

Implementation of Medical Abortion in Norway 1998-2013

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Elephant in the Dark

Some Hindus have an elephant to show.
No one here has ever seen an elephant.
They bring it at night to a dark room.

One by one, we go in the dark and come out
saying how we experience the animal.
One of us happens to touch the trunk.
“A water-pipe kind of creature.”

Another, the ear. “A very strong, always moving
back and forth, fan-animal.”
Another, the leg. “I find it still,
like a column on a temple.”
Another touches the curved back.
“A leathery throne.”

Another, the cleverest, feels the tusk.
“A rounded sword made of porcelain.”
He’s proud of his description.
Each of us touches one place
and understands the whole in that way.
The palm and the fingers feeling in the dark are
how the senses explore the reality of the elephant.

If each of us held a candle there,
and if we went in together,
we could see it.

(Rumi, 13th century Iran)

Scientific environment

This PhD project has been performed at the Department of Clinical Science at the University of Bergen, the Department of Obstetrics and Gynecology at Haukeland University Hospital in Bergen. Professor Line Bjørge has been my main supervisor and Professor Ole-Erik Iversen has been my co-supervisor.

Professor Line Bjørge, Medical Director of the Gynaecologic Cancer Unit at the Department of Obstetrics and Gynaecology at Haukeland University Hospital in Bergen, has experience with management of translational research projects focusing on both targeted therapy and genetic profiling of multicomplex disorders. She is also part of the Bergen Gynaecologic Cancer Research Group at the University of Bergen, which for several years has created a solid foundation in Bergen for translational research of gynaecological cancer.

Professor Ole-Erik Iversen, senior consultant at the Department of Obstetrics and Gynaecology at Haukeland University Hospital in Bergen and Department of Clinical Science at the University of Bergen, has through the last decade build up a large research portfolio on epidemiology of HPV infection and established a separate research unit for clinical HPV vaccine trials.

The project has been cooperation between Line Bjørge, Ole-Erik Iversen and Mette Løkeland. Introduction of medical abortion to new countries after 1990 was politically obstructed in spite of the obvious medical benefits and demands from women. In Bergen, Line Bjørge and Ole Erik Iversen formed parts of the team implementing medical abortion in Norway in 1998. The treatment was first offered to women pregnant in early first trimester and was a stepwise introduction under close clinical and scientific surveillance. In 2004 Mette Løkeland was included in the team. She has been the national promoter for realizing late first trimester medical abortions and home administration of misoprostol. As the treatment protocols were introduced to more clinics in Norway the percentage of all abortions performed medically increased.

Motivated by an interest in understanding the changing national trends in abortion treatment, the hospital surveys and registry study were planned and conducted.

The main funding source has been the Department of Clinical Science at the University of Bergen and the Department of Obstetrics and Gynaecology at Haukeland University Hospital.

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First I would like to thank my supervisor Professor Line Bjørge for lots of encouragement, support and believing in me all the way through the last 10 years. She is the fastest responder I know with an enormous work capacity and dedication. Skype has been our reliable means of communication at almost any time and from anywhere in the world. I could not have asked for a better or more devoted supervisor.

Secondly I appreciate the encouragement, support and inspiration from my co-supervisor Professor Ole-Erik Iversen, who has taught me about working with the media, lobbying and pursuing one's goals.

Without the positive and welcoming help and good cooperation from the nursing staff at the Outpatient Clinic and General Gynaecology Unit, the doctors and the heads of the Department of Obstetrics and Gynaecology, Haukeland University Hospital this work would probably never have come to fruition. Together we have managed to make the transition from surgical to medical abortion while focusing on women's interests. A special thanks goes to Linda Ertzeid and Ingrid Økland, who have played an important part in this from the very start in 2005.

I would also like to thank my co-authors for important contributions in preparing the studies, collecting information and making analyses. A particular thanks to Anders Engeland and Rupali Akerkar for necessary statistical help and to Tone Bjørge for guidance into the world of epidemiology. Thank you to Yvonne M. Lopes Vaksdal and Åse Vikse for help with illustrations.

Kevin Sunde Oppegaard has been my Norwegian friend in the world of abortion research and at conferences. Thank you for lots of laughs and discussions, and for convincing me to do the Finnmark experience at Hammerfest Hospital. Finnmark makes you understand the factor of distance and nature in accessing health services.

To my colleagues at the Abortion Registry for making the data available in a good quality and believing in the project. This is just the beginning. Thank you also to my

colleagues at the Outpatient Surgical Clinic, Betanien Hospital for all the patience and support. A special thanks to Knut Hordnes for challenging me, you are always delightful to work with.

I would also like to say thank you to a group of people who have supported and inspired me on my way to this thesis. My journey into the field of abortions started with a compulsory research essay as a medical student with Johanne Sundby as my supervisor in 1999. That paper was elaborated into a pamphlet on abortion published by Kvinnefronten in 2000, supported by the Ministry of Health and distributed to schools, health centres and Departments of Obstetrics and Gynaecology in Norway. Agnete Strøm in Kvinnefronten introduced me to the International Consortium for Medical Abortion, and Marge Berer, who is the editor of Reproductive Health Matters. With Marge's conference invitations, a new world of research opened up to me.

Thank you also to my colleagues at Førde Hospital where I started my training in Obstetrics and Gynaecology in 2002, for inspiration, trust and support when I wanted to implement medical abortion at the clinic. We became the first clinic to offer home administration of misoprostol in Norway.

A special thanks to my mother Magnhild Gravdal and my neighbours Wenke Seloter (my daughter's devoted bonus grandmother) and Jo Høyer for all the help. Without the space and time you have given me to write and live I would not have coped. Thank you also to Sven Erik Vaksdal for making my life shine.

Last but not least lots of gratitude to my wonderful and cheerful daughter Agnes who always reminds me about what the important things in life are and who has been impressively patient the last few months.

Bergen, December 2014

Mette Løkeland

Abstract

Background. Medical abortion is a secure way of terminating a pregnancy. Since 1998, medical abortion with mifepristone and misoprostol has been available in Norway. During the last 16 years, the accessibility and use have increased and the treatment protocols have both been simplified and designed for different stages of gestation.

Main objectives. In this project we aimed to describe the implementation process of medical abortion and different treatment protocols in Norway during the period 1998 to 2013. Another goal was to evaluate the possible effects of the introduction on availability of abortion, access to it, and characteristics of women requesting abortion (Paper I). We introduced two treatment protocols, for home administration of misoprostol (Paper II) and late first trimester abortions (Paper III), respectively and wanted to evaluate the extent to which they were efficient and acceptable.

Materials and methods. Information on abortion procedures and year of implementation was obtained through questionnaires sent to all Departments of Obstetrics and Gynaecology in Norway in 2008 and 2012 (Paper I). To portray traits of women undergoing abortion, data from 223,692 women recorded in the Norwegian Abortion Registry who requested an abortion between 1998 and 2013 were analysed. Women undergoing medical abortion were compared to women performing surgical abortion based on characteristics of the study population (Paper I). In an observational prospective study, the implementation of home administration of misoprostol was evaluated in a cohort of 1,018 women (Paper II). Women received 200 mg mifepristone in hospital and self-administered 800 mcg misoprostol vaginally. The main outcome measures were success rate, evacuation rate, pain, bleeding, acceptability and the influence of travel distance (Paper II). A protocol for late first trimester abortions was implemented and evaluated through an observational prospective study with a cohort of 254 women. Women with a gestational age of 63–90 days were included. They received 200 mg mifepristone and were admitted as day patients in hospital after 36–48 hours, where they self-administered misoprostol

vaginally. Every 3 hours, 400 mcg misoprostol was given orally until termination, with a maximum of 5 doses. The main outcome measures were evacuation rate, induction-to-abortion interval, pain, bleeding, number of misoprostol administrations needed and acceptability (Paper III).

Results. Norwegian hospitals have rapidly introduced new treatment protocols. The use of medical abortion increased from 5.9% to 82.1% between 1998 and 2013, and by 2010, all Departments of Obstetrics and Gynaecology in Norway offered medical abortion. Waiting time from registered requests until termination was reduced from 11.3 days in 1998 to 7.3 days in 2013. More women underwent an abortion at 4–6 weeks gestation when performing a medical termination (41.6%), compared to surgical abortion (16.7%). Compared to women with no previous abortion women with repeated abortions had a lower tendency to opt for medical abortion. (Paper I). Home administration of misoprostol was found to be an effective and acceptable method for abortion up to 63 days of gestation. Travel distance did not influence the treatment outcome variables (Paper II). The percentage of hospitals offering home administration increased from 23.7% in 2008 to 92.1% in 2012. (Paper I). Medical abortion was shown to be an effective method for termination of pregnancy in late first trimester, and it was found to be acceptable to Norwegian women (Paper III). We found an increased prevalence of hospitals offering this method from 23.7% in 2008 to 84.4% in 2012 (Paper I).

Conclusions. Norway has experienced an almost complete change in abortion treatment from surgical to predominantly medical between 1998 and 2013. Women access abortion at an earlier gestational age with the medical method compared to surgical, and waiting time between request and termination has been reduced by 35% (Paper I). Knowledge and experience received through the implementations of both late first trimester abortions and home use of misoprostol in early first trimester, unrestricted by travel distance (Papers II and III), have resulted in the availability of expanded treatment portfolios in most hospitals.

List of publications

- I. Løkeland, M., Bjørge, T., Iversen, O.E., Akerkar, R., Bjørge, L.: Implementing medical abortion with mifepristone and misoprostol in Norway 1998–2013. Submitted.
- II. Løkeland, M., Iversen, O.E., Engeland, A., Økland, I., Bjørge, L.: Medical abortion with home administration of misoprostol up to 63 days gestation. *Acta Obstet Gynecol Scand.* 2014; 93:647–53.
- III. Løkeland, M., Iversen, O.E., Ertzeid, L., Nappen, M.H., Dahle, G., Bjørge, L.: Medical abortion at 63–90 days of gestation. *Obstet Gynecol.* 2010; 115:962–68.

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Reprint of Publication III was made with permission from Obstetrics & Gynecology, the American College of Obstetricians and Gynecologists and Wolters Kluwer Health Lippincott Williams & Wilkins.

List of abbreviations

CRL	Crown-rump-length
CS	Caesarean section
EEA	European Economic Agreement
GP	General practitioner
HS	High sensitive
Mcg	Microgram
Mg	Milligram
NHS	National Health Services
NSOG	Norwegian Society of Obstetrics and Gynaecology
OR	Odds ratio
s-hCG	Serum- human Chorionic Gonadotropin
SPSS	Statistical Package for the Social Sciences
TOP	Termination of pregnancy
UK	The United Kingdom
UPT	Urine pregnancy test
USA	The United States of America
WHO	World Health Organization

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	What is already known	What is added by this study
Paper I	Through a systematic literature search we didn't find any studies presenting a complete national overview comparing characteristics of women performing medical and surgical abortion. Only one prevalence study of abortion protocols to all clinics. This study from the Netherlands found low uptake of medical abortion and few protocols following international guidelines. Abortion surveillance data are available from some countries, but few of them are complete.	Norway experienced an almost complete transformation in abortion treatment after the introduction of medical abortion in 1998. In 2013 82.1% of all abortions were completed medically. Women who opt for medical abortion perform their abortions significantly earlier in pregnancy than women choosing surgical abortion. The rate of abortions performed within 9 weeks gestation has increased from 44% in 1998 to 77.8% in 2013. Waiting time has dropped from 11.3 days in 1998 to 7.3 days in 2013. Norwegian hospitals offer treatment protocols in line with national and international guidelines.
Paper II	Home administration of misoprostol is acceptable to women and is equally efficient as hospital treatment. Many studies include travel limitations.	Efficacy of home administration of misoprostol was found to be identical to hospital treatment. High acceptability was confirmed by 95.1% of the women being content with home administration and this treatment option becoming the preferred method. We found no medical reasons to impose travel restrictions.
Paper III	A limited number of studies have been published on women performing abortion in late first trimester with mifepristone and misoprostol. Complete abortion rate is approximately 95% and acceptability is high. Number of misoprostol needed and induction-to-abortion time increase with gestation.	Late first trimester abortion was implemented as a treatment alternative. The rate of complete abortions in our study was 91.7%. Neither the number of misoprostol administrations needed nor induction-to-abortion time were dependent on gestational age. Serum-hCG can be used together with direct inspection of pregnancy products to confirm termination.

1. Introduction

“Why extremists always focus on women remains a mystery to me. But they all seem to. It doesn’t matter what country they’re in or what religion they claim. They all want to control women,” (Hillary Clinton, World Summit, New York 2012)

Termination of pregnancy is a frequently used procedure within the field of reproductive health. Despite this no other medical practice has the same political potency and is as controversial as abortion (1). Even though it is a minor procedure, it is one of the most frequent causes of maternal mortality and morbidity in the world (2). This is due to unsafe abortions in illegal settings, where access is restrictive or the health services are poor, concerning equipment, health personnel and knowledge (3, 4). This again results in unsafe abortion being a neglected global public health challenge mainly affecting women in the developing world (4). To diminish access to abortions, further restrictions like mandatory counselling, waiting time; who can offer abortion and where and when, have been introduced in the developed world (5). Deaths caused by unsafe abortion have been reduced from 69,000 in 1990 to 47,000 in 2008. This reduction is due in part to a replacement of unsafe surgical methods with medical abortion for illegal abortions particularly in Latin America and the Caribbean (2). World Health Organization (WHO) recommends abortion to be made available at the lowest appropriate level possible within the health system (6). Studies have shown that both manual vacuum aspiration and medical abortion are equally efficient and acceptable provided by mid-level health providers as well as by doctors up to nine weeks gestation (7–9). Surgical abortion requires more training and knowledge by health personnel to be safe and efficient (10). It is necessary for any abortion service to have access to and knowledge of surgical procedures in case of incomplete abortions, but at the same time, increased knowledge about and access to mifepristone and misoprostol could help further reduce maternal mortality. In places where the number of health providers is low, medical abortion could improve access to abortion. The process of scaling up access to abortion after liberalization of the abortion law in 2002 in Nepal is an important model for other developing countries that want to increase availability (11). The difficult landscape in

many remote and rural areas, and a lack of providers to perform safe surgery, limited access, and the Nepalese Government therefore decided to include medical abortion in the treatment portfolio (11).

The combination of mifepristone and misoprostol for medical abortion has been available since 1988. The use and efficacy for this combination treatment is thoroughly documented for use up to nine weeks gestation (12). Mifepristone and misoprostol have been made available in a growing number of countries since 1988 (Figure 1). The procedure has also been modified and introduced for both late first trimester and second trimester abortion (13–15). In 2005, WHO placed the combination of mifepristone and misoprostol for termination of pregnancy on its list of essential drugs (16).

1.1 International history of medical abortion

Mifepristone (RU-486) is an antiprogesteron and antiglucocorticosteroid (17) that was developed by Étienne-Émile Baulieu and other scientists while working for the French company Roussel-Uclaf in the early 1980s (18). It showed remarkable effect as an abortifacient and was introduced to the French market for that indication in 1988 (18). Due to controversies and pressure on Roussel-Uclaf by antiabortionists, the company wanted to withdraw mifepristone from the market. However, Roussel-Uclaf was put under pressure by the French government, which demanded that mifepristone was made available to women (18). The French government expressed that *"RU-486 is also the moral property of women"* (19). Mifepristone was only registered in a few countries until Roussel-Uclaf transferred the patent to the company Exelgyn, founded by the former chief executive of Roussel-Uclaf, Edouard Sakiz, in 1997 (20). Exelgyn was given the patent rights for use worldwide, except for the USA market, where the patent was transferred to The Population Council (19). Exelgyn produces only mifepristone and misoprostol and is consequently less vulnerable to sanctions. Mifepristone was registered for use in the United Kingdom in 1991 and Sweden in 1992 (19). In China, mifepristone was approved for medical abortion in 1986. China

has manufactured mifepristone without licence from Roussel-Uclaf (21). In 2013 mifepristone was registered in 60 countries (Figure 1). Though mifepristone-only can cause abortion, the efficacy is much lower than when used in combination with a prostaglandin analogue, only 60–80%, in comparison to 95% (1) (See also paragraphs 1.5 and 1.6). Misoprostol as a single drug for termination of pregnancy is used in many parts of the world, particularly in illegal settings where mifepristone is not registered (1). Efficacy for the misoprostol-only regimen is about 90% (1). Recommendations are to use mifepristone with the prostaglandin analogue misoprostol (12).

Unfortunately, prenatal exposure to misoprostol, in high dosages, is associated with an elevated risk for defined congenital malformations (22). Anomalies have not been identified after mifepristone use (23, 24).

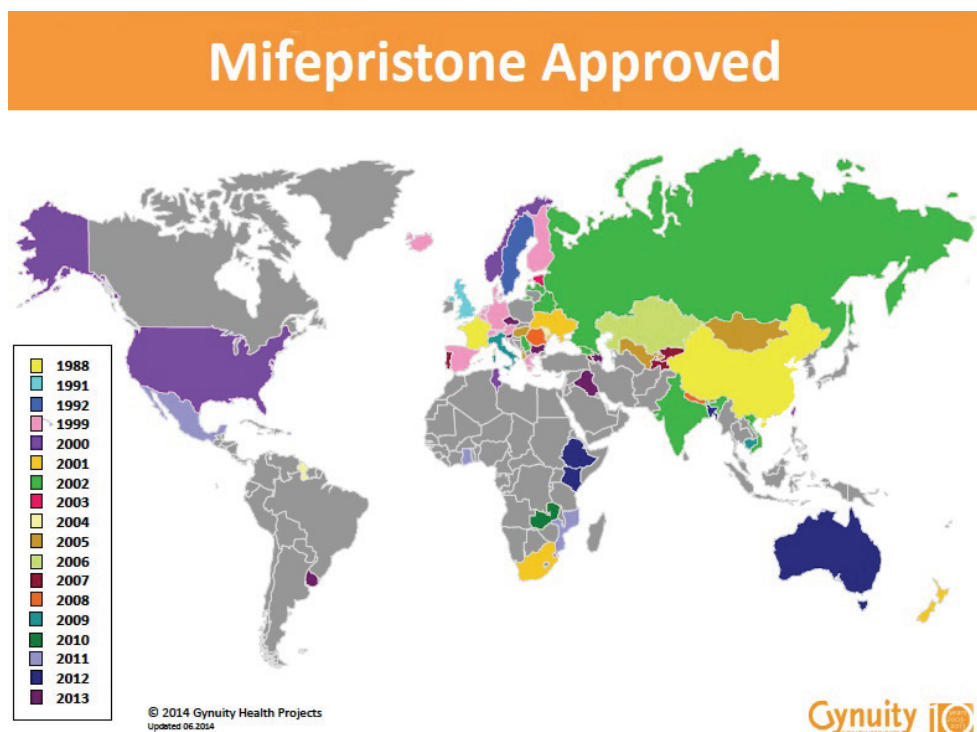


Figure 1. Map of mifepristone approvals (www.gynuity.org).

1.2 Norwegian history of medical abortion

Norway has had abortion on request up to 12 weeks gestation, according to the Norwegian Abortion Act, since 1979 (25). Abortion is completely free of charge and available at every hospital with a Department of Obstetrics and Gynaecology. According to the law, only doctors are entitled to perform abortions. The County Governor can approve facilities outside of hospital to perform abortions (25). In Norway, the first clinical trial with mifepristone was initially planned in 1989 at Ullevål University Hospital, Oslo. The Christian Democratic Party filed a proposal in Parliament to ban mifepristone from the Norwegian market. Before Parliament managed to deal with the “*mifepristone case*”, Roussel-Uclaf withdrew their suggested registration of mifepristone in Norway. Parliament for its part saw no reason not to allow the use (26). Although gynaecologists and the medical profession in general have been positive to the introduction and use of mifepristone, it has taken time to increase the accessibility. The European Economic Area (EEA) agreement that facilitated the access to drugs available in other EEA countries was put into action in 1994. Together with the establishment of Exelgyn in 1997, this enabled the introduction of mifepristone to Norway in 1998. The first hospital to introduce the combination of mifepristone and misoprostol for early first trimester abortion was Haukeland University Hospital, rapidly followed by two other university hospitals within the same year (Paper I). Mifepristone was registered for use in Norway in January 2001 (27), and Bjørge et al. published the first experience of medical abortion in Norway in 2001 (28). Home administration of misoprostol was introduced at the regional hospital in Førde in 2003. Only when the university hospitals Ullevål University Hospital and Haukeland University hospital introduced the possibility of home administration in 2005 (29) and 2006 (paper II), respectively, focus in the media led to a political reaction (30). A proposal to ban home administration of misoprostol, on the grounds that women should not be left alone with the possible emotional side effects an abortion could have, was made in Parliament by three parliamentarians (31). Their proposal was defeated, but resulted in a review made by the Directorate of Health (32). This report found home administration to be safe, efficient and preferred by many women. The conclusion was that the procedure should be offered as an option (32). Until

2008 surgical abortion was the most common procedure for terminations of pregnancies. Since 2008 the use of medical abortion has rapidly increased to 82.1% of all abortion performed medically in 2013 (33, Paper I).

In 2010 the Government allocated money in the National Budget for a pilot project where medical abortion could be offered by gynaecologists in outpatient clinics (34). The project started in 2012, run by the Directorate of Health (35), and the treatment option will be introduced early 2015.

1.3 Access

Worldwide access to abortion is dependent on many factors. First of all, safe abortion is dependent on national laws, and if these are restrictive, give access according to broad medical and social indications, or on request. On the other hand, laws are subject to interpretation, and there might be discrepancies between the wordings of the laws (*de jure*) and how they are applied (*de facto*) (36). Laws and regulations also restrict access to abortion through limiting when and where the procedures can be performed and by whom. Travel and abortion fees are limiting factors for women with few economic resources. Waiting time, mandatory counselling, and the right to conscientious objection are other factors that can reduce availability. Several of these factors have been affected by the implementation of medical abortion and some have been subject to political discussions (31, 37).

1.3.1 When

The Norwegian Abortion Act is fairly liberal compared to most other national laws. Women have the right to abortion on request up to 12 weeks gestation. After 12 weeks, women need the permission from a commission of two doctors to legalize a termination. Abortion is not to be permitted if the foetus is viable, except if the woman's life is at risk (25). A Public Hearing currently ongoing, from the Minister of

Health, suggests limiting abortion upwards to 21 weeks and 6 days (38, 39). The Norwegian law favours early abortion and is more restrictive to abortions after 12 weeks gestation. In comparison the Swedish law has abortion on request up to 18 weeks gestation (40), the English law has an upper limit of 24 weeks (41) and in the USA, there is no upper legal limit at national level, but different policies at state level (42).

1.3.2 Where

As mentioned, every hospital with a Department of Obstetrics and Gynaecology (Figure 2) are obliged to offer the procedure. Abortion should take place in hospitals, but the law includes a possibility for exceptions to the general rule. The County Governor can, as already mentioned, give permission for abortion to be carried out in other facilities (25). This exception was adopted in 2014 and makes it possible for gynaecologists in outpatient clinics to carry out medical abortions (see also paragraph 1.2) (35). Home administration of misoprostol complies with the law as long as mifepristone is taken under observation at the health facility supervising the treatment.



Figure 2. *Distribution of hospitals performing abortions in Norway*

Some politicians have even voiced the possibility of abortion being performed by general practitioners (GP) (43). That would increase accessibility even further, and be in line with WHO recommendations that abortion should be available at the lowest appropriate level possible (6). Figure 3 illustrates three different scenarios for access to medical abortion in the Norwegian region Finnmark.

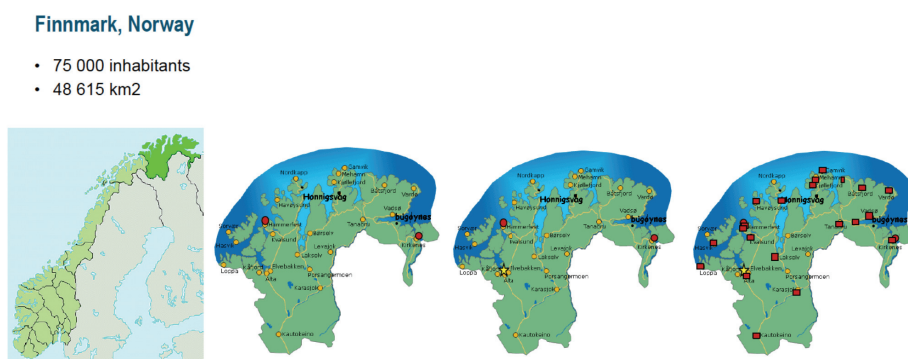


Figure 3. *Three scenarios for distribution of abortion treatment in Finnmark, Norway. 1. Hospital (current situation 2014) (red dot), 2. Gynaecologists (yellow dot), 3. General practitioners/primary health care (red box)*

1.3.3 Who

Only physicians are entitled to perform abortions according to the law, but the law does not prohibit delegation under supervision to other health professionals. Throughout the country, nurses have an increasingly important role in abortion treatment. In many hospitals they do counselling, hand out medication, care for women having the treatment in hospital and do telephone interviews for check-ups and controls. Medical doctors have commonly conducted the ultrasound for pregnancy confirmation and the determination of gestational length, and they prescribe the medication or perform the surgical abortion. A similar development in the abortion services has also been seen in Sweden (9).

1.3.4 Cost, counselling, conscientious objection and waiting time

A service free of charge is one of the most important factors to secure access to abortion. In Norway emergency treatment is available free of charge for everybody independent of legal citizenship status. Abortion is defined as an emergency treatment and as a consequence abortion is free of charge for everybody (44). Travel expenses are also refunded (45).

Counselling is not mandatory in Norway as in for example some other countries in Europe (46) and some states in the USA (47), but should be offered to all women as an option (25).

Health personnel in Norway have the right to conscientious objection in the case of performing or assisting during a surgical abortion or to prescribe and/or hand out the medication for medical abortion. The right to conscientious objection does not cover handling women who request an abortion, refusing to refer them or not performing an emergency surgical evacuation (25, 48). A public hospital is obliged to offer abortion services to women who request them and cannot claim a right to conscientious objection (25). These obligations stand in contrast to many other countries, where women's access is dependent on women finding a clinic or physician who is willing to perform an abortion (49). Norway witnessed a huge public debate in 2013–2014 after a proposal was raised by the Minister of Health to grant GP's the right to perform their conscientious objection according to the European Parliament Resolution 1763 (2010). After pressure and a public mass movement, the Minister of Health withdrew his proposition (37).

In some parts of the world waiting time is mandatory (46). There is no mandatory waiting time in Norway and women do not need a referral to access abortion. They can contact a hospital directly themselves. Even when there is no obligatory waiting time, women can still experience some delay. Waiting time between the making of a request for an abortion and when it is executed is highly dependent on logistics at hospital level (50, 51). Flow charts organizing and scheduling treatment determine when women are scheduled for a visit, the timing between first visit and abortion procedure,

and number of visits needed (Figure 3) (50, 51). Women prefer one single visit (51). The introduction of home administration of misoprostol has made it possible to reduce the number of visits.

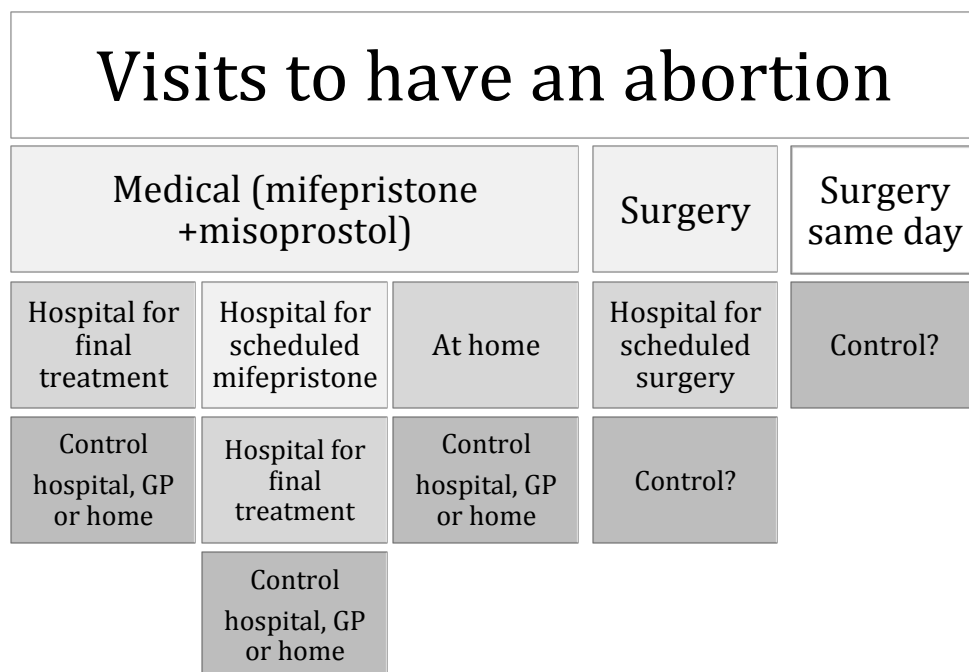


Figure 4. Number of visits to have an abortion with different protocols

1.4 Choice

Today a more informative model has replaced a paternalistic doctor-patient relationship. Patient autonomy equals the right to information and choice based on personal preference and has in some ways placed patients in the role of consumers (52, 53). The right to a choice is presented as an undivided positive opportunity and necessity (54). In psychological research on consumerism, one finds that people routinely violate so-called rational choices (55). To choose is not always easy. You might not always know if you made the right choice and if you regret your choice you

only have yourself to blame (55). Different personalities behave differently when it comes to choice and research has demonstrated that people who are more arbitrary towards choice and are happy with “*good enough*” the so called “*satisficers*” are happier than those who always want “*the best*”, the “*maximizers*” (55).

Knowledge about the importance of choice of abortion methods or other health treatments is low compared to studies on consumerism. A study from the United Kingdom (UK) in 1993 found that 54% had no preference and were willing to be randomised between surgical and medical abortion (56). Acceptability was high in all treatment groups, but slightly higher among women who were not randomised (56), and this was confirmed in a two-year follow-up study of the same population (57). They maintained a higher preference for vacuum aspiration and 69% rated the possibility of choice as very important (57). In comparison, the first study on medical abortion from Norway found that 69% of the women who opted for medical abortion and agreed to participate in the study were not willing to be randomised (28).

The question of choice probably holds a particularly strong importance regarding every aspect of abortion and abortion methods due to controversies surrounding abortion and its political arguments based on “*pro-choice*” (54). The question of maternal request for caesarean sections (CS) is an increasingly controversial issue that could be comparable to choice of abortion method (53). In a study from the UK following pregnant women and their preferred mode of delivery, the study found that even though most women supported the right to choose, they were uncomfortable with making the choice themselves. Women felt that health concerns were more important than choice, and that health professionals should have the final say providing the best health option. This tendency increased as the pregnancy developed (53).

A general principle is to use a less or non-invasive procedure if the conservative treatment is equally effective and acceptable or more than surgery. Minimal invasive procedures replace surgery to improve patient safety in many fields of medicine. After a time of building experience and skills, the new, less invasive and more cost-efficient procedure replaces the former procedures without question of patient choice. Many

Norwegian hospitals have decided that their method of preference is medical abortion independent of gestational age. This does not eliminate the access to surgical abortion, but women have to make an active request to obtain vacuum aspiration. This treatment practice has also been defended by the Norwegian Minister of Health (58).

Accumulating knowledge is a dynamic process. Opinion is modulated by information and experience and it is not always easy to define a preference. Most women also realize that health personnel are the experts in their field and want their guidance. At the same time as we recognize and respect individual preferences and interests, we have to evaluate if decision-making as we are used to think of it in consumerism is valid in a health setting.

1.5 Dosage of mifepristone

The first report on mifepristone as an abortifacient was published in 1982 (59). Initial studies administered mifepristone alone in repeated doses of 10–150 mg twice a day over a period of four to seven days (59-61). With an efficacy of 60–80% it did not offer a real alternative to prostaglandin only or vacuum aspiration (59, 62) until studies combining mifepristone in a single dose and a prostaglandin analogue revealed an efficacy of about 95% (59, 63). These results provided the basis for a protocol consisting of 600 mg mifepristone combined with a prostaglandin analogue (1, 59) (See also paragraph 1.2). The first Norwegian treatment protocol introduced in 1998 consisted of 600 mg mifepristone in combination with 800 mcg misoprostol vaginally (28). Since the early start of medical abortion, research has been performed to find the minimal effective dose of mifepristone and the most appropriate dose, type and administration form of prostaglandins to minimize side effects. A WHO randomised controlled trial found 200 mg mifepristone to be equally effective as 600 mg when combined with a prostaglandin (64), while a reduction to 50 mg mifepristone resulted in lower efficacy and was not recommended (65). Lowering the dose of mifepristone

to 100 mg was found to be promising in a WHO randomised equivalence trial (66). The recommendation in Norway is 200 mg mifepristone for all gestations (67, 68).

1.6 Administration of misoprostol

In the early protocols for medical abortion, mifepristone was commonly used together with the prostaglandin analogues gemeprost and misoprostol. Gemeprost was used through the vaginal route, and misoprostol orally. Gemeprost was registered for use up to 63 days gestation in Sweden and the UK and misoprostol was registered up to 49 days gestation in France and the USA (1). Misoprostol has reduced effect after 49 days gestation when used orally (1). Gemeprost is more expensive and unstable at room temperature in comparison to misoprostol and therefore less useful in all settings and particularly in the developing world. This has led to research establishing administration protocols for misoprostol with equal efficacy to gemeprost (69, 70). El Rafaey et al. identified as early as in 1995 that vaginal administration of 800 mcg misoprostol had higher efficacy and fewer side effects than 800 mcg misoprostol orally (Table 1) (70).

	Mifepristone 600 mg		Mifepristone 200 mg	
	Oral N=130 (%)	Vaginal N=133 (%)	Gemeprost 0.5 mg N=453 (%)	Misoprostol 0.8 mg N=457 (%)
Complete abortion	113 (87)	126 (95)	436 (96.2)	451 (98.7)
Incomplete	8 (6)	6 (4)	9 (2.0)	5 (1.1)
Ongoing pregnancy	9 (7)	1 (1)	8 (1.8)	1 (0.2)

Table 1. *Mifepristone with oral or vaginal misoprostol and mifepristone with vaginal gemeprost or misoprostol (69,70)*

With increasing gestational age, higher total doses of misoprostol are needed. Treatment protocols for late first trimester abortions and second trimester abortions include additional doses of misoprostol (13-15). A lower success rate for abortions after 56 days gestation is also observed and has prompted the addition of 400 mcg misoprostol offered for abortions up to 63 days gestation that have not been expelled within four hours (71-73).

Common side effects of prostaglandins are mainly gastrointestinal like nausea and diarrhoea (12, 62, 69, 70). A number of studies have experimented with different routes of administration to reduce unwanted side effects, increase success rate and improve acceptability (12, 62).

Pharmacokinetic studies have found a rapid increase in serum concentration after sublingual and oral administration and a more prolonged increase after vaginal use, while sublingual and vaginal use maintains a higher concentration after two hours. This correlated with higher uterine contractility after two hours following sublingual and vaginal use and more side effects after oral and sublingual administration (74, 75). Although buccal and sublingual administrations show similar success rates to vaginal use, the number of side effects is less for the vaginal administration route. (12, 62). In the revised Norwegian national guidelines, vaginal administration will be recommended with buccal use as an alternative to oral administration for repeat dosages of misoprostol (67).

To improve flexibility for women requesting abortion different intervals of 0–72 hours between mifepristone and misoprostol have been analysed (71, 76). Even though it is shown that maximum contractility is achieved 36–48 hours after mifepristone intake (77), several studies find no statistically significant difference in efficacy when misoprostol is administered at shorter intervals (71, 76). There seem to be some limits though. In the review by Wedsinghe et al. (76), efficacy for the treatment was lower when the intervals between mifepristone and misoprostol became shorter than eight hours and in a review by Raymond et al. they found reduced efficacy when the interval was shorter than 24 hours (71).

1.7 Follow-up protocols

Control procedures have seldom, if ever, been included in surgical abortion protocols. Robust systems for follow-up to identify failures have on the other hand been included in medical method protocols (78). Depending on the protocol used and gestational age, the failure rate is described to be in the range of 0.3%–3% (72, 78, 79). The low incidence rates make it difficult to evaluate the different follow-up procedures (78). Routine follow-up after a medical abortion included initially a clinical exam with or without vaginal ultrasound examination (78) and this has later often been referred to as “*the golden standard*”. The use of ultrasound and extra visits is neither cost- and time-efficient to the women nor to the health personnel (78). Therefore to increase access and simplify the medical abortion protocols in use, several other options for follow-up have been introduced and evaluated (78).

Although studies have found that women are fairly accurate at determining themselves whether the abortion has been successful or not (78, 80, 81), the accuracy is too low for self-assessment to be recommended as the only method. Use of s-hCG has the least false negatives. Commonly s-hCG levels at the time of mifepristone intake would be compared with s-hCG 6–28 days later as a reference for control (14, 82, 83). A decline in s-hCG of more than 80% or below a cut of value could be used as a marker of success (14, 82, 83). A drawback with this form of follow-up is the need for additional visits. Urine pregnancy tests (UPT) are becoming increasingly popular (Paper I). Women prefer the option of self-assessment with UPT to clinical exam (79). Unfortunately there is a risk of false negatives following the use of UPT (78, 79). Studies on the use of a combination of high and low sensitive u-hCG tests, self-assessment and telephone interviews show promising results (79, 84). Haukeland University Hospital has introduced a three step follow-up protocol starting with a high sensitive (HS) UPT (Figure 5).

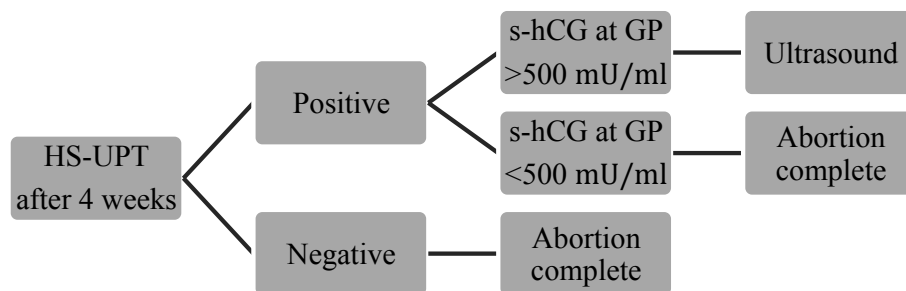


Figure 5. Follow-up protocol at Haukeland University Hospital

Endometrial thickness is not a good marker for surgical intervention following medical abortion (14, 82, 83), and several studies indicate that the rate of surgical evacuation is reduced with accumulated experience (1). A further reduction of unnecessary surgical interventions might be accomplished if ultrasound examination is left out of follow-up protocols (14, 64, 82, 83).

1.8 Home administration of misoprostol

Home administration of misoprostol is the most common procedure for medical abortion up to nine weeks gestation in the USA (85). In Europe the story has been slightly different. Except for Scandinavia, the access to home administration of misoprostol has been more restricted. Restrictions upward to a gestational age of 49 days, limitations on travelling time from the provider or complete prohibition of home administration reduce access (72, 86, 87). As many women prefer one single visit (51), the use of home administration for abortions at higher gestational ages has also been suggested. Recent publications have shown this to be an acceptable and efficient alternative up to 70 days gestation (88, 89). One study has also found home administration up to 12 weeks gestation to be tolerable (90).

1.9 Late first trimester medical abortions

Medical abortion for use up to nine weeks is well-documented through multiple studies including two Cochrane reviews (12). Already in 1998 Ashok et al. published a study of 298 women with a gestational age 9–13 undergoing medical abortion (91). Even though the study showed satisfactory results in line with results for medical abortion up to nine weeks gestation, medical abortion for this gestational age has not reached the same common use for termination of pregnancy. Through systematic literature search using the keywords mifepristone, misoprostol, medical abortion, 9–13, 9–12, 63–84, 63–90 and 63–91, we have been able to identify 14 studies on late first trimester abortions (Table 2). The research group in Aberdeen has authored six of them.

It has previously been found, as mentioned, that 200 mg mifepristone shows equal efficacy as 600 mg for medical abortion up to nine weeks gestation (12). In 12 out of 14 studies, women received 200 mg mifepristone with success rates equal to the study using 600 mg mifepristone, and similar to those documented in early first trimester abortions (12). One study used 200 mg mifepristone followed by repeat doses of gemeprost vaginally (92). The results of that regimen were equal to the combination of mifepristone followed by 800 mcg misoprostol vaginally and repeat doses of 400 mcg misoprostol until completion, which was used in 11/14 studies.

One study randomised between 200 mg mifepristone followed by either 800 mcg misoprostol vaginally or 600 mcg sublingually, and repeat doses of misoprostol if necessary. They found equal efficacy and acceptability between the two methods but more side effects of nausea and diarrhoea with the sublingual group (93). The two studies with misoprostol only (90, 94), and the combination of 200 mg mifepristone followed by 400 mcg misoprostol orally (90), had a lower success rate than the other studies.

Author	Place	Year	Included women (N)	Gestational age	Treatment protocol	Success rate
Ashok et al. (91)	Aberdeen, UK	1998	120	9–13 weeks	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal), repeat misoprostol 400 mcg	95%
Gouk et al. (95)	Middlesbrough, UK	1999	253	63–83 days	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal)	94.5%
Carbonell et al. (94)	Valencia, Spain	2001	150	9–12 weeks	800 mcg misoprostol vaginally (+ max extra 3 doses)	84.0%
Vyjayanthi et al. (92)	Carmarthen, UK	2002	25	9–12 weeks	Mifepristone + gemeprost (48 h, vag) max 5 doses gemeprost	96%
Ashok et al. (96)	Aberdeen, UK	2002	486	10–13 weeks	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal) repeat 400 mcg misoprostol. Randomised between medical and surgical	94.6% (MA) 97.9% (SA)
Hamoda et al. (97)	Aberdeen, UK	2003	483	64–91 days	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal) Repeat 400 mcg misoprostol	94.8%
Stewart et al. (98)	Sheffield, UK	2003	415	63–84 days	200mg mifepristone + 800 mcg misoprostol (48 h, vaginal). Repeat 400 mcg misoprostol	96%
Largeaud et al. (99)	French Guyana (in French)	2004	105	9–14 weeks	600mg mifepristone + 800 mcg misoprostol (48-72 h, vaginal). Repeat misoprostol	92.4%
Hamoda et al. (13)	Aberdeen, UK	2005	1076	9–13 weeks	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal) Repeat 400 mcg misoprostol	95.8%

Hamoda et al. (93)	Aberdeen, UK	2005	340	9–13 weeks	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal) or 600 mcg misoprostol (36-48 h, sublingually). Repeat 400 mcg misoprostol Randomised vaginal/sublingual	98%
Ashok et al. (100)	Aberdeen, UK	2005	368	10–13 weeks	200mg mifepristone + 800 mcg misoprostol (36-48 h, vaginal). Repeat 400 mcg misoprostol. Randomised medical/surgical	Preference study
Bracken et al. (101)	US, Vietnam, India	2007	321	64–84 days	200mg mifepristone + 800 mcg misoprostol (24-48 h, vaginal). Repeat 400 mcg misoprostol	89%
Dalenda et al. (90)	Tunis, Tunisia	2010	122	9–12 weeks	1. 200mg mifepristone + 400 mcg misoprostol (48h, oral) + 400 mcg misoprostol. 2. 800 mcg misoprostol (vaginal) + 400 mcg misoprostol	80.8% 77.4%
Løkeland et al. (14)	Bergen, Norway	2010	254	63–90 days	200mg mifepristone + 800mcg misoprostol (36-48h, vaginal). Repeat 400 mcg misoprostol	91.7%

Table 2. *Studies on late first trimester abortions presented with author, place, year, population, gestational age, treatment protocol and success rate*

Seven of the studies focusing on efficacy of the method also include measures of acceptability (acceptability of side effects, preference for future method and recommendation to others) (14, 90, 91, 93, 100, 101). They all found a high rate of acceptability, and all studies conclude that medical abortion in late first trimester should be offered as an option to women. The group from Aberdeen has also published a partially randomised patient preference study comparing medical and surgical

abortion at 10–13 weeks gestation. In this study the majority of the women would choose the same procedure for a new abortion if needed, and the preference was higher if they had a prior preference for the actual procedure before having the abortion (100).

1.10 The professional environment

The Norwegian professional environment of obstetricians and gynaecologists is relatively small, which facilitates transparency and the exchange of new knowledge and experience. The annual meeting of the Norwegian Society of Obstetrics and Gynaecology (NSOG) serves as an important conference for medical discussion and presentation of new research and is together with the biannual Nordic Congress of Obstetrics and Gynaecology the most frequently visited.

NSOG was the first medical society in Norway to publish national guidelines (in 1995 (Obstetric) and 1996 (Gynaecology)). The second guidelines were published in 2004 and included medical abortion. The recommended treatment protocol was in 2004 200–600 mg mifepristone, admission to hospital and administration of 800 mcg misoprostol vaginally after 42–48 hours, up to nine weeks gestation (102). In the current guidelines from 2009 the recommended protocol is 200–600 mg mifepristone, self-administration of 800 mcg misoprostol vaginally after 42–48 hours, either at home or in hospital, up to nine weeks gestation and 200 mg mifepristone, admission to hospital after 42–48 hours and the administration of 800 mcg misoprostol followed by up to five repeat doses of 400 mcg misoprostol until termination (68).

2. Aims of the thesis

Pregnancies can be terminated safely by medical abortion at any stage of gestation (1, 103). Medical abortion with mifepristone and misoprostol has been available in Norway since 1998. During the last 16 years the availability and use have increased and the treatment protocols have both been simplified and designed for different stages of gestation. Increased availability and knowledge about medical abortion have resulted in simplified regimens. Subsequently the establishment of different therapeutic modalities has facilitated the possibility of offering more individualized treatment to Norwegian women for termination of pregnancy.

Norway is one of few countries in the world with a full national registration of all abortions conducted. Through the Abortion Registry, the possibility exists to examine possible effects the change in abortion practice, from predominantly surgical to largely medical abortions, might have had on access to abortion and on socioeconomic determinants in the abortion population.

The specific aims were:

1. To describe the implementation process and possible effects the introduction of medical abortion to Norway in 1998 to 2013 has had on access and current medical abortion practice, and to compare characteristics of women according to abortion method used (Paper I).
2. To implement and evaluate the efficacy and acceptability of medical abortion with home administration of misoprostol up to 63 days gestation (Paper II).
3. To implement and evaluate the efficacy and acceptability of medical abortion at 63 to 90 days gestation (Paper III).

3. Material and methods

3.1 Data resources and study populations

3.1.1 Hospital surveys (Paper I)

A questionnaire was sent to all hospitals performing abortion in 2008 and 2012 (Appendix 1). Names, addresses and number of hospitals were found using Helseadresser.no, a web page delivered by the Norwegian Directorate of Health (Appendix 2). There was a reduction from the original list of 40 hospitals in 2008 to 38 in 2012 due to reallocation of services. The Abortion Registry in its annual report names 34 hospitals and reports receiving data from 44 different providers (33). The discrepancies between the list of hospitals and the number of providers in the Registry's annual report are due to some divisions within the same hospital reporting separately to the Abortion Registry (33). Some formerly independent hospitals have also been reallocated on an administrative level between 1998 and 2013 to a larger hospital, while maintaining services. We have chosen to include these formerly independent hospitals in our surveys.

After considering existing national guidelines (102), varieties of treatment protocols personally reported to us, and scientific literature, the study group designed the questionnaire. Questions related to intervals between intake of mifepristone and administration of misoprostol were unfortunately not included.

Hospitals that did not return the questionnaire received a phone call as a reminder. The response rate was 100% for both surveys.

Some discrepancies were found in the time specified as the first introduction of medical abortion in the questionnaires for 2008 and 2012 for some of the departments. In these cases we chose to primarily record data from the 2008 questionnaire.

3.1.2 Abortion Registry (Paper I)

Statistics on requests for, and termination of, pregnancy have been available in Norway since 1979. Statistics Norway was responsible for collecting and presenting these data from 1979–2005 (104). Since 2006, the Norwegian Institute of Public Health has been responsible for the statistics, and the institution has handled the data processing since 2008 (33). Processing, storage, collection and handling of data in the Abortion registry is governed by the Abortion Registry Regulation and the Health Registry Act (105). The purpose of the Abortion Registry is to produce statistics to monitor how the law on abortion is practiced, evaluate measures initiated to prevent unwanted pregnancies and abortion, and contribute to good resource utilisation and quality in the treatment of women's reproductive health (105). The information in the Abortion Registry is de-identified. The woman's name and personal identification number and other unique personal identifiers have been removed (105). Data are collected at hospital level through a standard form that contains check boxes with specific answer alternatives. The standard form has been changed a number of times since 1979, and three different forms have been in use between 1998–2013 (Appendixes 3, 4 and 5). The current form was created in 2006. Data approved by the Abortion Registry Regulation for inclusion are: date of birth, county and municipal residence, information on contraceptive use, gestational age, parity, number of previous abortions, previous medical history, abortion method, complications to the procedure; civil, occupational and educational status (105). Due to delay in developing the abortion form, registration of medical abortion as a specific method for abortion was first included in 2006.

Parameters from the Abortion Registry used in this study were; year of termination, year of birth, age, marital status, employment status, educational level, previous pregnancies, number of children, previous terminations, date of registered request for abortion and method used (Paper I).

The Abortion Registry contains data on all requests for an abortion, and some of them will not be fulfilled (Appendix 6). Requests that do not end in a termination commonly

lack information on most parameters. We analysed data comprising 223,692 terminations of pregnancies up to 12 weeks gestation in Norway 1998–2013.

3.1.3 The clinical cohorts (Papers II and III)

Two clinical cohorts were collected, established and analysed to evaluate the implementation of home administration of misoprostol and late first trimester medical abortion, respectively. The observational studies took place during the periods May 2006–May 2009 and October 2005–April 2007, separately. All women who chose to receive the treatments in question were registered. In total 1,018 women with a crown-rump-length (CRL) up to 23 were included in the study on home administration of misoprostol and 254 women with a CRL of 23–66 were involved in the late first trimester study. Data on parity, previous abortions, age of the woman, gestational age, CRL, date of mifepristone and misoprostol intake, s-hCG at mifepristone intake and at control, bleeding, pain and acceptability were recorded in both studies (Papers II and III). Travel distance and travel time was additionally measured in Paper II, and the induction-to-abortion interval, as well as the number of misoprostol administrations, was recorded in Paper III. Information in the files was crosschecked with data in the electronic patient system to ensure good data quality before storage. The information in the files was de-identified, validated and stored at the internal secured site at the quality control database at Haukeland University Hospital.

3.2 Treatment protocols, exposure and outcome variables

This section provides an overview and explanation of different variables that were chosen for the studies.

3.2.1 Paper I

Mifepristone dosage: According to national guidelines from 2004, recommended dosages were 200–600 mg (102).

Administration of misoprostol: National guidelines for administration of misoprostol recommended 800 mcg vaginally (102). Additionally we received reports on oral use of misoprostol and oral administration was therefore included as an option in the questionnaire.

Follow-up: Clinical exam with ultrasound was the only recommended protocol in the national guidelines from 2004. The use of s-hCG as the only form of follow-up was defined as low evidence in the national guidelines from 2004. We received information about hospitals using UPT, and follow-up being excluded from other hospitals and these options were included in the questionnaire.

Study period for the thesis: The first treatment with mifepristone and misoprostol was conducted in 1998. Data in the Abortion Registry up to 2013 were completed and quality controlled by April 2014 and could be included in the study. The two clinical cohorts had their own defined study period previously reported in paragraph 3.1.3.

Waiting time: Waiting time was defined as the mean difference in days between the dates a request for abortion was registered by the hospital until termination.

Gestational age: In the Abortion Registry gestational age is recorded as complete weeks and is based on 1. Ultrasound, 2. Clinical exam, 3. Last menstrual period (Listed in order of priority).

Medical abortion: Medical abortion was included as a specific option in the report form to the Abortion registry in 2006. For abortions prior to 2006, medical abortion has been defined as “injection of abortifacient” or “local application of prostaglandin” and simultaneously absence of surgery.

Repeat abortion: In Paper I, repeat abortions have been defined as one or more previous abortions. Numbers of previous abortions are primarily based on women’s self-report. In recent years the use of electronic patient journal systems is increasingly prevalent in Norwegian hospitals. Health personnel might be looking to them for additional information to improve the quality of data provided to the Abortion Registry. Prevention of unwanted pregnancies is one of the main goals of the Norwegian government (106).

Parity: Number of previously born children.

Educational attainment: Information on educational attainment was first introduced in the Abortion Registry in 2006, and is divided into three categories 1. Primary/secondary school, 2. High school/upper secondary school, 3. College/university.

Work force attachment: The Abortion Registry contains more subcategories to define work force attachment than those we chose for our study (Paper I) (1=full time and student, 2=full time, 3=part time and student, 4=part time and social welfare, 5=part time and applying for jobs, 6=part time, 7=student, 8=out of work, 9=social welfare). To reduce the number of categories we chose to redefine the original categories into four. Categories 1 and 2 were recoded into full time, categories 3–6 into part time, category 7 was maintained unchanged, and categories 8 and 9 were recoded into out of work/welfare.

3.2.2 Papers II and III

Treatment protocols: The Department of Obstetrics and Gynaecology at Haukeland University Hospital has many years' experience with medical abortion up to 63 days gestation. To improve women's options, a one single visit protocol was introduced for home administration of misoprostol. The already established treatment protocol in hospital for gestations up to 63 days, consisting of 200 mg mifepristone and 800 mcg misoprostol vaginally after 36–48 hours was chosen (Paper II). Treatment protocols from previously published studies were chosen and adapted for late first trimester abortions (13, 91). All women received 200 mg mifepristone and were admitted as day patients 36–48 hours later where they self-administered 800 mcg misoprostol vaginally, and a maximum of 5 repeat doses of 400 mcg misoprostol was given orally every 3 hours until expulsion.

Bleeding: Report based on self-assessment in Paper II and nurse evaluation in Paper III.

Pain: Pain was evaluated subjectively by the women (Papers II and III).

Follow-up in clinical studies: Standard follow-up protocol already in clinical use at the Department of Obstetrics and Gynaecology, Haukeland University Hospital, consisting of s-hCG after four weeks following mifepristone application was chosen for home administration of misoprostol (Paper II). Medical abortion for late first trimester abortions was a new treatment option in Norway. Due to no experience with medical abortion for this gestational age, a similar implementation protocol as the implementation of early medical abortion in 1998 was chosen (28). It consisted of ultrasound and clinical exam 1–2 weeks after termination. To evaluate the drop in s-hCG for this gestational age, a blood test for s-hCG was taken four weeks after mifepristone intake (Paper III).

Travel time: Travel time and distance was measured between the woman's registered address and the hospital's address using the website "Visveg" (<http://visveg.vegvesen.no/Visveg/mapviewer.jsf>).

Acceptability: A set of questions aiming to evaluate acceptability was applied in both clinical studies. In Paper II, women were asked during a telephone interview on the day of misoprostol administration if they would rather have been at the hospital or if they were more content with being at home. Answer alternatives were yes/no. In Paper III, women who came back for clinical follow-up were presented with the questions; I. Are you satisfied with the method? II. Would you choose the method again? III. Would you recommend the method to others? They could respond by answering yes, no, or unsure.

3.3 Data analysis

3.3.1 Abortion Registry

Data from the Abortion Registry was analysed using Statistical Package for the Social Sciences (SPSS), version 21 and R. The study population comprising 223,692 terminations up to 12 weeks gestation was subdivided in three ways to compare characteristics. First it was divided according to the abortion method being medical or surgical. Second, this group was subdivided into two time periods 1998–2007 and 2008–2013. These two time periods were chosen on the basis of surgical abortion being the dominant form of abortion prior to 2008 and medical abortion the most frequent form after 2008. This subdivision revealed no statistically significant differences in the characteristics of the study population between the two time periods and was not included in the study. Third, the population was divided according to abortion status, into women with no previous abortions and women with one or more previous abortions. Only data on women terminating a pregnancy up to 12 weeks gestation were included in the study.

Comparisons were made using frequencies, univariate and multivariate logistic regression analyses and presented as odds ratios (OR). All were adjusted for the woman's age and gestational age.

3.3.2 Hospital surveys

The data was recorded and analysed using SPSS version 18. We used frequencies and percentages to present the results. Figures were made using Excel.

3.3.3 The clinical cohorts

To establish the databases and analyse data we used SPSS version 15 to 18. Frequencies, median, range and percentages were calculated to summarize results. Median and range instead of mean was chosen because most data, like age of the woman, gestational age, parity, induction-to-abortion interval, for instance, were not evenly distributed. Tools used for constructing figures were Excel and SPSS.

Logistic regression analyses were made to establish statistical significance and associations between given variables and were presented as odds ratios (OR). Bivariate logistic regression analyses were used to determine association between gestational age and bleeding (Paper II), gestational age and induction-to-abortion interval (Paper III). To investigate the association between gestational age and pain adjusted for parity (Paper II), pain and parity adjusted for gestational age (Paper III), we used multivariate logistic regression analyses.

3.2 Ethical considerations

The studies performed have all the necessary approvals from the Committee for Medical and Health Research Ethics, Western Norway (number 2009/738). The use of data from the Abortion Registry included in Paper I has been permitted separately by the Norwegian Social Science Data Services (number 34010).

4. Summary of results

4.1 Paper I: Implementing medical abortion with mifepristone and misoprostol in Norway 1998–2013

After introducing medical abortion in 1998, a continuous increase in the percentage of all abortions performed medically was observed and found to be 5.9% in 1998 and 82.1% in 2013. To evaluate the uptake of medical abortion and the different treatment modalities at hospital level, two hospital surveys were conducted. They revealed a rapid increase from none of the hospitals offering medical abortion in 1997 to 50% in 2001 and 100% in 2010. Home administration of misoprostol was first introduced in 2003 and after nine years, in 2012 92.1% of all hospitals offered the treatment modality. A rapid uptake of late first trimester abortion was also found from the first treatment in 2005 to being available at 84.4% of all hospitals in 2012. Most hospitals followed national and international guidelines with a treatment protocol consisting of 200 mg mifepristone (94.7%), vaginal administration of misoprostol (94.2%) and UPT as follow-up (50%) in 2012.

To evaluate the effect of an almost complete change in abortion methods, data from the Abortion Registry was analysed in more detail. Our study revealed that abortions are carried out increasingly earlier in the pregnancy. More abortions were conducted before seven weeks gestation (adjusted OR 2.33; 95% CI 2.29–2.38) among women performing a medical than a surgical termination and the percentage of abortions performed within nine weeks increased from 44.0% in 1998 to 77.8% in 2013. Women with repeat abortions on the other hand, had a higher preference for surgical abortion and performed their abortions later in pregnancy. After the introduction of medical abortion protocols, waiting time has been reduced from 11.3 days in 1998 to 7.3 in 2013 for women requesting an abortion. Characteristics of women who performed a medical abortion or surgical abortion were relatively similar, except in the case of educational attainment where women opting for medical abortion had a slightly higher

educational level and women with repeat abortions had a poorer work force attachment and low educational level.

4.2 Paper II: Medical abortion with home administration of misoprostol up to 63 days gestation

We introduced home administration of misoprostol with no travel limits to simplify the abortion protocol for women in May 2006. It became the preferred method of abortion during the study period of three years, and 1,018 women choosing this treatment alternative were included. An efficacy rate of 93.6% complete abortions and an evacuation rate of 4.9% demonstrate results similar to other studies (12). On the other hand, we found that women with a gestational age of 56–63 days had higher odds for the need of surgical evacuation (OR 2.06; 95% CI 1.08–3.92). Prolonged bleeding was the most common reason for surgical evacuation. Only two women were in need of medical attention within the first 24 hours after administration of misoprostol. Bleeding increased with gestational age, but level of pain was independent from gestational age, but dependent on parity. Acceptability was high with 95.8% of all women being content with home administration of misoprostol. Only 7.1% of our study population lived further than one hour travel away. None of the treatment variables were influenced by travel distance.

4.3 Paper III: Medical abortion at 63 to 90 days gestation

After requests from women with a gestation over 63 days and who sought medical abortion we decided to introduce late first trimester abortions in 2005 inspired by previously published studies (13, 91). Two hundred and four women, approximately 55% of all women requesting abortion in late first trimester, volunteered to have a

medical abortion and were included in the study. With an overall complete abortion rate of 91.7%, a median of two misoprostol applications needed and a median induction-to-abortion interval of 4.5 hours and 93.9 % of all abortions completed within eight hours, our findings were in line with previous studies (13, 101). We found no statistically significant differences in induction-to-abortion interval or number of misoprostol doses needed between the different gestational ages. After four weeks s-hCG had been reduced by more than 97.3%. Women found the method highly acceptable, judging by our findings where 91.0% women (95% CI 87.5–94.5%) were content with the method, 76.1% (95% CI 70.9–81.4%) would choose the method if they needed an abortion again, and 81.9% (95% CI 77.2–86.6%) would recommend this treatment option to a friend.

5. Discussion

5.1 Methodological considerations

All studies have strengths and limitations. The purpose of this section is to discuss how the chosen methodology influences the results generated, the conclusions drawn and the consequences they may have for the obtained results.

5.1.1. Study design

In Paper I we used two different study designs. Firstly a quantitative, questionnaire-based survey to all hospitals performing abortion was used to investigate the prevalence of different treatment protocols and the implementation time of three treatment options, at hospital level. The surveys were conducted at two separate times in 2008 and 2012. We sought to examine a possible change in treatment trends before and after presenting the results of the first survey at the annual meeting of NSOG in 2008, and the publication of updated national guidelines in 2009 (68). Secondly we did a registry-based study with data from the Abortion Registry, which is a compulsory population-based registry where the women are de-identified. The study does not qualify as a historical cohort study (107), because data are de-identified, preventing us from following each woman separately. Rather than a cohort of women, it consists of a cohort of terminations of pregnancies up to 12 weeks gestation in a study period of 15 years. Women with repeat abortions within the study period are registered more than once, and their characteristics will be repeated and accumulated in comparison to women who only have one abortion. Neither does it qualify as a cross-sectional study (107), on the same basis that some women might occur several times in the dataset, and due to the data spanning a relatively long period of time. In our study we compared the characteristics of women who were exposed to medical abortion with women undergoing surgical abortion, and women with no previous abortion to women with repeat abortions.

Paper II and III are observational, prospective cohort studies (108), following women exposed to either home administration of misoprostol or medical abortion at 63 to 90 days gestation. This design was chosen because we wanted to evaluate the efficacy and acceptability of the treatment for women at our hospital. The treatment protocols were not experimental. Randomised trials are the golden standard because estimates of the treatment effects would be more statistically valid and reliable (107). We have not been able to identify any studies randomising home administration of misoprostol with hospital-based treatment. Ashok et al. have conducted the two only randomised trials comparing surgical and medical late first trimester abortions (see paragraph 1.9) (96,100). Our aim was to implement two treatment methods with as little delay as possible, and not to compare them with other existing treatment options. For that reason we did not choose to do a randomised trial.

The protocol for home administration of misoprostol was based on the already established procedure for women undergoing medical abortion up to 63 days in our clinic. A phone interview was chosen as the alternative contact with health personnel on the day of the actual abortion. Women were given the option of home administration of misoprostol regardless of travel time from the hospital. To evaluate the possible negative consequences for women living further than one hour from hospital, women were stratified between living closer or further away than one hour travel period (Paper II). For medical abortion at 63 to 90 days gestation, the protocol was based on internationally published studies (13, 91). The approach used for the latter was the same as when medical abortion was first introduced in 1998 (28).

5.1.2 Precision

The precision of a study is related to the extent of random errors. One way of assuring high precision is to increase the study sample size (107).

The number of hospitals, which received the survey, was 40/38. Although the absolute numbers are small, the response rate was 100%. As this includes the complete number

of hospitals providing abortions, the absolute numbers of participants could not have been increased (Paper I).

Since the Abortion Registry consists of an enormous amount of data, the precision was high. We chose to include women terminating their pregnancy up to 12 weeks gestation, and only 311 women lacking information on method and 358 women with extreme data were excluded from the analyses. The percentage of missing data was above 50% in the case of educational attainment, due to information on education not being included before year 2006, and not due to a random distribution of missing. As a result, data for almost 75% of women with a surgical abortion lacked information on educational level (Paper I).

We did not make calculations on sample size (Paper II and III) because these studies were observational cohort studies aiming at evaluating the implementation of new procedures. In retrospect, we acknowledge that to be able to evaluate the effect of travel distance this would have been favourable (see also paragraph 5.1.1). The number of women living more than one hour from hospital in the cohort examined was too small to see any statistically significant differences between them and women living closer, even though the total number of participants in the study exceeded 1,000 women (Paper II).

5.1.3 Validity

Hospital surveys: Selection bias (107) is unlikely in the hospital surveys, since we included all hospitals and there was a 100% response rate. Quality of the data was dependent on the responder at the actual hospital. Some discrepancies were found in the time specified as the first introduction of medical abortion in the questionnaires for 2008 and 2012 for some of the departments (see paragraph 3.1.1). Historical data will always be subject to recall bias. The number of hospitals providing each treatment option and the treatment protocols in 2008 and 2012 are on the other hand believed not

to be subject to bias, because these treatments were in use at the time of reporting them through the questionnaire.

Abortion Registry: Since the registry is compulsory, data are not subject to selection bias. The registry has never been compared and quality controlled against hospital data or other registries, and due to data being de-identified, this would not be possible. Data on parity, previous abortions, education, workforce attachment and marital status in the registry are based on women's self-report. Stigma surrounding for instance social welfare and abortion might influence what women are willing to report. The number of previous abortions might for that reason be underreported. The quality of data in the registry is therefore unknown. On the other hand the amount of missing data is low, except in the case of education. The number of women with extreme measures who were excluded from the material were 358/223,692.

We adjusted for gestational age because medical abortion is more prevalent before nine weeks gestation. Younger women might not have reached their maximum possible educational level, parity, and total number of abortions, or might not have entered the work force, so we also adjusted for the woman's age. Parameters that were adjusted for gestational age and the woman's age are: age, gestational age, parity, level of education, occupational status, marital status, previous abortions and method.

Cohort studies: The percentage of women lost to follow-up was 4.7% (Paper II) and 6.7% (Paper III). Measures of acceptability in Paper II were based on two questions where the only response alternatives were yes and no. The alternatives gave no room for options between yes and no, for example expressing a possible indifference, and we might have over rated the acceptability. The rapid increase in popularity of the method during the study period was hence seen as supporting our conclusion that the treatment was acceptable. A more fruitful approach could have been to ask about acceptability on a scale from 1 to 5 in line with standard quality of life assessments (109).

5.1.4 Generalizability

Data in Paper I came from a national compulsory register and hospital surveys to all hospitals performing abortion, with a 100% response rate, and are therefore generalizable for Norway. We believe the the findings to be transferable to other countries where abortion is covered by the National Health Services (NHS), and medical abortion is included among the treatment options available, as for instance other Scandinavian countries and the UK. The population data presented in Paper I reveals trends in line with data from Scandinavia (110) and Scotland (111) in regards to an increased use of medical abortion and concomitant shift of abortions being performed earlier in pregnancy. This trend, as well as the reduction in waiting time, is believed to be applicable to any country or region where access to medical abortion is increasing (Paper I). The rates of efficacy and acceptability found in the cohort studies are comparable with similar studies (12, 13, 87, 101, 103). High degree of reproducibility of results among studies strengthens the recommendation of these treatment options.

5.2 Major findings

5.2.1 Transition from surgical to medical abortion

After medical abortion was introduced in 1998 there has been an almost complete transition from surgical to medical abortion in Norway. This is similar to what is observed in the other Scandinavian countries (110) and in Scotland (111). After Portugal implemented their new law on abortion on request up to 10 weeks gestation in 2007, they chose medical abortion as their preferred abortion method in the public health system (112). Surgical abortions are performed in private clinics covered by the public health system and constituted 29.2% of all abortions in 2008 (112). The same trends in uptake of medical abortion are not necessarily seen in other countries, though it has been available for the same periods of time. Through a literature search using the words medical abortion, mifepristone, misoprostol, surgical abortion, trends and

implementation, 4 studies from France (113), the Netherlands (114), USA (10) and Vietnam (115) were identified and they reported the rate of all abortions performed medically. None of the studies presented figures more recent than 2011. Even though France together with China (21) has the longest history of providing medical abortion, the uptake has been slow. The slow increase in the use of medical abortion in France has partly been attributed to three factors: 1. strong regulations, 2. a minimal amount of research on medical abortion has been performed in France, and 3. medical abortion has primarily been available through public health services, and not the private services where most abortions are performed (113). In 2004 general practitioners were given the opportunity to provide medical abortion in France (116) and in 2007 49% of all abortions and 80% of all abortions under 63 days gestation were performed medically (113). The study from the Netherlands with data from 2005, presents an almost arbitrary distribution of methods and protocols, where 33.7% of the facilities use mifepristone and/or misoprostol for early termination of pregnancy (TOP), and 45.7% of the providers used either mifepristone or misoprostol as a single agent (114). After the registration of mifepristone in the USA in 2000, there was at first a rapid increase that later slowed down. Estimates for 2008 were that about 24% of med-eligible abortions were performed medically (10). In Vietnam, mifepristone was first introduced in 1992, and in 2011 23.1% of all abortions were performed medically (115). Except for in Scandinavia and Scotland, medical abortion does not seem to have replaced surgical abortion to a large extent (Figure 6).

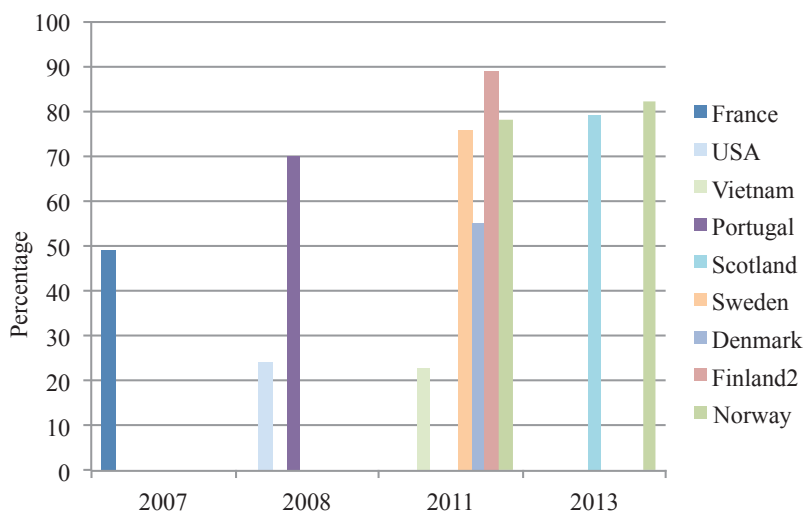


Figure 6. *Percentage of all abortions performed medically (France (113), USA (10), Vietnam (115), Portugal (112), Scotland (111), Sweden (110), Denmark (110), Sweden (110), Norway (33))*

In comparison to France, where the process of implementing medical abortion seems to have been top-down, instrumented by the Government and health authorities, the process in the USA and Norway has rather been bottom-up, driven by research and women's health advocates (113). In Norway, gynaecologists and the Norwegian Society of Obstetrics and Gynaecology (NSOG) have been a leading force in introducing medical abortion and promoting new treatment options (see paragraph 1.2). There has also been a task shift in work load from mainly physicians to nurses. At the same time, a transfer of almost all abortions out of the operation theatres and over to the out patient clinics releases capacity to other patient groups.

When resources are low, the health services have to make priorities (117). In a global health perspective, reduced costs without reduced quality of services is beneficial.

Studies show that task shifting might be an essential way to improve access to health services where there is a shortage of health personnel and poor resources (11, 118). Experiences from Norway could therefore also be beneficial for women's reproductive health on a global scale.

In Norway, TOPs were originally conducted by the junior trainees in Obstetrics and Gynaecology who would rapidly learn how to do a vacuum aspiration. In recent years, surgical abortion has been replaced by medical abortion (Paper I). Misoprostol instead of surgery is also exceedingly used as treatment for incomplete abortions (72, 119) and miscarriages (120). In a study from Finland, conducted at a time when the distribution between surgical and medical abortions was approximately 50–50%, medical abortion had slightly more adverse events than surgical abortion. This was mainly attributed to haemorrhage and incomplete abortions, while the majority with injuries were in the surgical group (121). Little is still known about the effect on surgical evacuation skills when medical procedures almost replace surgery completely.

5.2.2 Access

Waiting time and mandatory counselling is claimed to affect women's access to abortion in many countries (46, 47). In an overview from the USA it was found not to affect the women's decision but to influence personal and economic cost, and to result in a delay responsible for an increased number of second trimester abortions (47). In the Netherlands, on the other hand, where they have both mandatory counselling and five days waiting time 95% of all abortions are performed within the 12 first gestational weeks (46). This could still influence women's access to medical abortion, since many medical abortion protocols have an upper limit of 63 days, or in some places, as for instance France, a legal upper limit of 49 days for abortions in private practice (116). In France the law requires one week obligatory waiting time between the request for an abortion and termination. At the same time, many women wait about a week before they get an appointment with an abortion provider (113). By the time they are ready to terminate the pregnancy many women would have passed the upper

limit for a medical abortion. Norway has no mandatory waiting time, but the mean number of days between a request for abortion and termination was still 11.3 days in 1998. After the introduction of medical abortion the mean number of waiting days was reduced to 7.3 in 2013, and the reduction was mainly for women undertaking a medical abortion (Figure 7). In Figure 7, one can see an abrupt drop in waiting days for women opting for medical abortion, from approximately 12 to 8 days within the first years. After the introduction of home administration of misoprostol and most probably a single visit approach, a further reduction to 6.3 days is observed (Figure 7). This reduction has improved access to early medical abortion, and can also in part have contributed to the successful implementation of the procedure.

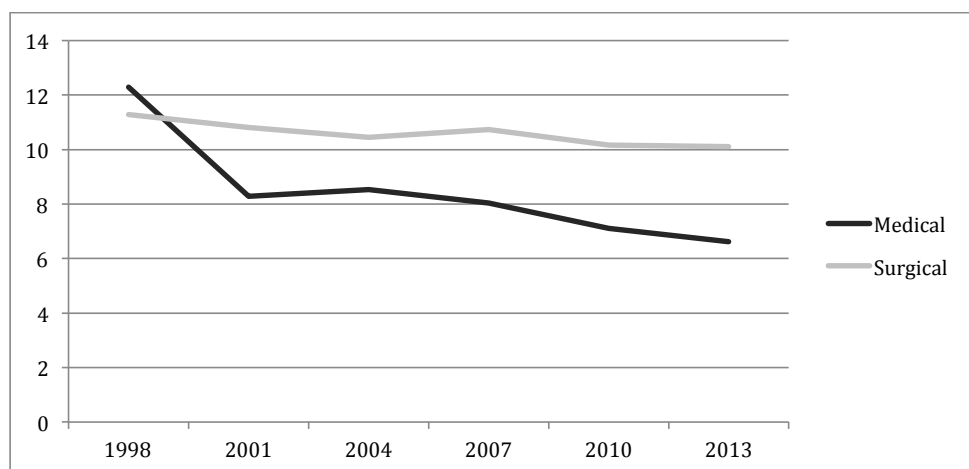


Figure 7. *The mean number of waiting days between a registered request at the hospital and termination*

5.2.3 Introducing new procedures

According to the hospital surveys Norwegian gynaecologists seem to be loyal to national guidelines and are eager to introduce new treatment options (Paper I). Results

from the 2008 survey were presented at the annual meeting of NSOG in September 2008. In the following months, Haukeland University Hospital, as a leading centre of expertise on medical abortion in Norway, received numerous contacts from gynaecologists and nurses from other hospitals requesting treatment protocols and information about home administration of misoprostol and late first trimester abortions. As a result of the numerous requests for treatment protocols from other hospitals, a new survey was conducted in 2012. This survey revealed a rapid increase in the uptake of home administration of misoprostol and late first trimester abortions after year 2008 (Paper I).

Experience with the treatment has accumulated over the years. Introduction of new and simplified treatment procedures was facilitated through a close cooperation with nurses. Medical abortion was seen as progress for women and a possibility of gaining new knowledge and medical responsibility among the nursing staff. This positive attitude has been one of the driving forces promoting a task shift in treatment responsibility and workload from gynaecologists to nurses. Increasingly nurses are also trained in operating ultrasound, simplifying the abortion process further and allowing women to complete their treatment with only one health professional, similar to what is seen in Sweden (122).

Home administration of misoprostol: When home administration of misoprostol up to 63 days gestation was introduced at Haukeland University Hospital in 2006, the only other options for home administration of misoprostol in Norway were up to 56 days in Førde Hospital (treatment protocol written by Mette Løkeland) and up to 49 days at Ullevål University Hospital (29). Numerous studies enforced a travel restriction of most commonly one hour on women requesting home administration of misoprostol (87, 123, 124). No studies with travel limits addressed the necessity of proximity to the provider. And at the same time, home administration up to 63 days was commonly in use in the USA without a mention of travel limitations (85). In our study (Paper II) no travel restrictions were made. Unfortunately it turned out that only 7.1% of our total study population comprising 1,018 women lived further than one hour away. For that reason, data comparing women living closer or further away than one hour were not

statistically significant. On the other hand, we found that only two women were in need of medical assistance on the day of misoprostol administration. These women are the only two women that would have been treated for complications before going home if they had performed medical abortion as day patients in hospital. Most surgical evacuations were done due to prolonged bleeding, at a time when these women would have left hospital if the termination had taken place there rather than at home. These findings supported travel limitations as not medically necessary at these gestational ages, even though the cohort was too small to compare women living further or closer than one hour from hospital (see paragraph 5.1.1) (Paper II). The number of women choosing this treatment option increased during the study period (Figure 8). As commented earlier (paragraph 5.2.2) this increase could have affected waiting time (Paper I).

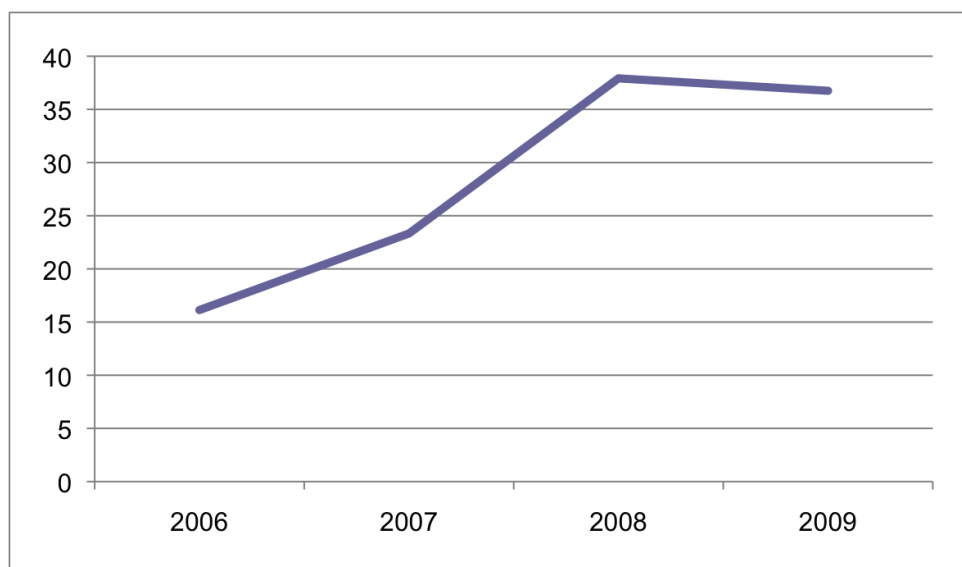


Figure 8. Mean number of home administrations per month at Haukeland University Hospital.

The risk of needing a surgical evacuation was increased for women with a gestational age of 56–63 days. This is in line with other studies (71) and supports the addition of 400 mcg misoprostol after four hours in cases of no expulsion to the treatment protocol for gestational ages above 56 days (67, 73).

Late first trimester abortions: Women were increasingly querying about medical abortion for late first trimester gestations. Previous experiences with second trimester medical abortions and the implementation of medical abortion in 1998 ensured confidence and a positive attitude towards implementing a new treatment option in our team. Approximately 55% of women eligible for medical treatment chose this option during the study period (Paper III). Slightly higher rates of surgical abortions in comparison to early medical abortion are however maintained at this gestational age (Paper I). We like to think of the survey and presentation at the annual meeting of NSOG in 2008 as a form of intervention resulting in a rapid increase in access to late first trimester abortions at Norwegian hospitals.

The complete abortion rate (91.7%) in our study was slightly lower in the first 254 women who received the treatment than in other studies (13). When revising our data for a further 705 women, the complete abortion rate had increased to 94.6%. There is considerable indirect evidence that there is a learning curve after the introduction of medical abortion (1). In a French study, physicians who performed the higher numbers of medical abortions per year had a higher rate of complete abortions than those who only conducted a few (116).

There was a reduction in s-hCG of more than 97.3% after four weeks, and we concluded that s-hCG can be used for follow-up also at this gestational age, in addition to observation of expelled pregnancy products at termination. As a single agent for follow-up it is less applicable, since late first trimester abortions are performed close to the 12 weeks legal limit in Norway. Through the inspection of expelled pregnancy products, all ongoing pregnancies were detected in our study and s-hCG was used as an additional control to secure the confirmation of a termination (Paper III).

5.2.4 Acceptability

There has been put much emphasis in research on doses, intervals between and administration of mifepristone and misoprostol to reduce side effects and increase acceptability (see paragraph 1.5 and 1.6). Surprisingly little research is done on pain in relation to treatment (125). Level of pain is always a subjective experience and it is partly a psychological and a physiological response (126, 127). Studies on surgical abortion have found psychological factors like pre-abortion depression and ambivalence about the abortion decision, nulliparity, and menstrual pain to increase the level of pain experienced (127). In our studies nulliparous women experienced higher levels of pain than parous women (Paper II and III), and the need for opiates decreased with increasing parity (Paper III). Research has found that nulliparity, higher gestational age and menstrual pain also increase the risk of pain in medical abortion (72, 128, 129). When we adjusted for parity in our study, no association between pain and gestational age was found (Paper II and III). Other studies confirm no relationship between pain and gestational age (130). There is no reason to believe that psychological effects like depression and ambivalence should have a different impact on pain during a medical abortion (126). Several participants commented, in the follow-up consultations, that the abortion provider had underestimated the level of pain, and this made them uneasy (Paper III). Studies have identified that acceptability was reduced among women who experienced more pain and bleeding than they expected (129).

In our studies women were given prophylactic analgesics in the form of diclofenac, paracetamol and kodeinsulphate (Paper II and III). In a German study of terminations up to 49 days gestation, only 22% required light analgesia (131), and a study randomising prophylactic and therapeutic ibuprofen for a medical abortion up to 63 days gestation found no differences in pain score between the groups (132). Kopp Kalner et al. found no association between the need for extra analgesics and acceptability (130). Much has yet to be investigated to find individual and optimal protocols for pain management.

Pursuing a different line of acceptability, an Italian study found that women undergoing a medical abortion resumed intercourse faster and had a higher sexual function after the abortion than women opting for surgical abortion (133). This could be related to a higher anxiety level and ambivalence towards the abortion seen among women opting for surgical abortion in comparison to medical abortion in some studies, rather than being a result of the method as such (131, 133). Though acceptability levels are generally high among women undergoing medical abortion, more can still be done to maximize acceptability and identify factors that improve acceptability. This is particularly important when medical abortion is replacing surgical abortion and the focus on individual choice of procedure is less prominent.

5.2.5 Choice

As argued in paragraph 1.4, choice is a complex issue that has to take into account both inner preferences and ambiguities and external values and recommendations. Choice is therefore very often irrational (52). At Haukeland University Hospital medical abortion was made the method of choice for early first trimester abortions in 2006 and late first trimester in 2007. These decisions are also made at other hospitals in Norway (58). Women who actively requested surgical abortion were given that as an option. As mentioned in paragraph 1.4 most procedural changes in medicine are based on evaluation and medical choice by the health service after a process of gaining experience and knowledge about the innovative treatments. The Norwegian Health Minister supports this choice on the hospital level, and believes that it is not contrary to patient rights of autonomy according to the law on patient rights (58). NSOG's educational committee has discussed the problems of maintaining skills in laparotomy when laparoscopy is replacing open surgery, a problem that could be transferred to vacuum aspirations. They have concluded that it is unethical to perform a laparotomy for the purpose of maintaining skills, and we have to find other ways of securing women's treatments.

In a study from Germany at a time when only 6% of all abortions were performed medically 52% of the women choosing surgical abortion stated that they chose surgery because it was a widely used and well known procedure (131). In the same study the decision on abortion method was highly influenced by advice from health personnel in 32.9% of the cases, mainly recommending surgical abortion (131). This coincides with initial experiences at Haukeland University Hospital when most women had little knowledge of medical abortion and relied on recommendations from their GP. Today when medical abortion is the most frequently used method this has changed in favour of medical abortion.

In the German study, women who chose surgical abortion were more ambivalent and had higher anxiety scores than those who chose medical abortion and 50% chose surgical abortion because they wanted to be unaware of the treatment (131). Making the choice of having an abortion can be an ambivalent and stressful task (131, 134). To some women making that choice is stressful enough, and they don't want to have to make yet another decision on method (134); while for others the choice itself is important (54). Medical abortion has increased women's participation. In many ways it has relieved the physician of the "burden" of being the active instrument in an abortion. Instead women actively ingest mifepristone and administer misoprostol themselves. Psychologically that is a wanted development for many women, but not for all (54).

Although making a choice on method based on medical preference on the hospital level is in line with what is happening in almost any field of medicine and is not seen as violating patient autonomy (58), we have to recognize the extraordinary position of abortion within the medical field. Abortion is, as mentioned, probably the most politicized treatment in medicine, surrounded with a variety of stigma and morals (1) and we should for that reason maybe be extra careful in respecting individual preferences of women. Unfortunately the violation of some women's preferences for surgical abortion has probably been the consequence of an almost complete transition from surgical to medical abortion.

6. Conclusions

We found an almost complete transition in treatment for unwanted pregnancies from surgical to medical abortion. There has been a relatively fast increase in the percentage of hospitals offering medical abortion to women after 1998, and a rapid increase in the provision of home administration of misoprostol and late 1.trimester abortions after 2008. Results from the surveys revealed that Norwegian hospitals offer a diversity of treatment protocols anchored in national and international guidelines.

Medical abortion requires fewer resources and the implementation of medical abortion, has given the hospitals a possibility to reallocate services for other patient groups without compromising access to abortion for women.

After the introduction of medical abortion the mean waiting time between a request for an abortion until termination dropped from 11.3 to 7.3 days and women perform their abortions earlier in pregnancy. Women with repeat abortions have higher odds for performing a surgical abortion and both women who opt for a surgical abortion and women with repeat abortions have a lower educational attainment, and perform their abortions later in the first trimester. It is not clear if the tendency to perform a surgical abortion for this group is related to a low acceptability of medical abortion as a method, or rather attributed to higher gestational age (Paper I).

Home administration became the most frequently used method for termination up to 63 days gestation at Haukeland University Hospital. Efficacy and acceptability of the treatment was high and in line with other studies (12). Women were given the option of home administration of misoprostol without limits to travel time between their home and the hospital. The study did not reveal any medical reasons to enforce travel restrictions of one hour for women who prefer home administration of misoprostol (Paper II). Access to home administration of misoprostol increased from 23.7% of all hospitals offering the treatment in 2008 to 92.1% in 2012 (Paper I).

Medical abortion at 63–90 days gestation was found to be highly acceptable with a rate of complete abortions of 91.7% that is similar to other studies (see paragraph 1.9).

Median induction-to-abortion time was 4.5 hours and 93.7% had a complete abortion within 8 hours. S-hCG dropped more than 97.5% in four weeks, and can together with an inspection of the pregnancy products, be used to confirm the termination (Paper III). The prevalence of hospitals offering this method increased from 23.7% in 2008 to 84.4% in 2012 (Paper I).

7. Implications and future research

The implications of implementing medical abortion have been an almost complete change in the abortion treatment. Norwegian gynaecologists seem to be informed about medical research, and acquire and implement early advances in treatment options, and follow protocols. With simplified procedures for termination of pregnancy, there has been a task shift in the treatment of women with unwanted pregnancies from physicians to nurses. Cost benefit has been substantially increased and release of medical and surgical capacity should have improved access for other patient groups without violating the access to abortion for women with unwanted pregnancies. Access to surgical abortion might have been reduced at the cost of women's choice of method. At the same time women have gained a more personalized treatment.

Future research

1. With vanishing numbers of evacuations being performed in early pregnancy both for termination of pregnancy and miscarriages, we need to evaluate and secure the quality of our surgical procedures.
2. Acceptability of medical abortion among women is high, but little is known about which factors are important in making the treatment more acceptable. Many important studies on the route of administration of misoprostol and dosages have been performed to reduce side effects. Pain management and modulation on the other hand have not been as thoroughly investigated.
3. Expansion of home administration of misoprostol beyond nine weeks gestation.
4. Expansion of home administration of misoprostol to primary health care for increased access.

8. Errata

Paper III: First sentence in Material and methods on page 962 “Participants for this case-control study” should read “Participants for this prospective observational study”.

Source of data

1. Baird DT. Medical abortion in the first trimester. *Best practice & research Clinical obstetrics & gynaecology*. 2002;16:16.
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APPENDIX 1

10 år med medikamentell abort i Noreg

Utfører de medikamentell abort (set ring)? JA /Nei Når vart det innført (mnd/år):.....

For kva gestasjonslengder har de tilbod om medikamentell abort (set ring og mnd/år innført)?

< 9 veker 9-12 veker: > 12 veker:

Har de tilbod om medikamentell abort heime? JA /Nei Frå når (mnd/dato):

For kva for gestasjonslengde har de tilbod om medikamentell abort heime (set ring)?

< 7 veker <8 veker < 9 veker > 9 veker (angi lengde).....

Kva for type kontroll nyttar de etter abort <9 veker (set ring)?

Klinisk/UL s-hCG u-hCG ingen

Kva for type kontroll nyttar de etter abort 9-12 veker (set ring)?

Klinisk/UL s-hCG u-hCG ingen

Kva for dose mifepriston nyttar de (set ring)?

200 mcg 400 mcg 600 mcg

Gjev de misoprostol (set ring): vaginalt/per oralt

Om lag kor mange abortar har de i året (2011)?.....

Om lag kor mange er medikamentelle (2011)?

Anna og eventuelle kommentarar:

.....

Dato utfylt:..... Avdeling:.....

Namn på den som utfyller skjemaet:.....

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 Assistentlege

Line Bjørge
 Ass.klinikkoverlege,
 Professor, dr.med

Ole-Erik Iversen
 Professor dr. med

Appendix 2

List of hospitals:

1. Akershus University Hospital, Lørenskog
2. Blefjell Hospital, Notodden (Only 2008)
3. Førde Hospital, Førde
4. Helgeland Hospital, Sandnessjøen
5. Hammerfest Hospital, Hammerfest
6. Kirkenes Hospital, Kirkenes
7. Stord Hospital, Stord
8. Haugesund Hospital, Haugesund
9. Stavanger University Hospital, Stavanger
10. Ålesund Hospital, Ålesund
11. Volda Hospital, Volda
12. Kristiansund Hospital, Kristiansund
13. Molde Hospital, Molde
14. Nordfjord Hospital, Nordfjordeid
15. Bodø Hospital, Bodø
16. Lofoten Hospital, Gravdal
17. Oslo University Hospital (Rikshospitalet), Oslo (Only 2008)
18. Ringerike Hospital, Hønefoss
19. St. Olav Hospital, Trondheim
20. St. Olav Hospital/Orkdal Hospital, Orkanger
21. Bærum Hospital, Gjøttum
22. Drammen Hospital, Drammen
23. Tønsberg Hospital, Tønsberg
24. Gjøvik Hospital, Gjøvik
25. Lillehammer Hospital, Lillehammer
26. Kongsvinger Hospital, Kongsvinger
27. Elverum Hospital, Elverum
28. Levanger Hospital, Levanger
29. Namsos Hospital, Namsos
30. Telemark Hospital, Skien
31. Østfold Hospital, Fredrikstad
32. Sørlandet Hospital Arendal, Arendal
33. Sørlandet Hospital Kristiansand, Kristiansand
34. Oslo University Hospital (Ullevål), Oslo
35. Tromsø University Hospital, Tromsø
36. Harstad Hospital, Harstad
37. Narvik Hospital, Narvik
38. Vesterålen Hospital, Stokmarknes
39. Voss Hospital, Voss
40. Haukeland University Hospital, Bergen

Appendix 3

Statens helsetilsyn		1. Til abortnemndas protokoll			Fødselsdato, navn, adresse	
GJENNOMSLAG - BRUK KULEPENN, SKRIV HARDT						
Sykehus		Saknr.				
Epikrise til					Telefon	
Trygdekommune		For Oslo, bydel				
Protokoll og journal ved svangerskapsavbrudd oppbevares i B-journal						
REGLER-INGEN	Fødselsår	Begjæringen mottatt dato		Begjæringen framsatt av		Fykeslegens samtykke iht § 9 a / b / c
	Sivil status		Er kvinnen samboende med barnefaren?			
OM KVINNEN	(1) ugift (2) gift (3) enke (4) skilt (5) separert (6) reg. partnerskap		(1) ja (2) nei (3) vet ikke			
	Yrkesaktivitet		Hvis (2) eller (3) på yrkesakt., fyll også ut her		Beskriv	
ANAMNESE	Date		Journal skrevet av		Er begjæringen underskrevet?	
	Spesifiser tidligere svangerskap nedenfor i kronologisk rekkefølge		Ant. tidl. svangerskap		Ønsker den abortsøkende rådgivning?	
	Måned		Utfall		Hvis ja, er tilbud om rådgivning gitt?	
	År		Koder		Prevensjonsbruk ved konsepsjonen	
STATUS	Allergi		Faste medisiner		Røyk	
	Vekt		BT		Ant. sig. dsdlig	
NEI/BEHANDL.	Siste mens, dato		Uterus størrelse tilsvarende		Klamydia prøve	
	Uterus		Adnex		Prove tatt i dag	
INGREPI/BEHANDLING	Primærnemndens behandling (når svangerskapet er ≥ 85 dager)		Søknaden er		Uten vedtak p.g.a.	
	Dato		Underskrift		Underskrift	
VED REISE	Inngrepet utført dato		Høyeste Hegar		Utført av lege	
	Koder (inntil 4)		Fri tekst			
Komplikasjoner under inngrepet		Kode				
Utredningsdato		Rt		ANTI-D		
		(1) Pos. (2) negativ		(1) Ja (2) Nei		

Appendix 4

Situens helseetbyn		Journal ved nemndbehandling av svangerskapsavbrudd (etter utgangen av 12. svangerskapsuke)		1. JOURNAL OG EPIKRISE	
Sykehus		Saksnr.		Kvinnens navn og adresse	
Epikrise til		Trygdelommene		Bydel	
Fødselsdato		Personnr.		Telefon	
Begjæringen	Begjæringen fremsatt av	Begjæringen fremmet etter utg. av 12 svangerskapsuke?	Fylkeslegens samtykke iht		
	<input type="checkbox"/> Kvinnen <input type="checkbox"/> Vergen	Begjæring mottatt dato	Legens navn	§ 9 a / b / c	
Om kvinnen	Sivilstatus (sett ett kryss)				
	<input type="checkbox"/> Gift <input type="checkbox"/> Samboer	<input type="checkbox"/> Ugift/enslig <input type="checkbox"/> Skilt/separert	<input type="checkbox"/> Enke <input type="checkbox"/> Annet		
Arbeid/skolegang/annet	Arbeid/skolegang/annet (sett evt flere kryss)				
	<input type="checkbox"/> Heltidsarbeid <input type="checkbox"/> Deltidsarbeid	<input type="checkbox"/> Skolegang/studier <input type="checkbox"/> Hjemmearbeid	<input type="checkbox"/> Permittert/arbeidsledig <input type="checkbox"/> Ufør	<input type="checkbox"/> Sykmeldt <input type="checkbox"/> Annet	
Anamnese	Journaldato	Journal skrevet av	Er begjæringen underskrevet?		
	Tidligere svangerskap	Spontanaborter under 12 uker	Dødføtelle/aborter over 12 uker	Provoserte aborter	Ønsker kvinnen rådgivning?
	Antall totalt	Derav levendef.	Antall	År for siste inngrep	Hvis ja, er tilbud om rådgivning gitt?
	Tidligere sykdommer	Hjertesykdom	Lungesykd.	Res. urinveisinfeksjon	Hepatitt
Status	Allergi	Faste medisiner		Røyking	
	Vekt	Høyde	BT	Cor	Pulm
	Abdomen	Adnexa	Samtykker ikke for røykeoppl. til MFR (kryss)		
	GU: VVP	Uterus			
Siste mens	Dato	Uker	Klamydiaprøve		
	(1) Pos. (2) Neg.	(3) Forurenset (4) Ikke tatt (5) Oppl. mangler	Prøve tatt i dag (kryss)		
Nemndbehandling	Primærnemndens behandling (nær svangerskapet er over 85 dager)	Søknaden er	Hvis uten vedtak		Begjæring innvilget/avslått iht. § 2.3 (Sett evt. flere kryss)
	Begrunnelse for avslag i primærnemnd. Evt. mindretallets begrunnelse skal protokolleres på eget ark.	<input type="checkbox"/> Innvilget <input type="checkbox"/> Avslått <input type="checkbox"/> Utan vedtak	(1) Trukket tilbake (2) Ikke møtt i nemnd (3) Ikke gravid	(4) Spontanabort (5) Annen årsak	Begjæring oversendt fylkeslegen for å bli prøvet av annen nemnd (jf. lovens § 9)
	Dato	Underskrifter av primærnemnda (to underskrifter)	Dato	Underskrift	
Fosterdiagnostikk	Er det utført:	Dersom utført diagnostikk, beskriv	Diagnoser, kode og beskrivelse		Diagnose bekreftet
	<input type="checkbox"/> Ultralyd <input type="checkbox"/> Prenatal diagnostikk	<input type="checkbox"/> Normalt <input type="checkbox"/> Patologi			<input type="checkbox"/> Ja, ved syning <input type="checkbox"/> Ja, ved obduksjon <input type="checkbox"/> Nei
Inngrep/Behandling	Er svangerskapsavbruddet utført?	Sv.avbruddet utført	Høyeste Hegar	Begrunnelse for ikke utført sv.avbrudd	
	<input type="checkbox"/> Ja, poliklinisk <input type="checkbox"/> Ja, under innleggelse <input type="checkbox"/> Nei	Dato	Antall mm	(1) Trukket tilbake (2) Ikke møtt (3) Ikke gravid (4) Spontanabort (5) Avslått i primærnemnd (6) Annen årsak	
	Utoft av lege	Inngrep i forbindelse med svangerskapsavbrudd (sett evt flere kryss)		Andre inngrep	
Ved utreise	Dato	Rh	Anti-d	Gitt av	Sykmeldt fra
	(1) Pos. (2) Neg.	(1) Ja (2) Nei			Sykmeldt til

Appendix 5

Folkeseinstituttet
 Nasjonalt folkehelseinstitutt
 Register over svangerskapsavbrudd
 Kalfarveien 31
 5018 Bergen

Meldeblankett for behandling av begjæring om svangerskapsavbrudd

Sendes fortløpende til register over svangerskapsavbrudd

2

Institusjon		Organisasjonsnummer		<input type="checkbox"/> Selvbestemt			
Epikrise til henvisende lege		Saksnr.		<input type="checkbox"/> Nemndbehandling			
Trygdekommune		Bydel		Fødsel dato			
Begjæring	Begjæringen fremsatt av			Begjæring signert av kvinnen og legen			Fylkesmannens samtykke iht. § 9
	<input type="checkbox"/> Kvinnen	Begjæringen datert	Begjæring mottatt dato	<input type="checkbox"/> Ja	Legens navn		<input type="checkbox"/> a / b / c
Om kvinnen	Sivilstatus nå			Borforhold nå (sett ett kryss)			Fylkesmannens samtykke iht. § 9
	<input type="checkbox"/> Gift	<input type="checkbox"/> Samboer	<input type="checkbox"/> Skilt/separert	<input type="checkbox"/> Ikke oppgitt	<input type="checkbox"/> Bor alene	<input type="checkbox"/> Bor sammen med ektefelle/samboer	<input type="checkbox"/> Bor sammen med andre: Foreldre/bokollektiv
Anamnese	Arbeid/skolegang/annet nå (sett evt flere kryss)			Høyeste fullførte utdanning			
	<input type="checkbox"/> Yrkesaktiv heltid	<input type="checkbox"/> Elev/student	<input type="checkbox"/> Arbeidssøkende	<input type="checkbox"/> Ikke oppgitt	<input type="checkbox"/> Grunn-/ungdomskole	<input type="checkbox"/> Videregående skole	<input type="checkbox"/> Høgskole/universitet
Anamnese	Journaldato		Journal skrevet av		Røyking		
	<input type="checkbox"/> Ja	<input type="checkbox"/> Av og til	Antall		<input type="checkbox"/> Kvinnen motsetter seg melding av røykeopplysninger		
Anamnese	Tidligere svangerskap med utfall (antall)			Provoserte aborter		Informasjon om innreps art og virkning jf. abl. § 5 gitt?	
	Fødsler etter 22 fullgatte uker	Spontanaborter før fullgatte 22 uker	Ekstrauterine svangerskap	Antall	År for siste avbrudd	<input type="checkbox"/> Ja	
Anamnese	Prevensjonsbruk da kvinnen ble gravid			Tilbud om rådgivning jf. abl. § 2.1 gitt?			
	<input type="checkbox"/> Ingen	<input type="checkbox"/> Kondom	<input type="checkbox"/> P-plaster	<input type="checkbox"/> Spiral	<input type="checkbox"/> Kvinne sterilisert	<input type="checkbox"/> Annet: Spesifikasjon	
Anamnese	Tidligere sykdommer			Tilbud om rådgivning jf. abl. § 2.1 gitt?			
	<input type="checkbox"/> Intet spesielt	<input type="checkbox"/> Hjertesykdom	<input type="checkbox"/> Lungesykd.	<input type="checkbox"/> Res. urinveisinfeksjon	<input type="checkbox"/> Hepatitt	Spesifikasjon	
Status	Faste medisiner						
	Vekt	Høyde					
Status	Siste mens		Uterus tilsvarende palpatorisk		Evt. UL-funn tilsvarende		Klamydiaprøve
	Dato	uker	uker		uker		<input type="checkbox"/> Ikke tatt
Nemndbehandling	Primærnemndens behandling (når svangerskapsavbrudd er over 84 dager (12 uker))		Andre mikrobiologiske prøver – spesifiser				
	Kvinnens fødselsnummer		Dato				
Nemndbehandling	Begjæringen er		Hvis uten vedtak:			Spesifiser	
	<input type="checkbox"/> uten vedtak	<input type="checkbox"/> Trukket tilbake	<input type="checkbox"/> Spontan abort	<input type="checkbox"/> Ikke gravid	<input type="checkbox"/> Ikke møtt i nemnd	<input type="checkbox"/> Annen årsak	
Nemndbehandling	Begjæringen innvilget iht. § 2.3 (sett ev. flere kryss)		Begrunnelse for avslag i primærnemnd. Bruk eget ark.			Begjæring oversendt fylkesmannen for behandling i klagene (jf. Lovens § 8)	
	<input type="checkbox"/> a	<input type="checkbox"/> b	<input type="checkbox"/> c	<input type="checkbox"/> d	<input type="checkbox"/> e	Dato, underskrift	
Fosterdiagnostikk	Fosterdiagnostikk		Dersom utført fosterdiagnostikk		Spesifisert klinisk diagnose		Diagnose bekreftet
	<input type="checkbox"/> Ikke utført	<input type="checkbox"/> Maternelle blodprøve	<input type="checkbox"/> Normal	Diagnosekode (ICD10) og beskrivelse		<input type="checkbox"/> Ja, ved syring	
Fosterdiagnostikk	<input type="checkbox"/> Ultralyddiagnostikk	<input type="checkbox"/> Fosterblodprøve	<input type="checkbox"/> Patologi			<input type="checkbox"/> Nei	
	<input type="checkbox"/> Magnetisk resonans	<input type="checkbox"/> Fostervannsprøve	Antall fostre:				<input type="checkbox"/> Obduksjon
Inngrepsbehandling	Avbrudd ikke gjennomført		Svangerskapsavbrudd gjennomført		Fosteret fjernet eller utstøtt:		Dato
	<input type="checkbox"/> Trukket tilbake	<input type="checkbox"/> Spontanabort	Metode:	<input type="checkbox"/> Kirurgisk	Antall gjenværende fostre:		
Inngrepsbehandling	Institusjonsoppf.		Andre inngrep		Komplikasjoner ved sv. avbruddet		Behandling ved komplikasjoner
	<input type="checkbox"/> Poliklinikk/dagpasient	<input type="checkbox"/> Ja	<input type="checkbox"/> Spiral satt inn	<input type="checkbox"/> Sterilisering	<input type="checkbox"/> Ufullstendig abort	<input type="checkbox"/> Kirurgisk revisjon av uterinhulen	<input type="checkbox"/> Laparoskopi
Inngrepsbehandling	Prevensjonsveil. gitt		Annet – spesifiser		Annet (Eget ark)		<input type="checkbox"/> Laparotomi
	<input type="checkbox"/> Ja	<input type="checkbox"/> Nei					<input type="checkbox"/> Biotransfusjon
Inngrepsbehandling	Fritekst						<input type="checkbox"/> Annet: – spesifiser

Appendix 6

Percentage of all requests for an abortion ending in a termination within 12 weeks gestation

