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Prioritizing Desiredness in Pregnancy of Unknown Location:

An Algorithm for Patient-Centered Care

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Abstract

Patient-centered care is one of the six aims for improvement in health care quality outlined by the National Academy of Medicine (previously known as the Institute of Medicine). We propose an algorithm for patients who are presenting with a pregnancy of unknown location that emphasizes pregnancy desiredness to improve patient-centered care. Health care professionals should assess pregnancy desiredness at a patient's initial consultation for evaluation of pregnancy of unknown location; desiredness, along with other clinical criteria, should guide management. For women with an undesired pregnancy, health care professionals should offer expedient active management. Uterine aspiration will allow for quick clinical diagnosis and resolution of the pregnancy. Alternatively, for women with a desired pregnancy or for those who are ambivalent, we recommend careful conservative management. Adopting this algorithm will recenter the patient in the complex management of pregnancy of unknown location.

Patient-centered care is consistent with the values, needs, and desires of patients, and it can be achieved when health care professionals understand patients' goals and experiences, and involve them in health care decisions. Patient-centered care is one of the National Academy of Medicine's (previously known as the Institute of Medicine) six major aims for health care quality improvement.^{1,2} Given the known benefits of patient-centered care on patient satisfaction and wellbeing, all areas of medicine should develop best

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practices that both rely on scientific evidence and prioritize patient values.³ Pregnancy, in particular, exists at the intersection of personal, cultural, and medical domains; as such, patients' preferences and values are paramount. Areas for improvement include streamlining timing of early pregnancy management, including pregnancy of unknown location.⁴ A systematic review of women with early pregnancy loss and ectopic pregnancy identified other problematic areas of care, including 1) addressing patients' distress, and 2) providing understandable information regarding their pregnancy complications.⁵ A prior review addresses patient centered care in the management of pregnancy of unknown location and supports the concept that the variation in individual risks and preferences, including pregnancy desiredness, should guide customized care.⁶

Early pregnancy evaluation may be complicated by an uncertain diagnosis and prognosis. When a patient has a positive pregnancy test but ultrasonography cannot confirm the location of the pregnancy, this is categorized as pregnancy of unknown location. Women who experience pain or bleeding in early pregnancy and have an uncertain diagnosis are more likely to experience anxiety compared with women with a certain diagnosis. At the first clinical encounter for pregnancy of unknown location, patients may have been previously unaware of the pregnancy, and health care professionals are often unable to provide reassurance or clarity, adding to patient anxiety, confusion, and sense of lack of control. Furthermore, a patient's thoughts and feelings about being pregnant may affect their experience with pregnancy of unknown location counseling and perspective on management options.

Adding to the complexity of the initial encounter, continued management of pregnancy of unknown location is not straightforward. Many factors are considered, including initial human chorionic gonadotropin (hCG) level, transvaginal ultrasound assessment, and hemodynamic stability. Initially, expectant management is often appropriate for a patient who is hemodynamically stable, when suspicion for ectopic pregnancy is low. Subsequent management involves serial hCG monitoring, repeat transvaginal ultrasound scan, and clinical assessments. As more information is gathered over the ensuing days, the diagnosis and management usually becomes more clear, but not always. For patients who have a desired pregnancy, this intensive ongoing monitoring may feel warranted, acceptable, and even desirable, if there is the potential to identify a normal ongoing pregnancy. However, for those with an undesired pregnancy who plan to have an induced abortion, this extended period of monitoring is of no benefit. In an effort to recenter patient preferences and priorities, we propose an algorithm that adds pregnancy desiredness as a critical factor to consider during management of pregnancy of unknown location.

ASSESS PREGNANCY DESIREDNESS

Pregnancy desiredness is a crucial piece of information when interviewing a woman with an early pregnancy to ensure that she receives care that is concordant with her goals and should always be addressed during an initial consultation. We recommend using nonjudgmental, open-ended questions (Fig. 1), because pregnancy intentions are multidimensional, involving the original planning and timing of the pregnancy as well as the patient's current emotional state. ⁹ Knowing a patient's pregnancy desire will shape the trajectory of care

for women with pregnancy of unknown location, directing the health care professional and patient toward either expedient active management for undesired pregnancies or careful conservative management for desired pregnancies. Pregnancy desiredness can change over time, so it is important to reassess a patient's desire to continue the pregnancy throughout this management algorithm.

UNDESIRED PREGNANCY: INITIATE EXPEDIENT ACTIVE MANAGEMENT

After determining the patient's values and identifying that she has an undesired pregnancy, the health care professional can discuss expedient active management with the patient. Several active management options exist. A diagnostic uterine aspiration can be offered with a discussion of risks and benefits of the procedure (Warden M, Schreiber CA, Steinauer J. Diagnostic criteria for nonviable pregnancy [letter]. N Engl J Med 2014;370:86). If the patient decides to proceed with the aspiration, the tissue should be immediately examined for products of conception. We recommend a serum hCG on the day of the procedure and a serum hCG the day after the procedure, unless products of conception are clearly identified. It should be recognized that the identification of products of conception in a patient with a pregnancy of unknown location may be difficult, or inaccurate, owing to the possible slow or abnormal development of an intrauterine pregnancy or if a small amount of tissue is obtained. If there are no products of conception identified on uterine aspiration (either through gross tissue examination or pathologic examination) or if the hCG does not fall appropriately 24 hours after the aspiration, the patient should be offered methotrexate. ^{10,11} Alternative active management strategies include empiric methotrexate and diagnostic laparoscopy. Diagnostic laparoscopy should be considered if there is a noted adnexal mass on an initial or follow-up ultrasound scan, if the patient has contraindications to methotrexate, or if clinical signs or symptoms have progressed. In patients for whom an intrauterine sac-like structure is clearly visible and there is a high likelihood for an early intrauterine pregnancy, medical management with mifepristone and misoprostol can be offered. 12,13 If this is chosen, close follow up with serial hCG is necessary to confirm pregnancy resolution. Ectopic precautions should also be reviewed with the patient before initiating medical management. The choice between strategies will be guided by the patient's clinical picture and a discussion of the risks and benefits of medical compared with surgical treatment. All of the described strategies should not be impeded by legal abortion restrictions, given that, by definition, a viable intrauterine pregnancy has not been diagnosed during this evaluation and that the intention is to diagnose, treat, and minimize morbidity from possible ectopic pregnancy.

The approach to the patient may be adapted based on the clinical situation or patient preference. For example, in the clinical scenario where there is a concern for but not clear diagnosis of an ectopic pregnancy, such as cases in which a suspicious adnexal mass is visualized on ultrasonography, the patient can be offered a diagnostic laparoscopy with concurrent uterine aspiration. The concurrent uterine aspiration could help identify the location of the pregnancy in scenarios in which an ectopic pregnancy is not clearly visualized on laparoscopy. Alternatively, patients can be offered empiric methotrexate without a diagnostic aspiration if they strongly desire to avoid a procedure, understanding the possible risk of teratogenicity if the pregnancy is intrauterine and continuing. Lastly,

for patients hoping to avoid a procedure and for whom the clinical suspicion for early intrauterine pregnancy loss is high, repeating an hCG level in 2 days may allow for spontaneous resolution of the pregnancy without intervention. Of these options, we recommend expedited uterine aspiration (Warden M et al. N Engl J Med), which offers a pathway to a quick final diagnosis while potentially avoiding the greater medical and surgical risks of methotrexate and laparoscopy. Furthermore, uterine aspiration reduces the risk of the patient returning to the emergency department with heavy bleeding requiring emergency surgery. Currently, there is no definitive way to manage a persisting pregnancy of unknown location, but ongoing research is exploring this topic.¹⁴

For a patient who does not plan to carry the pregnancy to term, expectant management until a final determination of location and viability only increases the risk of a possible ectopic pregnancy progressing to unscheduled interventions, rupture, and morbidity. Expedient active management will also likely reduce stress and anxiety for a patient who does not desire to continue the pregnancy regardless of viability.

DESIRED PREGNANCY: PROCEED WITH CAREFUL CONSERVATIVE MANAGEMENT

In patients with desired pregnancy or who are uncertain, we recommend careful conservative management, the goal of which is to keep the patient safe with close monitoring, while reducing the possibility of disrupting a potentially viable pregnancy. Patients who are stable and have low-to-moderate suspicion for an ectopic pregnancy should return in 48 hours for a repeat serum hCG. Before discharge from care, these patients should have a careful review of ectopic precautions with a health care professional. If the hCG is rising appropriately, the values can be followed until the hCG is greater than 2,500–3,500 milli-international units/mL, at which time a transvaginal ultrasound scan should be performed to attempt to visualize an intrauterine pregnancy. ¹⁰ The minimal rise that is expected for a normal pregnancy is 33% over a 48-hour period. ¹⁵

If the hCG is falling more than 50% since the previous value, the pregnancy is likely resolving spontaneously; hCG blood draws can then be taken at 7-day intervals. An hCG drop of 85% within 4 days or a drop of 95% within 7 days can rule out an ectopic pregnancy; patients with these trajectories no longer need to be monitored. ¹⁶ If the serum hCG falls less than 50%, expedient active management should be initiated, as this trajectory is diagnostic of an abnormal pregnancy but does not rule out an ectopic pregnancy. If the hCG rises less than 33% in a 48-hour period, the patient should be counseled regarding the nearly definitive likelihood of an abnormal pregnancy. At this point, we would recommend proceeding with active management as outlined above.

There are rare but possible outliers in hCG trends, in which a normal pregnancy results despite an abnormal hCG trend. ^{17,18} When a patient values the preservation of pregnancy, even when hCG trends are abnormal, careful conservative management can be considered with detailed counseling about risks, and strict monitoring.

CONCLUSION

A woman's pregnancy desires should be at the center of all discussions surrounding pregnancy management. Implementing patient-centered care for pregnancy of unknown location requires team-based approaches to ensure that diagnostic uterine aspiration and empiric methotrexate are quickly available. Instituting access to manual vacuum aspiration in the emergency department and office can be challenging, but successful strategies have been published. ^{19,20} For women who pursue careful conservative management, high-quality point-of-care counseling should be available at all hours for assessment of clinical stability and recommendations for management if emergent surgery is needed. The management of pregnancy of unknown location is decided based on multiple clinical factors. We recommend recentering the patient in management considerations by adding pregnancy desire to the key factors used to guide care in this complex but common clinical scenario. Future research is needed to study patient-centered algorithms for management of pregnancy of unknown location, and patient preferences for treatment.

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REFERENCES

- Constand MK, MacDermid JC, Dal Bello-Haas V, Law M. Scoping review of patient-centered care approaches in healthcare. BMC Health Serv Res 2014;14:271. [PubMed: 24947822]
- 2. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academies Press; 2001.
- 3. Rathert C, Wyrwich MD, Boren SA. Patient-centered care and outcomes: a systematic review of the literature. Med Care Res Rev 2013;70:351–79. [PubMed: 23169897]
- Miller CA, Roe AH, McAllister A, Meisel ZF, Koelper N, Schreiber CA. Patient experiences with miscarriage management in the emergency and ambulatory settings. Obstet Gynecol 2019;134:1285–92. [PubMed: 31764740]
- 5. van den Berg MMJ, Dancet EAF, Erlikh T, van der Veen F, Goddijn M, Hajenius PJ, et al. Patient-centered early pregnancy care: a systematic review of quantitative and qualitative studies on the perspectives of women and their partners. Hum Reprod Update 2018;24:106–18. [PubMed: 29040571]
- Fields L, Hathaway A. Key concepts in pregnancy of unknown location: identifying ectopic pregnancy and providing patient-centered care. J Midwifery Womens Health 2017;62:172–9. [PubMed: 27779816]
- 7. Barnhart K, van Mello NM, Bourne T, Kirk E, Van Calster B, Bottomley C, et al. Pregnancy of unknown location: a consensus statement of nomenclature, definitions, and outcome. Fertil Steril 2011;95:857–66. [PubMed: 20947073]
- 8. Richardson A, Raine-Fenning N, Deb S, Campbell B, Vedhara K. Anxiety associated with diagnostic uncertainty in early pregnancy. Ultrasound Obstet Gynecol 2017;50:247–54. [PubMed: 27484256]
- Santelli JS, Lindberg LD, Orr MG, Finer LB, Speizer I. Toward a multidimensional measure of pregnancy intentions: evidence from the United States. Stud Fam Plann 2009;40:87–100. [PubMed: 19662801]

 Tubal ectopic pregnancy. ACOG Practice Bulletin No. 193. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;131:e91–103. [PubMed: 29470343]

- 11. Rivera V, Nguyen PH, Sit A, Change in quantitative human chorionic gonadotropin after manual vacuum aspiration in women with pregnancy of unknown location. Am J Obstet Gynecol 2009;200:e56–9. [PubMed: 19168172]
- 12. Li CL, Chen DJ, Song LP, Wang Y, Zhang ZF, Liu MX, et al. Effectiveness and safety of lower doses of mifepristone combined with misoprostol for the termination of ultra-early pregnancy: a dose-ranging randomized controlled trial. Reprod Sci 2015;22:706–11. [PubMed: 25394644]
- 13. Li CL, Song LP, Tang SY, Zhou LJGY, He H, Mo XT, et al. Efficacy, safety, and acceptability of low-dose mifepristone and self-administered misoprostol for ultra-early medical abortion: a randomized controlled trial. Reprod Sci 2017;24:731–7. [PubMed: 27678099]
- 14. Barnhart KT, Sammel MD, Stephenson M, Robins J, Hansen KR, Youssef WA, et al. Optimal treatment for women with a persisting pregnancy of unknown location, a randomized controlled trial: the ACT-or-NOT trial. Contemp Clin Trials 2018;73:145–51. [PubMed: 30243810]
- 15. Barnhart KT, Guo W, Cary MS, Morse CB, Chung K, Takacs P, et al. Differences in serum human chorionic gonadotropin rise in early pregnancy by race and value at presentation. Obstet Gynecol 2016;128:504–11. [PubMed: 27500326]
- 16. Cameron KE, Senapati S, Sammel MD, Chung K, Takacs P, Molinaro T, et al. Following declining human chorionic gonadotropin values in pregnancies of unknown location: when is it safe to stop? Fertil Steril 2016;105:953–7. [PubMed: 26698678]
- 17. Benor A, Grazi R, Kulak D. A case report of an abnormal trend in hCG levels in a pregnancy complicated by ovarian hyper-stimulation syndrome. Case Rep Womens Health 2019;21:e00096. [PubMed: 30733923]
- 18. Chung K, Sammel MD, Coutifaris C, Chalian R, Lin K, Castelbaum AJ, et al. Defining the rise of serum HCG in viable pregnancies achieved through use of IVF. Hum Reprod 2006;21:823–8. [PubMed: 16311298]
- 19. Kinariwala M, Quinley KE, Datner EM, Schreiber CA. Manual vacuum aspiration in the emergency department for management of early pregnancy failure. Am J Emerg Med 2013;31:244–7. [PubMed: 23021402]
- Darney BG, Weaver MR, Stevens N, Kimball J, Prager SW. The family medicine residency training initiative in miscarriage management: impact on practice in Washington state. Fam Med 2013;45:102–8. [PubMed: 23378077]

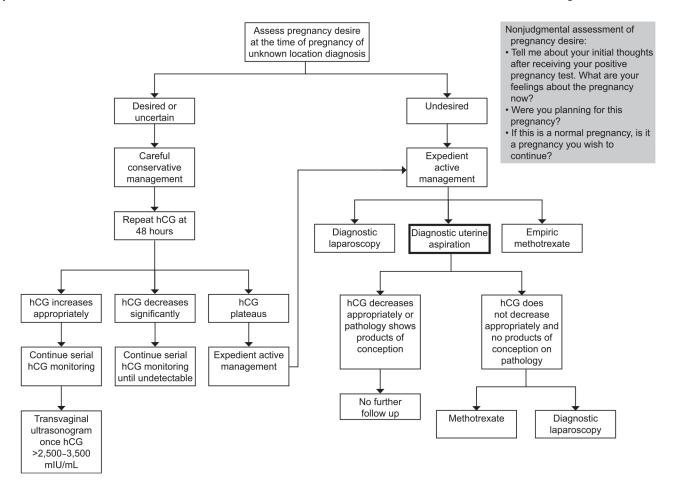


Fig. 1.Suggested clinical algorithm for management of a clinically stable patient with a pregnancy of unknown location. The *bolded box* highlights our recommended treatment option given it offers a pathway to a quick final diagnosis while potentially avoiding the greater medical and surgical risks of methotrexate and laparoscopy. Each patient encounter should be individualized. Repeated history, physical examination, laboratory testing and imaging, and assessment of patient values should be incorporated into each management decision. hCG, human chorionic gonadotropin.

Flynn. Patient-Centered Early Pregnancy Care. Obstet Gynecol 2020.