University of Colorado **Anschutz Medical Campus**

Reimagining Early Pregnancy Care

Clinical Pearls and Practical Strategies

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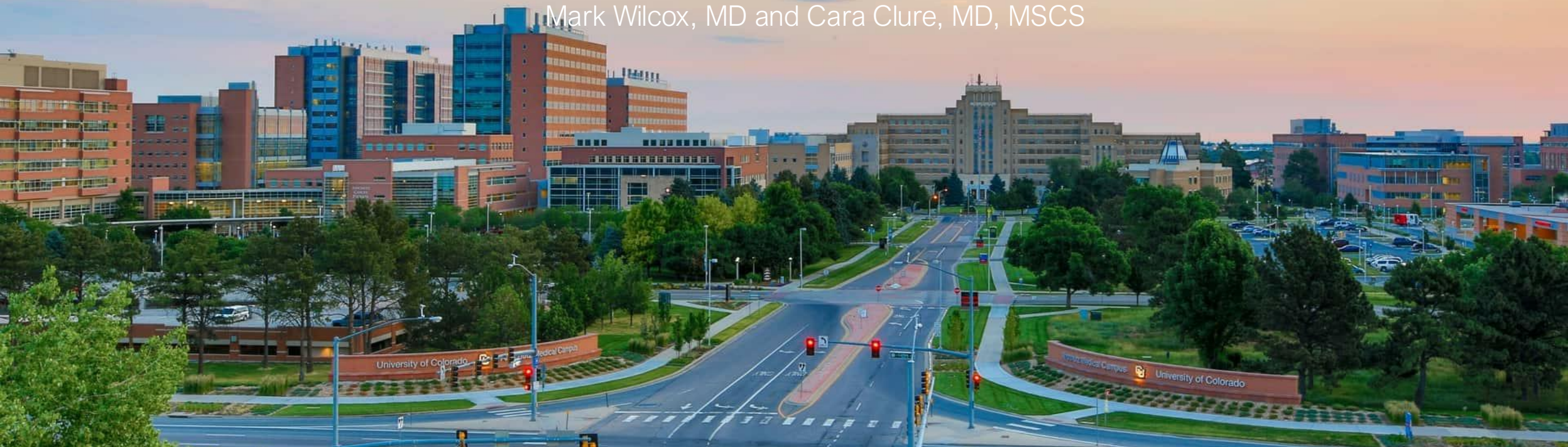


We have no disclosures

Objectives

Review	Clinical updates and pearls in early pregnancy care
Explain	Early Pregnancy Assessment Clinic (EPAC) model, highlighting differences from traditional care with a focus on patient experience
Share	Reflections on and tips for starting an EPAC

Gratitude to our team

- Co-founder Nancy Fang, MD
- Keisha Indenbaum-Bates, NP
- Colleagues Rebecca Cohen, MD & Lauren Thaxton, MD
- RNs Jessica Brown, Milena Sanchez Molina, & Shannon Rierden
- Practice manager Gabi Van Valkenburg

Clinical updates and pearls in early pregnancy care

Should Rhogam Be Given Before 12 Weeks?

- Fetal RBC exposure is far below levels required to cause sensitization
- Forgoing RhIg reduces cost and barriers
  - Aligns with ACOG, WHO, RCOG, SOGC, SFP, NAF, and NICE guidelines
- SMFM recommends that RhD testing and RhIg be *offered* for spontaneous and induced abortion <12 weeks
  - … but only in care settings where such testing is logistically and financially feasible and does not hinder access to abortion care
- Shared decision-making is essential

Horvath, et al., Contraception, 2022
Clinical Practice Update, Obstet. Gynecol., 2024
SMFM Statement, Am. J. Obstet. Gynecol., 2024

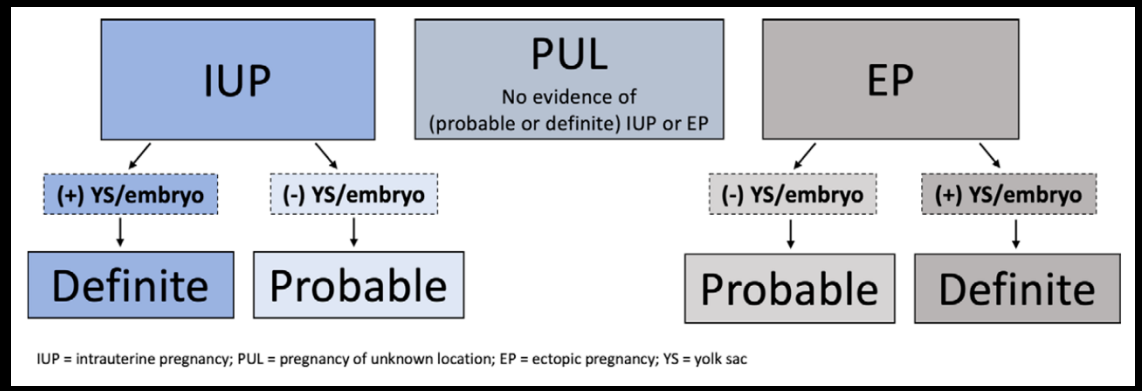
Updated First-Trimester Ultrasound Lexicon

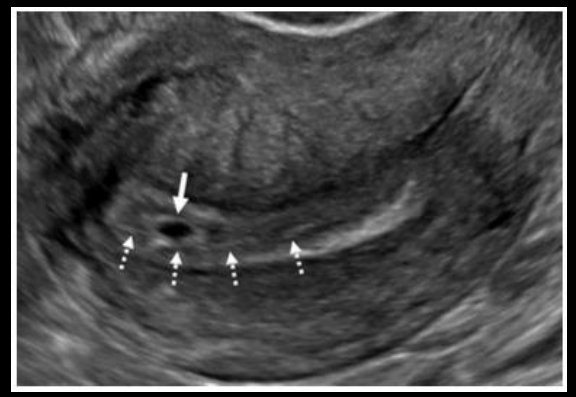
- Early Pregnancy Loss (EPL) replaces “pregnancy failure”
  - Supported modifiers:
    - concerning for
    - diagnostic of
    - in progress
    - Incomplete
    - completed
- “Cardiac activity” replaces “heartbeat / heart motion”
  - Reflects accurate embryologic development
  - Avoid:
    - live
    - living
    - viable
    - nonviable

Rodgers, et al., Radiology, 2024

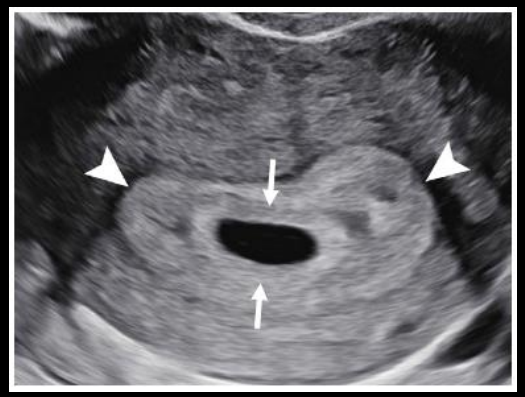
Updated First-Trimester Ultrasound Lexicon

- Updated definitions of pregnancy location
  - Intrauterine pregnancy (IUP): implantation in a normal intrauterine location
  - Ectopic pregnancy (EP): any abnormal implantation site—includes C-section scar, cervix, intramural, interstitial, ovarian, abdominal
- Pregnancy of Unknown Location (PUL) – precise use
  - Applies only when no probable or definite IUP or EP is seen
  - Empty sac = "probable GS/pregnancy" rather than PUL





Intradecidual sign



Double decidual sac sign

Rodgers, et al., Radiology, 2024

Reevaluating Diagnostic Criteria for EPL

- Evidence supports earlier definitive diagnosis
- Yet the SRU recommends higher thresholds (e.g., MSD ≥ 25 mm) and 14-day intervals

Table 1
A data-driven approach that uses evidence-based criteria to support transparent shared decision-making and expedited management of early pregnancy loss using measurement criteria by initial ultrasound

	Diagnostic criteria	Specificity % (95% CI)
Crown rump length measurement	Crown rump length ≥ 5.5 mm and no embryonic cardiac activity	**97.3 (92.3 – 99.1), *n* = 80**[9]
	Crown rump length ≥ 6.2 mm and no embryonic cardiac activity	**100 (96.6 – 100), *n* = 110**[9]
	Crown rump length ≥ 7 mm and no embryonic cardiac activity	Society of Radiologists in Ultrasound criteria[3]
Mean sac diameter	Mean sac diameter 16 mm and no yolk sac or embryo	**96.7 (94.3 – 98.1), *n* = 352**[9]
	Mean sac diameter 18 mm and no yolk sac or embryo	**98.9 (97.2 – 99.6), *n* = 360**[9]
	Mean sac diameter ≥ 21 mm and no yolk sac or embryo	**100 (99.0 – 100), *n* = 364**[9]
	Mean sac diameter ≥ 18 mm and ≥ 70 days since certain last menstrual period with no embryo	**100 (99.6 – 100), *n* = 907**[9]
	Mean sac diameter ≥ 25 mm and no embryo	Society of Radiologists in Ultrasound criteria[3]

Table 2
A data-driven approach that uses evidence-based criteria to support transparent shared decision-making and expedited management of early pregnancy loss using time-based ultrasound criteria

Index ultrasound finding	Days between ultrasound	Follow up ultrasound finding	Specificity % (95% CI)
Embryo with no embryonic cardiac activity regardless of crown rump length	≥ 7	Absence of embryonic cardiac activity	100 (96.5 – 100), *n* = 103
Mean sac diameter ≥ 12 mm (with or without yolk sac)	≥ 7	Absence of embryonic cardiac activity	100 (97.6 – 100), *n* = 150
Mean sac diameter < 12 mm (with or without yolk sac)	≥ 14	Absence of embryonic cardiac activity and mean sac diameter has not doubled	100 (99.2 – 100), *n* = 478
Gestational sac present (without a yolk sac)	≥ 14	Absence of embryonic cardiac activity	Society of Radiologists in Ultrasound Criteria
Gestational sac present (with a yolk sac)	≥ 11	Absence of embryonic cardiac activity	Society of Radiologists in Ultrasound Criteria

Doubilet, et al., N. Engl. J. Med., 2013
Chen, et al., Contraception, 2025

Reevaluating Diagnostic Criteria for EPL

- Patient history, serial hCG, goals → earlier, safe diagnosis
- Earlier diagnosis reduces:
  - emotional burden
  - prolonged bleeding/pain
  - unplanned emergency visits
  - delays in attempting conception

"We call to revise the current guidelines from the Society of Radiologists, and recommend including clinical data with evidence-based sonographic criteria to support the expedited management of early pregnancy loss"

Chen, et al., Contraception, 2025

Manage Early Pregnancy Loss with Mifepristone + Misoprostol For Everyone

- Mifepristone dramatically improves success
  - Complete expulsion with 1 dose misoprostol:
    - 67% with misoprostol alone
    - 84% with mifepristone pretreatment
- No reliable clinical phenotype for misoprostol-alone success
  - Previously proposed predictors do not hold
  - Early bleeding, nulliparity, EPL type, GA, cervical os status did not predict success in this trial

- Clinical Take-Home → Mifepristone pretreatment should be considered standard of care for medical management of EPL

Sonalkar, et al., Am. J. Obstet. Gynecol., 2020

Prioritizing Pregnancy Desiredness in PUL

1. Assess pregnancy desiredness at initial encounter:
    - Crucial information
    - Should be explored with nonjudgmental, open-ended questions
    - May change over time

Nonjudgmental assessment of pregnancy desire:

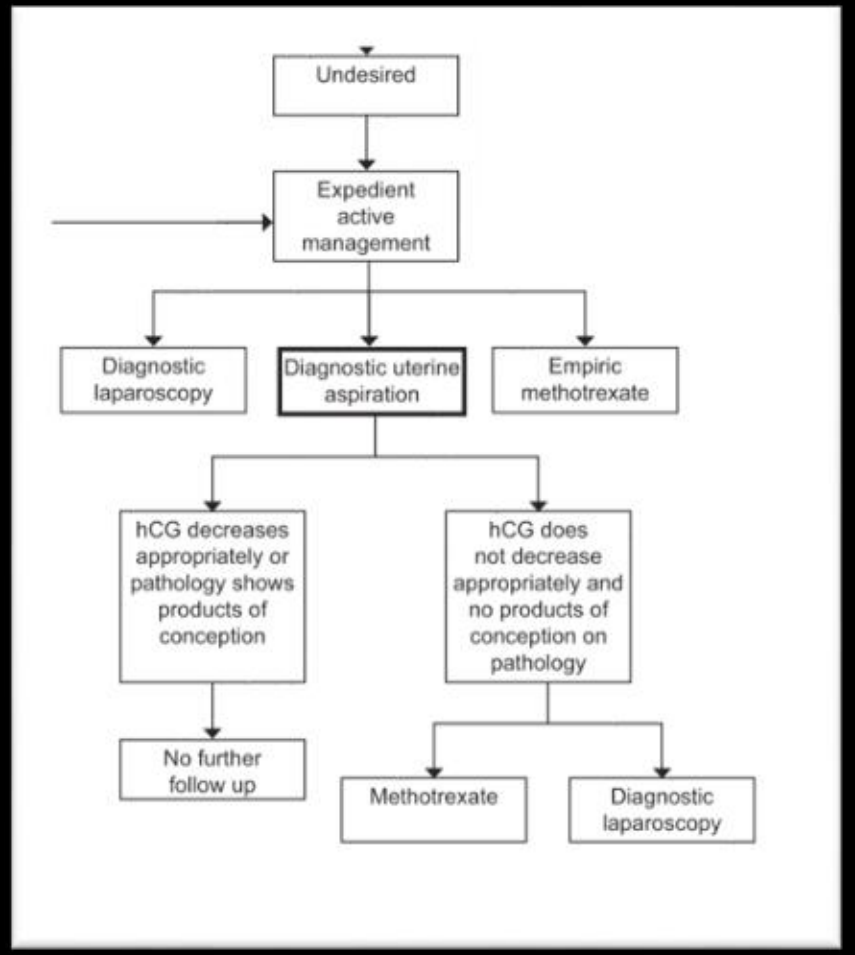
- Tell me about your initial thoughts after receiving your positive pregnancy test. What are your feelings about the pregnancy now?
- Were you planning for this pregnancy?
- If this is a normal pregnancy, is it a pregnancy you wish to continue?

Flynn, et al., Obstet. Gynecol., 2020

Prioritizing Pregnancy Desiredness in PUL

2. For undesired pregnancies, offer active management:
   - Diagnostic uterine aspiration (preferred)
   - MTX
   - Diagnostic laparoscopy
   - Mife/miso (when early IUP is likely)

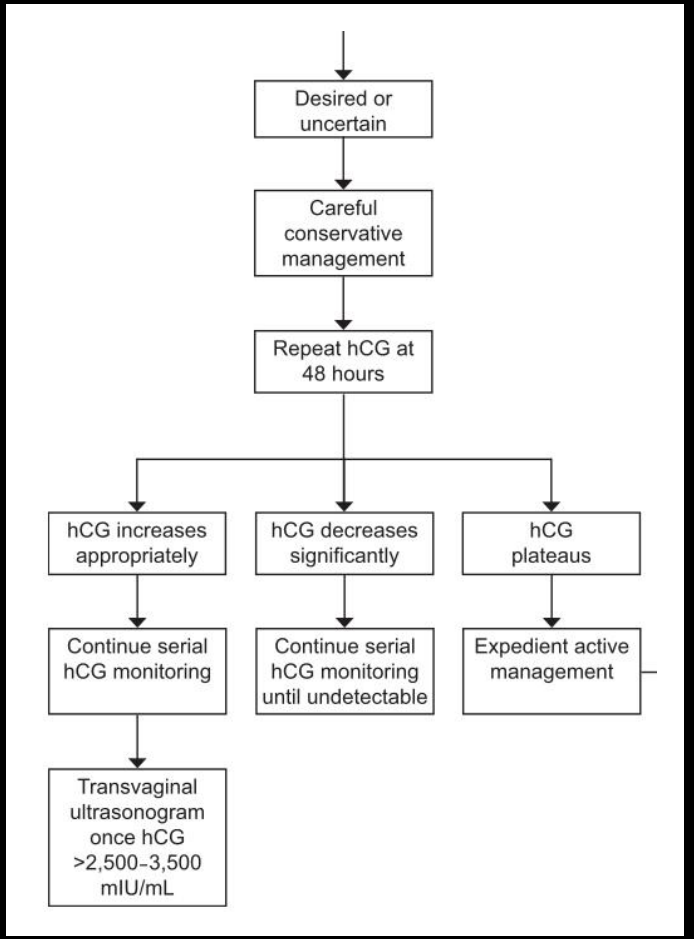
   Early intervention → reduces anxiety, avoids prolonged monitoring, mitigates risks of rupture or emergent intervention



Flynn, et al., Obstet. Gynecol., 2020

Prioritizing Pregnancy Desiredness in PUL

3. For desired or uncertain pregnancies, use careful conservative management
    - Serial hCG, repeat US when indicated, ectopic precautions
    - Guidance:
        - Rise ≥33% in 48 hr → more likely normal; continue monitoring
        - Fall >50% → resolving; can space out follow-up
        - Fall <50% or rise <33% → abnormal; consider active management



Flynn, et al., Obstet. Gynecol., 2020

ACT or NOT: Management of Persisting PUL

- Stable patients with persisting PUL
  - “Persisting” defined as
    - No IUP or EP is visualized by TVUS
    - Plateau or abnormal increase of serial hCG measurements
  - 255 patients randomized 1:1:1 to:
    - Expectant management (n=86)
    - Uterine evacuation → methotrexate if needed (n=87)
    - Empirical methotrexate (2-dose protocol) (n=82)
  - Primary outcome = successful resolution without changing strategy

Barnhart, et al., JAMA, 2021

ACT or NOT: Management of Persisting PUL

- Active management is superior to expectant management
  - 51.5% vs 36.0% successful resolution of pregnancy (95% CI 2.8–28.1)
  - ⬇ unscheduled surgeries (12.7% vs 26.7%)
  - ⬇ unscheduled MTX (15.5% vs 46.5%)
- Empiric MTX is noninferior to uterine evacuation
  - Success: 54.9% (empiric MTX) vs 48.3% (uterine evacuation)
  - Uterine evacuation shortened time to resolution by ~6 days compared with MTX in as-treated analysis

Barnhart, et al., JAMA, 2021

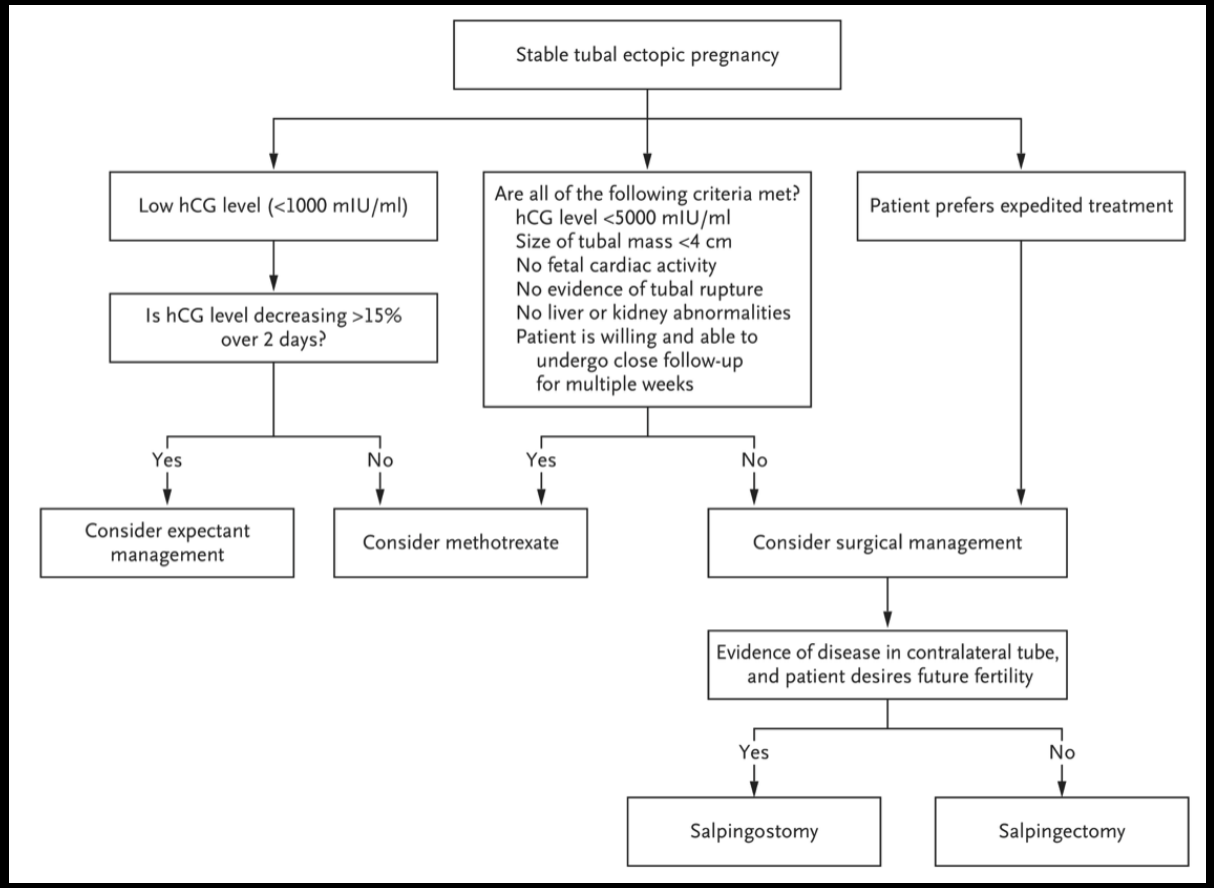
ACT or NOT: Management of Persisting PUL

- Clinical Take-Home
  - Active management more reliably resolves persisting PUL than expectant management, with fewer unscheduled interventions
  - Empiric MTX is reasonable alternative to uterine evacuation when diagnosis is uncertain and close follow-up is possible

Barnhart, et al., JAMA, 2021

Expectant Management For Carefully Selected Patients With Tubal Ectopic Pregnancy

- Who is a potential candidate?
  - Hemodynamically stable
  - No signs of rupture
  - Reliable follow-up
  - Low/declining hCG
  - Small adnexal mass
  - No fetal cardiac activity



Schreiber and Sonalkar, N. Engl. J. Med., 2025
Jurkovic, et al., Ultrasound Obstet. Gynecol., 2017
Mavrelos, et al., BMC Womens Health, 2015

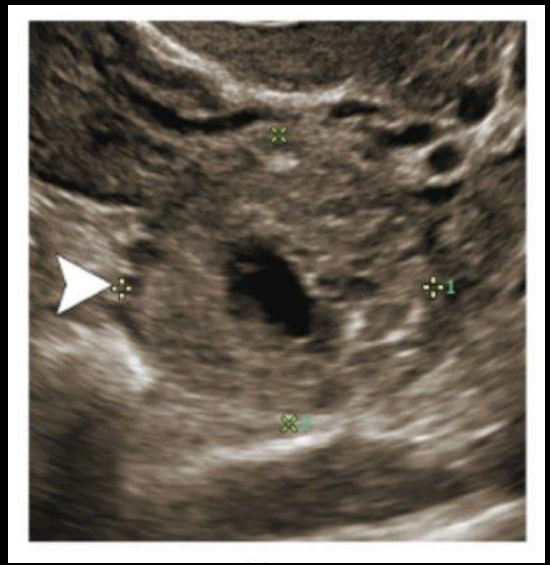
Expectant Management For Carefully Selected Patients With Tubal Ectopic Pregnancy

- Monitoring & when to abandon expectant care
  - Check hCG every 2–7 days until negative
  - Rising or plateauing values, new/worsening pain, or hemodynamic changes → switch to intervention (MTX or surgery)

Schreiber and Sonalkar, N. Engl. J. Med., 2025
Jurkovic, et al., Ultrasound Obstet. Gynecol., 2017
Mavrelos, et al., BMC Womens Health, 2015

Expectant Management For Carefully Selected Patients With Tubal Ectopic Pregnancy

- Counseling on time to resolution
  - Median hCG resolution ~18–20 days from peak/initial visit
    - 90th–95th percentile up to ~5–7 weeks
  - Higher starting hCG and slower early decline = longer course
  - US resolution may lag behind hCG negativity (rarely >3 months)



Schreiber and Sonalkar, N. Engl. J. Med., 2025
Jurkovic, et al., Ultrasound Obstet. Gynecol., 2017
Mavrelos, et al., BMC Womens Health, 2015

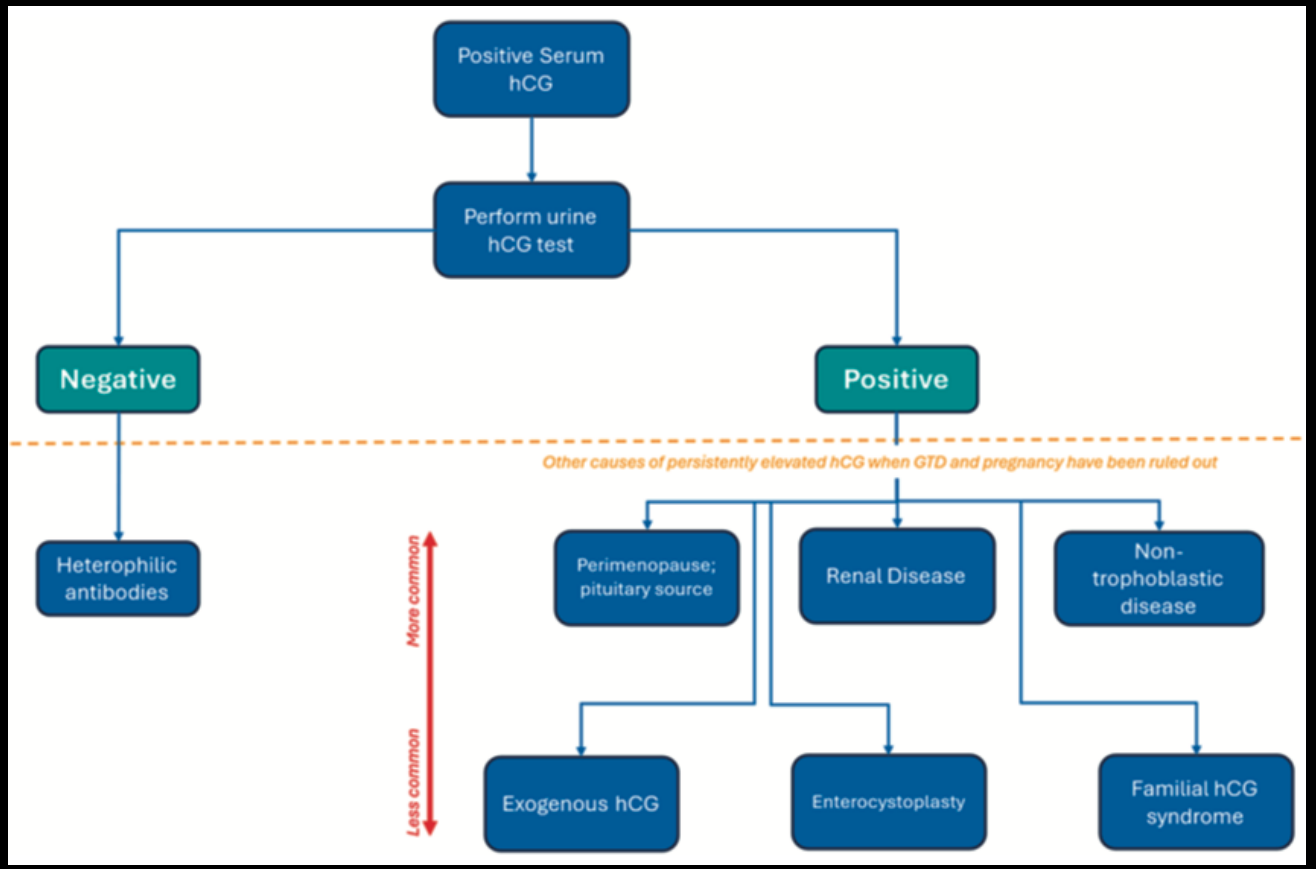
Evaluating Positive hCG in Nonpregnant Patients Without Malignancy

- Positive hCG results can lead to delays in care, unnecessary imaging, procedures, and even chemotherapy when misinterpreted
- If IUP, ectopic pregnancy, and GTD have been ruled out → evaluate for alternative etiologies per algorithm

ACOG Clinical Consensus #11, Obstet. Gynecol., 2026

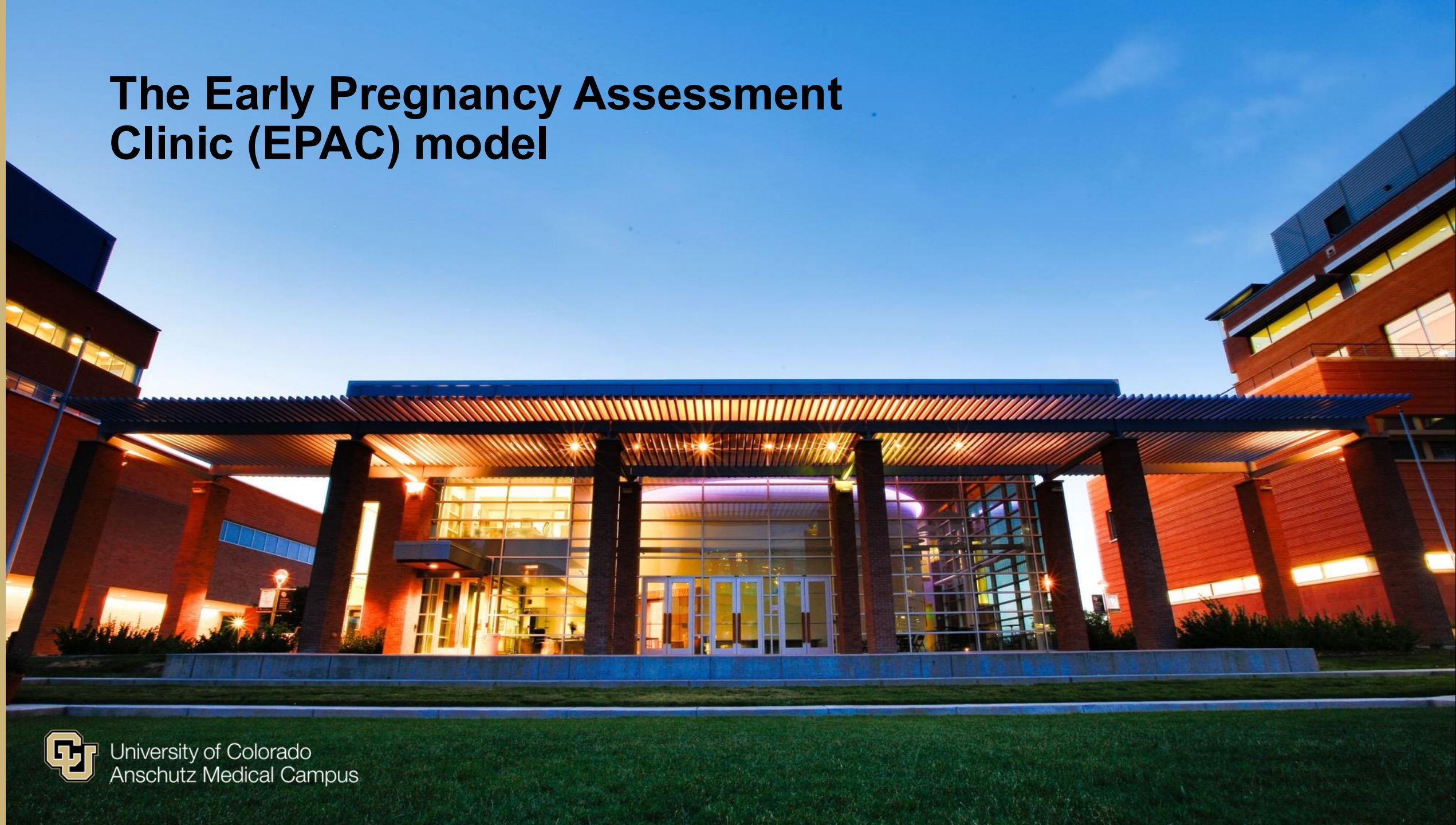
Evaluating Positive hCG in Nonpregnant Patients Without Malignancy

- Consider heterophilic antibodies
  - Paired urine + serum hCG (most common)
  - Serial dilution (lack of linearity = assay interference by heterophilic antibodies)
  - Preabsorption of heterophile antibodies
  - Repeat a serum assay using a different platform
- Measure FSH: FSH ≥40 IU/L + low stable hCG → pituitary source



ACOG Clinical Consensus #11, Obstet. Gynecol., 2026

The Early Pregnancy Assessment Clinic (EPAC) model



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Common Early Pregnancy Care Scenario

A 26-year-old G1P0, about 5 weeks from her last menstrual period, reaches out to your clinic for advice after experiencing 3 days of spotting and mild left-sided pelvic cramping, with a positive pregnancy test at home.

What would this patient's experience be at your institution?

What if?

- Patient is unestablished and presents to ED
- Patient established with CNM and ultimately found to have early pregnancy loss
- Reports clots and thinks they passed tissue
- IUD in place
- Visiting a friend locally and lives across the country
- History of ectopic
- Experiencing significant nausea/vomiting

Current Landscape of Early Pregnancy Care in the United States

- Gap prior to initiation of prenatal care at 8-10 weeks GA → patients seek care in a variety of settings
- Vaginal bleeding in early pregnancy accounts for ~500K ED visits annually
- Highest ED utilization in marginalized populations
- EPL care in ED – patients have longer time to resolution and more provider teams involved

Miller, et al., Obstet. Gynecol., 2019

What Matters to Patients?

Across 8 dimensions of patient-centered care, patients valued:

- Being treated as experiencing a significant life event (most reported)
- Clear, understandable information
- Compassionate staff who acknowledge distress and grief
- Partner/friend involvement
- Privacy and physical comfort
- Continuity, such as follow-up after loss

van den Berg, et al., Hum. Reprod. Update, 2018

What Matters to Patients?

Targets for improvement (as reported problematic by 50-85% of patients):

- Clear information on etiology of EPL
- Staff proactively discussing patient distress
- Informing patients of pregnancy loss with partner/friend present
- Follow-up phone calls after loss

van den Berg, et al., Hum. Reprod. Update, 2018

EPACs Improve Patient Experiences with EPL

Differences by setting

ED patients reported:

- Confusion about diagnosis
- Multiple handoffs, long waits
- Mixed or insensitive provider communication

Ambulatory patients reported:

- Streamlined care
- Clear counseling and options
- Provider empathy and individualized care

Common values across patients

Diagnostic clarity

Timely resolution

Compassion & individualized attention

Miller, et al., Obstet. Gynecol., 2019

EPAC/PEAC Model

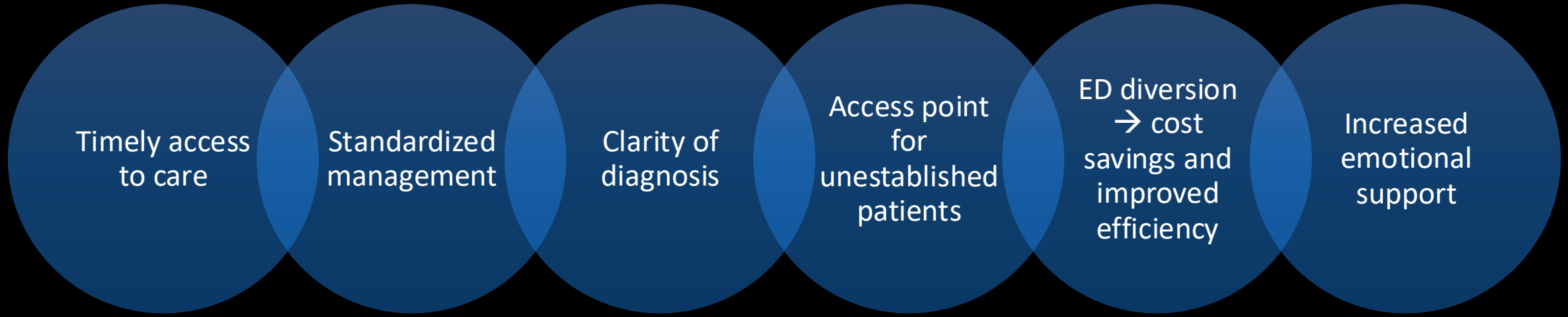
- Dedicated clinic or unit to provide high-quality, multidisciplinary patient care in early pregnancy from +UPT to initiation of prenatal care
- Standardized, evidence-based care algorithms for diagnosis
- Management through a patient-centered and pregnancy desiredness lens

History of EPAC model

- Developed in the 1990s in the UK
- UK's Associated of EPUs: >200 units at NHS hospitals with standardized algorithms for diagnosis/management
  - https://aepu.org.uk/
- Adopted in Canada in the 2000s

Bigrigg and Read, BMJ, 1991
Shorter, et al., Contraception 2021

EPAC addresses systemic challenges



Diagnoses managed in EPAC

Pregnancy of unknown location (PUL)	IUP of unknown prognosis	Early pregnancy loss (EPL)	Ectopic pregnancy
CSEP and other non-tubal ectopics	Gestational trophoblastic disease	Vaginal bleeding or pain in early pregnancy	Retained POCs after EPL or abortion
Early pregnancy following ART	Recurrent pregnancy loss	Undesired pregnancy	Hyperemesis Gravidarum

Services Provided in EPAC

- Point of care ultrasound
- Uterine aspiration (clinic or OR)
- Medication management of EPL
- Methotrexate administration
- Options counseling
- Abortion care
- Contraception
- Genetic testing of POCs
- Grief support
- Connection to prenatal care
- Referral to subspeciality care (MFM, REI, Genetics, Psychiatry)


Reflections on and tips for starting an EPAC
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EPAC at the University of Colorado

Current

- 5 days a week
- 1 outpatient location in East Denver
- 5 physicians, 1 NP, 3 RNs
- Referrals from Ob/Gyn, primary care, and ED (~75 monthly)
- Template with 45 min appts - virtual or in-person
- Maintain the “beta list”

Started in July 2024

- 2 half day clinic sessions/week
- 5 days a week referral coverage

Building an EPAC

Coordination

- Care coordinator(s)
- Provider Staffing
- Referral processes
- Grief support
- OR scheduling
- List management

Staff Skills

- Endovaginal sonography
- Ultrasound interpretation
- Uterine aspiration
- Sedation

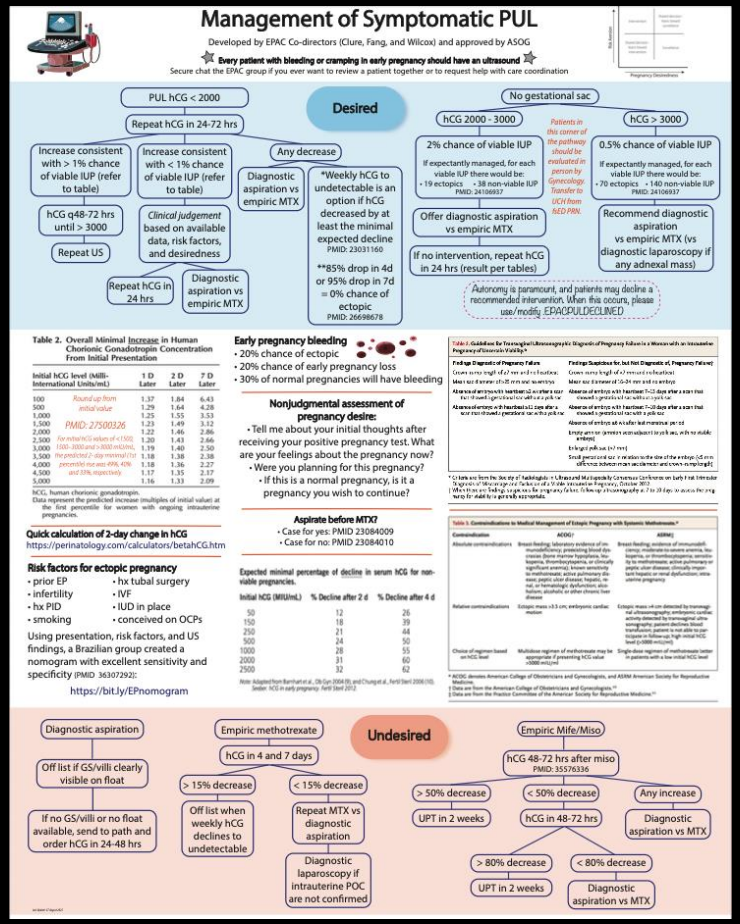
Services

- Sonography (POC vs sonographer)
- Phlebotomy

Medications

- Mifepristone
- Misoprostol
- Methotrexate
- Rhogam
- Lorazepam
- Midazolam
- Fentanyl

Protocol development



- Standardize care
- Build clinical consensus regarding diagnosis and management
- Prioritize desiredness
- Incorporate patient values
  - Time to resolution
  - Risk acceptance vs aversion

Take-home Message

- EPAC improves quality, reduces costs, and generates revenue
  - Standardized, evidence-based, rapidly accessible care
  - Longer visits, high complexity, high proportion of new patients, office procedures, POC US
- A care coordinator is invaluable
  - Consistently positive feedback from patients (continuity, access, support)
  - Consider the boundaries of this role and “back-up”
- Build a strong team
  - Recurring meetings and system for collaboration
  - Referral review, beta list management, complex cases
  - Emotionally taxing, elevated risk of burn-out

Resources to start an EPAC

- **You're not alone!**
  - Many EPAC clinics have started in the US
  - PENN invites anyone interested in starting a clinic to reach out: https://peace.med.upenn.edu
  - Society of Family Planning EPAC Special Interest Group
  - Please email us!
    - cara.clure@cuanschutz.edu
    - mark.wilcox@cuanschutz.edu
    - nancy.fang@cuanschutz.edu
    - keisha.indenbaum-bates@cuanschutz.edu

Miscarriage	• **TEAMM Project -** https://www.miscarriagemanagement.org
Contraception	• https://picck.org • https://www.bedsider.org
Early pregnancy clinics	• https://peace.med.upenn.edu
General reproductive health	• https://www.reproductiveaccess.org • https://www.innovating-education.org
Guidelines	• https://www.acog.org • https://www.nice.org.uk/guidance/qs69

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