Process of the development of medical abortion in Catalonia

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1. Introduction

As established in the World Health Organization's (WHO) Reproductive Health strategy, the issue of abortion must be tackled to accelerate the attainment of objectives defined at the World Health Assembly 2004 (millennium goals). In particular, it is important to address unsafe abortions, given that they have a direct impact on improvements in maternal health and in other aspects of social development.[1] There is wide consensus that in places where laws and public policies allow abortions on broad grounds, the incidence and complications of unsafe abortions are reduced to low levels.[2] In addition, it is known that the probability of a woman undergoing an abortion for an unwanted pregnancy is almost the same whether or not abortion is restricted by law.[3]

Numerous declarations and resolutions, mainly from developed countries, establish the importance of legal, safe access to abortion. Most of these define broad grounds for abortion, including physical and mental health of the mother, diseases and malformations of the fetus and social reasons.[4] In addition, the WHO regularly publishes studies and updates on methods, techniques and health policy strategies to help improve sexual and reproductive health. These frequently cover the topic of safe abortion.[5]

In its last publication on this topic,[5] the WHO recognized the increased availability of safe, effective medical methods (such as mifepristone and misoprostol). The correct use of these treatments is a great opportunity for women and health professionals, as well as for the planning and management of sexual and reproductive health programmes, given that they form part of the health system. Among its recommendations, the WHO establishes that the principles underlying the process of improving access to and the quality of abortion care must include that it is: managed from within a country's own health system; evidence-based; a process that includes many perspectives; participative and fair; free of discrimination; based on health and human rights objectives; and, above all, centred on the health system.

All of these recommendations and characteristics are incorporated into the project presented in this document. The project has been developed and fully implemented in Catalonia to improve the quality of abortion care and the health of women, who are its main recipients.

2. Background

Termination of pregnancy (TOP) was first regulated in Spain in 1985,[6] on the three grounds stipulated in the Criminal Code that was in force at that time:

- Risk to the life or health of the pregnant woman.
- Presumption of congenital defects (up to 22 weeks of gestation).
- Rape (up to 12 weeks of gestation).

On 5 July 2010, the Law on Sexual and Reproductive Health and Termination of Pregnancy[7] came into force. This introduced the following permitted periods and reasons:

- At the woman's request (up to 14 weeks of gestation).
- Risk to the life or health of the pregnant woman / serious fetal abnormalities (up to 22 weeks of gestation).
- Fetal abnormalities that are incompatible with life and/or a fetus with extremely serious disease that is incurable at the time of diagnosis.

The publication of the new Law (OL 2/2010 of 3 March) led to a major change in the health system, as it allows TOP on a woman's request during the first fourteen weeks of gestation, and for medical reasons at different weeks of gestation. The Law also stipulates a three-day period of reflection once a woman has received information on rights and public benefits that support maternity.

In addition, the Law specifies that abortion shall be included in the service portfolio of the National Health System (SNS), and that TOP shall be carried out in centres authorized for this purpose (hospitals and non-hospitals) in the public health network or associated with this network, in accordance with the provisions of Royal Decree 25 June 2010[8] that implements the Law.

To guarantee the provision of this service in Catalonia, the Catalan Ministry of Health (DS), together with the Catalan Health Service (CatSalut), planned the gradual implementation of a model of abortion care, in which women could exercise their right to abortion with guarantees of quality.

A notable aspect of the model is the inclusion of medical abortion for pregnancies in the first seven weeks in primary care facilities, specifically in Sexual and Reproductive Health Services (ASSIR) units. Consequently, the Catalan Ministry of Health asked the Agency for Health Information, Assessment and Quality (AIAQS; currently the Catalan Agency for Healthcare Quality and Assessment [AQuAS]) to review the effectiveness, safety and efficiency of various medical abortion methods, particularly those that refer to the first forty-nine days of gestation.

In Catalonia, by 2001 a protocol on medical abortion[9] had been drawn up on first-trimester TOP, as a result of the legalization of mifepristone (RU-486) for this purpose in February 2000.[10] The protocol was drawn up by a group of healthcare professionals, members of scientific associations and health administration representatives. In the protocol, the working group highlighted the need for periodic reviews.

In the same year and in the European Union, the European Parliament approved Resolution 2001/2128 (INI) on sexual and reproductive health and rights. The resolution indicated the inequalities between European women with respect to access to reproductive health services, contraceptives and TOP depending on their income and/or country of residence.[11]

Currently, TOP is legally regulated and is permitted in almost all European Union countries. Nevertheless, the requirements that are established vary by country: TOP can be requested without any justification in some countries (Austria, Denmark, Greece, Holland, Norway, Portugal and Sweden). In other countries, it is permitted if a state of stress is certified (Germany, Belgium, France and Switzerland). A third group are countries in which abortion is permitted in specific situations (mental or physical risk to woman or child and social or economic reasons: United Kingdom, Luxemburg, Finland and Italy). In Europe, the established limit varies between ten and fourteen weeks of gestation, except in Holland and Sweden where the limit is twenty-four and eighteen weeks, respectively.[12]

3. Development of the medical abortion protocol

In the framework of sexual and reproductive health policies and the model of abortion care, the Catalan Ministry of Health (DS) formed a working group in July 2010 to promote the use of medical abortion methods up to 49 days of gestation, based on current knowledge and scientific evidence and in accordance with WHO recommendations.[13] In addition, it requested a report from the AIAQS on the effectiveness and safety of medical abortions up to 49 days of gestation.

The document drawn up by the AIAQS[14] concluded that medical abortion, using a combination of mifepristone and misoprostol, is effective, safe and efficient and is therefore a valid alternative and preferable to surgical abortion in the first forty-nine days of gestation. The report highlights that the use of mifepristone combined with misoprostol is common practice in Europe and has fewer adverse effects.[15] As the proposed dose and route of administration of mifepristone and misoprostol differ from those described in the respective factsheets for authorized drugs, a protocol had to be drawn up, as specified in CatSalut Instruction 05/2010[16] on the use of authorized medications in conditions other than those established in the factsheet and Royal Decree 1015/2009,[17] which regulates the availability of drugs in special situations.

The protocol on medical abortion up to 49 days of gestation was written by various professionals specialized in gynecology and obstetrics (gynecologists and midwives), anaesthetics, pharmacology, epidemiology and psychology, as well as health administration professionals.

The medical abortion protocol incorporates the provision of drug treatment for TOP up to 49 days, in primary care facilities through Sexual and Reproductive Health Services (ASSIR) units. In accordance with this protocol, support material was created for medical abortion (informative leaflets, self-administration kit and personalized recommendations).

At the start of 2011, the DS approved the protocol for medical abortion up to 49 days of gestation. It then began to implement the protocol with a pilot trial in five ASSIR centres, which had been accredited by the Ministry of Health for medical abortions. The professionals in these

centres received specific training, in collaboration with the Catalan Institute for Health Studies (IES).

The pilot trial to introduce medical abortion included all requests for this procedure in the five ASSIR centres between 7 February and 31 March 2011. Subsequently, a report was drawn up.[18]

The report on this first stage concluded that the results were satisfactory, particularly in relation to effectiveness, safety, surgical termination and complications. In addition, the application of the protocol was considered satisfactory by the women and the professionals. The protocol was correctly followed in a very high percentage of women, most of whom had adopted a contraceptive method by the end of the process. The main results were:

- Of the 205 TOP undertaken, follow-up was not completed in 5 cases (2.4% loss of cases).
- 90% of the women stated that they would recommend this method.
- The medical treatment did not produce a termination in just 2% of the cases.
- 65% of the women chose to start to use a combination hormonal contraceptive on the same day as the misoprostol treatment. A total of 24.4% decided to use condoms and 9.3% selected other methods. There are no data on 1.0% of the cases.

The involvement and technical quality of participating professionals was notable, and a key factor in the development of this first stage. Their collaboration contributed to the recommendations established to extend the protocol.

The final version of the protocol was published in November 2011.[19]

In June 2014, the Catalan Agency for Healthcare Quality and Assessment (AQuAS) drew up another report that reviewed the effectiveness and safety of medical abortion up to 63 days of gestation (9 weeks), and self-administration in the case of misoprostol.[20] The report concluded that, according to available scientific evidence, the combination of mifepristone and misoprostol is a safe, effective method of abortion up to 63 days of gestation.

At the same time, and on the basis of these conclusions, the DS has updated and published a protocol for medical abortion up to 63 days of pregnancy,[21] which extends the offer of medical abortion up to 9 weeks of gestation, in accordance with the information established in the AQuAS report[20].

4. Roll-out and implementation

Medical abortion up to 49 days of pregnancy in ASSIR units was progressively introduced from 2011 onwards throughout the primary care area of the Catalan public health network. A series of steps were followed:

1. Incorporation of the provision of medical abortion (CatSalut) into the Catalan public health system's service portfolio.

2. Processing of the accreditation of Catalan ASSIR centres for medical abortions (DS).

3. Specific training for professionals at ASSIR centres who had to apply the medical abortion protocol (IES).

4. Presentation of the model of medical abortion provision to regional health sectors: health regions, ASSIR units, public network hospitals, primary care centres (DS and CatSalut).

5. Training of health professionals involved and related with medical abortion in the different regions (IES).

6. Incorporation of "061 CatSalut Respon" telephone assistance into the continuity of care involved in the provision of medical abortions, and training of professionals who carry out this task (IES).

7. To implement the Law in Catalonia, CatSalut created Instruction 02/2012.[22] The Instruction establishes the model and pathways of care to ensure continuity in all of the healthcare facilities involved: primary care, ASSIR, 061 CatSalut Respon, clinics contracted to carry out TOP, pharmacy services, public hospitals and centres that provide sexual health and reproductive care for young people, that are either contracted by or have an agreement with CatSalut.

5. Current situation

Currently, the abortion care model defined for Catalonia involves the entire public and private network, and specifies the service portfolio and level of resolution of each facility. CatSalut Instruction 2/2012[22] defined the provision of abortion established by the application of Law 02/2010. It was amended in 2013,[23] and the referral pathway for abortion was updated.

The new model includes some actions that were already being carried out prior to Law 2/2010, such as the emergency contraception programme for preventing unwanted pregnancies throughout the public network. From 2009 onwards, emergency contraception has been dispensed in pharmacies without prescription.[24]

Currently, the right to a termination of pregnancy under the suppositions and requirements established by the Law is ensured through two access pathways (public and private). The publicly funded abortion care pathway is illustrated in Figure 1.

In the case of termination of pregnancy at a woman's request, public access is through Sexual and Reproductive Health Services (ASSIR) units. In the case of termination of pregnancy for

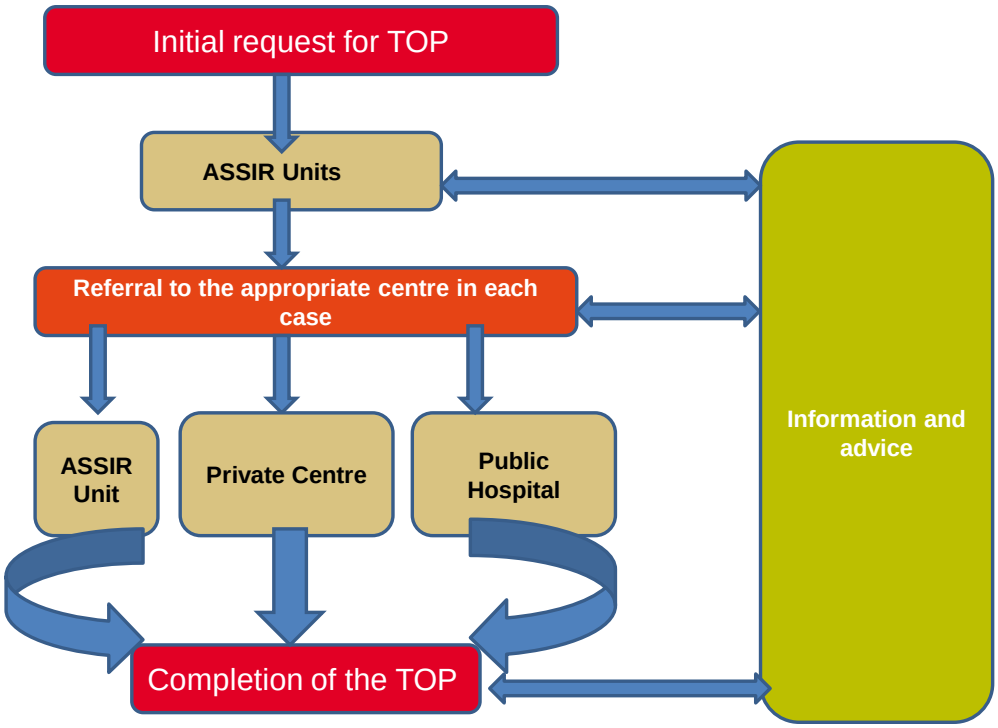
medical reasons, care is preferentially provided at a referral hospital within the Catalan Public Hospital Network (XHUP), depending on the complexity of the case and the resulting requirements.

In the private access pathway, a woman directly approaches a health centre that is authorised for termination of pregnancy and she covers the costs of the procedure.

A woman who requests termination of pregnancy (TOP) should always be directed to the ASSIR units that support primary care. In these units, she will be given information and advice on TOP and will be referred to the most appropriate centre in each case.

All women who wish to undergo a TOP must be given information on the different methods available, the conditions envisaged by the Law, the public and accredited centres that the woman can approach, and the service provision and cover provided by the public health service. The TOP must be carried out in an authorized centre, in accordance with the services available in the region. In all cases, once the termination method has been selected with the advice of a healthcare professional, informed consent must be obtained from the woman before the procedure can be undertaken.

Figure 1. Summary of the care pathway for publicly funded abortion



In cases of TOP on request (Article 14 of Organic Law 2/2010), the woman must be informed of the rights, public benefits and assistance available to support maternity, in the terms established in Sections 2 and 4 of Article 17 of Organic Law 2/2010. The information must be clear, objective and understandable. The woman must be given a sealed envelope containing printed information on the public aid available for pregnant women and on health cover during pregnancy and birth; workers' rights associated with pregnancy and maternity; benefits, tax benefits and other relevant information on incentives and financial aid to support the birth of infants; details of centres where information can be received on contraceptives and safe sex; and finally details of centres where the woman can receive advice before and after a TOP.[25 26 27] Once a woman has received the information and the sealed envelope, at least three days must pass before the procedure.

If the woman chooses a surgical termination, the ASSIR units must submit the usual referral form to the public hospital or private clinic contracted by Catsalut, indicating the number of weeks of gestation and the date of the last period.

In the case of TOP for medical reasons concerning the fetus up to twenty-two weeks of gestation – Article 15 b) of the Law – the pathway may be a little different. The woman must be informed in writing of the rights, public benefits and assistance available to support disabled people.[28] Once the woman has received the information, she will be referred to a SISCAT (Integrated Public Health System of Catalonia) hospital, preferably.

In the case of TOP due to fetal abnormalities that are incompatible with life, when this is stated in a report that has been issued by a specialist other than the doctor who will carry out the procedure, or when an extremely serious disease is detected in the fetus that is incurable at the time of diagnosis and this is confirmed by a clinical committee, the health service that detected the fetal abnormality or disease shall provide care for the woman and refer her preferably to a SISCAT hospital. If required, the clinical committee will be formed to issue the corresponding report.

CatSalut Instruction 7/2010[29] refers to actions related to the introduction in the CatSalut area of provisions related to the clinical committee, as envisaged in Organic Law OL 2/2010 of 3 March. Subsequently, the DS published two resolutions on what constitutes a clinical committee[30] and on how doctors on this committee should be appointed.[31]

6. Register on Voluntary Termination of Pregnancy in Catalonia

All terminations of pregnancy that are carried out in authorized public and private health centres in Catalonia,[32] regardless of the woman's place of residence, must be entered into the Register on Voluntary Termination of Pregnancy in Catalonia. The aim of this register is to provide data for official statistics of Catalonia and for epidemiological studies, according to Catalan legislation (Order of 10 December 1986)[33], and Law 12/1989 of 9 May on the public statistical function.[34] The register includes information on all TOP carried out in Catalonia since 1987.

Data are anonymous, and are gathered on the characteristics of women who undertake a TOP in Catalonia, the clinical circumstances and the procedures used. Subsequently, this information is included in abortion statistics compiled by the Spanish Ministry of Health, Social Services and Equality, in accordance with the procedure established in the Resolution of 27 July 2007[35] by the General Secretariat for Public Health.

Up to 2008, data were gathered in an anonymous, confidential printed questionnaire for each TOP. In 2008, the application IVE.NET was launched, which enabled centres to access the TOP Register online, securely and with assurances of confidentiality. This system also enables data input errors to be detected simultaneously. Most of the centres have progressively incorporated the online declaration of data. In 2013, over 90% of centres made their TOP declarations in this way.

The statistical information is published in reports by the DS[36] and the Spanish Ministry of Health, Social Services and Equality.[37] The reports include a description of the procedure, grouped according to characteristics of the women and by region. They can be accessed through the two institutions' websites.

7. Summary of statistical data

The provision of medical abortion up to 49 days of gestation in ASSIR units of Catalonia has been introduced progressively since 2011. It has now been extended to 34 ASSIR units that currently use this TOP method, according to data from January 2014.

The following tables show how the use of medical abortion has evolved since the introduction of the new Law in 2010 and the implementation of the procedure in Catalonia in 2011.

While the total number of terminations has dropped overall, the number of TOP carried out with drug treatment has increased, and this method is now used in over a quarter of all abortions.

The medical method is the only one used in ASSIR centres (as established in their accreditation), and is already applied in over half of the terminations carried out in hospitals.

The profile of women who currently undergo medical abortions is slightly different from those who opt for surgical terminations. Women in the medical TOP group tend to live with their partners and are mainly unmarried (although there are more married women than those that undergo surgical abortions). These women have higher levels of education and there is a higher proportion of businesswomen and freelancers, with lower rates of unemployment. They have more living offspring and fewer previous terminations than women who undergo surgical abortions. They tend to have been to a public family planning centre. In relation to their country of origin, there are more women from Catalonia than in the group of women who had surgical abortions, and almost 100% are resident in Catalonia.

Table 1. Evolution in the number of TOP and the centres that carry them out. Catalonia, 2010*- 2013

	Year			
	2010*	2011	2012	2013
Total number of TOP undertaken in Catalonia	24,305	22,614	21,956	22,083
Number of TOP-M**	101	1,261	4,638	6,380
Percentage of medical abortions (mifepristone and misoprostol)	0,4	5,6	21,1	28,9
Total number of centres that carry out TOP	34	57	69	75
Number of ASSIR units	0	19	31	34

*In 2010, medical abortions involving a combination of mifepristone and misoprostol had not been introduced. Therefore, the figures refer to RU-486.

**TOP-M: medical abortions (combination of mifepristone and misoprostol).

Table 2. Evolution of TOP by method and type of centre. Catalonia, 2010*- 2013

		Year							
		2010*		**2011**		**2012**		**2013**	
Type of centre	**TOP by method**	Number	%	Number	%	Number	%	Number	%
Hospitals	Number of TOP-M**	5	0.7	44	4.7	424	45.1	1,155	63.0
	Number of TOP – other methods	764	99.3	885	95.3	517	54.9	677	37.0
	Total	769	100.0	929	100.0	941	100.0	1,832	100.0
Outpatient centres	Number of TOP-M**	96	0.4	5	0.0	54	0.3	76	0.5
	Number of TOP – other methods	23,440	99.6	20,463	100.0	16,801	99.7	15,021	99.5
	Total	23,536	100.0	20,468	100.0	16,855	100.0	15,097	100.0
ASSIR units	Number of TOP-M**	0	0	1,212	99.6	4,160	100.0	5,149	99.9
	Number of TOP – other methods	0	0	5	0.4	0	0	5	0.1
	Total	0	0	1,217	100.0	4,160	100.0	5,154	100.0

*In 2010, medical abortions involving a combination of mifepristone and misoprostol had not been introduced. Therefore, the figures refer to RU-486.

**TOP-M: Medical abortions (combination of mifepristone and misoprostol).

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