

## Medication Therapy Management and Preconception Care: Opportunities for Pharmacist Intervention

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### Abstract

*As medication therapy management (MTM) continues to grow in the profession of pharmacy, careful consideration as to areas for positive patient impact is warranted. Given the current gaps in preconception care in the United States, and the accessibility and expertise of the pharmacist, MTM interventions related to preconception care may be valuable. This paper describes potential for pharmacist intervention in several different areas of preconception care. Notably, targeted medication reviews may be appropriate for interventions such as folic acid recommendations, teratogenic/category X medication management, immunizations, and disease state management. Comprehensive medication reviews may be warranted for selected disease states due to complexity of interventions, such as the management of diabetes. Comprehensive medication reviews may also be warranted if several targeted interventions are necessary, or if there are several medications or disease states requiring intervention. Pharmacists also have important roles in screening, support, and referrals needed for preconception care in the context of MTM. Patients may benefit substantially from pharmacist-directed MTM services related to preconception care. In addition, depending on clinical pharmacy service contracts and billing opportunities, pharmacists may be reimbursed for providing these services, generating sustainable revenue while fulfilling an important public health need.*

### Introduction

In recent years, medication therapy management (MTM) services have continued to grow at the state and national levels.<sup>1-3</sup> Other examples of MTM services have continued to expand as well, including disease state management (DSM), care transition efforts, and pharmacogenomic management.<sup>4-8</sup> Specific patient populations may be targeted or eligible for select services, such as those at high risk for hospital readmission in a care transitions program, or those suffering from chronic disease states that are enrolled into a DSM program.<sup>4,5</sup> The Centers for Medicare and Medicaid Services define both the comprehensive medication review (CMR) and the targeted medication review (TMR) as required services for Medicare Part D MTM programs.<sup>9</sup> Other third-party payers, such as state managed Medicaid programs, have also begun to reimburse pharmacists for providing MTM services.<sup>1</sup> CMRs may be useful in situations such as care transitions, where many disease states and medications may need to be reviewed.<sup>4</sup> Alternatively, TMRs may be more practical when one medication or disease state is specifically reviewed, such as during an over-the-counter or prescription drug intervention. Private insurance plans and government-based

programs may offer MTM billing for CMRs and TMRs, with billing commonly seen through a computerized clinical platform.<sup>1,3</sup> As one example of such a platform, OutcomesMTM (OutcomesMTM.com, Des Moines, IA) provides an opportunity to bill CMRs as well as TMRs, which may include recommending a specific therapy.

An important public health priority that may be addressed through MTM services is the provision of preconception care. The objective of preconception care is to improve the health of all women of childbearing age before pregnancy to prevent future health problems.<sup>10-12</sup> Interconception care, a subset of preconception care, focuses on the health of women between pregnancies;<sup>10</sup> therefore, preconception care is not exclusively reserved for women who have never conceived. (The term “preconception care” will be used throughout the paper to denote both preconception and interconception care.)

Preconception care comprises recognizing and addressing biomedical or behavioral issues that may pose a risk to the health of a woman or fetus. These interventions should occur before conception or very early in the first trimester for greatest impact.<sup>10,11</sup> Since many women may not obtain prenatal care until the eleventh or twelfth week of pregnancy, preconception care helps to ensure that the window of opportunity for these needed interventions is not

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missed.<sup>13</sup> As about half of all pregnancies in the U.S. are unintended,<sup>14</sup> and with 43% of those occurring among women inconsistently using contraception,<sup>15</sup> it is important for health care professionals to highlight the need for preconception interventions even for those not intending to become pregnant. It should be noted that these preconception care services also promote optimal health for all women.<sup>10</sup>

There are many potential roles for pharmacists to advance preconception care (Table 1). Pharmacists are well-suited to impact preconception care interventions, either directly through MTM services or through referral and collaboration with other healthcare professionals. The purpose of this paper is to highlight how proven preconception care interventions can be addressed through MTM. Opportunities for care are described below and categorized as potential TMRs or CMRs. However, pharmacist judgment is necessary to appropriately select the correct level of intervention based on the complexity and number of related issues or services needed for an individual patient.

### The Need for Preconception Care

In 2006, the Centers for Disease Control and Prevention (CDC) Preconception Care Work Group and the Select Panel on Preconception Care (SPPC) released goals (Table 2) and recommendations (Table 3) for preconception care.<sup>10</sup> Fourteen proven intervention for preconception care were identified based on published literature and clinical practice guidelines (Table 4),<sup>10,11</sup> although additional topics may also be considered as part of preconception care.<sup>16</sup>

The need for preconception care in the United States (U.S.) is great.<sup>10-12</sup> The CDC and SPPC have recommended that preconception care be viewed as part of routine healthcare for all women of childbearing potential.<sup>10,11</sup> (There are several considerations for men in the preconception period<sup>17</sup> which are outside of the scope of this paper.) While the way the information is presented and the perceived benefits may differ among those contemplating a pregnancy and “non-contemplators”, the intended outcomes are the same: to increase the intentionality of pregnancy and to improve a woman’s health status *prior to* pregnancy.<sup>18</sup>

The CDC has advocated that both clinical health and public health providers partner to provide preconception care to all women.<sup>10</sup> However, current literature suggests that many patients are not routinely receiving the necessary preconception education, counseling or interventions.<sup>10</sup> For example, according to a survey conducted by the Gallup Organization and the March of Dimes, about 40% of women aged 18-45 years reported taking a daily multivitamin or folic

acid tablet; the percentage widely varied by age. Among those who did not take daily folic acid supplementation, almost 90% of women surveyed indicated that they would be likely to do so if advised by a health care provider. Yet, only 12% of women aged 18-24 years, 41% of women aged 25-34 years, and 35% of women aged 35-45 years reported receiving information about folic acid from a healthcare professional.<sup>19</sup>

### Opportunities for Pharmacist Intervention via TMR

As many preconception-related interventions focus on one medication, intervention, or immunization at a time, it could be very valuable for pharmacists to engage in TMRs. Such services can be offered either at the point of dispensing, or in the form of a retrospective identification of a specific set of patients. Several elements of preconception care are listed below that may be addressed through TMR.

#### *Folic Acid*

All women of childbearing potential are recommended to take 400 micrograms of folic acid daily to reduce the risk of neural tube defect.<sup>20</sup> As it is difficult to receive adequate amounts of folic acid through diet alone, women are recommended to take either a folic acid supplement or a multivitamin containing the recommended amount of folic acid.<sup>21</sup> Certain groups should be advised to take greater doses of folic acid: women with diabetes (usually 4-5 mg/day), using antiepileptic drug (usually 4 mg/day), or having experienced a previous neural tube defect-affected pregnancy (usually 4 mg/day).<sup>20,22</sup>

#### *Teratogenic and Category X Medications*

Managing the use of teratogenic medications including antiepileptics, oral anticoagulants, and isotretinoin are also included among the interventions proposed by the CDC and SPPC. It is recommended that a woman using antiepileptic medications, whether for seizure disorders or other conditions, should defer conception until her condition is well-controlled on the minimum dose of medication, preferably monotherapy. Known potential teratogens should be avoided in the preconception period, if possible. She should also be provided education regarding increased folic acid supplementation as discussed above.<sup>10,11,23,24</sup> Warfarin is a known teratogen, and it is recommended to avoid warfarin exposure in early pregnancy. Women should use a less teratogenic anticoagulant such a heparin prior to conception whenever possible, keeping in mind the risk/benefit ratio for patients with certain conditions like mechanical heart valves.<sup>10,11,25</sup> Isotretinoin use is contraindicated during pregnancy; women of childbearing potential should ensure effective pregnancy prevention by utilizing two forms of contraception one month before, during, and for one month

after isotretinoin therapy.<sup>10,11,26</sup> While the iPLEDGE system is in place to minimize the risks associated with isotretinoin use among women of childbearing potential,<sup>27</sup> this type of program does not exist for all teratogenic medications. Finally, although not specifically included in the CDC and SPPC's targeted intervention list, women of childbearing potential receiving Category X drugs such as statins, ACE-inhibitors, and others, may be a good candidate for a TMR.

#### *Family Planning*

Family planning is also recommended to improve preconception health (Table 3).<sup>10,11</sup> Pharmacists are well-suited to take into account many aspects of care, such as concurrent drug therapies, folic acid use, and concurrent disease states when developing a reproductive life plan with patients to facilitate family planning.<sup>28</sup> Pharmacists can assist patients with identifying contraceptive products or methods most appropriate and acceptable for them and educate on proper and consistent use.<sup>29</sup> In addition, women who have any of the health risks included in Table 4 should be identified by pharmacists and counseled on effective contraceptive options and consistent, correct use. Pharmacists also can discuss other considerations such as proper nutrition and optimal birth spacing (18 to 59 months between last delivery and conception of the next pregnancy)<sup>30</sup> with patients.

#### *Vaccinations*

Pharmacists play an important role as immunizers. One particular advantage of pharmacists providing immunizations is the accessibility of the pharmacist when traditional physician's office-based practices are closed.<sup>31</sup> Women receiving preconception care may appreciate the availability of the pharmacist to provide appropriate immunizations as indicated. Additionally, beyond the immunization itself potentially generating revenue for the pharmacy, MTM reimbursement may be available for the clinical decision making process to ensure that the immunization is appropriate.

The CDC and SPPC include hepatitis B and rubella vaccination among the proven interventions. To reduce the risk of perinatal transmission and long-term consequences of hepatitis B, it is recommended that prior to conception, women who are at risk for contracting it should consider vaccination. It is also recommended that women who are seronegative to rubella should consider MMR vaccination prior to conception to avoid congenital rubella syndrome which may result from contracting rubella in the first trimester.<sup>10,11,24</sup> Once receiving the live vaccine, women should avoid conception for 28 days; the vaccine is contraindicated during pregnancy.<sup>32</sup> While not specifically mentioned in the 14 proven interventions, other vaccines

may be indicated for women during pregnancy or the preconception period per the Advisory Committee on Immunization Practices (ACIP) adult immunization schedule<sup>33</sup> and guidelines on vaccine use during pregnancy.<sup>32</sup>

#### *Screening, Support, and Referrals*

Point-of-care testing (POCT) is used in MTM to help with disease screening, disease assessment, and patient monitoring, and is possible for pharmacist or pharmacy technicians to perform in an outpatient setting.<sup>34</sup> Although pharmacists are not trained as diagnosticians, POCT has been used to assist pharmacists in screening populations for disease or risk of disease.<sup>35</sup> Given the accessibility of the pharmacist, risk and disease screening in the pharmacy may be valuable for certain patient populations. Obviously, counseling from the pharmacist could ensue to provide appropriate clinical recommendations. However, some instances remain when it is outside of the pharmacist's scope of practice or expertise to provide appropriate screening, assessment, or counseling for a given disease state. It is at this time that the Core Elements of an MTM Service Model framework describes that the pharmacist should be making appropriate referrals to ensure optimal care of the patient.<sup>36</sup> Aspects of preconception care where screening and pharmacist intervention could be appropriate include testing for HIV/AIDS, sexually transmitted infections (STIs), hypothyroidism, obesity, and maternal phenylketonuria (PKU).

To reduce the risk of perinatal HIV infection, it is recommended that women be screened and treated for HIV/AIDS. Women should also be screened and treated for STIs to minimize serious risks to mother and child.<sup>10,11</sup>

Untreated or undertreated hypothyroidism also poses serious adverse fetal and maternal outcomes; the American Association of Clinical Endocrinologists recommends routinely screening women for thyroid dysfunction by obtaining TSH measurements before conception or during early pregnancy. A woman's dose of levothyroxine must generally be increased for proper fetal development during the first trimester, and more frequent monitoring of serum TSH is warranted throughout pregnancy.<sup>10,11,37</sup> Additionally, pharmacists who can order laboratory testing as part of a collaborative practice agreement may want to pay careful consideration to the above testing recommendations when caring for patients who are intending to become pregnant.

Body mass index (BMI) should be calculated at least annually for women of childbearing age. Obese women (BMI $\geq$ 30) should receive counseling on appropriate weight loss and nutritional intake, including calorie and portion control and

physical activity that can be safely continued in pregnancy. Women should be counseled that conception should be delayed until optimal weight is achieved to reduce the risk of pregnancy complications and birth defects or fetal death.<sup>10,11,24</sup>

Finally, it is important to identify women who were diagnosed with PKU in childhood and have since relaxed dietary restrictions. Increased levels of phenylalanine can result in serious risks to the fetus. Women with PKU should be counseled to resume a restricted diet to achieve phenylalanine levels <6 mg/dL at least 3 months before conception and maintain phenylalanine levels of 2-6 mg/dL during pregnancy.<sup>10,11,24,25</sup>

#### *Tobacco, Alcohol, and Substance Abuse*

Pharmacists have achieved positive outcomes when conducting smoking cessation services.<sup>38,39</sup> Although these services are not limited to women who may become pregnant, there may be an additional level of concern and/or urgency when providing smoking cessation services as a facet of preconception care. If medications are recommended, either over-the-counter or as a prescription, a pharmacist may be able to bill for making such a recommendation.

Much published literature indicates that smoking results in negative consequences to maternal health and perinatal outcomes. Prior to conception, women should be encouraged to stop smoking. The highest cessation rates are seen in counseling with both behavioral and educational interventions. Data indicate that pharmacological smoking cessation aids are safe and effective in reproductive-age women; there is insufficient data on their use among women who are pregnant or nursing. Risks and benefits of smoking cessation therapy for a woman who is pregnant or nursing must be carefully considered using the most current data available.<sup>10,11,24,40</sup>

Women should additionally be counseled regarding use of recreational drugs or alcohol during the preconception period or pregnancy. Use of these substances may impair fertility, result in pregnancy complications, and/or cause grave harm to the fetus. Data indicate that even light drinking may have harmful effects to the fetus, so pregnant women should avoid alcohol completely.<sup>10,11,24,41</sup>

#### **Opportunities for Pharmacist Intervention via CMR**

With the growth of MTM in recent years, many more pharmacists are completing CMRs as a part of their regular job responsibilities. However, if a pharmacist is not aware of both the need and opportunity for appropriate preconception clinical considerations, he or she may not make appropriate

care interventions during the CMR. If a pharmacist discovers targeted interventions related to preconception care that accompany other unrelated targeted interventions, it may be appropriate to recommend a CMR instead of pursuing a TMR with a patient. Additionally, a pharmacist may discover several preconception-related interventions that are appropriate, and given the volume of discussion necessary, may find it valuable to schedule a CMR to review multiple interventions. Furthermore, a patient with many medications or multiple disease states may require education and clinical support that would warrant a CMR.

For example, due to the complexity of the disease state, a woman with diabetes may need a CMR in the preconception or interconception period. Women with diabetes poorly controlled at the time of conception and their offspring are at risk for serious complications. Therefore, in the months before conception women should strive to maintain a consistent blood glucose with HbA1C levels no higher than 6%,<sup>42</sup> and should look to do so using treatments that would be safe in pregnancy. As opposed to a more standard 7% HbA1C target,<sup>43</sup> the stringent 6% goal may be more difficult to achieve, especially when balancing hypoglycemia risks. Additionally, preferred pharmacologic and non-pharmacologic treatments in the preconception period may be different than the patient's current therapy. Not knowing about a woman's intent to become pregnant could result in a pharmacist recommending suboptimal or even unsafe therapies in this instance. Therefore, given the number and scope of changes and education related to all medications, a CMR may certainly be warranted. Women with diabetes should also be educated about folic acid supplementation as discussed above and receive information specific to nutrition and management of diabetes during pregnancy, including physical activity.<sup>10,11,24,42</sup>

#### **Conclusion**

Opportunities exist within the current MTM environment to improve preconception care. Pharmacists currently provide similar patient care interventions, and are well-positioned to provide clinical preconception care services to patients. Furthermore, opportunities for patient care may be missed by pharmacists who are unaware of the need for intervention. Depending on clinical pharmacy service contracts and billing opportunities, some clinical pharmacy opportunities may not only benefit patients, but may also generate revenue and therefore be financially sustainable. Pharmacists should consider incorporating preconception services as a part of a larger MTM and clinical service paradigm.

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**Table 1. Key roles for pharmacists in preconception health**<sup>29,44-46</sup>

Partner with patients in family planning
Provide education, counseling, and/or medication therapy management for patients as appropriate on proven preconception health interventions
Administer needed vaccinations to patients per state law
Collaborate with other healthcare providers to ensure all patients' preconception health needs are met
Utilize drug information skills to retrieve and interpret literature or provide information for patients and other healthcare professionals regarding medication use and drug toxicity during pregnancy or available data on animal reproduction tests
Raise awareness about preconception care among patients and other healthcare professionals
Advocacy
Research

**Table 2 Preconception health goals (CDC/SPPC)**<sup>10,11</sup>

Goal 1	Goal 2	Goal 3	Goal 4
<ul style="list-style-type: none"> <li>•Improve the knowledge, attitudes and behaviors of men and women related to preconception health.</li> </ul>	<ul style="list-style-type: none"> <li>•Assure that all women of child-bearing age in the U.S. receive preconception care services that will enable them to enter pregnancy in optimal health.</li> </ul>	<ul style="list-style-type: none"> <li>•Reduce risks indicated by a previous adverse pregnancy outcome through interventions during the interconception period.</li> </ul>	<ul style="list-style-type: none"> <li>•Reduce the disparities in adverse pregnancy outcomes.</li> </ul>

**Table 3. Recommendations to improve preconception health<sup>10,11</sup>**

<b>1. Individual responsibility across the life span</b>	<ul style="list-style-type: none"><li>• Counsel all patients to have a reproductive life plan and to implement via their preferred family planning methods</li></ul>
<b>2. Consumer awareness</b>	<ul style="list-style-type: none"><li>• Increase patient education and use of health services</li></ul>
<b>3. Preventive visits</b>	<ul style="list-style-type: none"><li>• Provide risk assessment and counseling regarding preconception health to all women of childbearing age</li></ul>
<b>4. Interventions for identified risks</b>	<ul style="list-style-type: none"><li>• Increase proportion of women receiving necessary interventions identified through screening</li></ul>
<b>5. Interconception care</b>	<ul style="list-style-type: none"><li>• Intensive interventions targeted to women who experienced adverse outcomes in prior pregnancy</li></ul>
<b>6. Pre-pregnancy check-ups</b>	<ul style="list-style-type: none"><li>• Before conception, provide a clinical visit to couples planning a pregnancy</li></ul>
<b>8. Public health programs and strategies</b>	<ul style="list-style-type: none"><li>• Integrate preconception health with existing public health programs</li></ul>
<b>7. Health coverage for low-income women</b>	<ul style="list-style-type: none"><li>• Improve access to preventive services among those with low income</li></ul>
<b>9. Research</b>	<ul style="list-style-type: none"><li>• Enhance knowledge about preconception care</li></ul>
<b>10. Monitoring improvements</b>	<ul style="list-style-type: none"><li>• Monitor via public health surveillance and other research mechanisms</li></ul>



**Table 4. Fourteen proven interventions for preconception care**<sup>10,11</sup>

Maternal conditions	<ul style="list-style-type: none"><li>•Diabetes</li><li>•Hypothyroidism</li><li>•Phenylketonuria</li><li>•Obesity</li></ul>
Teratogenic medications	<ul style="list-style-type: none"><li>•Antiepileptic drugs</li><li>•Warfarin</li><li>•Isotretinoin</li></ul>
Counseling	<ul style="list-style-type: none"><li>•Folic acid</li><li>•Tobacco</li><li>•Alcohol/illicit drugs</li></ul>
Screening	<ul style="list-style-type: none"><li>•HIV/AIDS</li><li>•Sexually transmitted infections</li></ul>
Vaccinations	<ul style="list-style-type: none"><li>•Hepatitis B</li><li>•Rubella</li></ul>