

# EARLY PREGNANCY FAILURE MANAGEMENT: A PREFERENCE-SENSITIVE DECISION

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**CONTRA COSTA REGIONAL  
MEDICAL CENTER  
NOON CONFERENCE SERIES**

***DISCLOSURE OF CONFLICT OF  
INTEREST***

- Speaker has nothing to disclose

# My Background and Experience

- UNC Med School (2004)
- Santa Rosa Family Medicine Residency (2007)
- Post-residency general practice
  - SF-DPH Community Health Network Primary Care
  - UCSF Family Medicine Residency preceptor
  - TEACH trainer
- UCSF Fellowship in Primary Care Research and Family Planning (2011)

# Objectives

1. To describe and discuss the four evidence-based management options for early pregnancy failure (EPF).
2. To review the evidence for patient preferences for EPF management.
3. To apply the shared decision-making framework to EPF management options.

# Outline

- Early pregnancy failure and loss
  - Definitions and Terminology
- Miscarriage management
  - Four options = Clinical Equipoise
  - A preference-sensitive decision
- Shared decision-making in miscarriage management
  - Patient Preferences
  - Provider Practices
  - Utilizing a structured approach to decision-making

# Early pregnancy failure (EPF)

- Includes all non-viable pregnancies in first trimester

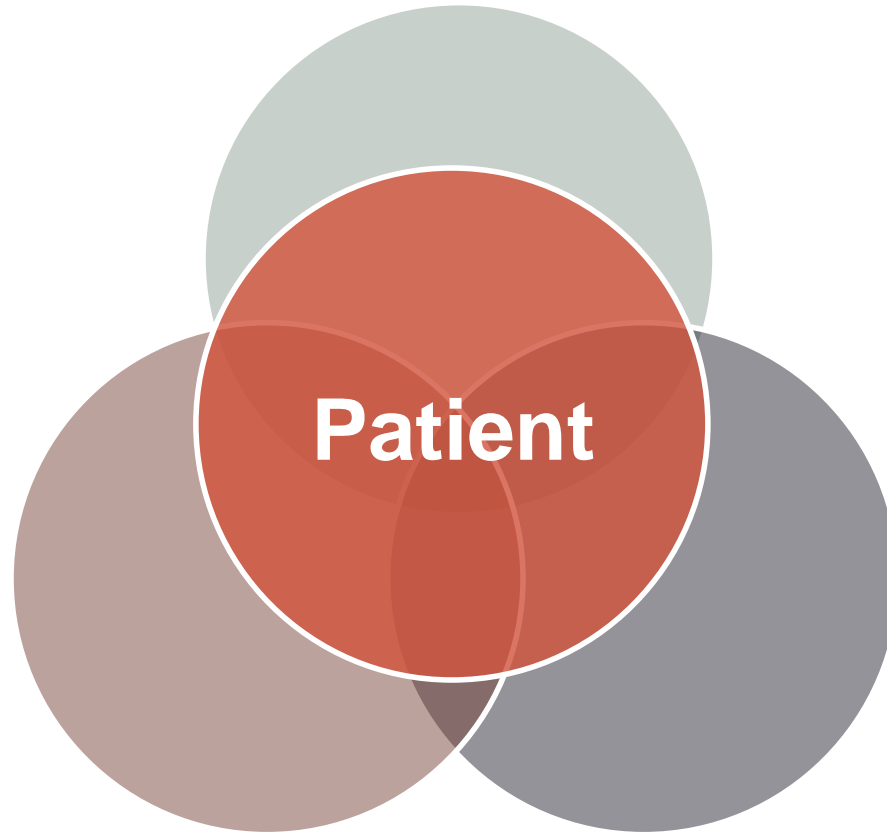
## A Common Experience

- 15-20% of clinically recognized pregnancies
- 1 in 4 women will experience EPF

# EPF management:

## A preference-sensitive decision

- Several treatment options are available and equivocal
- Best choice of treatment reflects patient's values and preferences



# Patient Case

- Ella is a 26 yo G1P0 presenting to urgent care clinic

“I’m 2 months pregnant and I’m bleeding! Am I going to lose the baby?”

# Patient Case

How do we care for Ella?

Clinical History:

- LMP
- First positive UPT
- Prenatal care thus far
- Bleeding & cramping
- Abdominal or one-sided pelvic pain
- Pregnancy intention

Work-up:

- PE?
- Labs?
- Ultrasound?

# Patient Case

- Ella's sure LMP was 9 weeks ago
- She had a positive UPT in clinic 2 weeks ago
- Her first prenatal care visit is scheduled for next week (meaning no ultrasound done yet this pregnancy)
- On exam her cervical os is closed

What can we tell Ella right now?

# Explaining bleeding in early pregnancy

- Keep the patient informed
  - Provide reassurance that not all vaginal bleeding & cramping signifies miscarriage, but avoid guarantees that “everything will be all right”...
  - Assure you are available and **BE** available throughout the process
- What does the bleeding mean?
  - 50% ongoing pregnancy rate with closed cervical os
  - 85% ongoing pregnancy rate with viable IUP on sono
  - 30% of normal pregnancies have vaginal bleeding

# EPF – Making the diagnosis

## Clinical diagnosis:

### Spontaneous abortion

Vaginal bleeding + IUP, <20 wks  
threatened, inevitable,  
incomplete, complete

## Ultrasound diagnosis:

### Anembryonic gestation

Gestational sac without  
embryonic pole  
MSD  $\geq$  16 – 25 mm

### Embryonic demise

5mm embryo  
with no cardiac activity



# $\beta$ -HCG utility in EPF diagnosis

- $\beta$ -HCG median serum concentration:
  - 4 weeks: 100 mIU/ml (5-450)
  - 10 weeks: 60,000 (5,000 – 150,000)

## Discriminatory Level

- Serum HCG at which a normal intrauterine pregnancy can be visualized on ultrasound
  - Trans-abdominal = 3600 – 6000
  - Trans-vaginal = 1500 – 2000
- Once beyond discriminatory level, limited role for “following betas”

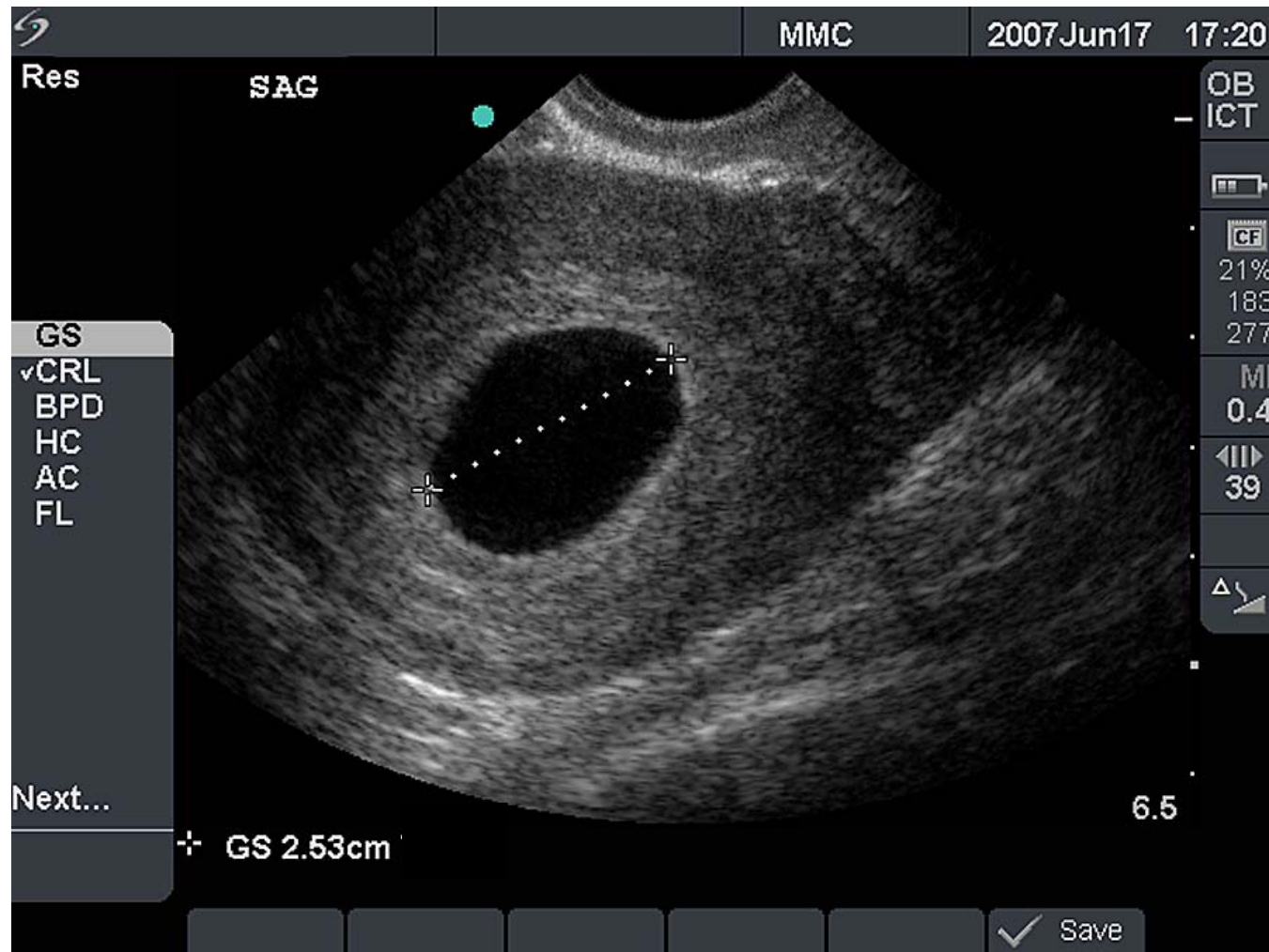
Nyberg 1985 Am J Roentgenol  
Dashefsky 1988 Radiology  
Goldstein 1988 Obstet Gynecol  
Fossum 1988 Fertil Steril



# Ultrasound milestones

	When should you see it?	Abnormality
Gestational Sac	Discriminatory Level $\beta = 1500-2000$	R/O ectopic Multiple gestation Complete SAB
Yolk sac	MSD $> 13-16\text{mm}$	(wait for fetal pole)
Fetal pole	MSD $\geq 20\text{mm}$ (16-25mm)	Anembryonic gestation
Cardiac activity	Fetal pole $\geq 5\text{mm}$	Embryonic demise

# Anembryonic gestation

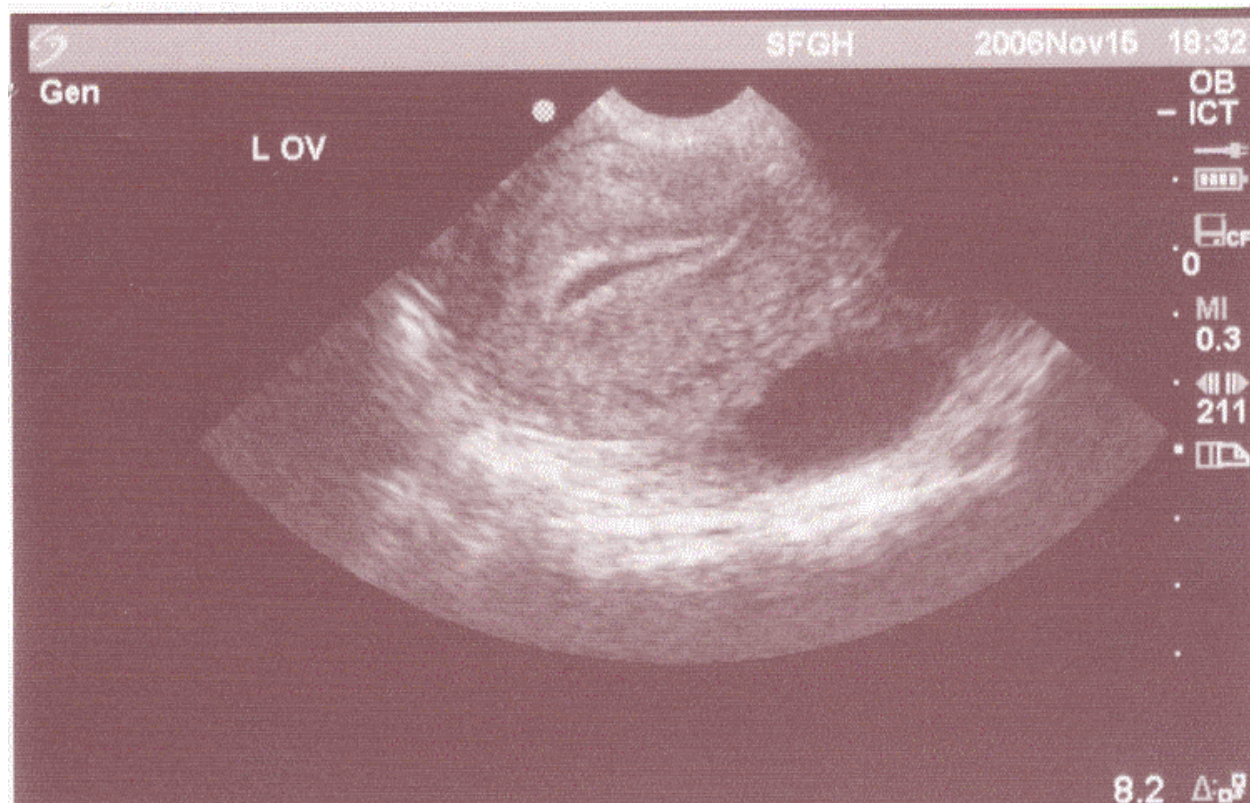


# Embryonic Demise



The fetal Crown-rump length (CRL)  
In this case 10.8 cm = 7 weeks 3 days

# Pseudosac



# Patient Case

- Ella's ultrasound is performed and shows a 10 mm embryo with NO cardiac activity

What are her options?

# EPF Management

Expectant



Medical



Aspiration



Depends on:

1. Hemodynamic stability
2. Patient preference and follow-up
3. Stage in process
4. Local resources



# Decision-making for EPF management

- Four treatment approaches for the clinically stable patient
  1. Aspiration w/ general/deep sedation (**operating room**)
  2. Aspiration w/ local/moderate sedation (**office-based**)
  3. Medical (misoprostol +/- mifepristone)
  4. Expectant
- All methods are **effective**, with equivalent **safety** and **patient acceptability**

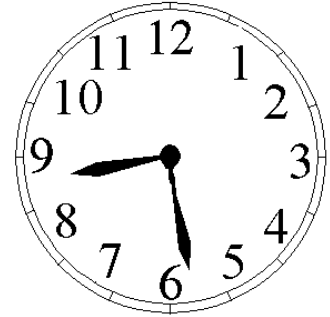
# EPF Management

## CASE OF CLINICAL EQUIPOISE

Best choice for management reflects  
patient's values and preferences



# Expectant Management



- “Watchful waiting”
- Can safely advise up to 8 weeks of waiting
- Definition of “success” varies widely in published studies
- Counseling with realistic expectations about:  
**Duration, Discomfort, and potential D&c**  
is important for patient acceptability
- Stage of miscarriage process impacts expected efficacy

# Expectant Management: Complete Abortion rate



	By day 7 (%)	By day 14 (%)	By day 46 (%)
Incomplete Ab (n=221)	53	84	91
Anembryonic gestation (n=92)	25	52	66
Embryonic demise (n=138)	30	59	76
Total (n=451)	40	70	81

Summary for waiting 1 – 2 weeks:

75 – 85% of women with incomplete ab can avoid suction

30 – 60% of women with embryonic demise can avoid suction

# Expectant Management



## Advantages

- Non-invasive
- Body naturally expels non-viable pregnancy
- Avoids anesthesia and surgery risks
- Allows for patient privacy and continuity of care

## Disadvantages

- Unpredictable outcome and timescale
- Process can last days to weeks
- Can have prolonged bleeding and cramping
- Despite waiting, may still need uterine aspiration

# Expectant Management



## Contraindications

- Uncertain diagnosis
- Severe hemorrhage or pain
- Infection
- Suspected gestational trophoblastic disease
- Indicated karyotyping

**Same contraindications for  
medical management**

# Medical Management

- Use of medications for active management of EPF
- Misoprostol
  - Stimulates uterine contractions & softens cervix
  - Inexpensive, easy storage
- Mifepristone
  - Anti-progestin used for pregnancy termination
  - Limited use in non-viable pregnancies



# Medical Management



## Advantages

- Non-invasive
- Safe
- Can be highly effective
- Avoids anesthesia and surgery risks
- Highly cost-effective
- Allows for patient privacy and continuity of care

## Disadvantages

- May cause heavier or longer bleeding
- Increased need for analgesics and pain control
- May cause short-term gastrointestinal and other side effects
- May still need uterine aspiration

# Misoprostol for EPF

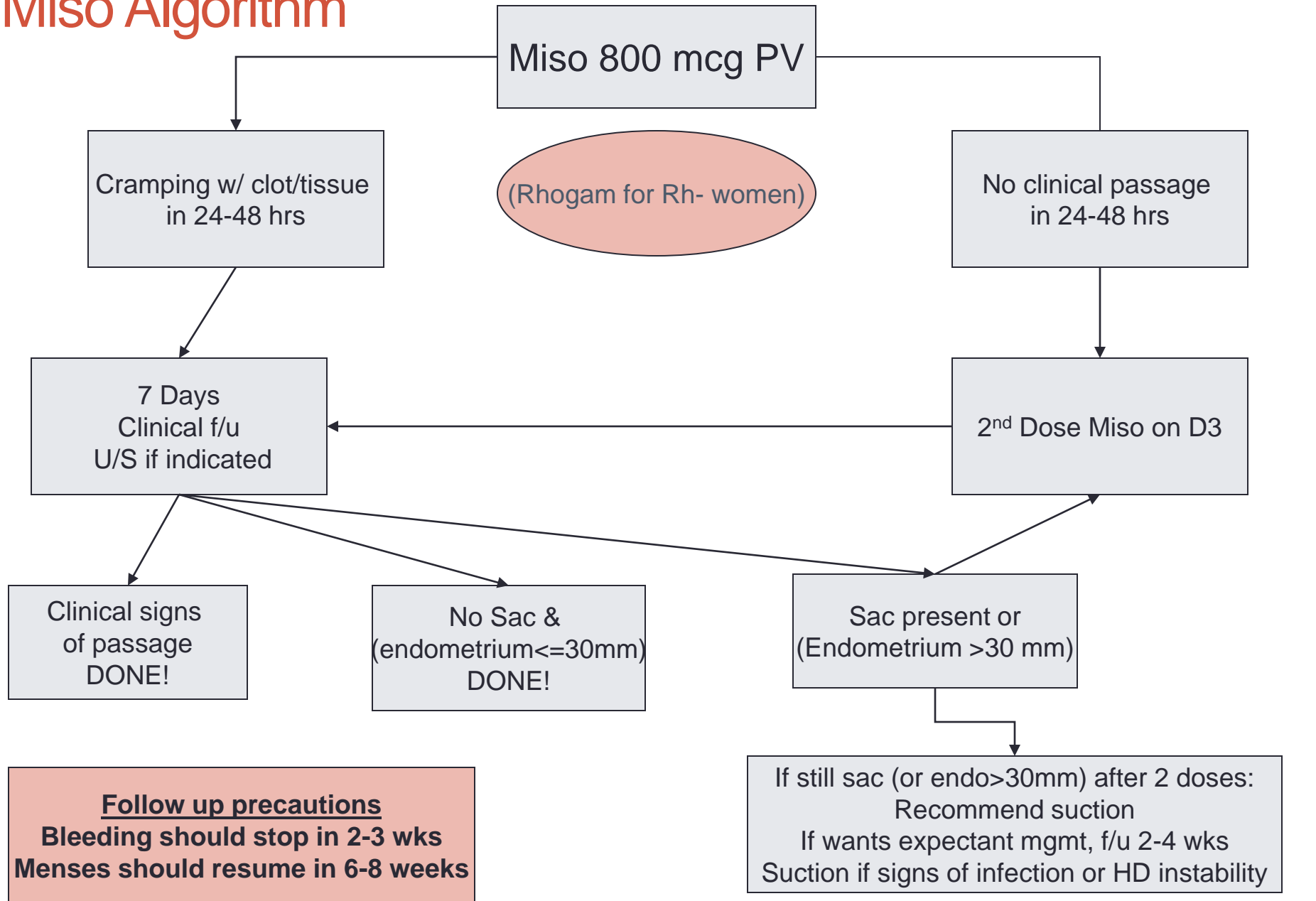


- Small studies with wide range of doses, follow-up and definition of success
- Common regimen:  
**800 mcg vaginally, repeat dose @ 24h PRN**
- Success (avoid surgical intervention) = 70 – 96%
- Higher success with longer follow-up  
→ Incomplete miscarriages have higher success

Zhang et al, NEJM, 2005  
Weeks et al, Obstet Gynecol 2005  
Sur et al. Best Pract ObG 2009



# Miso Algorithm



# Aspiration for EPF

- Historically done in operating room under general anesthesia
- Suction curettage with MUA or EUA has largely replaced surgical D&C
- Safe procedure that can be done in an office-setting in less than five minutes



# Operating Room Aspiration

## Advantages

- Predictable
- Offers fastest resolution of miscarriage
- Reduced duration of bleeding
- Low risk (<5%) of needing further treatment
- Can be asleep

## Disadvantages

- Rare risks associated with invasive procedure and general anesthesia
- More cost than office-based procedures
- More time and physical exams than office-based procedures
- May be more bleeding complications under general anesthesia than in office-based procedures

# Office-based Aspiration

## Advantages

- Predictable
- Offers fastest resolution of miscarriage
- Reduced duration of bleeding
- Low risk (<5%) of needing further treatment
- Pain control with local plus oral or IV meds
- Compared to OR management:
  - May allow improved patient access and continuity of care
  - Improved privacy
  - Less patient and staff time
  - Resource and cost savings

## Disadvantages

- Rare risks of invasive procedure
- Less pain control options in some settings





# Overall success rates



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**Expectant**  
(7 – 14 days)

**Missed EPF**

**30% - 60%**

**Incomplete**

**75% - 85%**



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**Misoprostol**  
(7 days)

**800 mcg PV**

**70% - 90%**

Anembryonic

81%

Embryonic Demise

88%

Incomplete

93%



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**Aspiration**

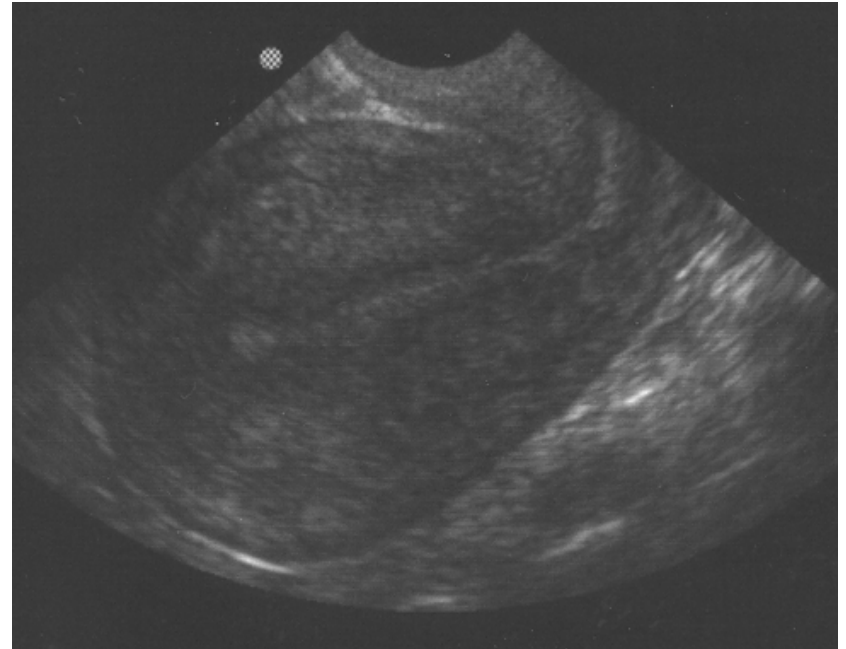
**97% - 100%**

# Patient Case

- Ella chose to use misoprostol at home
- She placed the pills vaginally and began having cramping and bleeding 2 hours later
- Her heavy bleeding lasted 4 hours, and she noticed one particularly large clot, that may have had tissue in it
- She still has some light bleeding today, 7 days later

She's here for F/U, what's next?

# Endometrial Thickness



Thickness of endometrium NOT associated with need for future intervention

# EPF Clinical Care – Key Points

## Clinical Checkpoints

- Clear diagnosis
- Pt is stable, has access to phone & emergency care
- Pain control
- Anticip guidance for bleeding, S/Sx infx
- Rh status
- Follow-up scheduled

## Counseling Tips

- Pregnancy intention
- Present all appropriate options to pt
- Feelings of guilt
- Future fertility
- “When can I start trying?”



# Decision-making for EPF management

- Four treatment approaches for the clinically stable patient
  1. Aspiration w/ general/deep sedation (**operating room**)
  2. Aspiration w/ local/moderate sedation (**office-based**)
  3. Medical (misoprostol +/- mifepristone)
  4. Expectant
- All methods are **effective**, with equivalent **safety** and **patient acceptability**

# EPF: A Preference-sensitive Decision

- Clinical equipoise
  - Best choice for management reflects patients values and preferences
- However, patients are dissatisfied by
  - Providers treating their miscarriage as mundane, with a lack of urgency or insensitivity
  - Information dissemination
  - Emotional support
  - Timing of management
  - Follow-up and aftercare



# What do we know about patient preferences?

- Patients have strong preferences
  - Challenges in recruitment for RCTs
  - Report higher satisfaction when treated according to patient's preference
- Patients have widely divergent preferences

No 'one best way' to treat miscarriage  
that suits all individuals.      *-Smith 2006*

# Patient preferences for EPF management

When extensive counseling is utilized, up to 70% of women will choose *expectant management*

When aspiration is indicated or preferred, the majority of women will *choose an office-based procedure* over one in the OR

# Patient Preferences

- Three key studies identify patient preferences and priorities in EPF management
- Two studies as extensions of the MIST trial
  - Petrou and McIntosh surveyed 630 women with a stated preference discrete-choice questionnaire
  - Smith, et al., conducted interviews and focus groups with 127 women
- Dalton and Harris, et al., in Michigan, followed 165 women prospectively through choosing between OR and office-based aspiration

# Patient Priorities

Pain

Time

Complications

Safety

Bleeding

Privacy

Anesthesia

Past  
experience

Finality

# Patient Preferences & Priorities

- For many women, preferences for management are largely determined by their feelings towards “the baby” or about the physical act of an aspiration

*"I didn't agree with abortion, and things like that, and to me [the D&C] felt the same"*

*"I was relieved that it had miscarried naturally...the thought of having it killed on purpose, that's how I would have seen [the D&C] "*

*"I think that that's one of the scariest things: knowing that something inside of you is dead"*

# Patient Preferences & Priorities

- Timing was also important to many women – time for grief and time for waiting

*'... it's very clean, very quick, wonderful operation, but, in a way, I think probably letting it miscarry helps to grieve in a funny way, because you're going through your grief all of the time that you are waiting for it to go, and then it goes, and you do a sort of mental realignment or whatever, you know, you have time to sort of prepare yourself.'*

*'... but, it was just awful, having to wait, like wait ...you know, I was walking around, waiting to lose my baby.'*

# Provider Practice

Training

Safety Data

Efficacy  
Data

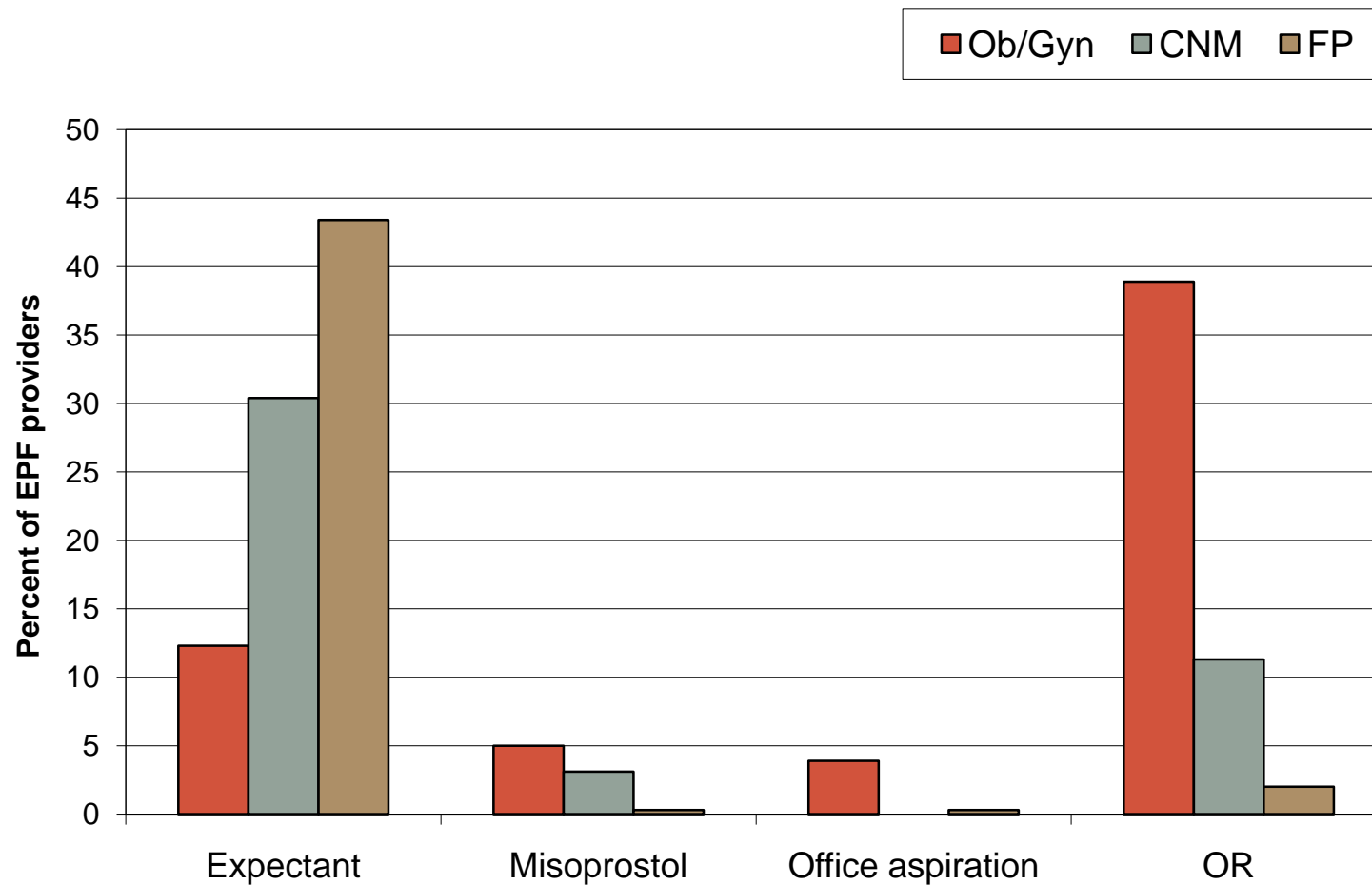
System  
Resources

Staff Buy-in

Assumptions



# EPF Management Practices in the U.S.



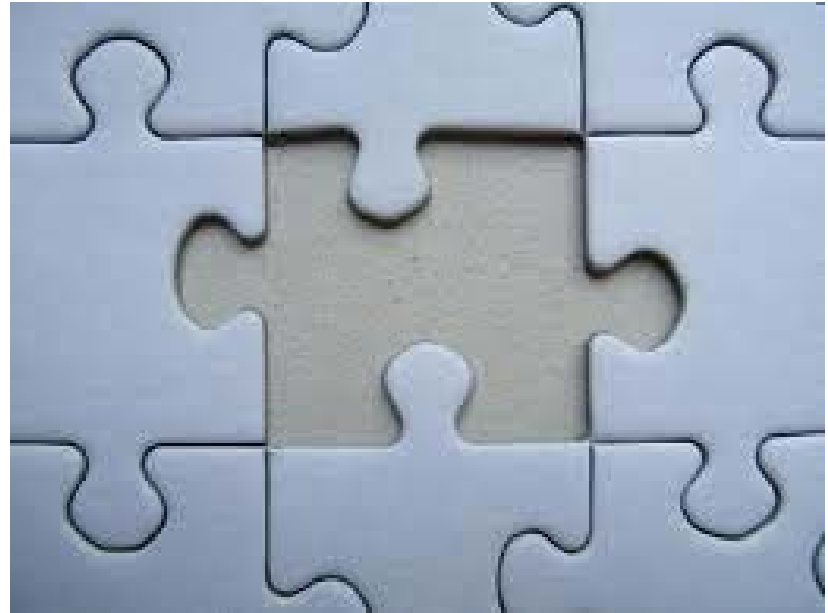
Adapted from Dalton 2010

# Barriers and Biases

- Misconceptions about safety and efficacy of misoprostol
- Space constraints, lack of nursing support, lack of training
- Assumptions that patients want to have a painless, asleep procedure for miscarriage management
- Unaware or unresponsive to cost-effectiveness data that support medication management above all, and office-based over OR aspiration

# Counseling: The missing piece?

Need a means to  
reconcile the  
mismatch between  
patient preferences  
and current clinical  
practice



# The Patient – Provider Interaction

- Counseling extremely important for patient choice and satisfaction
- Goal is to support women in identifying their values in and priorities for management
- One half of women would change their decision based on a physician's recommendation

# Shared Decision-making

“... a mechanism to decrease the informational and power asymmetry between doctors and patients by increasing patients’ information, sense of autonomy and/or control over treatment decisions that affect their well-being.”

Shared decision-making applies well to **preferences-sensitive decisions** and may maximize health treatments dependent on **both patients and providers having a role in managing illness**

# Shared Decision-making

Information  
Exchange

Deliberation

Negotiation &  
Agreement

1. Provider presents all relevant medical information
2. Patient provides information about personal circumstances, values, and priorities
3. Provider also discusses preferences while acknowledging personal values and biases
4. Decision is reached

# SDM: Information Exchange

	ADVANTAGES	DISADVANTAGES	RELATIVE EFFICACY*
<ul style="list-style-type: none"> <li>• Provider provides all relevant medical information</li> </ul> <p><b>EXPECTANT MANAGEMENT</b></p>	<ul style="list-style-type: none"> <li>• Non-invasive</li> <li>• Body naturally expels non-viable pregnancy</li> <li>• Avoids anesthesia and surgery risks</li> <li>• Allows for patient privacy and continuity of care</li> </ul>	<ul style="list-style-type: none"> <li>• Unpredictable outcome and timescale</li> <li>• Process can last days to weeks</li> <li>• Can have prolonged bleeding and cramping</li> <li>• Despite waiting, may still need uterine aspiration</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Embryonic demise or anembryonic pregnancy:</i> 16-75% Ankum [4]; Luise [31]; Bagratee [26]</li> <li>• <i>Incomplete abortion:</i> 82- 96% Gronlund [28]; Blohm [9], Bagratee [26]</li> </ul>
<p><b>MEDICAL MANAGEMENT (with misoprostol)</b></p>	<ul style="list-style-type: none"> <li>• Non-invasive</li> <li>• Safe</li> <li>• Can be highly effective</li> <li>• Avoids anesthesia and surgery risks</li> <li>• Highly cost-effective</li> <li>• Allows for patient privacy and continuity of care</li> </ul>	<ul style="list-style-type: none"> <li>• May cause heavier or longer bleeding</li> <li>• May cause short-term gastrointestinal and other side effects</li> <li>• May still need uterine aspiration</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Embryonic demise or anembryonic pregnancy:</i> 77-89% Herabutya [13]; Demetroulis [32]; Bagratee [26]; Zhang [14]; Ngoc [38]</li> <li>• <i>Incomplete abortion:</i> 61-100% Pang [39]; Moodliar [30]; Weeks [33]; Bagratee [26]</li> </ul>
<p><b>OFFICE-BASED ASPIRATION MANAGEMENT</b></p>	<ul style="list-style-type: none"> <li>• Predictable</li> <li>• Offers fastest resolution of miscarriage</li> <li>• Reduced duration of bleeding than expectant or medical</li> <li>• Low risk (&lt;5%) of needing further treatment</li> <li>• Pain control with local plus oral or IV meds</li> <li>• Compared to OR management: <ul style="list-style-type: none"> <li>- May allow improved patient access and continuity of care</li> <li>- Improved privacy</li> <li>- Less patient and staff time</li> <li>- Resource and cost savings</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Rare risks of invasive procedure</li> <li>• Less pain control options in some settings</li> </ul>	<ul style="list-style-type: none"> <li>• 95%-100% Milingos [27]</li> </ul>
<p><b>OPERATING ROOM (OR) ASPIRATION MANAGEMENT</b></p>	<ul style="list-style-type: none"> <li>• Predictable</li> <li>• Offers fast resolution of miscarriage</li> <li>• Reduced duration of bleeding than expectant or medical</li> <li>• Low risk (&lt;5%) of needing further treatment</li> <li>• Can be asleep</li> </ul>	<ul style="list-style-type: none"> <li>• More cost than office-based procedures</li> <li>• More time and physical exams than office-based procedures</li> <li>• Rare risks associated with invasive procedure and general anesthesia</li> <li>• May be more bleeding complications under general anesthesia than in office-based procedures</li> </ul>	<ul style="list-style-type: none"> <li>• 95%-100% Demetroulis [32]; Gronlund [28], Trinder [15]</li> </ul>

# SDM: Information Exchange

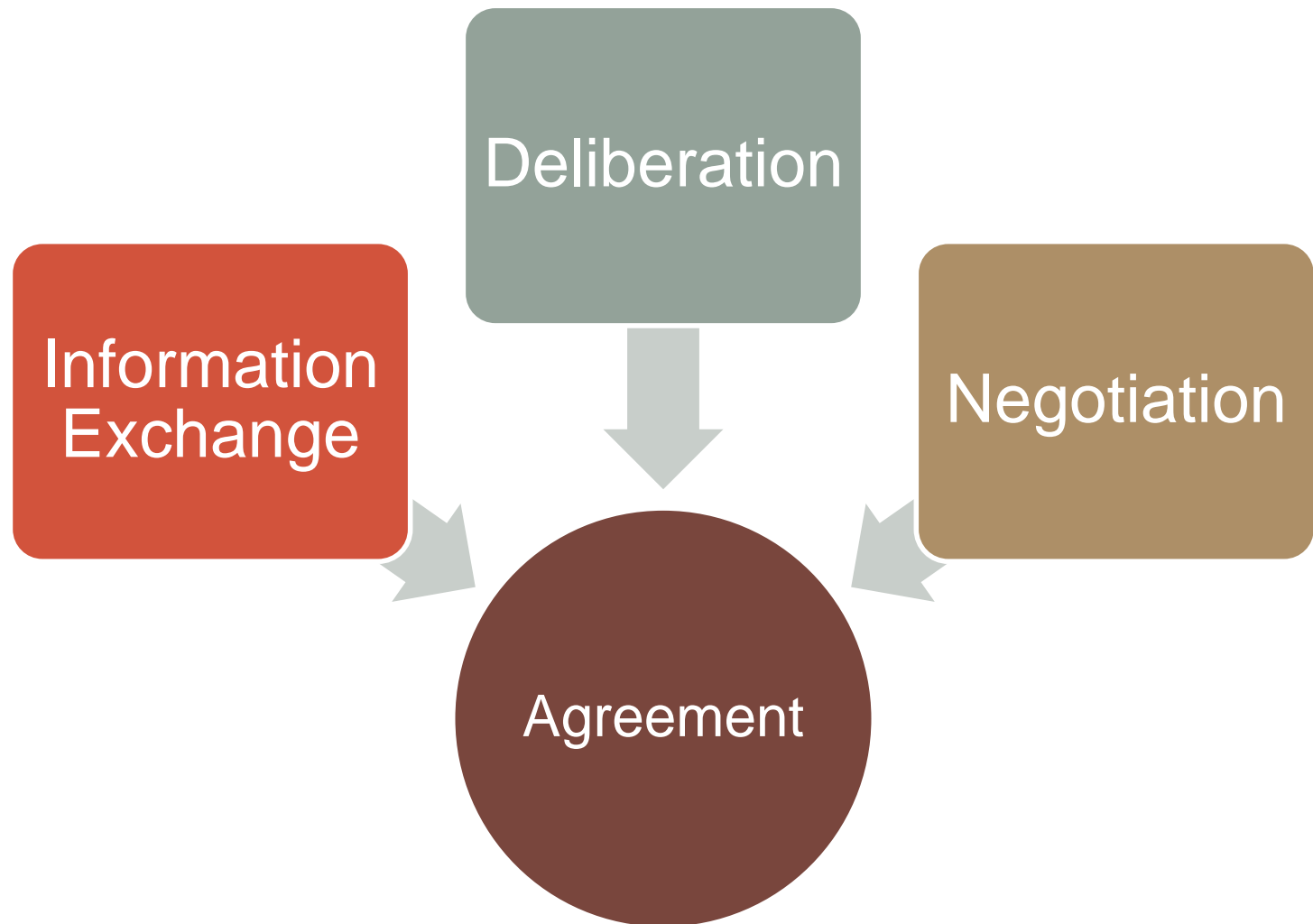
- Elicit patient priorities and preferences for management
- Create atmosphere conducive to patient participation
- Can use systematic method such as a decision aid or checklist

TREATMENT PRIORITY		Not Important	Somewhat Important	Most Important
Personal Factors				
	Treatment by your own provider			
	Recommendation of treatment from friend or family member			
	Recommendation of treatment from provider			
	Previous miscarriage or pregnancy termination			
	Want to experience symptoms of bleeding and cramping in private			
Emotional Factors				
	Most natural process			
	Do not want to see the pregnancy tissue			
Physical Factors				
	Least amount of pain			
	Fewest days of bleeding after treatment			
	Lowest risk of complications			
	Lowest risk of need for other steps			
	Want to avoid invasive procedure			
	Want to avoid medications with side effects			
	Do not want to see blood			
	In case of a surgical procedure, want to avoid going to sleep			
	In case of a surgical procedure, want to be asleep			
Time and Cost Factors				
	Shortest time before miscarriage is complete			
	Shortest time in the clinic or hospital			
	Fastest return to fertility or normalcy			
	Fewest number of clinic visits			
	Lowest cost of treatment to you			
Other Factors (please list):				

# SDM: Deliberation & Negotiation

- Provider facilitates deliberation and negotiation by integrating medical information with patient preferences
- Negotiation may be more effective if provider assumes role of **healthy detachment**
  - *an examination of personal preference or bias to establish self-awareness and allow for a non-judgmental and non-directive discussion of management options*
- Providers can prepare by acknowledging that how they present options to patients may be influenced by
  - training
  - available resources
  - perceptions of patient preferences

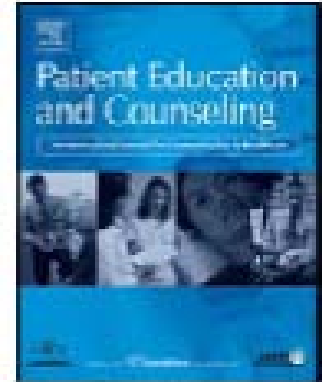
# SDM for EPF



# Is SDM the magic answer?

- SDM is not for all patients or all women
- But it does create a partnership and balance of power during the intimate and personal experience of miscarriage
- For more answers to how women want to make decisions about miscarriage management, stay tuned....

# Thank you and thanks to my co-authors!



Counseling women with early pregnancy failure: Utilizing evidence,  
preserving preference

Robin R. Wallace<sup>a,\*</sup>, Suzan Goodman<sup>b</sup>, Lori R. Freedman<sup>c</sup>, Vanessa K. Dalton<sup>d</sup>, Lisa H. Harris<sup>e</sup>

*Patient Education and Counseling* 81 (2010) 454–461

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