



Preconception Counseling: Identifying Ways to Improve Services

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Abstract

Objective The aim of this retrospective study was to evaluate the maternal conditions for which preconception services are provided and the routine services and recommendations offered through the Maternal Fetal Medicine group at the University of Colorado (CU). The study sought to determine how services and recommendations differ by maternal condition, demographics, and reproductive health history.

Materials and Methods Charts of patients who received preconception counseling through the CU MFM department during 2018 were reviewed to evaluate maternal conditions and the type of counseling patients received. Patients were grouped by their referral reason and subsequently by counseling recommendations to either proceed with immediate conception, defer immediate conception pending completion of further recommendations or to not conceive.

Results Of the fifty-nine patients referred to preconception counseling, 52% ($n = 31$) of the women were referred for maternal disease, 40% ($n = 24$) for infertility, 32% ($n = 19$) for previous poor obstetric outcomes, 30% ($n = 18$) for advanced maternal age and finally, 15% ($n = 9$) for gynecologic anatomic abnormalities.

Conclusion During the initial evaluation, 58% ($n = 34$) of patients were determined to have no concern for immediate conception while 7% ($n = 4$) were ultimately advised to not conceive. Using this data, we identified areas of preconception counseling that standardization will improve by ensuring patients receive comparable services and advice.

Keywords

- ▶ preconception counseling
- ▶ MFM
- ▶ maternal-fetal medicine
- ▶ conception
- ▶ prenatal

Preconception care is aimed at optimizing women's health prior to pregnancy to achieve the ideal safety and well-being of the woman, fetus, and neonate.¹ The objective of preconception counseling is to educate women on how best to achieve a

healthy pregnancy by addressing current health issues and modifiable risk factors so that the patient may experience the safest possible pregnancy while reducing the risk of adverse events for the fetus and neonate.² Education is a crucial

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component to achieving health before and through pregnancy and is a cornerstone of preconception counseling.³

Research has suggested that access to preconception care increases favorable birth outcomes through health maintenance and education.⁴ The American College of Obstetrics and Gynecology provides guidelines for preconception which are aimed at improving pregnancy outcomes for all women, but especially those considered to be at high risk for pregnancy, delivery, and child complications.² While some aspects of preconception care are based on research findings, many women do not access this care⁵ and little work has been done to specifically examine how preconception care is implemented, how well advice is followed, and ultimately whether care or specific aspects of care improve specific outcomes.⁶⁻⁹

Most of the published literature about preconception care has focused either on preconception care as part of primary care^{9,10} or various aspects of preconception recommendations in respect to specific disease states,^{11,12} with little focused on specifically addressing the characteristics and outcomes of the spectrum of care provided by Maternal-Fetal Medicine (MFM) specialists. MFM practice provides care for high-risk pregnancies and conditions ranging from systemic lupus erythematosus to patients with a history of gestational diabetes or hypertension, as well as providing guidance to women with prior poor pregnancy outcomes.¹³ Preconception care in the primary care setting is crucial for many women to achieve healthy pregnancies, but there is little information on how to optimize the expertise of MFM physicians in the management of more typical high-risk patients or for women seeking preconception counseling for other reasons.

The aim of this retrospective study was to evaluate the conditions for which preconception services are provided and what specific services and recommendations are offered through the MFM group at the University of Colorado (CU). The study sought to determine how services and recommendations differ by maternal condition, demographics, and reproductive health history.

Methods

Electronic medical records (EMRs) were used to identify women who received preconception care at the University of Colorado Maternal-Fetal Medicine Preconception Clinic between January 2018 and December 2018. Fifty-nine women were determined to have preconception counseling listed as a chief complaint or reason for the clinic visit during this date range, making them eligible for this retrospective study.

A chart review was conducted on each study participant by a single individual (K.B.) using an EMR system. The primary location of patient information within the EMR was the preconception visit notes. The visit notes recorded the recommendations made by the provider, any laboratory tests or imaging advised, as well as information on results and referrals made. Information about the patient's obstetrical history, including the outcomes of all previous pregnancies and the well-being of the patient during the

pregnancy was also collected, if available. This included any pregnancies that occurred during the 12 months following the original preconception counseling visit.

When available, demographics, gynecologic/obstetric (OB) history, general health history, medications, immunizations, substance use, and mental/social/family history were collected on each patient and recorded in a secure REDCap database. Data on general health/medical history were collected and included a positive history of any of the following: polycystic ovary syndrome, asthma, diabetes mellitus (types I or II), chronic hypertension, systemic lupus erythematosus, irritable bowel disease, cancer, thyroid disorders, depression, anxiety, bipolar, deep vein thrombosis/pulmonary embolism, eating disorders, and previous surgical history.

Reasons patients were referred to preconception counseling fell into five main categories based on the presence of diagnoses in the patients' EMR: (1) maternal disease, (2) infertility, (3) previously poor OB outcomes, (4) advanced maternal age (AMA), and (5) gynecologic anatomical abnormality. Patients were often referred to counseling for more than one reason, and therefore, one patient might be grouped into multiple categories of referral. Of the 59 patients referred, there were a total of 101 reasons for preconception referral. Examples of referral for maternal disease included high body mass index (BMI), history of thrombophilia, mental health, cancer, and cardiac disease. Previously, poor OB outcome included recurrent pregnancy loss, intrapartum maternal health complications, preterm premature rupture of membranes (PPROM), and postpartum complications. AMA is defined by the patient being at least 35 years of age at the time of prospective due date. Patients referred for uterine, cervical, tubal, or ovarian abnormality were grouped into a gynecologic anatomic abnormality category. Examples included uterine fibroids, bicornuate, unicornuate, or septum uterus.

Recommendations given to patients after their preconception appointments were grouped into three categories: (1) no concern with immediate conception, (2) delay conception until recommendation are met, and (3) advised not to conceive. Data for these groups were found in the provider notes for the preconception counseling appointment.

This study was approved as exempt by the Colorado Multiple Institutional Review Board.

Results

EMR data from 59 women who attended a preconception counseling appointment at the University of Colorado Maternal-Fetal Medicine Preconception Clinic in 2018 were included in this retrospective chart review. The majority (73%, $n=43$) of the patients were Caucasian and married (76%, $n=45$). Twenty-five percent ($n=15$) of all patients identified as nonwhite, with the largest nonwhite percentage, (10%, $n=6$) identifying as other.

The median maternal age of patients was 37.5 years. Thirty-seven percent ($n=22$) had a normal BMI, while 56% ($n=33$) were overweight, obese, or morbidly obese. Twenty-

Table 1 Demographics for patients receiving preconception counseling through the University of Colorado Department of Maternal-Fetal Medicine during 2018

| | | Number of patients (%) |
|---------------------------------------|-----------------------|------------------------|
| Total number of patients in the study | | 59 |
| Maternal age group (y) | 15–20 | 0 (0%) |
| | 21–25 | 4 (6.78%) |
| | 26–30 | 8 (13.56%) |
| | 31–35 | 18 (30.51%) |
| | 36–40 | 14 (23.73%) |
| | 41–45 | 7 (11.86%) |
| | 46–50 | 7 (11.86%) |
| | 51–55 | 1 (1.69%) |
| 56–60 | 0 (0%) | |
| Maternal BMI (kg/m ²) | Underweight (< 18.5) | 4 (6.78%) |
| | Normal (18.5–24.9) | 22 (37.29%) |
| | Overweight (25–29.9) | 17 (28.81%) |
| | Obesity (30–34.9) | 7 (11.86%) |
| | Morbid obesity (> 35) | 9 (15.25%) |
| Average maternal weight, height, BMI | Average weight | 168.5 lbs |
| | Average height | 65.4 in |
| | Average BMI | 27.4 |
| Median maternal weight, height, BMI | Median weight | 153 (100–306 lbs) |
| | Median height | 66 in (54–71in) |
| | Median BMI | 25.6 (15.7–49.4) |
| Marital status | Married | 45 (76.27%) |
| | Unmarried | 5 (8.47%) |
| | Single | 3 (5.08%) |
| Maternal race/ethnicity | Caucasian | 43 (72.88%) |
| | African American | 3 (5.08%) |
| | Asian/Pacific | 1 (1.69%) |
| | Native American | 2 (3.39%) |
| | Hispanic | 3 (5.08%) |
| | Other | 6 (10.16%) |
| | Unknown | 1 (1.69%) |
| Insurance | Private | 53 (89.83%) |
| | Income dependent | 2 (3.39%) |
| | Uninsured | 0 (0%) |
| | Unknown | 4 (6.78%) |

Abbreviation: BMI, body mass index.

two percent ($n = 13$) of all patients had a mental health diagnosis abstracted from their medical record, though only one patient was referred to preconception counseling for having the mental health diagnosis of bipolar type 1. Of the 59 patients, 3% ($n = 2$) were current tobacco smokers, 8% ($n = 5$) were current marijuana smokers, 22% ($n = 13$) reported current alcohol use, and 45% ($n = 27$) had an unknown substance use history (►Table 1). Most (73%; $n = 43$) of the women were planning pregnancy within the next calendar year.

Depending on indication for referral, patients were typically evaluated according to an algorithm demonstrated by the embedded flowcharts. Fifty-three percent ($n = 31$) of the 59 women were referred to preconception counseling because of maternal disease. The most common reasons for inclusion into this group were high BMI (23%, $n = 7$) and history of thrombophilia (23%, $n = 7$). Of these 31 patients, 52% ($n = 16$) were found to have no concern for immediate conception, 19% ($n = 6$) were advised to defer conception pending completion of recommendations, and 10% ($n = 3$) were counseled to not proceed with immediate conception (►Fig. 1). Twenty-four patients were referred for infertility, of which 50% ($n = 12$) were planning in vitro fertilization and 29% ($n = 7$) had a diagnosis of primary infertility. Fifty-four percent ($n = 13$) were determined to have no concerns for immediate conception, 25% ($n = 6$) were advised to defer, and 4% ($n = 1$) were advised to not proceed with immediate conception (►Fig. 2). Thirty-two percent ($n = 19$) of women were referred to preconception counseling because of previous poor OB outcomes. Among this group, the primary reasons for referral included recurrent pregnancy loss (36%, $n = 7$), pre-eclampsia (15%, $n = 3$), PPRM (10%, $n = 2$), and postpartum hemorrhage (10%, $n = 2$). Fifty-seven percent ($n = 11$) of women who were referred to counseling because of previous poor OB outcomes were determined to have no concerns with conception, 36% ($n = 7$) were advised to defer pending completion of recommendations, and 5% ($n = 1$) were advised not to conceive. Fifteen percent ($n = 9$) of patients had a uterine, cervical, tubal, or ovarian anatomic abnormality for which they were referred. Of these, 33% ($n = 3$) were found to have no concern for immediate conception, 44% ($n = 4$) were counseled to defer pending completion of recommendation, and 0% was advised to not proceed with conception (►Fig. 3). Thirty-one percent ($n = 18$) of women were referred for AMA. Among women in referral group 4 AMA, 72% ($n = 13$) were determined not to be at immediate conception risk, while 22% ($n = 4$) were advised to defer conception pending completion of recommendations and 0% was advised not to conceive (►Fig. 4).

Of the 59 total patients, 58% ($n = 34$) were found to have no concern with immediate conception, regardless of reason for referral to preconception counseling, 5% ($n = 3$) were advised not to proceed with immediate conception, and 11% ($n = 7$) did not have a documented initial preconception recommendation (►Fig. 5).

Twenty-five percent ($n = 15$) of patients were advised to defer immediate conception until the completion of recommendation(s). These patients were further advised to undergo further evaluation and/or testing. The first category was laboratory testing, which often included thyroid-stimulating hormone (TSH) and hemoglobin A1c (HbA1c). The second was evaluation by a specialist or management by a primary care provider (PCP). For maternal disease, these recommendations were often referrals to cardiology for cardiac function testing (46%, $n = 7$), dietician for weight and nutrition optimization or to the patient's PCP for medication management and optimization (13%, $n = 2$). The final category was lifestyle changes which typically included weight loss (46%,

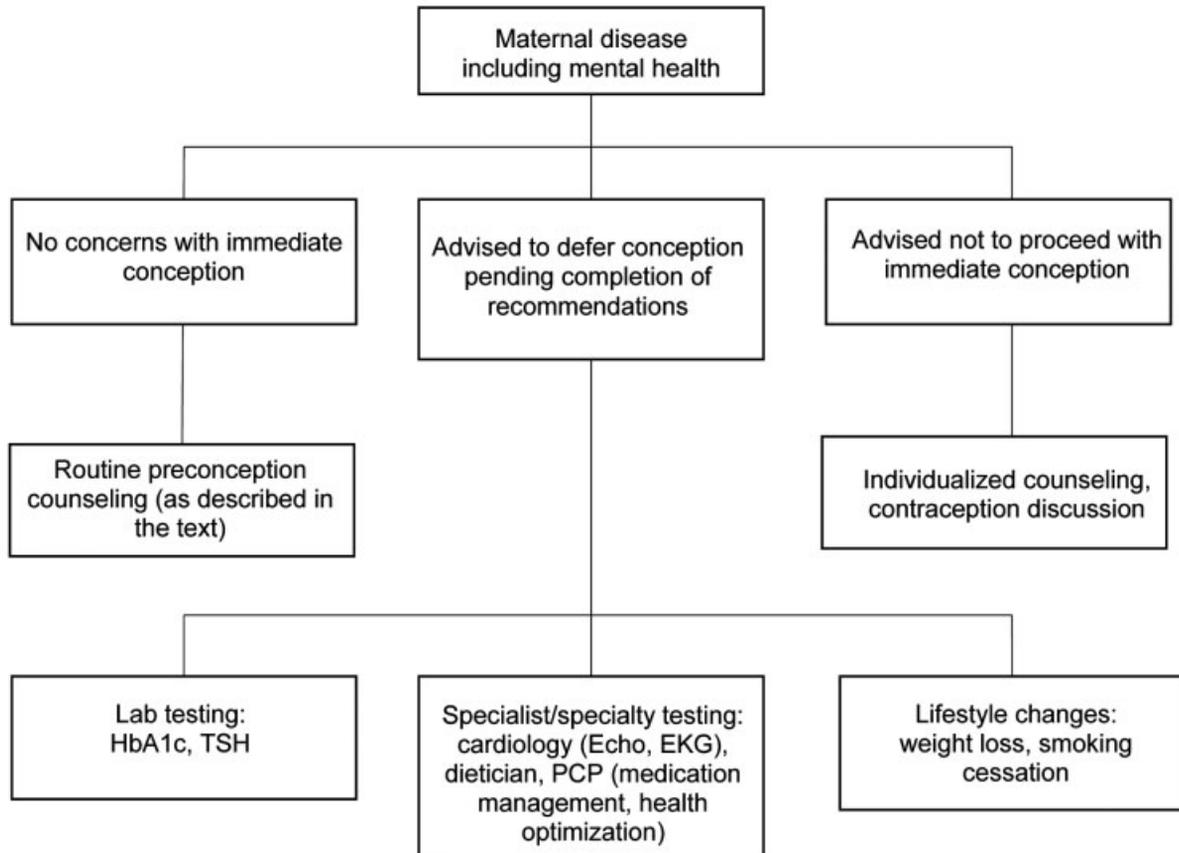


Fig. 1 Maternal disease and mental health recommendations. Flowchart guide for counseling patients referred to MFM counseling for maternal disease and/or mental health conditions. EKG, electrocardiogram; HbA1c, hemoglobin A1c; MFM, Maternal-Fetal Medicine; PCP, primary care provider; TSH, thyroid-stimulating hormone.

$n = 7$), smoking cessation, and exercise. After completing the recommendation(s), patients were re-evaluated for a final conception recommendation. The final recommendations included: (1) ultimately no concern with conception, (2) recommendation of delaying conception, and (3) ultimately advised not to conceive.

Forty percent ($n = 6$) of patients initially advised to defer conception were referred for maternal disease, of these patients, 57% ($n = 4$) were ultimately cleared for conception with no concern, 14% ($n = 1$) were advised to delay conception, and 14% ($n = 1$) were advised against conception. Another 40% ($n = 6$) of patients initially advised to defer conception were referred for infertility. Of these patients, 66% ($n = 4$) ultimately had no concern for proceeding with conception on final recommendation and 22% ($n = 2$) were still pending recommendation completion at the time this study was submitted. Forty-seven percent ($n = 7$) of patients initially advised to defer conception were referred for previous poor OB outcome. For these patient's final recommendation upon completion of initial studies/lifestyle modifications, 28% ($n = 2$) were cleared for conception, 28% ($n = 2$) were advised to delay conception, and 42% ($n = 3$) were still pending results. Twenty-seven percent ($n = 4$) of the patients initially recommended to delay conception were referred for AMA, of these patients, 75% ($n = 3$) ultimately had no concern for conception and 25% ($n = 1$) were still

pending result at the time of this study. Finally, 27% ($n = 4$) of patients initially advised to defer conception were referred for a gynecologic anatomic abnormality. One hundred percent of these patients after completing recommended evaluations or procedures were then ultimately found to have no concern for moving forward with conception.

Discussion

Women were referred to preconception counseling at a University of Colorado Maternal-Fetal Medicine Preconception Clinic for a variety of reasons with maternal health being the most cited reason for referral. Referred women also had a diverse range of reproductive history and previous OB outcomes. In our study, 7% ($n = 4$) of patients were ultimately counseled to either further delay conception or to not conceive. This is the first study we are aware of to publish the percentage of patients advised by MFM providers to not conceive.

Almost three quarters of our sample was Caucasian. According to the most recent census data, the Denver area demonstrates a diverse racial distribution with 55% of the population identifying solely as Caucasian, not Hispanic or Latino, 30% identifying as Hispanic, 10% identifying as African American, and 4% identifying as Asian.¹⁴ Thus, our sample does not reflect our geographic area or even the

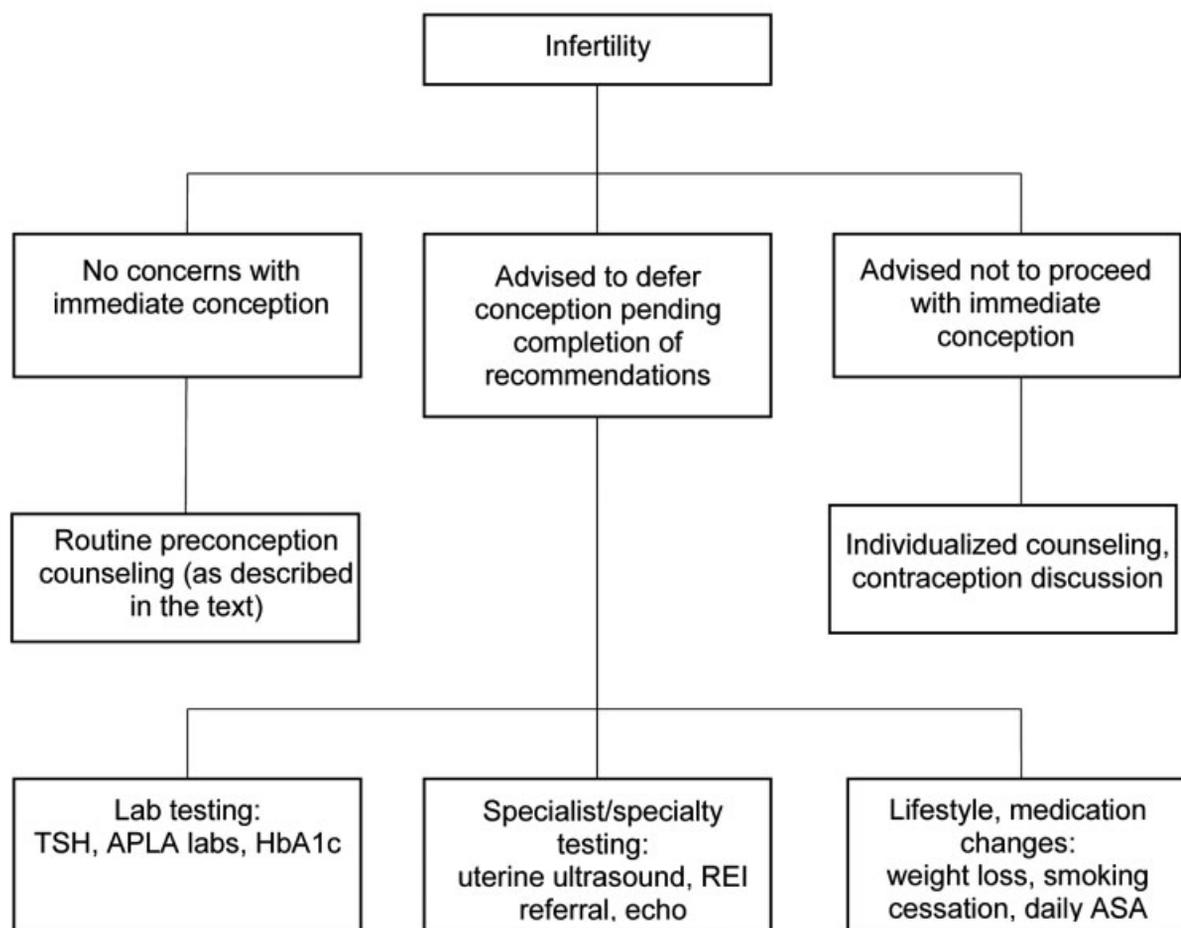


Fig. 2 Infertility recommendations. Flowchart guide for counseling patients referred to MFM counseling for infertility. ASA, Aspirin; APLA, antiphospholipid antibody; HbA1c, hemoglobin A1c; MFM, Maternal-Fetal Medicine; REI, reproductive endocrinology and infertility; TSH, thyroid-stimulating hormone.

demographics of the OB/gynecology clinics at the same institution. This is concerning because women of minority groups have increased maternal mortality and adverse fetal outcomes^{15,16} and are also less likely to access preconception care.¹⁷

Different reasons for the incongruity between the population and the patients referred have been suggested. One study found that patients with Hispanic ethnicity, higher parity, unintended pregnancy, or without insurance were less likely than their Caucasian counterparts to receive preconception counseling.¹⁸ Another study of Hispanic and African American women demonstrated one-third of participants with chronic medical conditions was unaware of preconception health risks and, therefore, did not seek preconception care.¹⁹ Health disparities affecting minority women has also been found to decrease these women's access to preconception counseling and management of preexisting conditions, directly affecting pregnancy outcomes.²⁰ Another study examining the intricacies of delivering preconception care to adolescent, diabetic women identifying as Hispanic, demonstrated the extent to which cultural and religious barriers need to be carefully addressed to optimize preconception counseling.²¹ Since providing

adequate preconception care allows for health intervention and management offering improved pregnancy outcomes, it is a vital aspect of health care that should be available to all women of childbearing age.^{22,23} It is crucial for preconception counseling to be widely available to all women, not just those actively contemplating conception, to optimize maternal and fetal health.¹⁵ The discrepancy of women from minority groups receiving prenatal care represents a serious health care system flaw that needs to be remedied with improved patient outreach and provider referrals.

Of the women referred for preconception care, 56% ($n = 33$) were either overweight, obese, or morbidly obese, though only 11% ($n = 7$) were referred to counseling for high BMI. The average BMI for patients referred for this reason was 41, while the average BMI for all patients was 27. Although a conversation regarding weight optimization was frequently documented by health care providers for patients with BMIs categorized as overweight or greater, there was not an agreed-upon target for BMI, weight, or target pound loss. Reduction in maternal BMI by 10% prior to conception has been associated with a decrease in peripartum maternal complications such as preeclampsia, preterm delivery, and stillbirth.²⁴ According to the World Health Organization, the

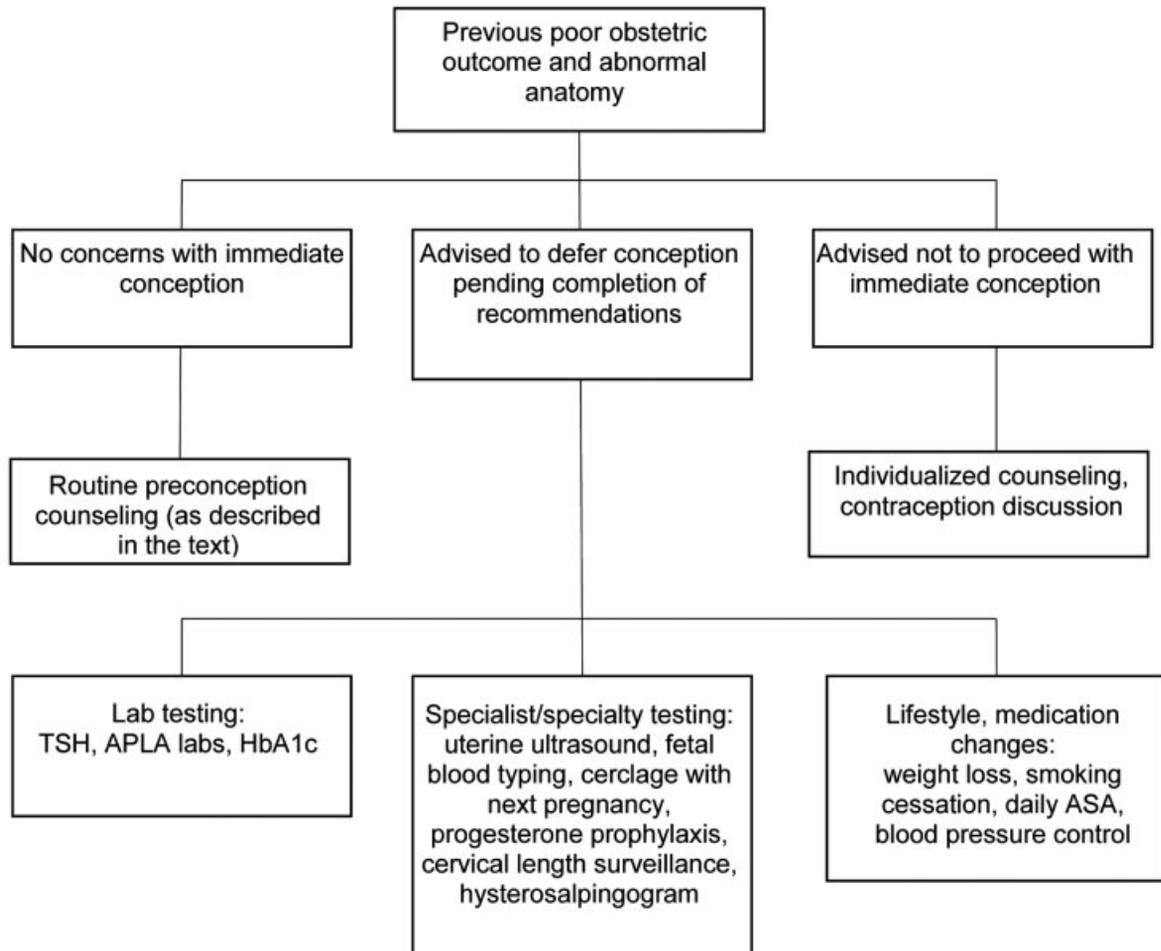


Fig. 3 Previous poor obstetric outcome and abnormal gynecologic anatomy recommendations. Flowchart guide for counseling patients referred to MFM counseling for previous poor obstetric outcome and/or abnormal gynecologic anatomy. ASA, Aspirin; APLA, antiphospholipid antibody; HbA1c, hemoglobin A1c; MFM, Maternal-Fetal Medicine; TSH, thyroid-stimulating hormone.

recommended BMI for pregnant women is within the normal BMI range of 18.5 to 24.9 to decrease complications associated with underweight patients, including small for gestational age and low birth weight as well as prepregnancy overweight/obesity complications such as macrosomia, and subsequent childhood overweight/obesity.^{25,26} Chart documentation for all patients who are counseled on preconception weight loss should detail the conversation to provide direction for future appointments and pregnancies.

Patients were most likely to be referred for maternal disease. Preconception recommendations included, laboratory testing, evaluation by a specialist or management by a PCP. Lifestyle changes were also widely recommended and included weight loss, smoking cessation, and exercise. Previous authors have suggested that these interventions can improve pregnancy outcomes.¹ For patients who were found to have no concern for immediate conception, they were offered general preconception counseling which included discussions of prenatal vitamin use, genetic carrier screening, dietary optimization, and substance use avoidance. We found that there was significant variability in the provider documentation of recommendations and which recommen-

ations were standard. For the patients advised to not immediately conceive, they were offered individualized counseling based on their specific referral reason and health conditions.

The second most common reason for referral was infertility. Patients with infertility are referred to preconception clinics with MFM providers to be evaluated for any maternal medical concerns prior to proceeding with pregnancy. After receiving medical clearance, patients are then evaluated for infertility in separate reproductive endocrinology and infertility clinics. For patients advised to defer immediate conception, the laboratory tests recommended were most often TSH, HbA1c, and antiphospholipid laboratories. The specialty referrals were to reproductive endocrinology and cardiology. Specialty imagining most often advised was for uterine ultrasound or hysterosalpingogram (HSG). Patients were also advised on lifestyle changes, including starting aspirin with pregnancy. Patients referred for infertility who were recommended to proceed with conception received general preconception counseling. Though there were consistent recommendations from different providers regarding infertility counseling, there was not a standard collection of

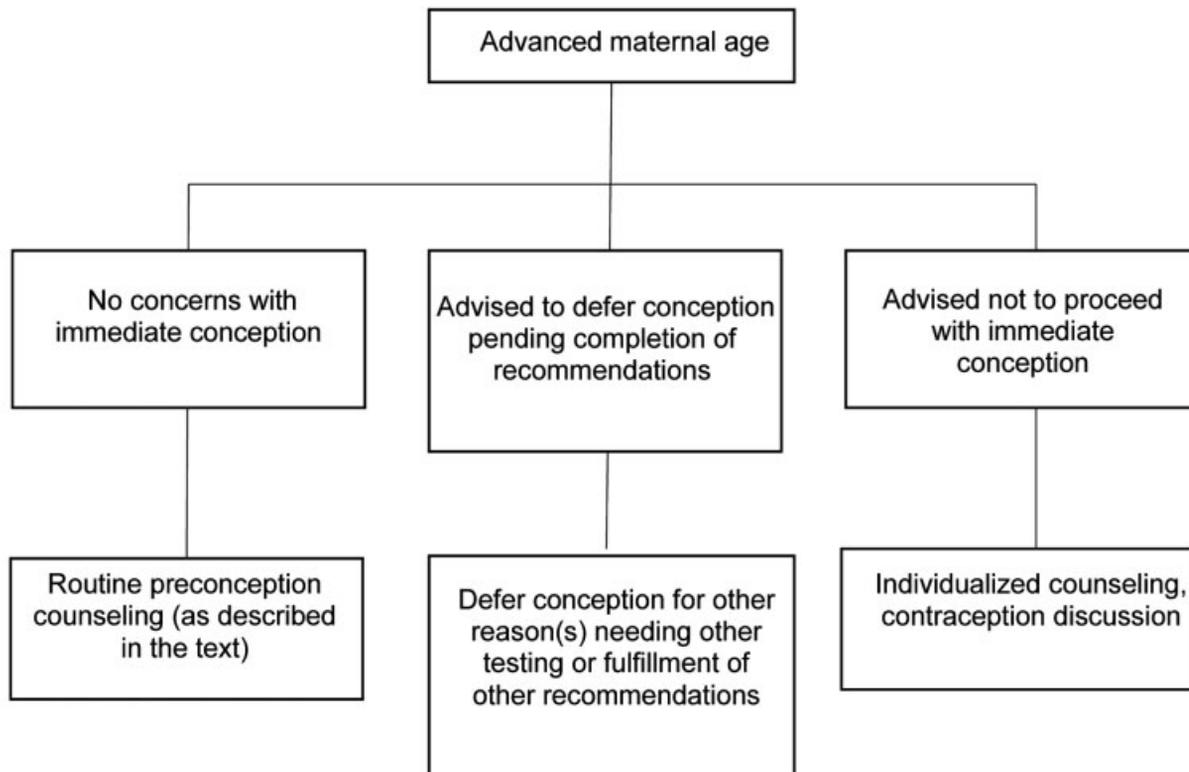


Fig. 4 Advanced maternal age recommendations. Flowchart guide for counseling patients referred to MFM counseling for advanced maternal age.

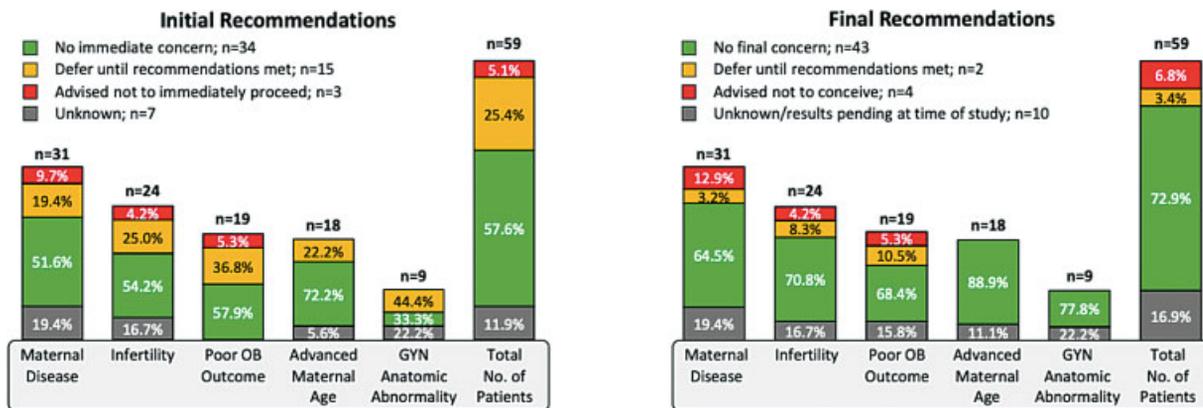


Fig. 5 Referral specific patient recommendations for proceeding with conception. Figure demonstrates the breakdown for patient referral reason and the preconception counseling recommendation given (colorized).

recommendations. There is no standard patient, making it difficult to widely structure and define how individual counseling appointment should be arranged.

Patients referred for previous poor OB outcomes and abnormal anatomy were similarly counseled. For patients with previous poor OB outcomes, laboratory testing was similar to that recommended for infertility and included TSH and antiphospholipid laboratories. For patients with both poor OB outcome and abnormal anatomy, recommendations for specialty testing included uterine ultrasound, cerclage placement, use of progesterone prophylaxis in a subsequent pregnancy, cervical length surveillance, and HSG. Lifestyle recommendations for both groups of patients included

weight management, smoking cessation, and blood pressure control.

Patients referred for AMA received general preconception counseling, though there was often an emphasis in the documentation about routine prenatal screening. Patients referred for AMA who were recommended not to conceive had coexisting referral reasons, such as maternal health concerns.

The patients who were cleared for immediate conception received general preconception counseling in addition to patient-specific counseling to optimize their health before and throughout pregnancy. The majority of these patients had documentation outlining the general preconception

counseling in their EMR. For these patients, the documentation regarding counseling was provider specific, though usually included recommendation for the patient to continue or begin taking a prenatal vitamin and aspirin, a schedule for routine screenings and other recommendations related to maintaining a healthy diet and lifestyle recommendations. There was not clinic-wide documentation used by providers to encompass general preconception recommendations and some of the patients did not have documentation of standard preconception advice. The patients without general preconception recommendations documented tended to be the relatively more complex patients. Documentation for these patients reflected more extensive conversations about specific aspects of the patient's health or previous reproductive complications. More often for these patients, provider documentation focused on counseling for the specific referral reason with less emphasis on general preconception topics.

The primary limitation to this study is the lack of consistent follow-up for patients. There are several reasons patients were often lost to follow-up after their initial preconception counseling visit. The most common being that the patient was referred to MFM by a PCP who is outside the University of Colorado Hospital system, so any subsequent pregnancy outcomes were unknown and not documented in their CU EMR. Additionally, without documentation in their CU EMR, it could not be determined whether a patient followed the MFM specialist's recommendations. Patients may have also been lost to follow-up due to changes in the desire for pregnancy and/or exploration of other options for parenthood. At the time of this study, there was not a system in place to follow-up with patients to evaluate the efficacy of the recommendations and referrals in regard to optimized preconception health. There was also not any method of following patients to assess for how often patients seen at a MFM clinic were successful in conceiving and the outcomes of any pregnancies. Obtaining follow-up information on patients is crucial to properly guide future MFM practice recommendations as well as to understand how patients follow counseling and what effect this counseling may have on their pregnancy health and outcomes. Ideally, patients seen at CU MFM clinics will be followed up for 2 years to observe how well recommendations were followed and to track the extent to which following recommendations resulted in pregnancy success.

Another limitation is that not all the relevant information for patients was available in their EMR. Upon data collection, it was apparent that there was a lack of standardization in the type and amount of information collected from each patient. Although each patient filled out a clinic intake form with demographic information, missing from the form was pertinent data which would better allow providers to counsel patients and make recommendations. Utilizing a detailed intake form which is standard to all CU MFM clinics will bridge this gap in patient data and allow for a more complete MFM counseling appointment.

The finding of documentation and recommendation discrepancies among MFM providers suggests the use of a standardized template would be beneficial for MFM clinics.

A standardized template would provide a user-friendly method for documenting general preconception recommendations on which all women should be counseled. We recommend that MFM preconception clinics can implement a standardized intake form and standard recommendations for all preconception patients. These recommendations include prenatal vitamin (PNV), hand washing, vaccine status, and carrier screening. An ideal template would also address standard lifestyle counseling such as dietary and substance avoidance and optimal preconception BMI. The standardized template should also consistently include a section to document discussions regarding contraception. While documenting contraception should be standard for all women, it should be particularly emphasized for women who are recommended to delay conception. In addition to a template detailing common recommendations for all women, this study suggests modifiable templates, notably in regard to the reason for referral, will streamline both follow-up care. These modifiable templates will also increase the ease with which other providers, such as those the patient is referred to or their PCP, are able to review a patient's notes from their MFM consultation.

The goal of this article was to identify opportunities for preconception care improvement and to develop a rubric to guide providers of preconception care to facilitate delivery of optimal care. The findings of our study allowed us to develop flowcharts based on the recommendations and overall course of action taken by CU MFM providers. These flowcharts, illustrated in the results section, are intended to serve as a foundation of standard preconception recommendations. The findings from this study also support the implementation and use of a standard intake in MFM clinics. A standardized form that all patients fill out upon clinic intake should include several sections to optimize the patient's preconception recommendations by providing all relevant details of the patient's health and well-being. The important sections on a standard intake form include demographics, reproductive history, medical and mental health history, vaccination history, substance use, family and travel history, intimate partner violence, dietary and exercise habits, and desire for carrier screening. Reproductive history should detail outcomes of all previous pregnancies, any pregnancy complications, pregnancy plans, and contraception use. By utilizing a standardized intake form, MFM specialists will be provided with all relevant patient information to counsel patients. These forms will also contribute valuable data for future retrospective studies looking at different populations of patients or certain risk factors and the effect on conception and pregnancy outcomes.

Conclusion

Reviewing the available EMR data provided a range of recommendations with information on how frequently the recommendations are followed by patients referred to preconception care. By identifying aspects and outcomes of the current preconception care at CU, this study developed clinical care recommendations for improved preconception

care and provides preliminary data for a prospective study of the success and limitations of preconception services. Findings also contribute relevant details about the specifics of preconception care, the utility for patients, and the impact on pregnancy outcomes.

Conflict of Interest

None declared.

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