\mu\text{g}$ ) in order to reduce the relative risk of venous tromboembolism. Evidence related to the impact of administration methods on venous tromboembolism risk is not conclusive.

**Quality of evidence:** Low quality.

### Final Recomendations 12.

#### **Is obesity a risk factor for the use of combined hormonal contraceptives?**

The use of combined hormonal contraceptives is not advised for women with BMI equal or higher than 35 kg/m<sup>2</sup>, due to the resulting significant risk of tromboembolism. The relative risk of tromboembolism increases with the body mass index and doubles in the cases of BMI  $\geq 30$  kg/m<sup>2</sup>.

**Quality of evidence:** Low quality.

### Final Recomendations 13.

#### **Does a woman's weight diminish the efficiency of the hormonal contraceptive method?**

A woman's weight does not affect the efficiency of hormonal contraceptive methods, except for the transdermal patch, which should be used by women whose weight is below 90 kilograms.

**Quality of evidence:** Low quality.



## 4. RECOMMENDATIONS

### Emergency contraception:

#### Final Recommendations 14.

#### **Are there any efficiency differences between the use of levonorgestrel and ulipristal acetate as emergency contraceptives?**

- There are no differences in terms of efficiency between levonorgestrel and ulipristal acetate when administered within the first 72 hours after unprotected intercourse.

**Quality of evidence:** Moderate quality.

- The efficiency of levonorgestrel and ulipristal acetate has not yet been directly compared between 73 and 120 hours after unprotected intercourse.

**Quality of evidence:** Low quality.

- Indirect data have proved the efficiency of levonorgestrel up to 96 hours (the technical file admits 72 hours) and of ulipristal acetate up to 120 hours.

**Quality of evidence:** Low quality.

#### Final Recommendations 15.

#### **Are there any differences in terms of adverse effects between the use of levonorgestrel and ulipristal acetate as emergency contraceptives?**

- No differences were found in the rate of adverse effects between the two treatments.

**Quality of evidence:** Low quality.

- The adverse effects observed were of mild nature.

**Quality of evidence:** Low quality.

#### Final Recommendations 16.

#### **Does the free dispensation of the levonorgestrel emergency contraception pill increase the incidence of sexually transmitted diseases (STDs) or non-use of regular contraception?**

Research studies on advance provision or free dispensation reveal that:

- a) it does not increase the incidence of STDs
- b) it does not increase the frequency of unprotected sexual relations
- c) it does not alter regular contraception patterns.

**Quality of evidence:** Low quality.

## 4. RECOMMENDATIONS

### Intrauterine contraception:

#### Final Recommendations 17.

##### **Should antibiotic prophylaxis be used in any circumstance for IUD insertion?**

The administration of antibiotic prophylaxis before IUD insertion does not provide any benefits.

**Quality of evidence:** Low quality.

#### Final Recommendations 18.

##### **Is the use of misoprostol useful to facilitate IUD insertion?**

· The usual use of misoprostol for IUD insertion has not yielded any benefits

· Depending on the clinical traits of the uterine cervix, there is evidence that said measure could be useful for some situations

**Quality of evidence:** Low quality.

#### Final Recommendations 19.

##### **IS IUD insertion (Cu vs LNG) advisable among teenage population?**

· Age and parity are not contraindications for the use of IUDs of copper or levonorgestrel

· As it is a long-lasting method, it facilitates fulfillment and permanence, apart from being highly efficient.

**Quality of evidence:** Low quality.

#### Final Recommendations 20.

##### **Should LNG IUD be replaced after the age of forty?**

When the LNG IUD has been inserted as contraceptive at the age of 40 or more, it may be kept for said function until menopause.

**Quality of evidence:** Low quality.

#### Final Recommendations 20.

##### **Should LNG IUD be replaced after the age of forty?**

When the LNG IUD has been inserted as contraceptive at the age of 40 or more, it may be kept for said function until menopause.

**Quality of evidence:** Low quality.

## 5. COLLABORATORS

- BAYER
- CHIESI
- GEDEON RICHTER
- HRA
- JANSSEN
- MSD
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