Do Nothing, Do Something, Aspirate: Management of Early Pregnancy Loss in the Outpatient Setting

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Disclosures

- Sarah Prager receives honoraria from UpToDate for co-authoring six topics related to early pregnancy loss; also receives honoraria for developing content and training on IUDs
- Kelly Quinley – nothing to disclose
- Robin Supplee – nothing to disclose

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Objectives

1. Understand the diagnosis of early pregnancy loss (EPL)
2. Describe relevance of EPL management in the outpatient setting
3. Describe the uterine evacuation procedure using the manual uterine aspirator (MUA)
4. Express an awareness of the range of values each member of the healthcare team brings to EPL care
5. Highlight the importance of providing non-judgmental care to patients

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Nomenclature

Early Pregnancy Loss/Failure (EPL/EPF)
Spontaneous Abortion (SAb)
Miscarriage

These are all used interchangeably!

Manual Uterine Aspiration/Aspirator (MUA)
Manual Vacuum Aspiration/Aspirator (MVA)
Uterine Evacuation
Suction D&C/D&C/dilation and curettage

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Background

- Early Pregnancy Loss (EPL) = nonviable, intrauterine pregnancy < 13 weeks' gestation
- EPL is the most common complication of early pregnancy
  - 15–20% clinically recognized pregnancies
  - ~ One million EPLs each year in the U.S.

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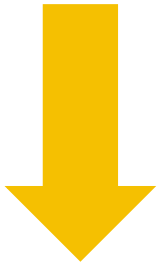
Pregnant + Bleeding in the ED

Bleeding in early pregnancy accounts for 3% of ED visits for all women ages 15-44

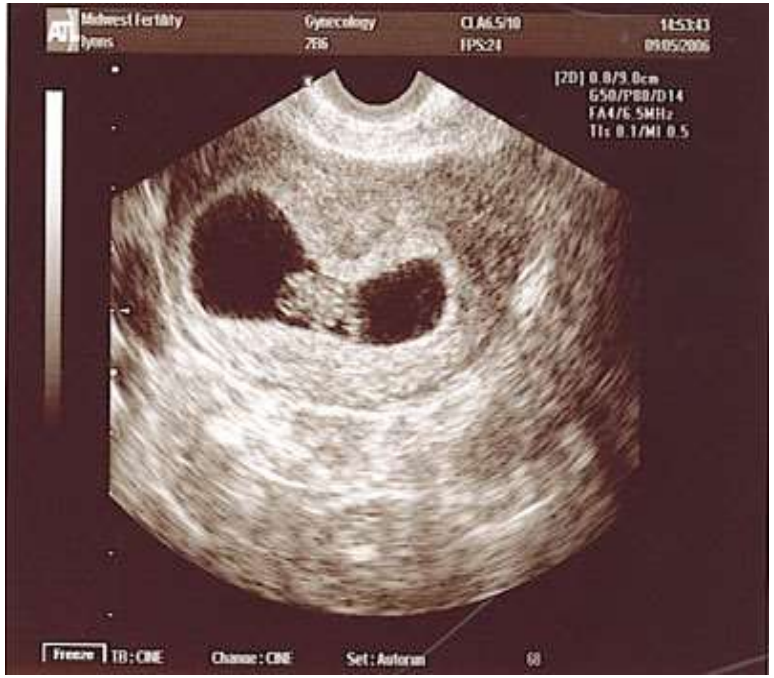


900,000 annual ED visits

Benson, L. 2021

Sam

26 yo G2P1 presents with vaginal bleeding after a positive home pregnancy test. An ultrasound shows a CRL of 7mm but no cardiac activity.



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Risk Factors for EPL

- Age
- Prior EPL
- High gravidity
- Maternal BMI < 18.5 or > 25
- Endocrine disorders (thyroid disease, diabetes)
- Maternal infection
- Smoking, alcohol, cocaine
- NSAIDs
- Caffeine (> 200mg per day)
- Low folate levels
- Environmental pollutants
- Structural inequalities/racism





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Etiology of EPL

- Chromosomal abnormalities (50%)
  - Trisomies (50-60%)
  - Polyploidies (20%)
  - Monosomy X (12%)
  - Other
- Maternal factors
  - Structural abnormalities
  - Maternal infection/endocrinopathy/thrombophilia
- Unexplained

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Clinical Presentation of EPL

- Bleeding
- Pain/cramping
- Falling or abnormally rising ßhCG
- Decreased symptoms of pregnancy
- No symptoms at all!

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Society of Radiologists in Ultrasound Guidelines for Transvaginal Ultrasonographic Diagnosis of Early Pregnancy Loss*

Findings Diagnostic of Early Pregnancy Loss†	Findings Suggestive, but Not Diagnostic, of Early Pregnancy Loss‡
Crown–rump length of 7 mm or greater and no heartbeat	Crown–rump length of less than 7 mm and no heartbeat
Mean sac diameter of 25 mm or greater and no embryo	Mean sac diameter of 16–24 mm and no embryo
Absence of embryo with heartbeat 2 weeks or more after a scan that showed a gestational sac without a yolk sac	Absence of embryo with heartbeat 7–13 days after an ultrasound scan that showed a gestational sac without a yolk sac
Absence of embryo with heartbeat 11 days or more after a scan that showed a gestational sac with a yolk sac	Absence of embryo with heartbeat 7–10 days after an ultrasound scan that showed a gestational sac with a yolk sac
	Absence of embryo for 6 weeks or longer after last menstrual period
	Empty amnion (amnion seen adjacent to yolk sac, with no visible embryo)
	Enlarged yolk sac (greater than 7 mm)
	Small gestational sac in relation to the size of the embryo (less than 5 mm difference between mean sac diameter and crown–rump length)

*Criteria are from the Society of Radiologists in Ultrasound Multispecialty Consensus Conference on Early First Trimester Diagnosis of Miscarriage and Exclusion of a Viable Intrauterine Pregnancy, October 2012.

†These are the radiologic criteria only and do not replace clinical judgment.

‡When there are findings suspicious for early pregnancy loss, follow-up ultrasonography at 7–10 days to assess the pregnancy for viability is generally appropriate.

Reprinted from Doubilet PM, Benson CB, Bourne T, Blaivas M, Barnhart KT, Benacerraf BR, et al. Diagnostic criteria for nonviable pregnancy early in the first trimester. Society of Radiologists in Ultrasound Multispecialty Panel on Early First Trimester Diagnosis of Miscarriage and Exclusion of a Viable Intrauterine Pregnancy. N Engl J Med 2013;369:1443–51.

Sam

26 yo G2P1, CRL of 7mm but no cardiac activity

Sam and partner request information on all the treatment options. You confirm the rest of the history.

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Management Options

Do Nothing: Expectant management

Do Something: Medication management

Aspirate: Uterine Aspiration

Sotiriadis A, Obstet Gynecol 2005
Nanda K, Cochrane Database Syst Rev 2006

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Expectant Management

- Requirements for therapy:
  - <13 weeks gestation
  - Stable vital signs
  - No evidence of infection

- What to expect:
  - Most expel within 2 weeks after diagnosis
  - Prolonged follow-up may be needed
  - Acceptable and safe to wait 4+ weeks post-diagnosis

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Expectant Management

- Miscarriage is often painful
- For patients wanting expectant (or medical) management, give pain medications for home use:
  - NSAIDs
    - Ibuprofen 800 mg q 8
    - Naproxen 500 mg q 12
  - Narcotic (e.g. oxycodone) only as needed
- Recommend adding heating pad/hot water bottle

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Expectant Management: Outcomes

Overall success rate 81%

Success rates vary by type of miscarriage (helpful to tailor counseling)

- Incomplete/inevitable abortion: 91%
- Embryonic demise: 76%
- Anembryonic pregnancies: 66%

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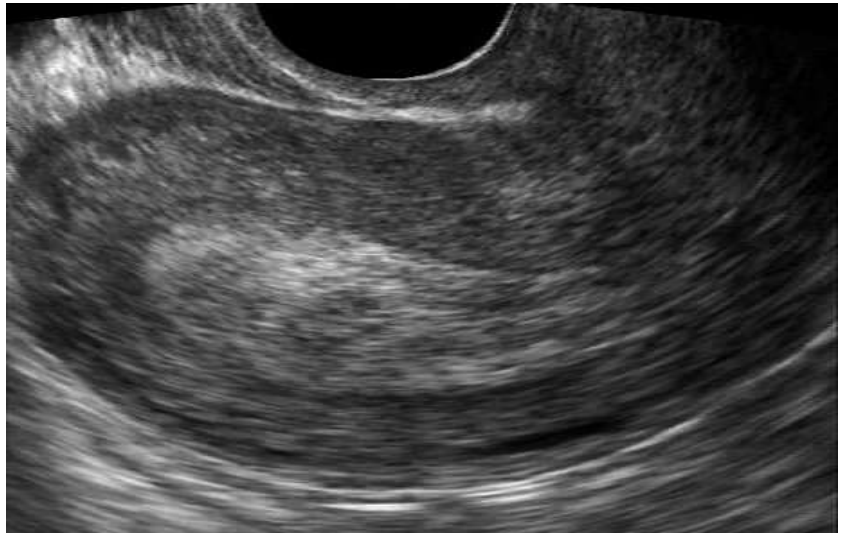
Luise C, Ultrasound Obstet Gynecol 2002

What is Success? Definitions Used in Studies

- Ultrasound documentation of absence of gestational sac
    - Surgical intervention is not required for asymptomatic women with thickened endometrial stripe
- Alternative options: phone calls, hcg measurements



Harwood B, Contraception 2001
Reynolds A, Eur. J Obstet Gynecol Reproduct. Biol 2005

When to Intervene for Expectant Management?

- Continued gestational sac
- Clinical symptoms
- Patient preference
- Time (?)
- Vaginal bleeding and positive UPT are possible for 2–4 weeks
  - Poor measures of success

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Sam

26 yo G2P1, CRL of 7mm but no cardiac activity

Sam is continuing to bleed, though not heavily. Sam calls the clinic a few days later and reports that she is feeling anxious waiting and would like to do something.

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Medication Management

- Misoprostol

- Misoprostol + Mifepristone

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Medication Management: Requirements

- <13 weeks gestation
- Stable vital signs
- No evidence of infection
- No allergies to medications used
- Adequate counseling and patient acceptance of side effects

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Misoprostol

- Prostaglandin E1 analogue
- FDA approved for prevention of gastric ulcers
- Used off-label for many Ob/Gyn indications:
  - Labor induction
  - Cervical ripening
  - Medical abortion (with mifepristone)
  - Prevention/treatment of postpartum hemorrhage
- Can be administered by oral, buccal, sublingual, vaginal and rectal routes
- Cost effective, stable at room temperature

Chen B, Clin Obstet Gynecol 2007

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Misoprostol Dosing

- 800 mcg per vagina or buccally
- Repeat at 12–24 hours, if incomplete
- Repeat 3-4 hours after first dose if ≥ 9 weeks (*discharge home with additional doses)
- Measure success as with expectant management
- Intervene with uterine aspiration management as needed (same as with expectant management)
- Success rate depends on type of miscarriage
  - ~ 100% with incomplete abortion
  - 87% for all others

Wood SL, Obstet Gynecol 2002; Bagratee JS, Hum Reproduct 2004; Blohm F, BJOG: Int J Obstet Gynecol 2005.

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Medication Management: Mifepristone & Misoprostol

Mifepristone: Progestin antagonist that binds to progestin receptor: Used with elective medical abortion to “destabilize” implantation site

- Current evidence-based regimen: **200 mg mifepristone + 800 mcg misoprostol**
- Success rates for mifepristone & misoprostol in EPL:
  - 83.8% by day 2 (67.1% miso alone) RR 1.25[1.09 to 1.43]
  - 87.8% by day 8 (71.1% miso alone) RR 1.23[1.10 to 1.39]
- Need for uterine aspiration:
  - 8.8% by day 30 (23.5% miso alone) RR 0.37[0.21 to 0.68]
- **Mifepristone improves outcomes; use if you can**

Gronlund A, Acta Obstet Gynaecol 1998; Nielsen S, Br J Obstet Gynaecol 1997;
Niinimaki M, Fertility Sterility 2006; Schreiber CA, Contraception 2006
Schreiber CA, Mifepristone Pretreatment for the Medical Management of EPL. NEJM June 2018

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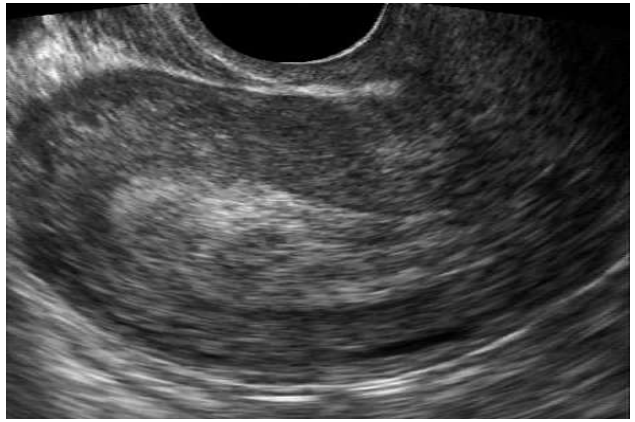
Successful Medication Management

- Ultrasound documentation of absence of gestational sac
    - Surgical intervention is not required for asymptomatic patients with thickened endometrial stripe
- Alternative options: phone calls, hcg measurements



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Sam

26 yo G2P1, CRL of 7mm but no cardiac activity

What if instead, Sam opts to go directly to uterine aspiration? Sam is concerned about the unpredictability of medication management. Is Sam a good candidate for aspiration?

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Uterine Aspiration Management

Who should have management with uterine aspiration?

- Unstable
- Significant medical morbidity
- Infection
- Very heavy bleeding
- *Anyone who wants uterine aspiration*

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Uterine Aspiration Management

Electric vacuum aspiration

Manual uterine aspiration

~~Sharp curettage~~

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What is a Manual Uterine Aspirator?

- Locking valve
- Portable and reusable
- Equivalent to electric pump
- Efficacy same as electric vacuum (98%–99%)
- Semi-flexible plastic cannula

Creinin MD, et al. Obstet Gynecol Surv. 2001.; Goldberg AB, et al. Obstet Gynecol. 2004.
Hemlin J, et al. Acta Obstet Gynecol Scand. 2001.

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Advantages of MUA treatment in the ED

Simple	Safe	Fast
Efficacious	$$ Sparing	Common
Hospital admits & OR resources	Improves ED flow	Reduces repeat visits

Demetroulis 2001; Lee and Slade 1996; Kinariwala 2013; Blumenthal 1994; Torre 2012

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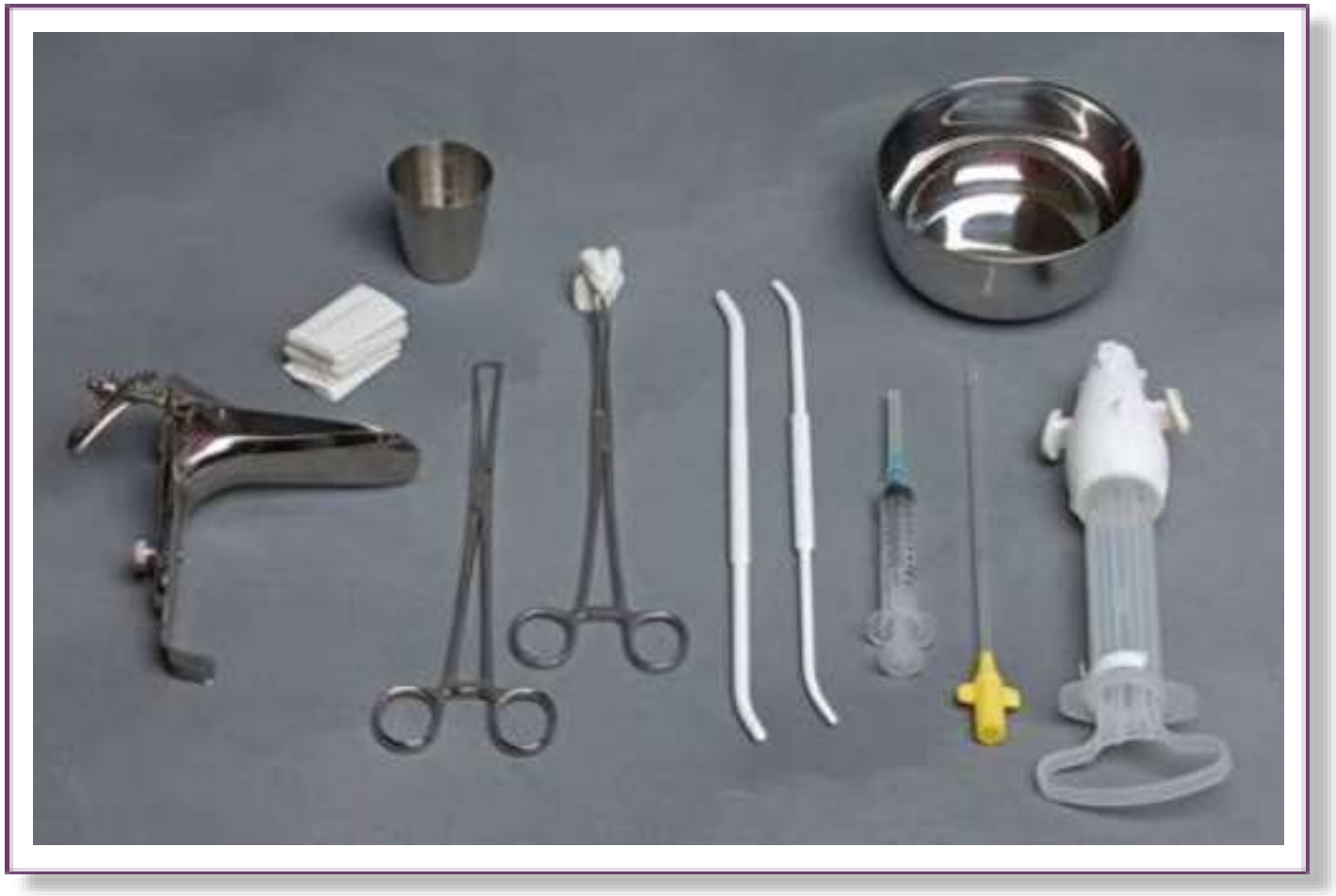
MUA Instruments



Step-by-step guide available on IPAS website

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Complications with MUA

- Very rare
- May include:
  - Incomplete evacuation
  - Uterine or cervical injury
  - Infection
  - Hemorrhage
  - Vagal reaction

MVA Label. Ipas. 2004.

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Oral Pain Medications for Uterine Aspiration

- NSAID
  - Ibuprofen 800 mg
  - Naproxen 500 mg
- Benzodiazepine
  - Lorazepam 1-4 mg PO/SL
  - Diazepam 2-10 mg PO
- Narcotic
  - Not routinely recommended
  - Doesn't improve pain control
  - Increases vomiting

- Paracervical block!
  - E.g. 20cc 1% lidocaine
- Ancillary anesthesia
  - Importance of psychological preparation and support
  - RCT demonstrated benefit of music/headphones

Micks E, et al. Hydrocodone-acetaminophen for pain control in first trimester surgica a randomized controlled trial. Obstet Gynecol. 2012 Nov; 120(5): 1060-9.

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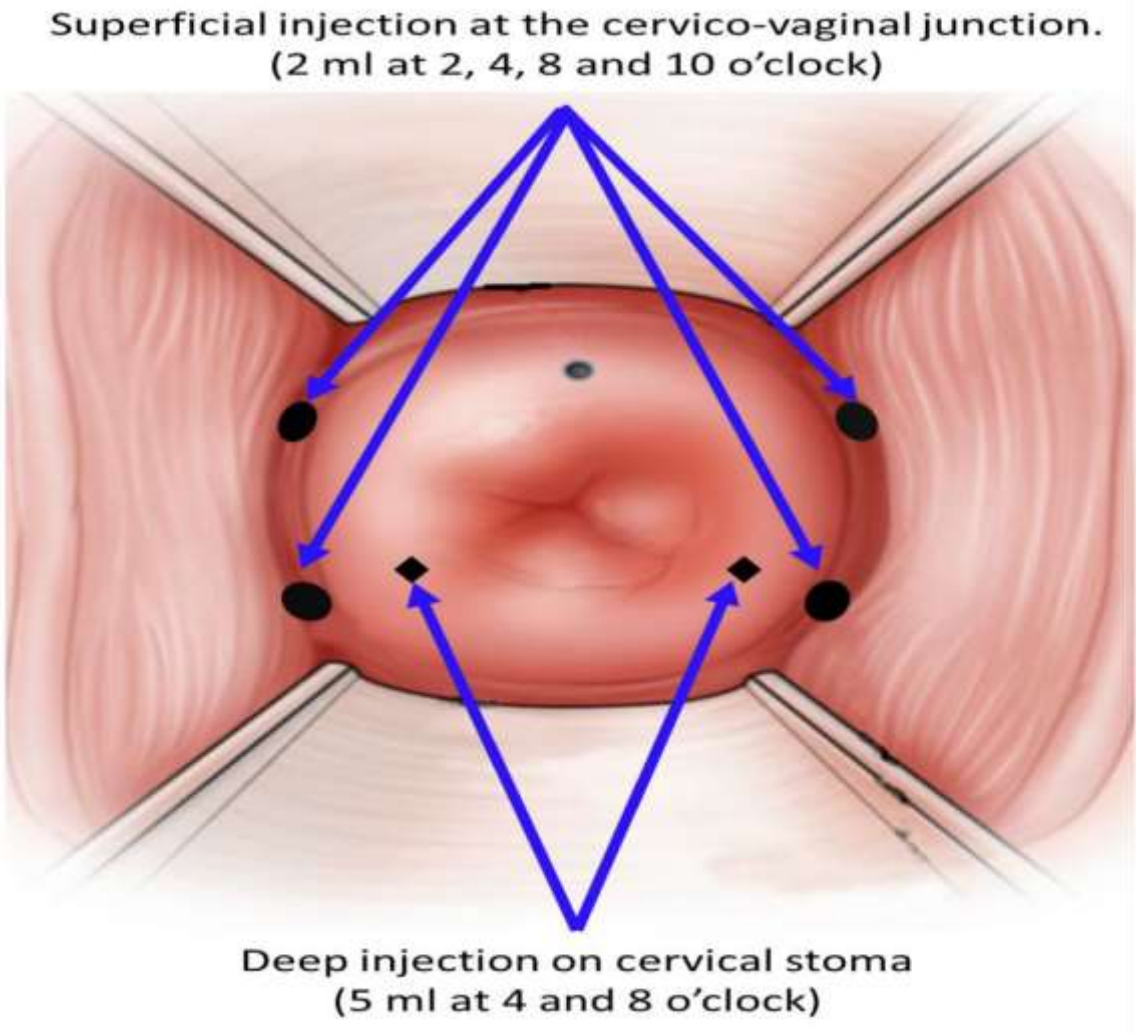
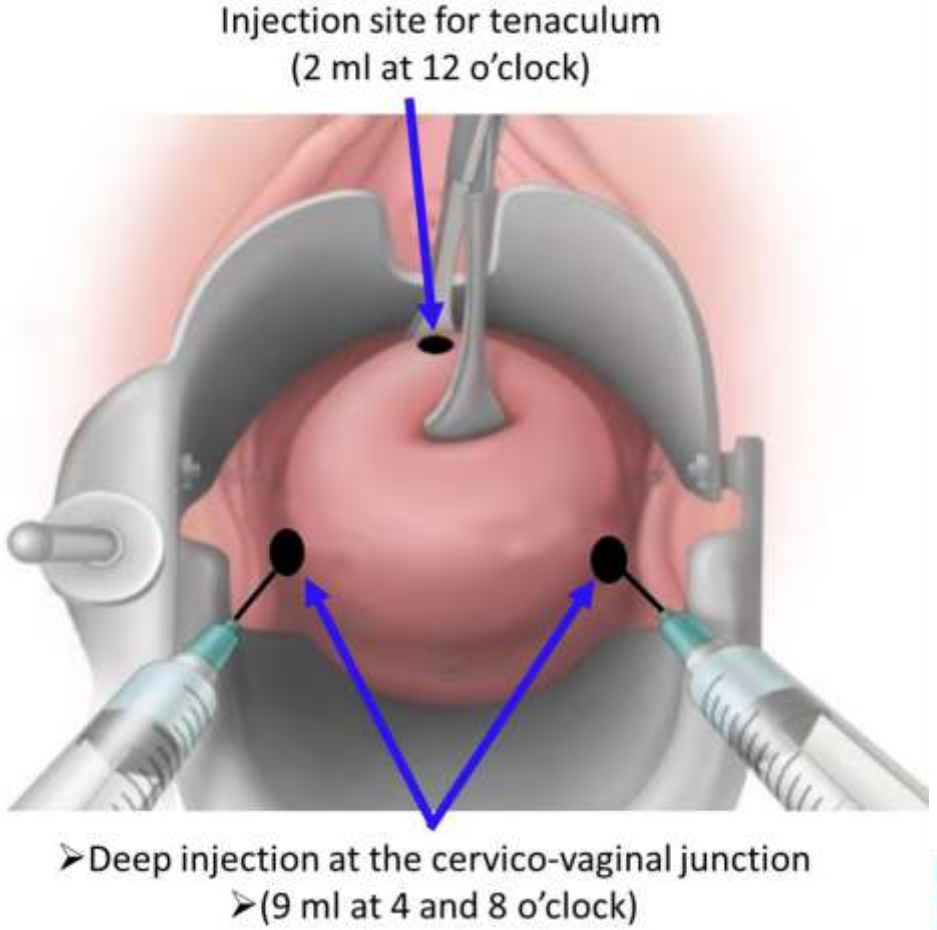
Paracervical Block





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Castleman L, Mann C. 2002. Maltzer DS, et al. 1999.

Table 4. Adverse Events and Acceptability of Medical and Surgical Treatment of Early Pregnancy Failure.*

Variable	Misoprostol	Vacuum Aspiration	P Value†
Adverse event			
Hemorrhage requiring hospitalization with or without blood transfusion — % (no./total no.)	1 (5/488)	1 (1/148)	1.0
Hospitalization for endometritis — % (no./total no.)	<1 (2/488)	0 (0/148)	1.0
Fever (temperature ≥38.0°C [100.4°F]) — % (no./total no.)	3 (13/477)	4 (6/148)	0.41
Emergency visit to hospital within 24 hr after treatment — % (no./total no.)	3 (15/488)	2 (3/148)	0.59
Unscheduled hospital visits — % (no. of visits/total no. of patients)‡	23 (114/488)	17 (25/148)	0.09
Change in hemoglobin between day 1 and day 15 — g/dl§	−0.65±1.10	−0.18±0.89	<0.001
Decrease in hemoglobin ≥2 g/dl — % (no./total no.)§	9 (38/421)	4 (5/134)	0.05
Decrease in hemoglobin ≥3 g/dl — % (no./total no.)§	5 (19/421)	1 (1/134)	0.04
Nausea — % (no./total no.)¶	53 (250/472)	29 (41/141)	<0.001
Vomiting — % (no./total no.)¶	20 (96/475)	7 (10/142)	<0.001
Diarrhea — % (no./total no.)¶	24 (113/473)	10 (14/142)	<0.001
Abdominal pain — % (no./total no.)¶	99 (473/476)	95 (134/141)	<0.001
Pain-severity score¶‖	5.7±2.4	3.2±2.4	<0.001
Acceptability — % (no./total no.)			
Would probably or absolutely recommend this procedure	83 (379/456)	83 (125/150)	0.95
Would probably or absolutely use this treatment again	78 (357/456)	75 (112/150)	0.36

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Zhang, NEJM 2005

Best Practices in Counseling

- Put aside YOUR preconceived notions of how the patient may be feeling about the pregnancy, the pregnancy loss and options for management
- Consider remaining silent after providing initial results or information
- Determine if the pregnancy is desired
- Ask open-ended questions and use active listening
- Provide reassurance. Don't guarantee that "everything will be alright."
- Normalize emotions and validate feelings
- Validate difficulties of having EPL addressed in an emergency room or new clinic
- Encourage the patient to seek emotional support from others
- Be thoughtful disclosing personal information

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Sam

26 yo G2P1, CRL of 7mm but no cardiac activity

Sam has the uterine aspiration with MUA procedure right there in the emergency department.

The procedure is uncomplicated and questions after include:

“Can I get pregnant right away?”

“Am I at risk for another miscarriage?”

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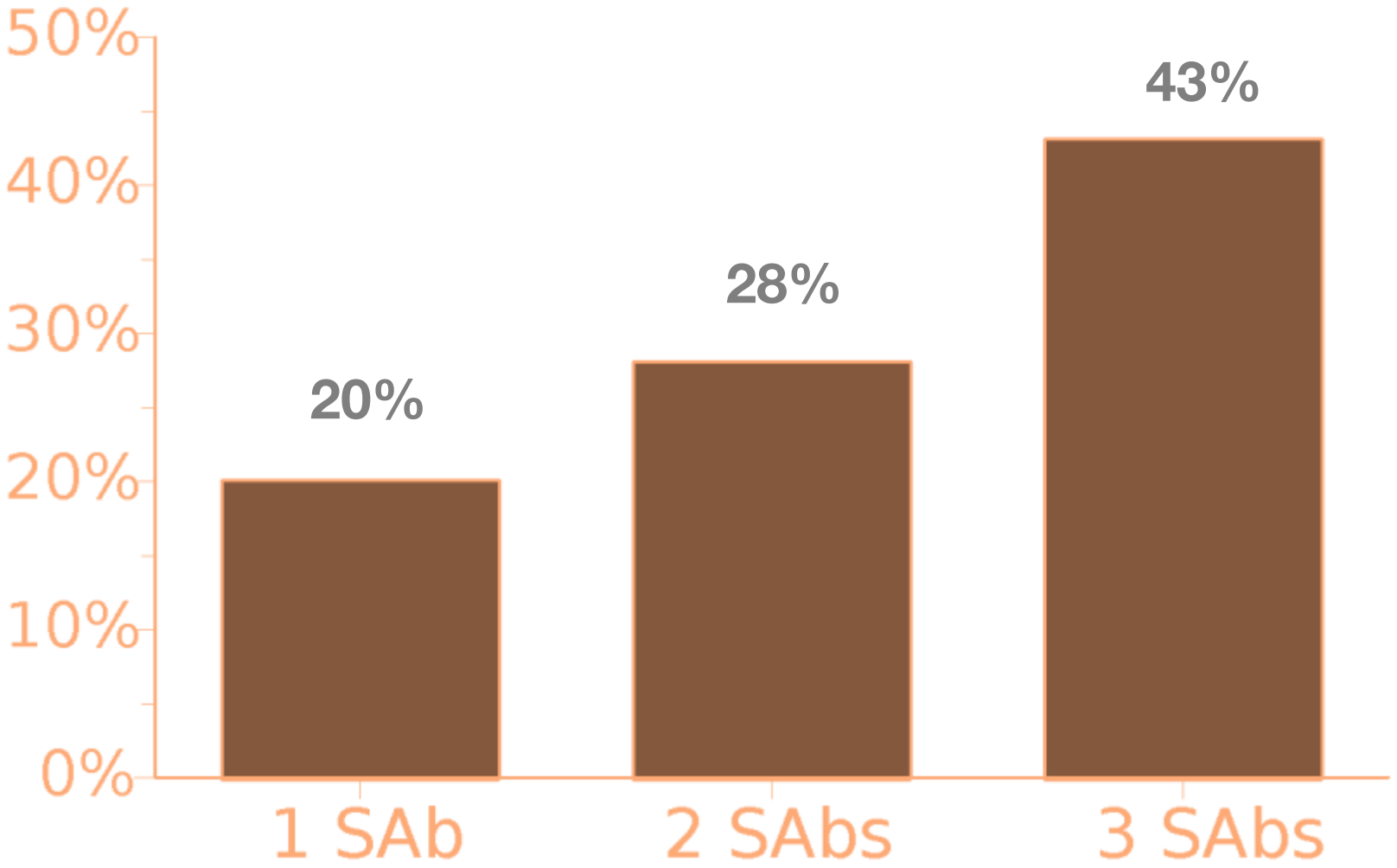
Future Miscarriage Risk



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Post Early Pregnancy Loss Care

- Poor evidence for Rhogam need in early pregnancy
  - US recommendations mixed, ACOG still in favor
- No evidence for pelvic rest
- No evidence for delaying a conception
- Initiate contraception upon completion of procedure (even IUDs)
- Expect light-moderate bleeding for 2 weeks
- Menses return after 4-8 weeks
- Negative ßhCG values after 2–4 weeks (don’t recommend routine checking)
- Grief counseling when appropriate

Goldstein R, Am J Obstet. Gynecol 2002; Wyss P, J Perinat Med 1994;
Grimes D, Cochrane Database Syst Rev 2000

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More Information on EPL

- UW TEAMM website: www.miscarriagemanagement.org
- UCSF website: www.earlypregnancyresources.org
- HPSRx Enterprises (sole MUA equipment distributor): www.hpsrx.com
- Papaya Workshop Videos: www.papayaworkshop.org
- Reproductive Health Access Project: www.reproductiveaccess.org
- Don’t Talk About the Baby documentary: www.donttalkaboutthebaby.com

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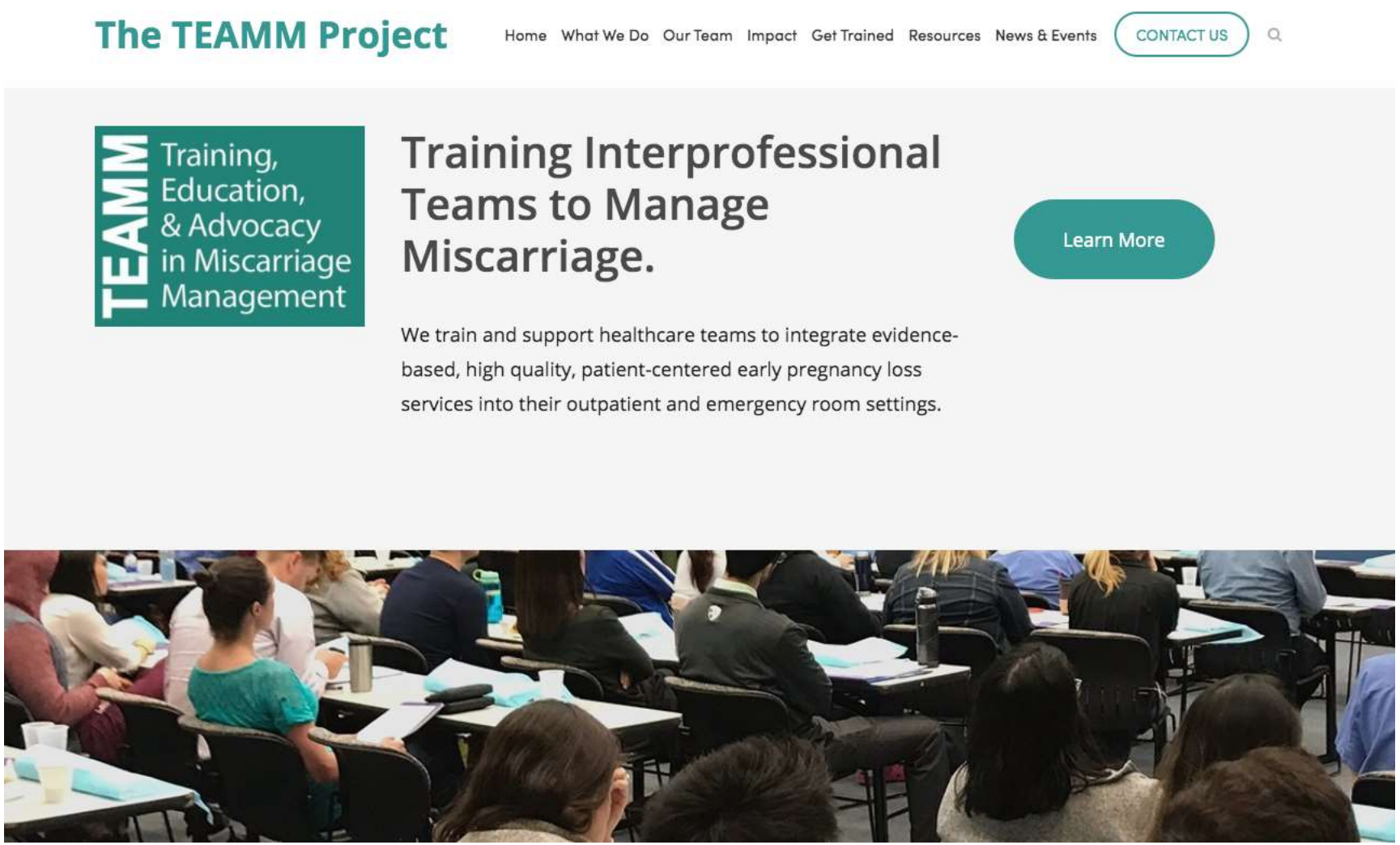
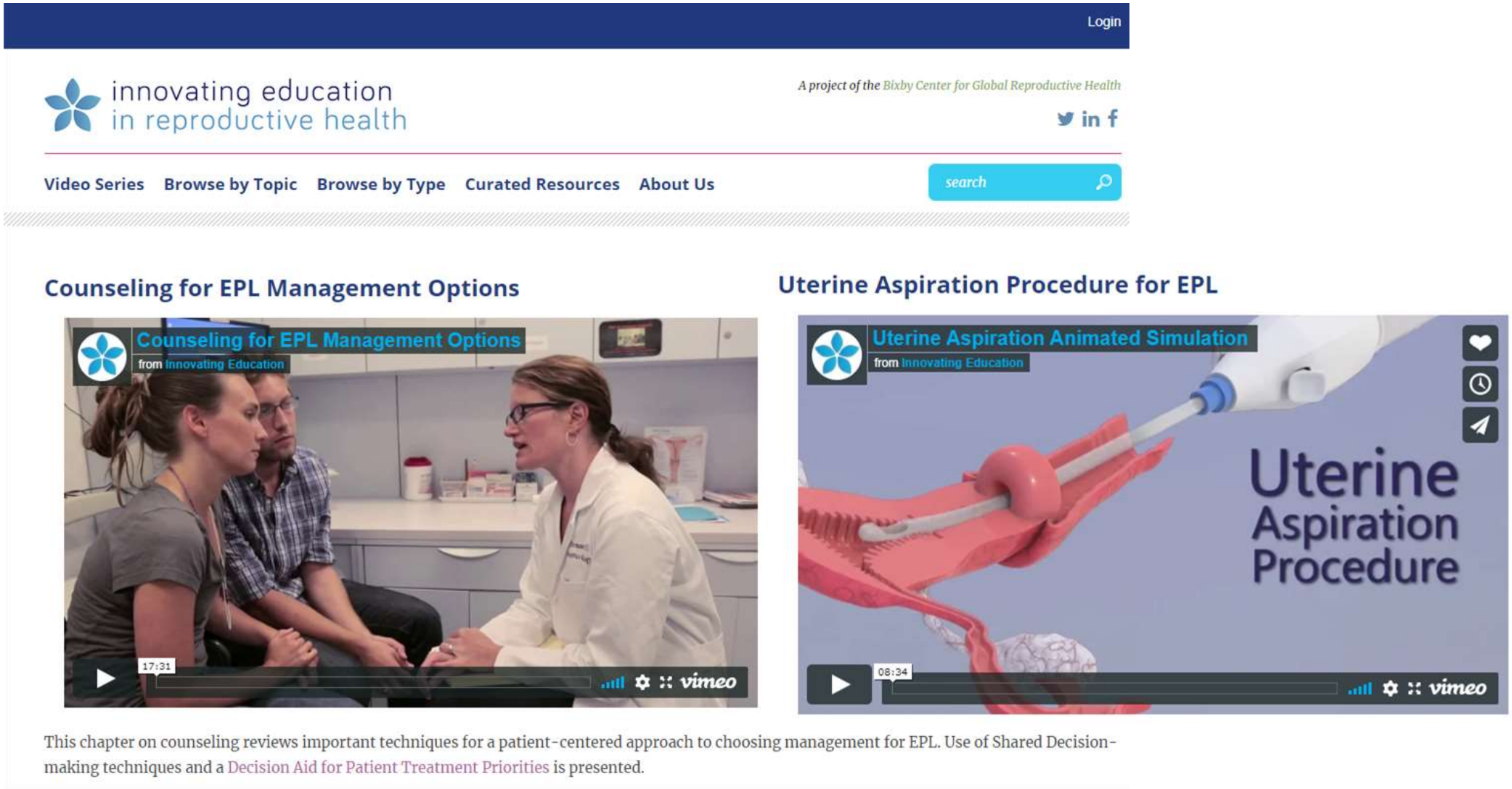
UW TEAMM Resources



Innovating Education (UCSF)



QUESTIONS?

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Steps for Implementation of an EPL Protocol in the Outpatient and ED Settings

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Additional Learning Objectives

1. Anticipate common barriers to EPL implementation
2. Design a protocol for clinical care of EPL in the outpatient setting and emergency department
3. Create an interprofessional implementation plan that clearly outlines key decision makers and roll out strategy
4. Consider ongoing EPL trainings for support staff

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Barriers to moving surgical EPL care out of the OR

- Provider preference for providing uterine aspiration in OR
- Proximity of miscarriage management to abortion procedures
- Limited availability of support staff or procedural space
- Difficulties integrating EPL care into scheduling and flow
- Uncertainty about responding to patients' emotional needs

Dennis, A, 2015.

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Resources needed to extend/improve miscarriage care

- Identification of a “champion”
- Involvement of key stakeholders early, especially nursing leadership
- Designing interprofessional trainings
- Systems for tracking equipment and supplies
- System for tracking POC pathology results
- Persistence and patience
- **Clear protocols & explanation of roles (PA/NP/MD/nursing)**

Dennis, A, 2015, Darney B, 2013.

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Protocol development - Outpatient clinics

- How to build on protocols for pre-existing procedures
  - Cerclage placement
  - IUD insertion
  - LEEP / Cone Biopsy
- Decide on pain regimen that will available
  - PO
  - IV
- Preparations for complications
- Nursing involved in initial drafting

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Protocol development – Emergency departments

- Modify an outpatient MUA protocol
- Key clinical points to clarify
  - Who will be performing MUA, what supervision needed
  - Is ED nurse presence required
  - Pain management - is sedation needed?
- Clearly define what procedural materials needed
  - Stocking responsibilities
  - Cost centers for materials

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Tandem protocol and workflow development

- Use protocol drafting to also develop patient care workflow
- Identify key decision makers
  - OUTPATIENT: Champion, nursing supervisor, midwife/PA supervisor, dept chief
  - ED: Champion, nursing manager, ED Technician manager, dept chief
- Discuss hesitations among these groups while developing protocol
  - Nursing hesitations
  - Pain management
  - POC disposal

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Timing and design of roll out

- Meetings prior to roll out
  - Nursing staff - imagined patient walk through
  - Hopes and hesitations
  - Grand rounds vs educational session with didactic and hands on MUA workshop
  - Key stakeholders meeting
  - Draft ongoing training plan for new APCs, nurses, physicians
- Plan initial cases to be straightforward & don't perform MUAs before roll out date

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QUESTIONS?

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