Delivering Preconception Medication Therapy Management Services in the Community Pharmacy

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This knowledge-based activity is targeted for all pharmacists and pharmacy technicians and is acceptable for 1.0 hour (0.1 CEU) of continuing education credit. This course requires completion of the program evaluation and at least a 70 percent grade on the program assessment questions.

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Learning Objectives

After completion of this program the reader should be able to:

1. Define preconception care.
2. Discuss the need for preconception care.
3. Explain preconception care interventions that may be provided by a community pharmacist.
4. Describe how preconception care may be provided to patients via medication therapy management.

Background

While literature has long supported the accessibility of the community pharmacist and the value that the community pharmacist can provide to enhancing patient care, billing for such non-dispensing, counseling-focused services in the community pharmacy has been limited. However, opportunity for billing for such services has expanded in recent years under the term medication therapy management (MTM).[1] Although such examples of direct patient care may go by many different names, including pharmaceutical care and patient counseling, MTM may be both an effective model for enhancing health care for patients and a great opportunity for pharmacists.[1,2] For the purpose of this continuing education program, the term MTM will be used as it tends to be frequently used by pharmacists and payors.[1]

Over the past several years, the focus of MTM services has been for patients suffering from multiple disease states, having potential issues from polypharmacy, taking high-risk medications and/or experiencing transitions of care.[3] However, pharmacists additionally conduct MTM services to aid patients with different needs such as those with mental illness or traumatic brain injury.[3] Preconception care represents another area of patient care that pharmacists can impact through MTM.[4]

What Is Preconception Care?

Preconception care involves the recognition and management of biomedical or behavioral issues among women of childbearing potential that must occur before or very early in pregnancy to reduce risks to the health of a woman or her baby.[5] Care for women between pregnancies, or interconception care, is also part of preconception care.[5] There are numerous clinical interventions that may result in improved maternal and infant outcomes.[6] The Centers for Disease Control and Prevention (CDC) Preconception Care Work Group and the Select Panel on Preconception Care (SPPC) conducted a review of the literature and determined evidence-based preconception care recommendations (Table 1). The groups also developed national goals for preconception care (Table 2). As approximately half of all pregnancies in the United States are unintended,[7] the window of opportunity to address risks early in pregnancy are often missed. In addition, about half of all couples with an unintended pregnancy report using contraception in the month prior to conception.[7] Therefore, preconception health interventions should be routinely offered to all women of childbearing potential (typically defined as aged 15 to 45 years), even if they are using contraception, since the interventions also promote optimal health for women regardless of pregnancy intention.[5]

Currently, there is a great need for preconception care in the United States.[8] Although a public health priority,[9] current literature suggests that most patients are not routinely receiving the necessary education, counseling or interventions.[8] For example, in a recent survey of women in four states (Maryland, Michigan, New Jersey and Ohio), only 18.4 percent reported speaking with a health care professional about five or more of 11 possible lifestyle behaviors and prevention strategies before the pregnancy of her most recent live-born infant.[8] These missed opportunities may result in grave consequences on many levels, both for individual families and society.[5] Not addressing health risks in the preconception period can result in lifelong morbidity or mortality for the infant and/or in significant detrimental effects to the mother.[5] In addition, there are estimates that billions of dollars could be saved through preconception care by preventing birth defects and other chronic complications.[10,11]

Providing Preconception Care through Medication Therapy Management

With their accessible nature and extensive knowledge and training, community pharmacists are ideally situated to advance preconception care.[4,12] Through the structure of MTM,

Table 1. Evidence-Based Preconception Care Interventions.[5]

Issue	Recommendation	Rationale
Folic acid	All women aged 15-45 years should take 400 micrograms (0.4 milligrams) of folic acid daily in a multivitamin or folic acid tablet. Women with diabetes, previous pregnancy affected by a neural tube defect, using anti-epileptic drugs, or who have a BMI >35kg/m^2 should take 4-5 milligrams daily.	Adequate levels of folic acid reduce the risk of neural tube defects (NTD)—serious birth defects of the brain and spinal column. The neural tube closes 28 days after conception.
Category D or X medications*	Prescription, OTC or herbal drugs that may cause fetal harm should be identified and exposure should be minimized; patients should be switched to a less teratogenic agent if possible. Women taking these drugs should consistently use effective contraception to avoid inadvertent fetal exposure.	These drugs increase the risk of spontaneous abortion, miscarriage, fetal death and/or serious birth defects.
Hepatitis B vaccine	Patients at risk for acquiring hepatitis B should be vaccinated.	Prevents mother-to-child transmission of hepatitis B and subsequent long-term liver complications.
Measles, mumps, rubella (MMR) vaccine	Women who are seronegative to rubella should receive the vaccine prior to conception. Conception should be avoided for 28 days after receipt of a live vaccine. Do not give live vaccines during pregnancy.	Prevents congenital rubella syndrome—serious birth defects that result from fetal exposure to rubella.
Smoking	Women should be counseled to stop smoking before conception and aided appropriately.	Tobacco increases the risk of preterm birth, low birthweight, and other adverse fetal outcomes.
Alcohol and illicit drug use	Women should avoid alcohol and illicit drugs.	Exposures increase the risk of premature birth, low birth weight, birth defects, fetal alcohol spectrum disorder (from alcohol use) or neonatal abstinence syndrome (from illicit drug use).
Diabetes	Women with pregestational diabetes should have good glycemic control (HbA1C <7%, if this can be achieved without hypoglycemia) using preferred medications.	Diabetes and high blood sugar at the time of conception increase the risk of birth defects and other complications.
Hypothyroidism	Women with hypothyroidism should be monitored more frequently and doses of levothyroxine adjusted as necessary.	Proper levothyroxine levels reduce the risk of spontaneous abortion, stillbirth, low birth weight or neurological problems.
Maternal phenylketonurea (PKU)	Women with PKU should resume a low phenylalanine diet before conception and during pregnancy.	Lowering phenylalanine levels reduces the risk of mental retardation.
Obesity	Women who are obese should receive counseling regarding appropriate weight loss and nutritional intake before conception.	Obesity increases the risk of neural tube defects, preterm delivery and other complications.
HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome)	Women should be screened for HIV/AIDS prior to conception.	Initiation of appropriate drug therapy can reduce the risk of mother-to-child transmission.
Sexually transmitted infections (STI)	Women should be screened for STI prior to conception.	Treatment of STI can prevent complications including birth defects, fetal death, spontaneous abortion, mental retardation and blindness.

* The CDC/SPPC publication focused on antiepileptic drugs, warfarin and isotretinoin; however, all drugs (prescription, over-the-counter or herbal) that may be harmful to the developing fetus should be addressed as appropriate.

elements of preconception care can be addressed by pharmacists via targeted or comprehensive medication review; counseling and education; or screening, support, and referrals (Table 3). [4]

The Core Elements of an MTM Service Model, as adopted by many pharmacy organizations in 2008, defines MTM as having five core elements: a medication therapy review, a personal medication record, a medication-related action plan, intervention and/or referral, and documentation and follow-up.[13] The process by which MTM and other related activities takes place is further defined by the Joint Commission of Pharmacy Practitioners.[14] Medication therapy management services are often completed as comprehensive medication reviews (CMRs), which involves a complete review of the patient's disease states and medications, or as targeted medication reviews (TMRs), which may look at a subset of that patient's disease states and/or medications with a focus on brief interventions. Ideally, TMRs take place following a CMR, but that may not always be the case. [13] While this continuing education program suggests certain interventions that may be more appropriate through a TMR or a CMR, it is ultimately the pharmacist's judgement as to which type of MTM service is most needed for a particular patient.

While billing under Medicare/Medicaid and other private insurances may take place in physician office-based practices for pharmacist-provided non-dispensing services, MTM billing through Medicare Part D and other third-party payors may be a much more viable option in the community pharmacy setting.[15] While preconception needs of most Medicare Part D members may be quite limited, private insurance plans or other third-party payors may cover MTM services and cover a younger subset of patients. In many community pharmacies, two platforms commonly used for documentation and billing for MTM services are MirixaPro and OutcomesMTM.[16,17] Many chain pharmacies have existing relationships with both companies, but those not affiliated with either of these companies can find contracts and other materials necessary for establishing a business relationship with one of these companies at their websites.[16,17]

This continuing education program focuses on three particular preconception care interventions: folic acid use, Category D or X medications, and vaccines. Intervention in each of these three areas greatly reduces the risk of serious fetal harm (especially birth defects, miscarriage, stillbirth and/or chronic disease)[5] and provides overall health benefits for the mother. The interventions below represent effective and evidence-based strategies to positively impact maternal and child health (Table 1).

Folic Acid Use

All women of childbearing potential should be recommended to take 400 micrograms (0.4 milligrams) of folic acid daily.[18] It is difficult for women to obtain 400 micrograms of folic acid through diet alone. Therefore, women should be advised to take either a multivitamin containing 400 micrograms of folic acid or a folic acid tablet containing 400 micrograms.[19] Some women may have barriers to multivitamin use (e.g., upset stomach or added expense); in these instances, the folic acid tablet may be preferred. If a prescription is provided for the folic acid or multivitamin product, it may be covered by the patient's insurance, which may lessen the expense burden.

Women at greater risk of having a child with a neural tube defect should take higher doses (4 to 5 milligrams/day) of folic acid. These include women with diabetes; using antiepileptic drugs; who have had a previous pregnancy impacted by a neural tube defect; or who have a BMI (body mass index) greater than 35 kg/m^2.[20] In addition, if claims data demonstrate that a woman is receiving a prenatal vitamin/folic acid supplement for less than 80 percent of days covered, pharmacists should intervene with the patient to increase adherence. Whereas 80 percent of days covered is a common metric for identifying poor adherence in many community pharmacies and MTM programs, some medications

Table 2. National Goals Related to Preconception Care.[5]

Goal 1	Goal 2	Goal 3	Goal 4
• Improve the knowledge, attitudes and behaviors of men and women related to preconception health.	• Assure that all women of childbearing age in the United States receive preconception care services that will enable them to enter pregnancy in optimal health.	• Reduce risks indicated by a previous adverse pregnancy outcome through interventions during the interconception period.	• Reduce the disparities in adverse pregnancy outcomes.

Table 3. Suggested Methods to Address Recommended CDC/SPPC Preconception Care Interventions through MTM.[4]

Targeted Medication Review (TMR)	Folic acid use
	Harmful medications (Category D or X)
	Immunizations
	Family planning
Comprehensive Medication Review (CMR)	Diabetes
Screening, Support, and Referrals	Testing for HIV/AIDS and sexually transmitted infections
	Hypothyroidism
	Obesity
	Maternal phenylketonuria (PKU)
	Tobacco, alcohol, and illicit drug use

Note: It is ultimately the pharmacist's judgement as to which type of MTM service is most needed for a particular patient. In addition, pharmacists may address any of the above during an existing CMR appointment.

may require substantially greater adherence. Individualizing care to the patient and specific medication(s) in question may be of great value.

Category D or X Medications.
Female patients aged 15 to 45 years who are receiving Category D or X medications or other medications of serious concern (e.g., angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), HMG-CoA reductase inhibitors (statins), tetracyclines, aliskiren, bupropion/naltrexone, carbamazepine, isotretinoin, methotrexate, misoprostol, orlistat, phenytoin, primidone, valproic acid and derivatives, warfarin) should receive education on their drug therapy. Patients may be taking some potentially harmful herbal or over-the-counter (OTC) products with or without the direction of a prescriber, which may also necessitate intervention. As appropriate, the patient's prescriber should be contacted with recommendations for drug therapy modifications to a drug that is less likely to cause fetal harm, or at least the notification that a patient may be taking a product with likelihood of fetal harm to begin dialogue about other possible alternative options. Such communication may even be valuable in the event of herbal or OTC medication use with likelihood of fetal harm as the prescriber may want to be aware of such use of products in his/her patient. Women who are not currently planning a pregnancy and remain on a potentially harmful medication should be recommended to initiate therapy with effective contraception and counseled on consistent and correct use.

It should also be noted that as of June 30, 2015, the U.S. Food and Drug Administration (FDA) will be utilizing a more descriptive labeling system to indicate risks of drug use during pregnancy and will replace the A to X categorization system.[21] However, until all drug information resources have been updated, it is appropriate to still target drugs that were formerly in the Category D or X designation for this intervention.

Vaccines
If a female patient aged 15 to 45 years is a candidate for hepatitis B or MMR (measles, mumps, rubella) vaccination, the pharmacist should offer to provide vaccination (if the pharmacist is allowed by state law to do so – Table 4) or to contact the patient's prescriber with a request for vaccination. Although these two vaccines were specifically included in the CDC/SPPC preconception care guidelines, there are other vaccines the CDC recommends before, during and after pregnancy.[22]

Communication, Documentation, and Follow-Up
When making recommendations and counseling patients, it is important to keep in mind whether the patient plans to have a pregnancy in the near future (contemplator) or not (non-contemplator).[23] Given the high rates of pregnancy unintendedness, preconception care interventions cannot be solely reserved for contemplators.[23] However, the focus of the counseling and reason for the recommendation should be individualized to the patient.[23]

Non-contemplators are typically quite concerned about their overall health and well-being; therefore, the health benefits of the intervention for the *woman* should be stressed to the non-contemplator.[23] For example, promoting the health benefits of multivitamins/folic acid or describing the consequences associated with infection with measles, mumps, ru-

bella or hepatitis B will be important for non-contemplators. For those contemplating a pregnancy, explaining the benefits to *infant* outcomes may resonate more than with a non-contemplator.[23] For example, when making the recommendation for an intervention, counsel contemplators about the increased risks of birth defects with insufficient folic acid use; the increased risks of birth defects or miscarriage with Category D or X medication use or rubella exposure in the first trimester; and the risk of mother-to-child transmission of hepatitis B. When patients exhibit resistance or ambivalence about change, motivational interviewing may be one helpful strategy for facilitating effective discussion and helping them to make a positive change (see Table 4 for a good resource on motivational interviewing). Other strategies to affect change will be population and setting-dependent. Free educational materials (Table 4) may also be helpful to initiate conversations with patients.

Encourage patients to have a reproductive life plan and to consider their preferences regarding the number and timing of children.[24] There are tools available to assist patients in developing these reproductive life plans, and sample counseling points have been published (Table 4).[24] Recommend appropriate contraception to patients based on their plans and personal preferences, and educate them about correct and consistent contraception use until they are ready to have a pregnancy.

Like any other non-dispensing service in the pharmacy, documentation will be helpful and likely necessary. Many pharmacies are already familiar with documentation of non-dispensing services through documenting vaccine administration. A similar workflow setup could be used for other non-dispensing interventions depending on the workflow and documentation process of the specific pharmacy. Although documentation is helpful even when non-dispensing services do not involve billing, most other billable non-dispensing services should be documented. If the pharmacy already has a workflow model in place to facilitate targeted or comprehensive MTM interventions, adding services related to preconception care to this model could be viable. For example, notes could be set to remind the pharmacist that

Table 4. Resources for Pharmacists.

Requirements to Provide Immunizations

Requirements will vary by state. Refer to State Board of Pharmacy website, for example:
Immunization by Pharmacists and Pharmacy Interns. Ohio State Board of Pharmacy, 2015.
Available at: pharmacy.ohio.gov/Documents/Pubs/Special/Immunizations/Guidance%20Document%20-%20Immunization%20by%20Pharmacists%20and%20Pharmacy%20Interns%20%28Effective%203.19.2015%29.pdf.

Motivational Interviewing

Motivational interviewing for medication adherence. Initial release date 6/1/2015; Expiration date 6/1/2018.
Available at: elearning.pharmacist.com/products/4263/motivational-interviewing-for-medication-adherence.

Free Sources of Patient Education Materials

Preconception care:	CDC Show Your Love Campaign for contemplators and non-contemplators. Available at: www.cdc.gov/preconception/showyourlove/. CDC Health Educational Materials for Women and Men. Available at: www.cdc.gov/preconception/freematerials-health-edu.html.
Medication use:	CDC. Treating for Two. Available at: www.cdc.gov/pregnancy/meds/treatingfortwo/aboutus.html.
Folic acid:	National Birth Defects Prevention Network. Available at: www.nbdpn.org/national_birth_defects_prevent.php and www.nbdpn.org/faaw2015.php. CDC. Available at: wwwn.cdc.gov/pubs/CDCInfoOnDemand.aspx?ProgramID=5.
Vaccines:	CDC. Available at: www.cdc.gov/vaccines/pubs/downloads/f_preg.pdf.

Worksheets and Counseling Points for Reproductive Life Plans

Reproductive life plan tool for health professionals. Centers for Disease Control and Prevention, 2014.
Available at: www.cdc.gov/preconception/RLPtool.html.

counseling is appropriate at the point of dispensing of Category D or X medications, or that questioning the patient about vaccination may be helpful.

Most pharmacists do not need to be reminded that a single intervention with a patient may not be enough to create lasting and persistent change. While some interventions, such as providing an immunization, may be straightforward and require little follow-up, other changes, such as the decision to start a daily multivitamin, may require follow-up to ensure adherence. A patient may be contacted via phone to ask if there have been any issues with the new medication or if the patient has any questions. Alternatively, a pharmacist could follow-up with a patient when that patient comes to the pharmacy to pick up other medications, particularly if the multivitamin or folic acid product is purchased as an OTC product where the pharmacist may not be notified of future purchases. Finally, documentation of such follow-up may also be appropriate and/or necessary for billing of non-dispensing clinical services.

Conclusion

As stated by the International Pharmaceutical Federation, "Evidence of the contribution of pharmacists in improving maternal, newborn and child health has been gathered in many countries . . . pharmacists could contribute even further, if and when they are empowered to work within the full scope of pharmacy services appropriate in their country."[25] Community pharmacists are well-qualified and well-positioned to improve maternal and infant outcomes by providing preconception care. Use of MTM to provide these services may result in a sustainable model for pharmacist intervention for this and potentially other public health priorities.

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Assessment Questions

1. Approximately what percentage of pregnancies are unintended?
    A. 10%
    B. 30%
    C. 50%
    D. 70%

2. Preconception care should be reserved only for women planning a pregnancy in the near future.
    A. True
    B. False

3. How much folic acid is recommended daily for most women of childbearing potential?
    A. 0.04 mg
    B. 0.4 mg
    C. 4 mg
    D. 40 mg

4. Which group(s) of women should be advised to take 4-5 mg of folic acid daily?
    A. Women with diabetes
    B. Women who are obese
    C. Women taking anti-epileptic drugs
    D. Women who have had a previous pregnancy affected by a neural tube defect
    E. All of the above

5. _____ is recommended to prevent congenital rubella syndrome.
    A. Hepatitis B vaccination
    B. MMR vaccination
    C. Influenza vaccination
    D. Tdap vaccination

6. Women receiving a Category D or X medication should also consistently use an effective contraceptive product, if possible.
    A. True
    B. False

7. Which of the following looks at a subset of a patient's disease states and/or medications?
    A. CMR
    B. TMR

8. In order to effectively facilitate change in preconception care, it may be most constructive and helpful to counsel non-contemplators regarding
    A. the woman's overall health
    B. the infant's overall health

9. Motivational interviewing may be most appropriately used to help patients who are
    A. resistant to change
    B. motivated to change
    C. are actively soliciting support to change
    D. are actively soliciting pressure to change

10. Which of the following gives support to a policy of documenting MTM encounters?
    A. Documentation can help with justification of billing of MTM services
    B. Documentation may create substantial electronic data storage needs
    C. Documentation is time-intensive and creates a significant burden on pharmacy staff
    D. All of the above

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There is no fee to obtain credit for this program. To receive continuing education credit for this program, you must answer the above questions and fill out the evaluation form. Please visit ***www.raabecollegeofpharmacy.org/mtm*** to enter the required information OR fill out the form on the following page and mail to the indicated address. Please allow two to three weeks for electronic distribution of your continuing pharmacy education credit to CPE Monitor.

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All information must be printed CLEARLY to ensure accurate record keeping for attendance and the awarding of continuing education credit. You MUST provide your CPE Monitor# and Month and Day of birth to receive credit.

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Program Content:	**Strongly Disagree**				**Strongly Agree**
The program objectives were clear.	**1**	**2**	**3**	**4**	**5**
The program met the stated goals and objectives:					
1. Define preconception care.	**1**	**2**	**3**	**4**	**5**
2. Discuss the need for preconception care.	**1**	**2**	**3**	**4**	**5**
3. Explain preconception care interventions that may be provided by a community pharmacist.	**1**	**2**	**3**	**4**	**5**
4. Describe how preconception care may be provided to patients via medication therapy management.	**1**	**2**	**3**	**4**	**5**
The program met your educational needs.	**1**	**2**	**3**	**4**	**5**
Content of the program was interesting.	**1**	**2**	**3**	**4**	**5**
Material presented was relevant to my practice.	**1**	**2**	**3**	**4**	**5**
Audio/visual and/or printed materials aided the learning process.	**1**	**2**	**3**	**4**	**5**
The program used effective teaching/learning methods.	**1**	**2**	**3**	**4**	**5**
The learning assessment activities were appropriate.	**1**	**2**	**3**	**4**	**5**
The program showed good objectivity and no commercial bias.	**1**	**2**	**3**	**4**	**5**
Would you recommend this program to a colleague?	**1**	**2**	**3**	**4**	**5**

What was the most valuable part of this program? _____

Based on what you have learned what one change do you plan to make in your practice? _____

Comments: _____

Suggestion for future programs you would like to see: _____

Answers to Assessment Questions—Please Circle Your Answer

1. A B C D	3. A B C D	5. A B C D	7. A B	9. A B C D
2. A B	4. A B C D E	6. A B	8. A B	10. A B C D

Any questions/comments regarding this continuing education program can be directed to Lauren Hamman, Advanced Administrative Assistant for the Office of Continuing Education (email: l-hamman@onu.edu, phone 419-772-2280).

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