**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012

**Question:** E12-069

**OUTCOME 1:** Population Health

**Topic:** RU486

**Type of Question:** Hansard Page 49, 31 May 2012

**Number of pages:** 1

**Senator**: Senator Fierravanti-Wells

**Question:**

With regard to the 2012 death of a patient following the administration of RU486:

a) Please provide a copy of the treatment protocol used by that authorised prescriber with the application for approval to supply the drug.

b) Is the authorised prescriber still authorised to supply RU486?

c) Has there been a review of the treatment protocols used by that practitioner?

d) Has there been any change to the treatment protocols used by that practitioner?

e) Has there been a review of the treatment protocols for other practitioners?

**Answer:**

a) A copy of the protocol, with identification of the prescriber redacted for privacy reasons is attached.

b) Yes.

c) Yes.

d) Yes.

e) Yes.

E12-069
Attachment A
to

Medical Protocols

[redacted]

[redacted]

# *Early medical abortion using mifepristone and misoprostol*

| Rev | Date | Comments | By | Chk | App |
|---|---|---|---|---|---|
| 1 | May 2009 | First version | [redacted] | [redacted] | May 2009 |
| 2 | Aug 2009 | Amendments | [redacted] | [redacted] | Aug 2009 |
| 3 | Mar 2011 | Scheduled review | [redacted] | [redacted] | June 2011 |
| 4 | Dec 2011 | Amendments following TGA request for opt-in monitoring | [redacted] | | |

## *Aim of this procedure*

To outline the [redacted] process for medical abortion up to 9 weeks gestation.

## *When is this procedure used?*

For all medical abortions up to 9 weeks gestation.

## *Who uses this procedure?*

The Centre Manager is responsible for managing this policy.
All team members involved in the consultation and treatment process process.
Only appropriately trained providers endorsed by [redacted] can dispense mifepristone.

## *Using this procedure*

**Definition**

The [redacted] is the brand name for the medication abortion process used in [redacted].

A medication abortion is an effective method for early abortion. It is the termination of early pregnancy resulting from abortion-inducing medications and without primary surgical intervention.

A mifepristone and misoprostol regimen is the preferred regimen at [redacted] in Australia.



[redacted]

NB. Medication abortions should only be undertaken in centres that have adequate access (either onsite or through arrangement with another provider) to medical facilities equipped to provide emergency treatment of haemorrhage, incomplete abortion and emergency resuscitation.

## 1. *Client Screening*

A [redacted] client can have a [redacted] at any time, provided she has made an informed voluntary choice, is no more than 9 weeks (63 days) gestational age and there are no medical contra-indications. She must meet the legal requirements for termination of pregnancy in the state where the service is provided.

There is the option for clients to have decision-making counseling.

### 1.1 Considerations

- Age
- Last normal menstrual period (LNMP)
- Menstrual history (regularity, flow)
- History of cramping, abdominal pain or vaginal bleeding since LMP (consider ectopic pregnancy and spontaneous abortion)
- Contraceptive use (correct or incorrect)
- Gravity and parity, including:
  - i) abortions, miscarriages
  - ii) history of ectopic pregnancy
  - iii) caesarean section, any obstetric complications
- Current symptoms of sexually transmitted infection (STI) or pelvic inflammatory disease (PID).
- Medical history (especially severe asthma)
- Blood pressure (BP)
  - refer if systolic BP is greater than 170, or diastolic BP is greater than 110
- Current medications
- Allergies

### 1.2 Contra-indications to [redacted]

- Gestational age greater than 9 weeks (63 days). The client should be referred to have an [redacted] if up to 12 weeks. (Refer [redacted] *Procedure*)
- Known or suspected ectopic pregnancy – mifepristone and misoprostol are not effective treatments for ectopic pregnancy. (Refer *Early Pregnancy & Suspected Ectopic Pregnancy Policy*)
- Allergy to either mifepristone and/or misoprostol
- Adrenal failure or long-term corticosteroid therapy
- Haemorrhagic disorder or anticoagulant therapy
- IUD in situ – this must be removed prior to the MSMP taking place

- Presence of pelvic infection if severe (as indicated by abdominal/cervical motion tenderness, adnexal mass, mucupurulent discharge or high fever), this should be treated first. If mild, [redacted] can proceed once antibiotics have been commenced.

## 1.3 Special considerations

- Breast-feeding – there is a theoretical risk of diarrhoea in the breastfeeding infant. Defer breastfeeding for 6 hours following misoprostol.
- Severe anaemia
- Concurrent illness with significant diarrhoea
- Serious systemic illness – eg. liver disease, cardiac disease, renal disease, epilepsy, should be evaluated individually to determine the safest method of abortion.

## 1.4 Assessment of gestational age

All clients requesting termination of pregnancy must have an accurate assessment made of their gestational age.

An abdominal ultrasound should be performed to assess for the presence of an intra-uterine pregnancy and assess gestational age. Only if an intra-uterine gestation is not visible on abdominal ultrasound should a trans-vaginal ultrasound be considered. (Refer *Ultrasound Scanning Procedure*)

If an intra-uterine pregnancy cannot be confirmed, ectopic pregnancy must be excluded. (Refer *Early Pregnancy and Suspected Ectopic Policy*)

An ultrasound examination report from another provider confirming gestational age is acceptable. If there has been no history of pain or bleeding it is not necessary to repeat the ultrasound examination.

## 1.5 Laboratory Tests

a) Urine Pregnancy Test
A urine pregnancy test is not routinely performed. It is only required if an intra intra-uterine gestation is not visible on abdominal ultrasound, prior to proceeding to a trans-vaginal ultrasound.

b) Quantitative ßhCG Test
Serum levels should be measured where no intra-uterine gestation is confirmed but a urine pregnancy test is positive (refer *Early Pregnancy & Suspected Ectopic Pregnancy Policy*)

c) Rhesus (Rh) determination
All clients must have their Rh group determined and documented. The determination may be obtained on-site or by an external pathology provider. (Refer *Rhesus Determination and Administration of Anti-D Policy*)

d) Haemoglobin determination
Pre-operative haemoglobin determination is not routinely necessary in first trimester terminations. Severe anaemia can be detected while doing the physical examination and should be investigated and treated.

## 2. *Procedural Information and Informed Consent*

In order to make an informed choice, the client must be provided with information in language she can understand. Translated written information or a translating telephone service should be used when necessary

The client must understand the following eight points:

1) what a [redacted] is and how the mifepristone and misoprostol will be administered

2) that the client should be sure about having a [redacted] before proceeding but if she changes her mind she can decide against having the process at any time before it takes place

3) that there are certain risks as well as benefits involved in having a MSMP. These risks (below) must be explained in a way that the client can easily understand:
   - excessive bleeding
   - infection
   - retained pregnancy tissue
   - continuing pregnancy

4) that there are the following possible side-effects:
   - cramps and bleeding
   - nausea and vomiting
   - diarrhoea
   - fever / chills

5) that if the [redacted] fails to terminate the pregnancy, it is recommended that a surgical termination be performed as there may be birth defects associated with the medications used. There are reports of foetal malformations after the administration of misoprostol although the effect of mifepristone alone on a foetus is not known

6) the number of visits to the centre required, transport to and from the centre, and the telephone support available

7) that follow up contact is essential to ensure that the client does not have an infection, a continuing pregnancy or retained products of conception - vaginal bleeding is not proof of complete expulsion

8) that there is another alternative for first trimester abortion – the MSP (surgical aspiration abortion).

The client must be given the opportunity to ask for clarification of any of the process information as well as the opportunity to ask any questions and have them answered satisfactorily. It is also important to address any anxiety and questions that she may have about viewing the products of conception, as well as privacy and/or hygiene issues.

The reason for a client seeking a termination should be explored. The decision to go ahead with a [redacted] must be the voluntary decision of the client alone. This decision must not be made for the client by her husband, partner, family member, friend, service provider or anyone else.

The consent discussion and agreement to proceed must be carried out by the attending doctor. The client must sign the *Consent to the Use of Mifepristone and Misoprostol for Medical Abortion* and *Medical Abortion: Mifepristone & Misoprostol Risk Information Sheet* in the presence of the attending doctor.

Summary of comparisons between the [redacted] (mifepristone and misoprostol) and the [redacted]

| [redacted] Medical Process | [redacted] Procedure |
|---|---|
| High success rate, but lower than a [redacted] (up to 98% - World Health organization, 2003) | High success rate (over 99%) |
| May be used in early pregnancy up to nine weeks since LMP | May be used in early pregnancy: up to 12 weeks since LMP |
| Usually avoids instrumentation | Instruments inserted into the uterus |
| Requires at least two centre visits | Can be completed in one centre visit |
| Medications cause a process similar to a miscarriage | A clinician performs the procedure |
| Abortion usually occurs within 24 hours of the second medication being taken | The procedure is completed in 5 - 10 minutes |
| The process will occur in your own home | Procedure performed at a [redacted] |
| Oral pain medication can be used | Local anaesthetic or intravenous sedation |

## 4. *Contraception & sexual health screening*

Contraceptive options and appropriate sexual health screening must be offered to all clients undergoing a [redacted]

Screening for Chlamydia (PCR urine) is offered at the time of consultation. (Refer *Chlamydia Screening Policy*)

A contraceptive method may be started immediately after the [redacted]. Insertion of an IUD/IUS should be deferred until the 2 week check or at the next period. (Refer discharge instructions and *Initiation of Contraceptive Methods Policy*)

## 5. *The medical abortion*

### 5.1 Mifepristone

- blocks the action of progesterone and thereby:
  - stops the pregnancy growing and causes detachment
  - softens and dilates the cervix
  - makes the uterus more likely to contract
- rapidly absorbed orally in 15 minutes. If the client vomits more than 15 minutes after taking it, the dose does not need repeating
- supplied in 200milligram tablets, stored at room temperature

### 5.2 Misoprostol

- a prostaglandin licensed in Australia to prevent gastric ulceration caused by NSAIDs such as ibuprofen, naprosyn, and others
- makes the uterus contract, causing cramps and bleeding
- may cause short-lived nausea, vomiting, diarrhoea, fever or chills
- supplied in 200 microgram tablets, stored at room temperature

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## 5.3 The [redacted] regimen

- Initial visit day 1: In the [redacted] the client takes **200mg** of mifepristone orally. The client is given 800 mcg of Misoprostol (4 tablets) to take home with clear instructions on their administration. (The dispensing of medications must be recorded in the Client Record and Mifepristone Register.)
- 24 - 48 hours after taking mifepristone the client takes **800mcgm** of misoprostol buccally at home, placing the 4 tablets between the cheek and gum for at least 30 minutes. Any undissolved tablet residue remaining after this time can then be swallowed.
- If no bleeding has occurred within 24 hours after the first dose of misoprostol, the client should return to the centre and be given a second dose of 800mcg misoprostol
- It is not necessary to inspect for products of conception
- The client may opt for a follow-up message from [redacted] 3 to 5 days following ingestion of mifepristone to remind them of symptoms that are of concern in relation to infection, incomplete abortion and therapeutic failure and of the support centre telephone number.
- Approximately 2 weeks after her initial visit, the client returns to the centre for an evaluation (see Follow-up Appointment below)
- Antibiotics are not given routinely
- For Rh negative women, Rh immune globulin (250IU) should be administered within 72 hours of the administration of mifepristone. (Refer *Rhesus Determination and Administration of Anti-D Policy*)

## 5.4 Bleeding and cramping

The onset of bleeding and cramping is usually within four hours of taking misoprostol; nearly all clients will have experienced the onset within 24 hours.

Sometimes bleeding can occur after taking mifepristone but before taking misoprostol. Misoprostol should still be taken as directed at the recommended time.

Bleeding occurs in almost all cases, however, this is not in any way proof of complete expulsion. A follow-up appointment is absolutely necessary to confirm that the pregnancy has been terminated.

Cramping can range from mild to severe.

Bleeding and cramping usually exceeds the typical levels of menstrual bleeding and cramping.

Bleeding and cramping should diminish once the pregnancy is expelled.

Significant cramping does not usually last longer than 24 hours.

Mild bleeding can continue for 30 days or more.

**Problem bleeding:**

- If a client saturates two (or more) sanitary pads per hour for two consecutive hours then this is designated 'problem bleeding'. As part of her discharge instructions the client **must be** given instructions about whom to contact if she experiences this type of bleeding.

**Pain management:**

- Counselling and reassurance are crucial to managing pain.
- Clients should be advised to rest, use hot packs on the abdomen and take pain relief medication as required.
- Analgesics such as paracetamol, ibuprofen, naprosyn and codeine may be beneficial taken shortly before the misoprostol and as required, at the recommended dose. NSAIDs can be taken with misoprostol.

## 5.5 Other side effects

These are generally short lived and may include:

- nausea
- vomiting
- diarrhoea
- fever and chills

## 6. *Discharge Instructions*

The client must receive verbal and written discharge instructions in a language she can understand.

These instructions should cover the following:

- how and when the mifepristone and misoprostol are to be administered
- who to contact with any queries (including a 24 hour contact number)
- the normal range of symptoms and side-effects that a client can expect after taking these two forms of medication
- the use of pain relief medication
- the need for the client to have pelvic rest for one week (no sex or vaginal douching, no tampons, no bathing or swimming)
- the importance of keeping the follow up appointment in 2 weeks (please see below). Vaginal bleeding occurs in almost all cases and is not in any way proof of complete expulsion
- family planning methods should be started as soon as possible (as fertility can return in less than 2 weeks after a medical abortion). Oral contraceptives, vaginal rings, injectables and contraceptive implants can be commenced once bleeding has commenced following administration of misoprostol, or at the time of [redacted] if more practical. IUD/IUS may be inserted once abortion is confirmed to be complete or at the next period. All methods may be commenced at time of follow-up, if the possibility of repeat pregnancy can be confidently excluded (eg.

abstinence) and with appropriate advice given regarding the time to effectiveness. Refer *Initiation of Contraceptive Methods Policy.*

**Warning signs and symptoms of possible complications:**

The client should immediately return to the centre or seek immediate medical attention if she experiences:

- heavy vaginal bleeding (soaking two or more sanitary pads per hour for two consecutive hours or large fist-size clots)
- prolonged heavy bleeding or severe cramping
- severe cramping which is not relieved by pain relief medication
- feeling unwell, including weakness, nausea, vomiting or diarrhea with or without a fever, ~~chills or malaise~~ lasting six or more hours or occurring more than 24 hours after misoprostol
- any abnormal vaginal discharge
- severe abdominal pain or nausea.

## 7. *Follow-up appointment*

Follow-up message:

The client may opt for a follow-up message from [redacted] 3 to 5 days following ingestion of mifepristone to remind them of symptoms that are of concern in relation to infection, incomplete abortion and therapeutic failure and of the support centre telephone number.

Follow-up appointment:

The client must return for a follow-up appointment approximately two weeks after having a [redacted].

At this appointment the provider should take a history of events since the previous visit (see [redacted] *Client Feedback Survey* for much of this information).

Completion of the abortion process may be confirmed by a combination of:

- history of events
- signs and symptoms
- abdominal ultrasound examination
- urine pregnancy test (may be positive up to 30 days after a [redacted])
- falling serum ßhCG levels (if done)

The provider should assess for the presence of:

- a continuing pregnancy
- retained products of conception
- persistent heavy bleeding
- signs of infection

If the [redacted] is complete the provider should:

- answer any final questions the client may have
- review her contraceptive options

- provide information about additional health services as appropriate
- document completion of the process in the client record, noting any adverse events or complications

## 8. *Complications and their treatment*

### 8.1 Continuing pregnancy

Occurs in 1 – 2 % of all cases

Confirmed by an increase in gestational age, as measured on ultrasound examination, and in most cases a detectable foetal heartbeat. (A non-viable, non-progressing gestation is considered retained products - see below.)

Continuing pregnancy requires a [redacted] (aspiration abortion).

### 8.2 Retained products or "incomplete abortion"

Occurs in 1 – 2 % of all cases

If clinically suspected or evident on ultrasound only, without significant symptoms, such as heavy bleeding or cramping:

- give explanation that tissue may be expelled during subsequent vaginal bleeding or with next menstrual period OR
- give misoprostol, either 400mcg buccally or 600mcg orally as a single dose OR
- carry out a [redacted] (if it is the client's preference)

Persistent heavy bleeding or cramping requires a [redacted].

### 8.3 Excessive bleeding

The client should contact the centre or seek medical assessment if she saturates two (or more) sanitary pads per hour for two consecutive hours or experiences large, fist-size clots.

Excessive bleeding may require an [redacted] for clinically significant haemmorhage or if it is the client's preference.

A clinically significant haemorrhage is defined as:

- a drop in haemoglobin / haematocrit
- hypovolaemia
- othostatic hypotension

Ergometrine (0.2mg IM) can be administered up to three times, 5 – 10 minutes apart.

Haemorrhage requiring a transfusion occurs in 0.1 - 0.2% of all cases

### 8.4 Infection

Infections are rare in medical abortion (~0.3%).

Symptoms and signs of infection may include:

- persistent pelvic pain

[redacted]

- sustained fever over 38° C
- fever more than 24 hours after taking misoprostol
- atypical presentation can occur without fever, severe abdominal pain, or pelvic tenderness, but with significant leukocytosis, tachycardia, or haemoconcentration

For mild infections, oral antibiotics are prescribed:

Doxycycline 100mg bd for 10 days OR azithromycing 1g, repeated 1 week later

PLUS

Amoxicillin/clavulanate 875/125mg bd OR metronidazole 400mb bd for 10 days

If severe infection or sepsis is suspected, the client should be hospitalized for treatment.

A high index of suspicion is needed to rule out sepsis (from e.g. *Clostridium sordellii* or other species e.g. Streptococcus) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhoea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. Most of these deaths occurred in women who used vaginally administered misoprostol. No causal relationship between mifepristone and misoprostol use and an increased risk of infection or death has been established.

## 8.5 Summary of situations necessitating surgical intervention

- continuing pregnancy
- incomplete abortion or retained products of conception associated with heavy bleeding or cramping
- orthostatic hypotension associated with haemorrhage or heavy bleeding
- anaemia, especially with on-going blood loss
- client unable to return to the centre or has no access to emergency services
- it is the client's preference



[redacted]

[redacted]

## Documents Relating to this Procedure

Informed consent policy
Ultrasound Scanning procedure
Early Pregnancy and Suspected Ectopic policy
Rhesus Determination and Administration of Anti-D policy
Chlamydia Screening policy
Initiation of Contraceptive Methods Policy

## Records Relating to this Procedure

[redacted] Admission Notes
Medical Abortion: Mifepristone & Misoprostol Information Sheet
Medical Abortion: Mifepristone & Misoprostol Risk Information Sheet
Consent to the Use of Mifepristone and Misoprostol for Medical Abortion
Medical Abortion Aftercare booklet
Mifepristone Drug Register

## References to this Procedure

[redacted]

Termination of pregnancy - A resource for health professionals, RANZCOG, 2005
The Care of Women Requesting Induced Abortion - Evidence-based Clinical Guidelines Number 7, RCOG, 2011~~05~~
Frequently asked clinical questions about medical abortion, WHO, 2006



[redacted]