1. Title Page

Evaluating treatment options and patterns of care in early pregnancy failure

Study Team:
Vanessa K. Dalton MD, MPH (PI)
Associate Professor
Director, Program on Women's Health Care Effectiveness Research
Department of Obstetrics and Gynecology
L4000 Women's' Hospital
University of Michigan Medical School
Ann Arbor, MI 48109
734-647-9726
Fax 734-647-9727
daltonvk@med.umich.edu

Johnson, Timothy (Mentor)
University of Michigan Medical School, Department of Obstetrics and Gynecology

Mark Fendrick, MD (Co-Mentor)
University of Michigan Medical School, Department of Internal Medicine

Steven Heeringa, PhD (Co-Mentor/Cosponsor)
University of Michigan, Institute for Social Research

Sarah Clark, MPH (Consultant)
University of Michigan Medical School, Department of Pediatrics

Katie Gold, MD (Consultant)
University of Michigan Medical School, Department of Family Medicine

Ken Guire, MS (Consultant)
University of Michigan School of Public Health, Department of Biostatistics

Lisa Kane-Low, CNM, PhD (Consultant)
University of Michigan Medical School, Department of Obstetrics and Gynecology

Xiao Xu, PhD (Consultant)
University of Michigan Medical School (formally)

Organization: University of Michigan Medical School, L4000 Women's' Hospital
University of Michigan Medical School, Ann Arbor, MI 48109

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Project Officer: KAY ANDERSON

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2. Abstract

Purpose: The goal of this K08 proposal was to further develop the PI's skills as a health services researcher. The PI completed didactic coursework and used her institutional resources, including strong mentorship, to complete training in claims analysis, survey methodology, and cost-effectiveness analysis.
Scope: Although most women are thought to be treated with either surgery in an operating room or expectant management, reasonable options also include office-based procedures and medical treatment with misoprostol. The purpose of this research proposal was to understand how early pregnancy failure (EPF) is currently managed and to examine the effect of using patient preferences to determine treatment on cost.
Methods: Treatment patterns were characterized using claims data in statewide health plan and surveys of a national sample of women's healthcare providers. (Usual Care) Patient surveys were also conducted to characterize preferences. Patient treatment choice was estimated using treatment patterns in a setting where all 4 options are available. (Expanded Care) The final analysis will compare cost under Usual Care and cost under Expanded Care, using a cost-effectiveness analysis.
Results: Under the statewide health plan, less than 1% underwent treatment with misoprostol or office-based surgery. Beliefs about patient preferences and prior training were associated with treatment patterns used by providers. In an Expanded Care setting (n=1747), treatment was distributed as follows: 47% expectant, 17% misoprostol, and 35% surgical. Of those undergoing surgery, 57% did so in an office setting. The cost-effectiveness analysis is underway.

Key Words: early pregnancy loss, patient treatment preferences, cost

3. Purpose

Nearly 25% of women will have a pregnancy loss at least once in their lifetime. Despite this high prevalence, little is known about how pregnancy loss is typically managed and even less is known about patient treatment preferences. Further, it is unknown whether patient characteristics, such as race and ethnicity, influence the type of treatment provided. The overriding purpose of this proposal is to understand how early pregnancy failure (EPF) is currently managed, to examine treatment preferences, and to predict how patient treatment choice will affect cost of EPF management. Traditionally, management of pregnancy loss has been dilation and curettage (D&C), most often occurring in an operating room. This practice was established during a time when patients with pregnancy loss typically presented with acute hemorrhage and/or infection. However, technological advances, such as ultrasound and sensitive biochemical pregnancy tests, allow a nonviable pregnancy to be diagnosed well before the onset of these symptoms. Under these conditions, safe treatment options include expectant management and drug therapy to cause the uterus to expel the nonviable products. Alternatively, surgical management can be done in an office-based setting, which offers significant cost savings over the same procedure performed in an operating room. Neither published literature nor our preliminary data support routine operative room management schemes on the basis of safety, cost, or patient preference. EPF provides an opportunity to further patient-centered care while possibly maximizing patient satisfaction and lowering costs.

Specific Aim I: To quantitatively describe treatment patterns for EPF management.

a. To characterize treatment patterns of EPF among women in two Michigan health plans.

b. To identify regional and/or hospital factors associated with treatment patterns.

c. To identify patient factors associated with treatment patterns.

We quantitatively describe current treatment patterns in EPF using a retrospective review of administrative and billing data. *We hypothesized that most women with EPF undergo either surgical management in an operating room or expectant management and that regional and patient factors, such as race, are associated with practice patterns.*

Specific Aim II: To identify provider and patient factors associated with treatment preferences and patterns.

a. To describe provider knowledge, attitudes, and treatment preferences for early pregnancy failure.

b. To describe patient treatment preferences and satisfaction with care after EPF.

Using survey methodology, we examined provider and patient factors associated with treatment patterns and preferences. Data were collected using self-administered, written questionnaires from a national sample of healthcare providers and of women presenting for EPF treatment. *We hypothesized that providers' treatment preferences reflect current patterns as identified in Specific Aim I, but these patterns are not consistent with patient treatment preferences.*

Specific Aim III: To simulate the clinical and economic consequences of an expanded care model compared to usual care.

We compare the costs of two care models: 1) usual care, consisting of either expectant management or surgical management in an operating room, and 2) expanded care, consisting of expectant, medical, office-based, and operating room management. *The analysis for this aim is still underway*. We are using our findings from Specific Aims I and II to approximate the distribution of patients into each treatment arm and the available literature for complication and success rates. *We hypothesize that expanding treatment options and allowing patient preferences to dominate treatment choice in EPF will result in cost savings while meeting patient preferences.*

4. Scope

Epidemiology of early pregnancy failure (EPF)

First trimester pregnancy loss is very common. Estimates of loss after clinical signs of pregnancy have occurred range from 14% to 19%, and estimates increase when early, unrecognized pregnancies are included. As early diagnosis has become possible, there is growing recognition of the frequency of EPF, and patients often present for care at earlier gestations. Because providers are faced with different clinical situations, a better understanding of effective and safe treatment options is needed.

Management of EPF and Patient Preferences

Treatment options for early pregnancy failure include expectant management, surgical evacuation, and medical completion. Traditional management has been dilatation and curettage (D&C), most often occurring in an operating room. Treatment patterns evolved during a time when many women presented with hemorrhage or infection; therefore, urgent surgical intervention was indicated. However, because highly sensitive pregnancy tests are able to diagnose a pregnancy before the first missed menses and there is widespread availability of ultrasound, many patients present prior to the onset of symptoms, such as bleeding or infection. Under these circumstances, safe treatment options include expectant management, surgical evacuation, or medical completion. Even so, treatment patterns may not reflect these new clinical situations. Though there are no population-based studies describing usual care in the United States, data from South Africa, Europe, and Canada indicate that most patients are still being managed in an operative suite often under general anesthesia.

Patient Preferences

There is little evidence that current treatment practices involve patient preferences. Focus groups exploring what women value in healthcare reveal that women want privacy, good communication with their physician, and efficient services without waiting. Often, operating room procedures lack privacy and involve long waits. A small Canadian survey of women's treatment preferences for a hypothetical EPF found that many women expressed a strong preference for expectant management. But, participants also indicated that physicians influenced their selection greatly, and about 50% indicated that they would change their choice based on a physician's recommendation.

Very few studies have examined specific treatment choices among patients seen for EPF. Recently, a group in the Netherlands interviewed women diagnosed with EPF about their views on medical treatment with misoprostol as compared to suction curettage. In this study, patients were presented with the risks and benefits of both options and asked for their treatment preferences with varying rates of success with misoprostol. They found that about 50% of women interviewed would choose medical management if its success rate exceeded 65%. Other studies in Europe and India have indicated that, when given a choice, many women prefer to avoid general anesthesia for uterine evacuations. Our previous work studied women's acceptance of and preference for office-based uterine evacuations compared to the same procedure in an operating room setting. We also found that women differ with regard to their anesthesia preferences and that experiencing higher levels of pain than expected negatively affects satisfaction. Overall, we concluded that many women will choose to have their procedure in an office setting and that satisfaction levels are high among those who choose to do so.

Expectant Management

Waiting for spontaneous passage of the products of conception after EPF is an alternative treatment approach. A recent prospective, uncontrolled study of 263 women reported a success rate of 83%. In this study, there were no transfusions and a low rate of infection (3%). Small, randomized trials indicate that success rates, hemorrhage, and infection are not different between expectant and surgical management in patients expected to pass small amounts of tissue. A recent Cochrane review and others have concluded that neither treatment was superior. Therefore, patient preference should play a dominant role in decision-making.

Medical Management

In recent years there has been a growing interest in medical completion of EPF with misoprostol. Several protocols have been studied with significant variation in the reported success rates, ranging from 52% to 95%.

The largest study to date was conducted as part of the NICHD Management of Early Pregnancy Failure Trial. This study reported findings of 652 women randomized to either vaginal misoprostol or vacuum aspiration. This trial reported a success rate of 84% 8 days after misoprostol insertion and concluded that medical treatment of EPF with vaginal misoprostol was a "safe and acceptable approach."

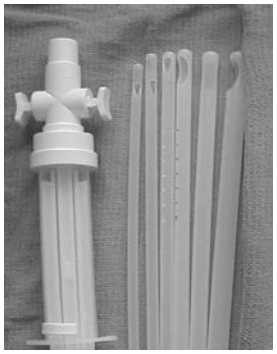


Figure 1: Manual Vacuum Aspirator (Ipas, Chapel Hill, NC)

Suction Dilation and Curettage

Suction dilation and curettage (suction D&C) is a method for uterine evacuation. Traditionally, this is accomplished using an electric suction device (EVA) and a rigid cannula that is introduced into the uterine cavity, but it can also be done with a hand-held suction device referred to as manual vacuum aspiration (MVA). (**Figure 1**) A sharp curette is sometimes used, often in an attempt to ensure complete uterine evacuation. Surgical complications after suction D&Cs include incomplete evacuation (2-3%) and infection (0-10%). Rare complications include hemorrhage, uterine perforation, and---very rarely---death. Many serious complications have been attributed to the use of the sharp curette or general anesthesia. Although complications are infrequent, there is little evidence to support routine surgical intervention for early pregnancy failure, and there is even less to support the need to perform procedures in an operative suite or under general anesthesia.

Cost of managing EPF

Suction D&Cs in the operating room for EPF are one of the most common procedures done by gynecologists. Because EPF is so common and is often managed by surgical intervention, treatment costs contribute significantly to healthcare spending. One recent U.S. study has examined the use of MVA in an ambulatory setting to treat symptomatic early pregnancy failure in an emergency setting. This study reported a 71% reduction in hospital stay and a 41% reduction in cost after moving these cases from an operative suite to an ambulatory setting. Other studies outside of the U.S. have also demonstrated a significant resource saving after implementing the use of MVA for early pregnancy failure. Others have shown a cost benefit to primary medical management schemes over initial surgical management. A cost-effectiveness study examining the four possible treatment options concluded that office-based MVA was the most cost-effective option, but it cautioned that patient preference should play a significant role in treatment selection. Another key limitation of the existing studies on cost is that they have little direct relevance to actual practice, because cost itself is rarely used in EPF treatment decisions. A more relevant assessment of cost would be to estimate the impact of expanding treatment options available. We hypothesized that this expansion, coupled with using patient treatment preferences, would result in lower costs compared to current care models.

Significance

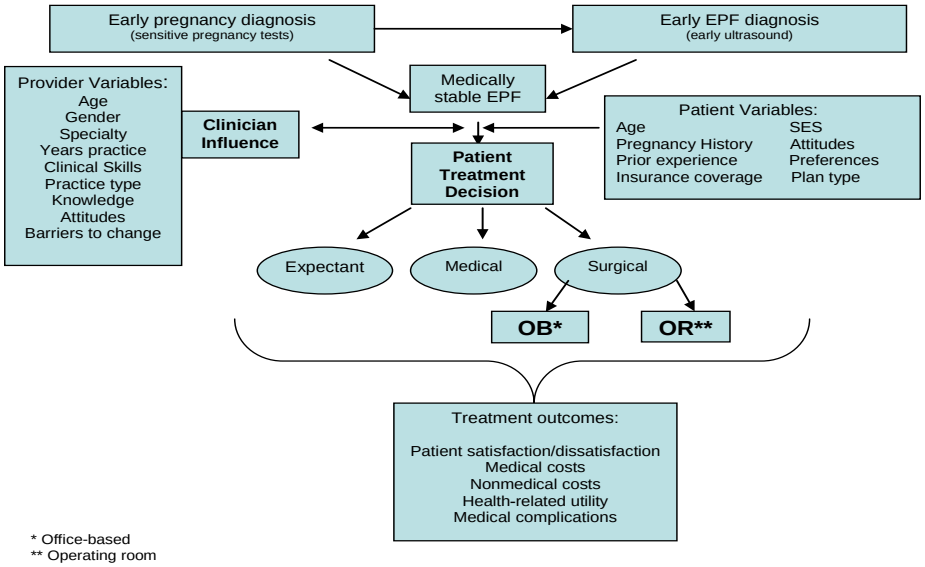
Pregnancy loss is a common event. Few studies have compared different treatment options with regard to patient and provider preference and resource use. Much of this proposal discusses the cost savings offered by moving EPF management out of the operating room. More importantly, not only are alternative options safe, but many patients may prefer them. Patient preferences should play a dominant role in EPF treatment decisions in the absence of medical risk factors. At this time, however, we have little information regarding patients' preferences and what factors or beliefs drive them. Nor do we understand providers' preferences. These findings could be used to inform providers and health systems in efforts to improve care while considering costs.

5. Methods and Results for Aims I-III

Introduction

This research proposal had two primary goals. 1.) To advance our knowledge about current patterns and treatment preferences in EPF management. 2.) To explore the effect of using patient preferences to determine treatment choice for EPF on overall cost. **Figure 2** illustrates the different aspects of decision-making in EPF.

Figure 2: Management of Early Pregnancy Failure Theoretical Model



We identified three levels of study: 1.) current treatment patterns, 2.) patient and provider preferences, and 3.) the impact of offering all four treatment options and using patient preferences to determine treatment, as compared to usual care, on cost. Our main hypothesis was that a patient preference-driven treatment model would result in a shift away from operating room management. Therefore, adopting a patient-centered treatment approach would result in less resource use while meeting patients' treatment preferences. For the purposes of this proposal, the two care models are defined as follows:

Usual Care: This strategy reflects the current clinical pathway of EPF management. Based on existing European and North American literature and our preliminary work, we predicted that women with EPF are most often treated with either expectant management or surgical management in an operating room.

Expanded Care: This strategy represents an evidence-based expanded care model for EPF management. It provides the patient with all available treatment options that have been found safe and effective: expectant management, medical treatment, office-based surgical procedure, and OR-based surgical procedure. Patients are able to choose one treatment option that is deemed most preferable to them. We assume that this model applies only to patients without medical contraindications to any of the treatment options. **This is the current model offered by our health system.**

Experimental Design

Aim I used claims data to describe current treatment patterns, and Aim II used survey methodologies to examine provider and patient factors influencing care patterns, such as demographics, knowledge, attitudes, prior experience, and barriers to change. Aim II will also describe patient-reported preferences for treatment options, explore patient's acceptability of different treatment processes, and examine patient satisfaction after treatment for EPF. Finally, Aim III compares two care models with regard to cost and patient utility using the findings of Aims I and II.

A. Aim I: To quantitatively describe treatment patterns for EPF management.

To describe current treatment patterns, we conducted a retrospective review of EFP treatment among M-CARE and Michigan Medicaid enrollees using administrative data.

- *Methods:*

We constructed a database consisting of all first trimester pregnancy losses submitted to two claims systems between January 1, 2001, and December 31, 2005, for beneficiaries between ages 18 and 45. To obtain a diverse, representative sample from a variety of practice settings, we included both enrollees in private health plans and Medicaid participants. M-CARE offered a variety of plan options: Health Maintenance Organization health plan, Point of Service Plan, Preferred Provider Organization health plan, Medicaid plans and Health Savings Accounts. Because diagnostic uncertainty would influence treatment, we reviewed all diagnostic and procedural codes submitted for 8 weeks before and after the initial EPF diagnosis. Patients with claims (either a procedure or diagnostic code) indicating a gestational age beyond the first trimester, suspected ectopic pregnancy, a delivery, or gestational trophoblastic disease were excluded from the study.

First, we identified EPF cases using the presence of diagnosis codes for early pregnancy failure (The International Classification of Diseases, 9th Revision codes 632, 634 and 637). All diagnostic and procedural codes submitted to each health plan were queried for the 42 days before and after the initial EPF diagnosis. A repeat episode of EPF was based on a second diagnosis code for EPF at least 180 days after the initial diagnosis.

Cases with a procedure code corresponding to a uterine evacuation were classified as surgical (CPT codes 59812, 59820 or 59830). Surgical cases were further classified as either operating room cases or office procedures using a combination of facility codes, location codes, and the presence of a departmental anesthesia charge. If there was a departmental anesthesia revenue code or an operating room revenue code, we classified the procedure as occurring in an operating room. Otherwise, if the facility type or place of service was a hospital, inpatient facility, or ambulatory surgical center, and the place of service was not an office, the procedure was also classified as occurring in an operating room. Alternatively, if the place of service was "office" and/or if the facility type and place of service were not hospitals, and there were no inpatient procedure or revenue codes, the procedure was classified as occurring in an office. All other cases were coded as other/unknown treatment location due to missing or conflicting information.

Cases without procedure codes corresponding to a surgical uterine evacuation were classified as either medical or expectant management. To distinguish the two, we searched for pharmacy claims for misoprostol at any time during the 30 days prior to or after diagnosis. Cases with a pharmacy claim for misoprostol were classified as medical management. Cases with no pharmacy claim or CPT codes corresponding to a surgical evacuation were classified as expectant management. Additional information, such as patient demographics, was collected when available.

Classification validation: We validated our classification methods by conducting chart reviews on a random sample of 200 women treated in the university-affiliated health plan. Because all treatment options were readily available in this system, this sample was expected to provide the diversity needed to estimate our misclassification in the statewide health plan. The charts were reviewed by a trained abstractor to verify diagnosis and treatment modality. The validation process found 25 of 200 (12.5%) randomly selected charts did not have evidence of an EPF despite having been assigned such a diagnosis code. In 80% of these cases, it appeared that the patient was actually being seen for complaints or complications after undergoing an induced abortion elsewhere, which may share a diagnosis code with an "incomplete miscarriage." Treatment of these cases were "correctly" classified by our scheme as expectant management, and none required additional treatment. When examining the whole validation sample, we found the classification scheme accurately identified treatment type. Of the cases we classified as surgery, 26 of 26 were actually treated with surgery, and our scheme correctly identified the procedure location in 76.9% cases. Only one case in the sample was classified as medication treatment, which was correct. Of the remaining 171 cases classified as expectant management, only one instance of misclassification was identified (0.6%). Overall, we concluded that our classification methods accurately differentiated between surgery, medical, and expectant management and reasonably identified treatment location.

- *Results:*

In total, 25,087 cases of EPF were initially identified in the state Medicaid database during the years of interest. Of these, 3,498 were found to have additional procedure or diagnosis codes suggesting a coding error, and 278 had invalid diagnosis codes. Once these cases were excluded, 21,311 episodes were analyzed. Using the same process, 1,493 cases were included from the university-affiliated plan database. Treatment patterns for the Medicaid enrollees and the university-affiliated health plan groups are presented in **Figure 3**. Statewide, patients were more likely to be treated with a surgical uterine evacuation than patients in the university-affiliated system (35.3 vs. 18.0%, p<.000). This trend persisted when we examined diagnostic subgroups. For instance, having a "complete abortion" as opposed to an "incomplete abortion" did not explain this difference. Medical treatment with misoprostol was uncommon in both groups. The proportion of surgical cases completed in an office setting was 0.5% in the statewide sample and 30.5% in the university-affiliated plan sample (p<0.000). (**Figure 4**)

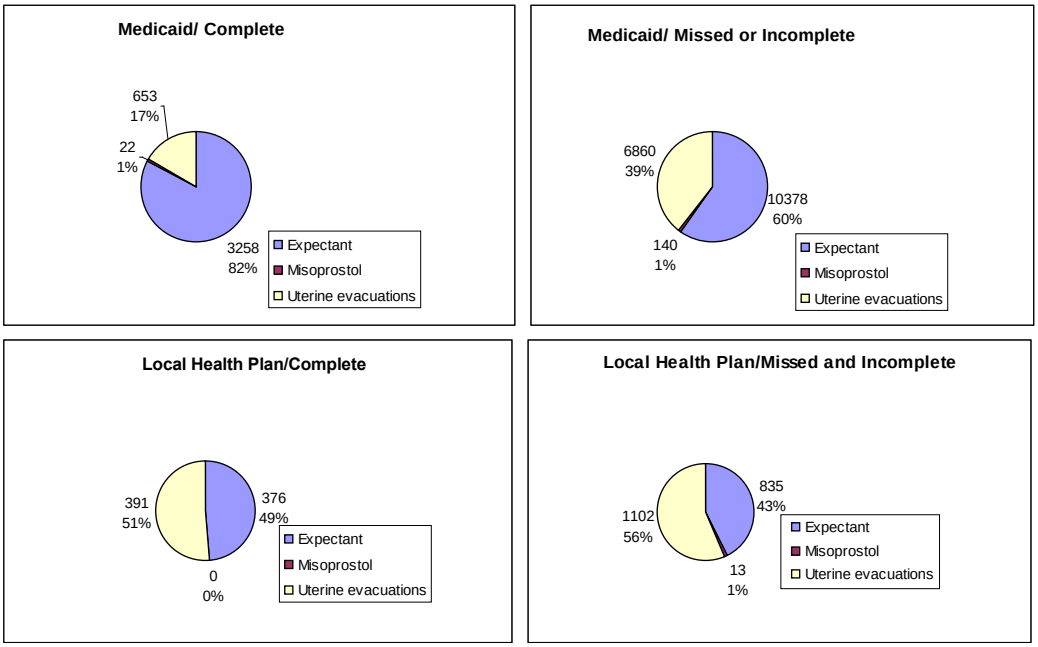


Figure 3: Treatment patterns by diagnosis and health plan

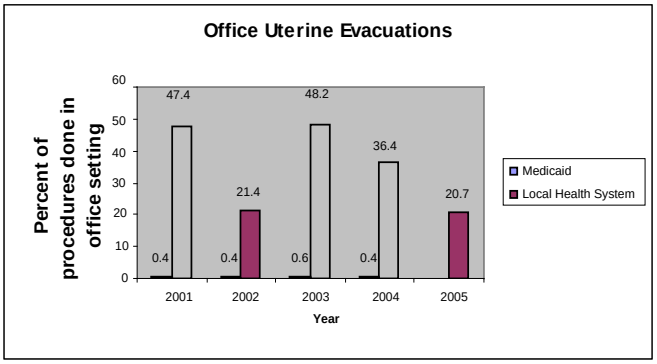


Figure 4: Proportion of surgical uterine evacuations performed in an office setting by study year and health plan

Because enrollee race was only available in the statewide Medicaid dataset, we examined patient factors associated with surgical treatment in thiswith treatment type. Whites were more likely to be treated with surgery than either African-Americans or Hispanics (p<0.001). Further, African Americans and Hispanics were more likely to be diagnosed with a completed spontaneous abortion at presentation than Whites (20.9 and 19.2% versus 17.1% respectively, p<0.05). We were unable to determine whether this difference explained the difference in treatment patterns because the Medicaid data could only be provided in aggregate. Further, women under 20 years old were less likely to be treated surgically than 20-39 year olds (p<0.025).

We examined both datasets for changes over time. In the Medicaid group, misoprostol use was uncommon but increased over the study period from 0.3 to 1.2% (p<0.001). In the university-affiliated health plan, the proportion of cases treated with surgery increased significantly from 16.5% to 32.6% (p<0.000) over the study period. This did not occur in the statewide Medicaid group. The proportion of surgical cases that appeared to be completed in an office setting did not change over time in either group.

- *Discussion:*

  Treatment options for EPF include expectant management, medical completion with misoprostol, or surgical evacuation in either an office or an operative suite. Treatment patterns in Michigan do not appear to reflect either evidence-based practices or patient preferences. Rather, this study suggests that women in Michigan are typically managed either expectantly or with surgical uterine evacuation in an operating room. Our findings also suggest patient factors, such as age and race, may be associated with treatment type, which has important implications for improving clinical care. However, the main factor determining treatment patterns is most likely having access to providers offering a range of treatment options.

  Although this study was primarily designed to examine overall treatment patterns, we found that women in the local university-affiliated health plan are much more likely to have an office uterine evacuation than women enrolled in Medicaid. We believe that the main explanation for this treatment difference is that members of the university-affiliated health plan have access to a network of providers offering this service, whereas women in other parts of the state do not. It is also possible that particular populations, such as low-income or minority women, do not accept office procedures to the same degree as women in the university-affiliated system, but our study cannot assess such differences.

  Although we were not surprised to find that office uterine evacuations were uncommonly used, our previous work with women experiencing EPF concluded that office procedures are acceptable and sometimes preferable over the same procedure in an operating room. After office uterine evacuations were introduced into our health system, there was a surge of referrals indicating a high level of enthusiasm. Over time, utilization decreased slightly as patients and providers became familiar with the benefits and limitations of office procedures. Moving even some procedures out of an operating suite offers the potential of substantial cost savings. Still, a wide range of obstacles or disincentives probably limit the availability of office uterine evacuations, including discomfort with office procedures in general or a lack of perceived demand for such service. It is also possible that office uterine evacuations for EPF are uncomfortably similar to induced abortions and some providers are reluctant to add the service to their practice.

  Patient race and age were associated with being treated with a surgical procedure among our study sample, which has not been described previously. Although African American women and Hispanic women were more likely to present with a “completed abortion” based on ICD-9 coding, this study could not assess how much of the disparity was explained by this difference. It may be that these groups had a harder time accessing care, therefore presented after spontaneous passage of products had already occurred. Alternatively, there may be community-based influences resulting in treatment preference differences between these groups. Our study could not explain these findings, but these treatment differences warrant further study.

  Our study methodology has several limitations. First, this methodology cannot explain the reasons underlying the identified treatment patterns, including associations with patient race or socioeconomic status. We also could not distinguish between patients who began with expectant management but went on to have a surgical uterine evacuation and those who primarily elected to have surgery. Further, administrative codes are often difficult to interpret, misclassification is common, and we would likely misclassify those who went outside their insurance plan for treatment. For instance, we doubted that the distinction between cases that were coded as complete versus incomplete abortions was very accurate; therefore, we do not comment on the “appropriateness” of the relatively high number of surgical interventions done in the complete group. We also found that over 10% of women identified as having an EPF by diagnosis code had no evidence of it upon chart review. Still, our classification scheme was able to determine treatment type with a high degree of accuracy, which was our primary objective. We opted not to attempt to correct for this bias in the larger database for two reasons. First, it is possible that the university-affiliated system is more likely to see these cases because of referral patterns. Second, we were primarily interested in validating our methods of treatment classification, which was not affected by these cases. Still, some degree of similar misclassification would probably be present in other data sources, as well. Based on our findings, this bias would likely increase the apparent proportion of cases managed expectantly.

- *Conclusions:*

Women experiencing EPF in these Michigan health plans appear to be treated predominantly expectantly or with surgical uterine evacuation in an operating room. Use of misoprostol and/or office uterine evacuations are very uncommon despite evidence supporting their safety and effectiveness. As several studies have consistently demonstrated high acceptance of both office evacuations and treatment with misoptrostol, the treatment pattern in Michigan is probably not driven by patient preference. Because providers likely influence this care pattern, a better understanding of provider attitudes toward these "newer" treatment options is needed, to encourage the adoption of models of care that have proven safety, efficacy, and patient acceptance.

B. Aim II: To identify provider and patient factors associated with treatment preferences and patterns.

Although we believe there are benefits of offering the Expanded Care model to both patients and providers, we have little information about how physicians perceive such a change from usual care and what barriers hinder such a change in practice patterns. Further, we have little information regarding women's treatment preferences and what they would choose when all options are available. We examined these factors using a population-based survey of providers and patients. **We hypothesized that providers' treatment preferences reflect current patterns as identified in Specific Aim I, but these patterns are not consistent with patient treatment preferences.**

Aim IIa: To describe provider knowledge, attitudes, and treatment preferences for early pregnancy failure.

Providers are a powerful influence on treatment selection in many clinical situations, including EPF management. Therefore, a successful change in clinical care patterns requires a better understanding of the providers' perspective.

- *METHODS:*

We characterized current EPF treatment practices using a cross-sectional survey of providers in the United States. Potential participants were randomly selected from membership lists of the American College of Obstetricians and Gynecologists, the American College of Nurse Midwives, and the American Academy of Family Physicians. After accounting for the proportion of providers practicing obstetrics and non-response rates, we mailed 3,591 surveys in order to enroll 300 providers from each specialty. We used repeat mailings, limited the survey length, and provided a small financial incentive ($2.00) to encourage response. Questionnaires were initially mailed in January 2008, and two follow-up mailings were sent to non-responders between March and June 2008. Providers were excluded if they were not practicing in one of the targeted specialties or had not evaluated or treated anyone with EPF in the past 6 months.

We developed questionnaire items by consensus and a literature review. We drew heavily from previous work on provider behavior change and adherence to evidence-based practices. To ensure that the questionnaire was applicable to targeted provider types, an interdisciplinary group of investigators contributed to its development. Survey items addressed several areas, including 1) provider and practice characteristics, such as age, sex, and practice setting, 2) use of office procedures in general, 3) current treatment practices for EPF, 4) knowledge and attitudes about different treatment options, and 5) barriers to adopting misoprostol use and office uterine evacuations.

The survey consisted of three types of questions. Closed-ended/forced-choice questions were used to elicit practice patterns, experience with office procedures, and provider knowledge of different treatment options. Ranking (1 = most preferred, 4 = least preferred) was used to assess provider treatment preferences and provider perception of patient treatment preferences. Level of agreement with a series of statements was used to assess attitudes and beliefs about the different treatment options and perceived barriers to adopting misoprostol and office uterine evacuations.

We planned to enroll 300 providers from each specialty, for a total of 900 respondents. With a sample size of 900, or 300 in each subgroup, we would have 90% power to detect a 10% difference in the proportion of providers who use a particular treatment option. Descriptive statistics were used to describe our sample population with regard to age, sex, years of practice, and specialty. Overall treatment patterns were compared initially between specialties. Using Pearson's chi-dquared and t-tests, our initial analyses focused on testing for differences in knowledge, attitudes, barriers, and treatment patterns among groups of respondents defined by independent variables like practice specialty, years in practice, and practice setting (e.g., university hospital or private practice). Because misoprostol and office uterine evacuations were the least commonly used treatment options, we focused our multivariate analysis on identifying factors associated with using these treatment modalities. We used logistic regression to identify which provider characteristics and attitudes were associated with the use of misoprostol and office uterine evacuation over the past 6 months. Prior to bivariate testing, we planned to include provider sex, specialty, and prior abortion training in the model, because we expected these factors to be associated with practices. We used bivariate testing to identify other covariates significantly ($p<0.05$) associated with use of misoprostol or office uterine evacuation, which would be included in the model. Finally, attitudes specific to misoprostol use and those specific to office uterine evacuation use were included in their respective regression models. Data were analyzed with SPSS 16.0 (SPSS Inc, Chicago, IL).

- *RESULTS:*

In total, 2,040 out of 3,591 contacted participants responded to our mailings, for an overall response rate of 56.8%. Within each specialty, response rates were 51.1, 70.9, and 53.5% for obstetrician/gynecologists (Ob/Gyns), certified nurse midwives/certified midwives (CNMs/CMs), and family physicians (FPs), respectively. Of these, 1,040 were excluded because they had not evaluated or treated a patient for early pregnancy failure in the past 6 months. An additional 24 respondents were excluded because they were not employed by one of our targeted practitioner groups. This process left 976 respondents eligible for further analysis.

As expected, practices differed significantly between provider specialties. For instance, Ob/Gyns were much less likely than other providers to report that their patients were managed expectantly (12.3 vs. 36.3% respectively, $p<0.001$). Misoprostol use was most commonly reported among Ob/Gyns ($p<0.001$), but only 19.3% of Ob/Gyns reported that more than 25% of their patients were treated with misoprostol. In fact, most providers had not used misoprostol at all in the past 6 months. Similarly, office uterine evacuations were uncommon among all groups, even Ob/Gyns. Only 16.2% reported ever using office evacuations to treat EPF in the past 6 months. Finally, referrals were also an important feature of services: 32.7% of CNMs/CMs and 37.4% of FPs reported referring over 25% of patients to specialists for EPF treatment.

Personal rank of the four treatment options differed by provider specialty. Expectant management was the most commonly reported "*most preferred*" treatment by both CNMs/CMs (55.2%) and FPs (64.5%). Only 24.4% of Ob/Gyns reported expectant management as "most preferred." A uterine evacuation in the operating room was reported to be the "most preferred" option by 137 (45.7%) of Ob/Gyns. Treatment with misoprostol was frequently ranked second best treatment: 33.2%, 61.8%, and 60.7% of Ob/Gyns, CNMs/CMs, and FPs respectively. Office uterine evacuations were most frequently cited as "*least preferred*" among Ob/Gyns, (37.2%) and CNMs/CMs (43.9%), whereas operating room uterine evacuations were most commonly the "*least preferred*" option among FPs (41.8%). As provider ranking of misoprostol and office uterine evacuation increased, the likelihood of misoprostol and office uterine evacuation use in the last 6 months increased ($p<0.001$).

In addition to their own preferences, participants also reported how they believed *patients* rank the four treatment options. Perceived patient preferences followed the same overall pattern as provider personal preference: expectant management was most commonly believed to be "*most preferred*" treatment by both CNMs/CMs and FPs, and uterine evacuation in the operating room was most frequently believed to be the "most preferred" option by Ob/Gyns. However, there was some evidence that providers believe their patients' treatment preferences differ from their own. For example, fewer healthcare providers believed that their patients would consider uterine evacuation as the "most preferred" treatment than they would personally

(15.6% vs. 28.4%, p<0.001, perceived patient and provider rank, respectively). Also, more providers believed that their patients considered expectant management as "*most preferred*" than they would personally (62.3% vs. 48.1%, p<0.001 patient and provider rank, respectively).

Views toward misoprostol and office uterine evacuation use in EPF treatment were similar among the three groups of providers, with a few exceptions (**Table 1**). FPs were most likely to identify barriers to implementing misoprostol use in their practice (p<0.01). Although Ob/Gyns reported the most favorable views toward office uterine evacuations, 65.7% agreed that most women preferred general anesthesia, and 46.4% agreed that the best treatment for EPF is an operating room uterine evacuation. Office space limitations was the most frequently identified barrier to offering office uterine evacuations.

Table 1: Provider attitudes and beliefs towards EPF treatment

	Number (%) of providers in agreement			
	Obstetrician/ gynecologist (n=301)	**Certified nurse midwife/midwife (n=352)**	**Family medicine practitioner (n=290)**	**p-value**
Provider attitudes and beliefs towards EPF treatment				
Best treatment is operating room D&C	142 (46.4)	125 (35.1)	81 (28.6)	<0.001
Best treatment is D&C as soon as possible	69 (22.9)	99 (27.7)	53 (18.8)	NS
Trial of expectant management is safe	238 (77.5)	265 (74.0)	212 (75.2)	NS
Misoprostol treatment is safe	213 (70.3)	229 (63.8)	176 (62.2)	NS
Office D&C is riskier than operating room D&C	94 (30.7)	114 (32.0)	108 (38.3)	NS
Office D&C should not be offered	28 (9.2)	53 (14.8)	41 (14.6)	<0.001
Most patients want D&C under general anesthesia	201 (65.7)	165 (46.2)	122 (43.1)	<0.001
Barriers to misoprostol use in EPF				
Lack surgical or nursing backup	22 (7.3)	44 (12.4)	101 (34.7)	<0.001
Lack nursing support	56 (18.5)	63 (17.9)	131 (45.0)	<0.001
Too little patient demand	55(18.2)	55 (15.7)	101 (34.7)	<0.001
Barriers to office uterine evacuations for EPF**				
Office space limits	142 (46.4)			
Reimbursement concerns	66 (21.8)			
Nurses or office staff oppose	60 (19.7)			
No support in the literature	10 (3.3)			
Lack appropriate training	40 (13.3)			
Too few patients prefer office uterine evacuations	71 (23.3)			

Proportion of providers in agreement with each statement was compared using Pearson's Chi-Square
** Barriers to office uterine evacuations was limited to Ob/Gyn respondents
Numbers may not add up to 100% due to missing items

Bivariate tests concluded that provider specialty, practice setting, years in practice, and prior training in induced abortion were significantly associated with ever using misoprostol and with performing office uterine evacuations, but provider sex and race were not. When we examined misoprostol use, our multivariate analysis concluded that a healthcare provider's belief that misoprostol is safe was associated with misoprostol use (OR=2.68, p<0.001), but a belief that patients would not accept treatment with misoprostol is negatively associated with its use (OR=0.16, p<0.001). After controlling for provider sex, specialty, years in practice, practice type, and prior induced abortion training, prior induced abortion training was not significantly associated with misoprostol use in the multivariate model, but it remained significantly associated with use of office uterine evacuation.

- *COMMENT:*

Beliefs about the relative safety of treatment options, perceived patient preferences, and prior training experiences were associated with treatment patterns for EPF in this multidisciplinary group of healthcare providers. Our findings also suggest that providers perceive that their personal treatment preferences are different than their patients. Whether this discordance results in more women undergoing operating room uterine evacuations than is either needed or preferred could not be assessed by this study, largely because we do not know how much patient preferences explain current treatment patterns. However, given that providers affect treatment choice greatly,[2, 12, 13] it is plausible that provider treatment preferences are an important influence on current treatment patterns.

The generalizability of our study may be limited by a few factors. Our findings may not apply to all clinicians providing care to women with EPF, as we did not include all types, such as nurse practitioners. Our response rate of 56% was similar to other healthcare provider surveys, and it is possible that our survey participants may not reflect the views of nonresponders. This would be particularly problematic if nonresponders use office uterine evacuations and misoprostol to a greater degree than responders. Based on age and sex, our respondents were very similar to members of the three sampled organizations (mean age and % female of ACOG, ACNM, and AAFP members was 50.9, 48.9, and 49.2 years and 46.9%, 97.8%, and 43.6%, respectively.) This similarity suggests that our sample is a reasonable representation of members overall.

Additionally, because we were unable to assess whether early adoption of misoprostol and/or office uterine evacuations is occurring, we could be underestimating current use. Finally, we could not exclude the possibility that patient preferences are entirely responsible for current treatment patterns. For instance, we could not determine if patients were offered office uterine evacuations but almost always chose operating room evacuations. However, fewer than 10% of providers reported offering office uterine evacuations in their practices, and previous work has shown that women often prefer clinic evacuations for EPF over operating room procedures. Therefore, we concluded that service availability is an important factor.

Misoprostol and office uterine evacuation use for EPF was less than one might expect based on available studies on safety and patient acceptance. About a third or more of providers in this study indicated concern about the safety of misoprostol and office uterine evacuations for EPF treatment, though their safety and efficacy have been consistently demonstrated. Similarly, the safety and efficacy of office uterine evacuations has been established by clinical studies of women undergoing induced abortion and EPF treatment. Misinformation about the safety of misoprostol and/or office uterine evacuations may be contributing to the apparently slow adoption of these options for women seeking treatment for EPF despite the solid evidence base to support these treatment options.

A belief that women will not accept misoprostol treatment or office uterine evacuations may also be preventing adoption of these options. In truth, we know relatively little about what women desire in EPF care. However, various clinical trials designed to primarily assess efficacy and safety indicate that misoprostol and office uterine evacuations are acceptable and may be preferred by many women. Other work suggests that a substantial proportion of women will choose to avoid general anesthesia for surgical uterine evacuations for EPF and induced abortion. From this work, it appears that women's treatment preferences for EPF are diverse.

Because misoprostol and office procedures are techniques frequently used in induced abortion care, we anticipated that clinicians with induced abortion training may behave differently than others. However, only one fifth of the Ob/Gyns in this sample reported having had formal induced abortion training. Increasing access to induced abortion training is one approach to improve EPF care. However, recognizing that some trainees will opt out of induced abortion training, office uterine evacuation skills and misoprostol use should still be taught in training programs as effective methods of EPF treatment. This training is especially important because EPF is one of the most common clinical problems encountered by health providers for women, and training may be an important predictor of future practice.

The greater reliance on surgical treatment by Ob/Gyns in our study sample is probably misleading, because they are often seeing women who request surgical management after "failed" expectant or medical management, or they prefer primary surgical treatment. However, it may also be the case that practitioners trained as surgeons perceive surgical management strategies to be optimal, and non-surgeons perceive nonsurgical options to be optimal, even though all approaches are equivalent from a safety and efficacy standpoint. Differences in misoprostol use among provider types, however, are more important because its use does not require surgical privileges. It was somewhat unexpected that misoprostol use was so uncommon among FPs. This may be explained by the fact that CNMs/CMs often have consulting arrangements in place with Ob/Gyns, so they may perceive fewer barriers to misoprostol use, such as having surgical backup available. Targeting the apparent reluctance to use misoprostol among FPs could greatly improve access for women desiring medical treatment.

Women are diverse in their treatment preferences, and ensuring access to a range of services is probably the most important thing we can do to improve care. Even though the efficacy of misoprostol and office uterine evacuations is well-established, our study suggests that EPF care patterns are still largely dominated by expectant management and operating room uterine evacuations. These findings are consistent with other studies examining practices regionally. Targeting inaccurate beliefs about the safety of misoprostol and office uterine evacuation and clarifying patient preferences may increase the willingness of providers to adopt new practices to meet patient needs. EPF is one of the most common clinical problems faced by healthcare providers caring for reproductive-aged women; therefore, improving services in this area will have a large impact on patient experience and satisfaction.

Aim IIb: To describe patient treatment preferences and satisfaction with care after EPF.

There is little information on how women with EPF view their treatment options and what factors influence their treatment choice. Nor do we have a good understanding of whether different treatment processes affect patient satisfaction or their functional status. This aim sought to enroll women who have yet to finalize their treatment choices in order to describe patients' treatment preferences, the factors that influence decision-making, and their satisfaction with care. This study consisted of two self-administered questionnaires. The first was administered prior to discussing the treatment plan with their provider, and the second was administered 6 weeks after successful treatment.

- *METHODS:*

We enrolled women presenting with EPF at less than or equal to 12 weeks gestation without contraindications to expectant, medical, or surgical treatment options. These criteria included bleeding, infection, suspected ectopic pregnancy, significant cardiopulmonary disease, bleeding disorders, poorly controlled diabetes, morbid obesity, significant anemia, and seizure disorders.

Our sample was obtained through the providers employed by the University of Michigan. We used a range of recruitment methods including study flyers, posting on websites, and notifying patients of the study through the nursing staff in their providers' offices. In total, we planned to enroll 500 women. Possible participants were offered enrollment at the time of EPF diagnosis, documented by ultrasound and/or serial beta HCGs. If they agreed, a study coordinator or investigator contacted them to arrange a meeting where they were provided more information and consented if they agreed to participate. These meetings occurred at a location selected by the participant (often at a health center). After completing the consent form, participants completed the first of two surveys prior to meeting with their provider. Because we wanted to ensure that patients were informed of all treatment options prior to making their decisions, nursing staff provided verbal and written education regarding different treatment options prior to survey completion.

Data were collected using two self-administered questionnaires. The questions were developed using published literature, expert consensus, and our preliminary data. Forced-choice questions were used to collect information on knowledge of treatment options, treatment preference, and definition of treatment success. A 5-point scale (not important to most important) was used to measure subjects' treatment priorities and decision-making processes.

Expectant and medical management require a process of waiting for days to weeks for expulsion of the uterine contents. For instance, medical management may take over a week and several visits to complete, but it is still preferable to patients who strongly prefer to avoid surgery. In order to better understand this aspect of patient preferences, we used clinical scenarios describing different waiting times and success rates followed by questions designed to estimate thresholds that are acceptable to patients.

The second survey, mailed 6 weeks after treatment completion, assessed satisfaction with treatment choice, satisfaction with the decision process, and whether they had decision regret. Satisfaction was measured using level of agreement (strongly disagree to strongly agree) to a series of statements. We also used versions of published scales, such as the Holmes-Rovner scale. Decision regret was measured using level of agreement to a single statement: "If I had to make the decision again, I would have picked a different treatment." Finally, we used modified versions of previously validated scales to measure health-related quality of life and depressive symptoms, such as the Short-Form Health Survey or the Perinatal Grief Scale. This survey also assessed complications, number of visits, transportation costs, and number of work days lost.

In addition to the survey data, we conducted a chart review to collect medical and surgical history, date of treatment completion, and complications. Treatment completion was defined as either 1) date of last surgical uterine evacuation or 2) date of ultrasound documenting empty cavity for either expectant or medical management. Complications included infection, retained products of conception/hematometria, hemorrhage (<500 cc), emergency room visits, and admissions. We also documented the need for more than one treatment type.

Our primary outcomes of interest were patient treatment preferences and treatment acceptability, which were measured by:

- Initial treatment choice/preference
- Acceptable time to "cure"
- Treatment regret
- Rate of overall dissatisfaction with care by treatment group

- *Results*

We initially sought to enroll 500 women, but we encountered a number of difficulties in recruitment that ultimately resulted in our closing the study after enrolling 165 women. The key issues in this decision were as follows:

1. **We needed to enroll women prior to making their treatment decision in consultation with their provider**. In order to characterize women's personal preferences, we needed to survey them prior to being influenced by provider preferences. This aspect of our eligibility requirements proved to be extremely challenging. The main reason was that, in most instances, women got in-office ultrasounds and were counseled on their treatment options at the same visit. We attempted to revise our eligibility requirements to include women who had already made their treatment decision with their provider but had not yet been "treated." Although not ideal, we reasoned that we could at least attempt to measure women's perceptions on their roles in treatment decision-making. But in order to examine this perception, we still needed to survey them prior to their first treatment experience. Unfortunately, this did not permit enrollment of women who selected medical management because, typically, these women took their misoprostol before we could administer the first survey.

2. **Women who successfully used expectant management were difficult to identify**. We found that selecting "expectant management" after meeting with providers was extremely uncommon. We believe in part this was due to the fact that most women were diagnosed weeks after the pregnancy had stopped progressing, so in a sense they had already trialed expectant management. We also believe that those who successfully passed the pregnancy without intervention often presented to the provider after the process was complete, if at all. Using a health center to recruit this population was not useful.

Although we got over 25 calls from our community postings, none of these women qualified to participate, as they had completed their miscarriage.

3. **The main objective of the patient surveys was to populate the treatment arms in Aim III**. Because it became clear that our recruiting success was not balanced between all treatment types, the survey data could not be used to populate our treatment arms. We decided that using administrative data was a more accurate means to estimate the distribution among treatment arms in a health system in which all options were available. Given the amount of resources that would have been needed to improve our recruitment, we concluded that continued efforts to increase recruiting were not justified only by our desire to characterize treatment preferences in more detail. We concluded that using other data sources to complete our main Aim was the preferred approach.

Given that we amended our data sources for Aim III, at this point we have only conducted limited descriptive analysis to determine patient participation in treatment decision-making and access to their preferred treatment. To do this, we primarily used two measures: 1) level of agreement between treatment received and treatment preferred ("At this time, which treatment do you MOST prefer?") and 2) "Who do you feel really made the decision?" Less than 2% felt that ultimately they did not contribute to the final decision-making; 85% agreed that their personal preferences were the most important factor in deciding on the treatment plan. Responses to these items provided us with some assurance that our decision to use administrative claims data to estimate patient treatment choice in our health system is reasonable.

In addition to using the above items for Aim III, we still anticipate exploring the findings of our survey data to examine other aspects of treatment decisions in EPF care. (For instance, 1/3 of participants reported that they had a period of expectant management but ultimately decided to move to another treatment choice.) Because of the significant recruiting bias we experienced, it is not clear at this point that these data are publishable; however, we plan to use them as preliminary data in a grant resubmission. In fact, our descriptive findings were used in an application to design a patient decision tool for EPF. We anticipate resubmitting this application in the Spring of 2013.

C. Specific Aim III: To simulate the clinical and economic consequences of an expanded care model compared to usual care.

Though research demonstrates sufficient evidence for the safety and efficacy of several treatment options, there are no studies examining the systemic economic consequences of offering all options to patients. In this Specific Aim, we will incorporate the results from Specific Aims I and II to examine the clinical and economic consequences of an expanded care model for EPF management as compared to usual care.

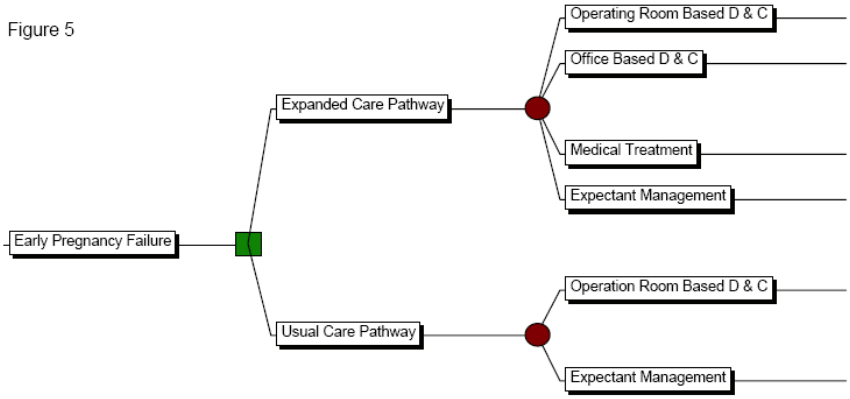
- *Hypothesis:*

We hypothesize that expanding treatment options and allowing patient preferences to dominate treatment choice in EPF will result in cost savings while meeting patient preferences.

- *Methods:*

We will use a decision model to perform the cost-effectiveness analysis comparing Expanded Care with Usual Care for the management of EPF.

Figure 5



The analysis will be conducted from society's perspective. We will assume that all patients will be cured. Completed treatment will be defined as successful uterine evacuation. For each management strategy, we will measure cost and clinical events until 2 weeks after treatment completion. Both direct and indirect costs will be included in our model. Direct medical costs, including hospital costs, outpatient care costs, laboratory charges, and physician professional fees associated with each treatment and any resulting complications will be determined using the latest Medicaid reimbursement rate without geographic adjustment. Medication costs will be estimated using the price information reported in Red Book®. Data from the University of Michigan Data Warehouse's cost accounting system (TSI). Specifically, we will examine the service utilization and costs among 1,700 women treated in our health system. As different treatment options may require several hospital or clinic visits, we will also include direct nonmedical costs, such as transportation and parking, in the model. Productivity loss will be estimated using the national average wage rate and reported average length needed for each procedure/visit (or length of hospital stay) found in the literature and our previous survey work. The patient survey conducted in Specific Aim IIb will provide information on the number of missed work days as well as transportation and parking costs.

- *Outcome Measures*

Our primary outcome of interest is the comparative cost of the two treatment *models*, Usual Care versus Expanded Care, in cost-saving per case.

Findings from Specific Aim I will provide detailed information to help outline the distribution of patients receiving each alternative treatment (i.e., OR-based D & C versus expectant management) in the Usual Care Pathway. We assume that patient preference plays a significant role in healthcare quality and would drive the distribution between different treatment options in the Expanded Care Pathway. **Patient preferences will be estimated from patterns of care in our health system where all options are available.** Between 2009 and 2011, 1,747 women underwent treatment for EPF in our health system: 47% expectant, 17% misoprostol, and 35% surgical. Of those undergoing surgery, 57% did so in an office setting.

The cost-effectiveness analysis is currently underway. We have conducted a systematic literature review through MEDLINE to determine the success rate of each treatment option and its associated probability of having complications. Complications considered in this study include infection, retained products of conception, hemorrhage, and the need for more than one treatment. Cost-effectiveness ratios comparing Usual Care with Expanded Care as well as comparing the four treatment options will be calculated.

Sensitivity analysis will be conducted, allowing several parameter values in the model to vary, and we will examine its impact on our decision outcome. In particular, as the Expanded Care Pathway is a new care model for managing EPF, there is uncertainty regarding the exact distribution of patients choosing each alternative treatment. Therefore, we will vary the values of these probabilities using sensitivity analysis. A reasonable range of the values will be decided based on published literature and findings from Specific Aim IIb. Values resulting in a decision switch will be noted, indicating the threshold for one care pathway to dominate the other. All analysis will be conducted using PrecisionTree® (Palisade Corporation, Ithaca, New York).

6. Overall Conclustions, Significance and Future Research:

Academic interest in EPF treatment has grown quickly over the past several years, in large part as a result of recent clinical trials demonstrating the safety of several treatment options. Subsequently, a number of interest groups have sought to disseminate knowledge of these treatment options to both the public and the healthcare communities. As advocates of patient-centered care, we have engaged in these educational programs to help interested parties adopt medical options and office-based surgery into their clinical practices. We admit, however, that there are limited data on what different patient groups desire; therefore, we plan to apply these methods to other populations and systems in future work.

Thus far, our main findings confirm our hypothesis that current treatment patterns do not reflect evidence-based practices. Most women appear to be treated with only two of the four effective options, even though there is some reason to believe that all options are acceptable to many women. Provider-related factors are probably partially behind these patterns. Women's healthcare providers lack sufficient knowledge on the full range of options, lack previous training, and may have a misperception of what women want in their care. Findings from a health system in which all treatment options are available suggest that, once all options are available, more women will be managed outside of an operating room setting. Early analysis suggests that this new distribution in treatment patterns does account for patient treatment preferences.

Although we have not completed the final cost-effective analysis, we believe that these findings will have significant implications for practice. Based on treatment utilization patterns in our health system, it seems clear that adding alternative options has the potential of cost savings, given the number of patient apparently moved out of the operating room. However, we are also sensitive to the possibility of the unintentional effects introducing new treatment options might have on patterns of care. For instance, might the convenience of office procedures change the indication for surgical intervention, therefore increasing the proportion of patients who undergo surgical management, as has been seen with the introduction of laparoscopic cholecystecomy? Our experienced team will continue to monitor the impact of change in EPF care over time.

7. List of Publications

1. Dalton VK, Harris L, Cohn L… et.al. Treatment patterns for early pregnancy failure among Michigan Medicaid participants. *Journal of Women's Health* 2009;18:1-7 (NIHMSID# 183463)
2. Dalton VK, Harris LH, Kane-Low L…et.al. Provider knowledge, attitudes and treatment preferences for early pregnancy failure. *Am J Obstet Gynecol* 2010;202:531.e1-8 (NIHMSID# 179408)
3. Wallace RR, Goodman S, Freedman LR…et.al. Counseling Women with Early Pregnancy Failure: Utilizing Evidence, Preserving Preference. *Patient Educ Couns* 2010;81:454-61. Epub 2010
4. Dalton VK, Harris LH, Bell J… et.al. Treatment of early pregnancy failure: Does induced abortion training affect later practices? *Am J Obstet Gynecol* 2011;204:493 (NIHMSID# 272868)
5. Wallace R, Dehlendorf C, Vittinghoff E… et.al. Early pregnancy failure management among family physicians. *Fam Med* 2012. *In press*.