



The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

SUBMISSION
TO
THE SENATE COMMUNITY AFFAIRS
LEGISLATION COMMITTEE
ENQUIRY INTO THE PRIVATE MEMBERS
BILL

13 JANUARY 2006

*This was (verbally) presented to the Senate Community Affairs
Legislation Committee by Dr Christine Tippett,
Senior Vice President
of
The Royal Australian and New Zealand College of Obstetricians
and Gynaecologists on Thursday 15 December 2005*



Introduction

Mr Chairman, Members and participating Members of the Senate Community Affairs Committee, I would like to thank you for your invitation to the Royal Australian College of Obstetricians and Gynaecologists (RANZCOG) to give evidence to your committee which is considering the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU 486) Bill 2005 - seeking to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutics Goods Administration.

The RANZCOG is a training and standard setting organisation committed to pursuing excellence in the delivery of health care to women throughout their lives.

We do not nor would it be appropriate for us to hold a position on the rights or wrongs of abortion. We are however firmly of the opinion that if a woman has chosen to have an abortion, she should not only have available to her accurate and appropriate information about abortion, but she should be able to choose to have a safe medical abortion rather than a surgical abortion if that is her preference.

There is clear evidence that some women would prefer not to have a surgical procedure if that could be avoided and also clear evidence that this is a safe if not safer option for pregnancy termination up to nine weeks gestation.

Access to safe abortion is a health care issue and should be provided as an integral part of broader sexual health services. The politicisation of this issue is regrettable although probably inevitable. We consider it is no longer acceptable that RU486 be subject to the restricted goods provision. Should this bill be passed and were the drug to become available to Australian women after evaluation by the TGA, there is no evidence to support the contention that the availability of a method of medical termination will increase the numbers of terminations undertaken in this country.

Medical Termination is available to women in New Zealand, North America, the United Kingdom, much of Western Europe, Russia, China Israel and many other countries. We are strongly of the view that the Therapeutic Goods Amendment (Repeal of the Ministerial responsibility for approval of RU 486) Bill 2005 should be supported to enable this medication to be made available to Australian women after appropriate evaluation and regulation by the Therapeutics and Goods Administration.



An Overview of Mifepristone (RU486)

Mifepristone is a synthetic anti-progesterone which has a proven role in women's health care.

Progesterone is a hormone made in large quantities in pregnancy. It is essential to stimulate and maintain the development of the endometrium or the lining of the uterus, which enables a pregnancy to implant or establish itself in the uterus and to grow.

Mifepristone by antagonising progesterone causes the endometrium to degenerate so that a pregnancy cannot be sustained. If a pregnancy is not in the uterus i.e. it is an ectopic or tubal pregnancy, where there is not an established endometrium, mifepristone is not effective in interrupting the pregnancy and this is an important consideration when the drug is used. It is important to establish that a pregnancy is in the uterus prior to the administration of mifepristone.

Safety and Efficacy of Mifepristone (RU486)

There is a substantial body of literature establishing the safety and efficacy of mifepristone when used in conjunction with a prostaglandin analogue, usually misoprostol, to induce early abortion. There have been an estimated 500,000 early medical terminations in North America since mifepristone was approved as an abortifacient in 2000 and over one million in Europe.

The British College of Obstetricians and Gynaecologists published National Evidence-Based Clinical Guidelines on The Care of Women Requesting Induced Abortion, in September 2004.

They evaluated the efficacy of medical and surgical termination.

They included in their recommendations that:

- Ideally abortion services should be able to offer a choice of recommended methods for each gestation band.
- Medical abortion using mifepristone, plus prostaglandin, is the most effective method of abortion at gestations less than 7 weeks.
- Medical abortion using mifepristone and prostaglandin termination continues to be an appropriate method for women in the 7-9 week gestation band.
- Conventional suction termination should be avoided at gestations below 7 weeks.

The reasons for these recommendations relate to the failure rate of early surgical termination and an increased incidence of women who have a medical termination requiring surgical intervention to completely evacuate the uterus after later medical terminations. This is estimated to be between 2-4% increasing with increasing gestational age.



In November 2005, The RANZCOG ratified its document, 'Termination of Pregnancy - A Resource for Health Professionals'. This is also an extensively researched document and both this and the RCOG document address issues of side effects and complications. (*Please refer to attachment*).

As surgical termination is accepted as a safe procedure, it is pertinent to compare the side effects and maternal mortality of medical termination with surgical termination.

Serious complications are rare and occur in approximately 4/1000 procedures with either method. Mortality and serious morbidity occurs less frequently than if a pregnancy went to term. There are few randomised trials comparing early medical and surgical termination but the data presented in both documents is a compilation of the best available evidence.

A recent Danish study of 50,000 surgical procedures reported a complication rate of 3.4/100 within two weeks of the procedure with bleeding re-evacuation or infection being the most common.

Maternal mortality rates relating to surgical termination in Australia and North America are of the order of 0.3-0.8/100,000 and most recent data indicates the commonest cause was related to anaesthesia.

Serious complications with medical terminations are rare with overall rates due to haemorrhage infection of 2.7-3.0/100 and 2.0/100 requiring surgical evacuation of retained tissue.

There have been four maternal deaths recently reported from North America where there has been an association with medical termination of pregnancy. Although mifepristone has not been sited as the causative agent, this gives an estimated mortality rate comparable with that of surgical termination.

No intervention is without risk. One cannot avoid risk. Maternal mortality associated with an ongoing pregnancy is ten times higher than that associated with termination of pregnancy.

Contraception is advocated to prevent unwanted pregnancy. The risk of having a stroke related to taking the pill is about the same as the risk of dying due to a pregnancy termination however we consider the pill a safe drug and quite rightly so.

Medical termination using mifepristone is a safe procedure and Australian women should have a choice with regard to the type of termination they undergo. There is good evidence that women value choice and are more likely to be satisfied with a method they choose.



The Clinical Application

The greatest risk with mifepristone is that it is potentially too easy to use.

A doctor must be trained to undertake a surgical termination safely and for mifepristone to be used safely training and education of practitioners and the development of best practice guidelines is essential. The RANZCOG would wish to be involved in the development of such guidelines.

Conclusion

The RANZCOG strongly supports the Therapeutics Goods Amendment Bill 2005.

It is not appropriate that mifepristone continues to be subject to the restricted goods condition which has effectively denied Australian women the choice of medical termination of pregnancy which is recognised as a safe alternative to surgical termination of pregnancy.

The appropriate body to evaluate and regulate this drug is the Therapeutics and Goods Administration and in fact it is inconsistent and inappropriate for mifepristone to be evaluated or assessed by any other body.

We would be optimistic that were mifepristone to be subject to the same evaluation process as all other medications that an application would be made to the TGA for approval.

Dr Christine Tippett
Senior Vice President
RANZCOG