Oregon State University College of Pharmacy

Self-Assessment Questionnaire compared to the US MEC

	Question	MEC Category and Explanation			
		Corresponding MEC Category	CHC	POP	DMPA
	What is your age?	**Age**	Age by itself is not a risk factor and women with no other risk factors can safely use CHC's until menopause. The reason to ask this question would be to combine it with another risk factor. So, a women who is ≥ 35 years old + smoking should not use CHC's.	Age is not a contraindication, but increasing age can have an increase in co-morbidities. This should be taken into account when looking at the whole patient.	
	Do you think you might be pregnant now?	**Pregnancy**	The US MEC actually does not give pregnancy a category, but says it is "not applicable" because the use of contraception is not needed at that point. There is no known risk to the mom or baby if CHC's are inadvertently taken while pregnant.	POP's and DMPA do NOT cause birth defects. This question is only asked as there is no need to use contraception while pregnant.	
	Did you ever experience a bad reaction to using hormonal birth control? If yes, what kind of reaction occurred?		This question could get at the high-risk side effects like cholestasis, but it could also get at the more common side effects. If a patient answers "yes" to this question, it should be followed-up with questions to find out what the reaction was. Other information that should be gathered includes how severe the reaction was, if it went away, and what was done about it.	The clarifying answer to this question should give an indication to the severity, and type of reaction. If the reaction was to an estrogen-containing contraceptive, then it would be appropriate to change her to a progestin-only contraceptive.	
	Have you ever been told by a medical professional not to take hormones?		There is no category in the US MEC for this, but if the patient answers "yes" to this, the pharmacist should ask follow-up questions to see if she knew the reason why. If the underlying risk is resolved (i.e. postpartum, breastfeeding or surgery), and no other risks are present, it would be fine to prescribe CHC's. If the underlying reason is a risk that will not be resolved (i.e. genetic risk for clots, history of clots, etc.) then it would be more appropriate to refer the patient to her PCP to discuss other contraceptive options.	If the patient answers "yes" to this question, follow-up questions to clarify should be asked. Many times, the patient was told this with regard to estrogen-containing contraception and the patient could still use a progestin-only contraceptive.	
	Do you smoke cigarettes?	**Smoking**	Women that smoke are at an increased risk for CVD, and this risk increases with age and number of cigarettes smoked per day. Regardless of how many cigarettes smoked, any woman who smokes and is over the age of 35 years old has a category 3 or 5 and should not be prescribed CHC's. One other interesting fact about women on CHC's is that smoking has very high rates of breakthrough bleeding (BTB) and spotting that gets worse with the number of cigarettes smoked and the longer they are on the CHC. After the first cycle there is a 30% increase in BTB compared to non-smokers and after 6 cycles there is an increase of 86% of BTB in women smokers on a CH. Women who report persistent BTB should be asked about their smoking status, and if positive, this would be a good time to encourage that she quit. The categories related to smoking are: • Age < 35 years = category 2 • Age ≥ 35 years o + < 15 cigarettes/day = category 3 o + ≥ 15 cigarettes/day = category 4	Smoking is a category 1 for progestin-only contraceptive methods, and can safely be given. However, this is a good time to reinforce smoking cessation as these women have higher rates of breakthrough bleeding, which can be even worse with progestin-only contraceptives.	

	Have you had a recent change in vaginal bleeding that worries you?	**Vaginal Bleeding**	Some vaginal bleeding might be unexpected but not worrisome, so pharmacists should be asking some follow-up questions to find out the circumstances around the vaginal bleeding and to determine an underlying cause for the vaginal bleeding or spotting. For instance: bleeding can occur after getting a pap smear or sexual intercourse and would not be worrisome. However, unexplained bleeding can be a symptom of a sexually transmitted infection. A woman with worrisome or unexplained bleeding should be referred to a women's health care provider. A woman may need to be seen more urgently if she reports additional signs/symptoms of infection (such as abdominal pain, fever, nausea/vomiting, or vaginal discharge or odor). While it is important to identify women with unexplained bleeding (suspicious for a serious condition), the MEC is a category 2 for CHC's and POP's but a category 3 for DMPA. Therefore pharmacists could still prescribe these other methods if there was a concern.	The primary reason for including this question in the self-assessment is because DMPA should NOT be given to women with unexplained vaginal bleeding. In the case of CHC's or POP's, these methods could be stopped immediately if necessary as part of the work up. However, this is not the case with DMPA and the effects of the injection will last for 3 months making it difficult to determine the origin or concerning and unexplained vaginal bleeding.
	Have you given birth within the past 21 days? If yes, how long ago?	**Postpartum (see also breastfeeding)**	Recent evidence indicates that women within 3 weeks post-partum are at a very high risk for experiencing a clot, (baseline risk is 1-5/10,000, risk with CHC's is 3-9/10,000, and the risk in the postpartum period is as high as 40-65/10,000)! Because of the risk, all women < 21 days (3 weeks) postpartum should not be prescribed CHC's. Between 21-42 days postpartum, the risk starts to go down, but women with other risks present are still at a category 3. The US MEC has the following categories. < 21 days postpartum = category 4 21-42 days postpartum = category 2 If other VTE risks are present = category 3 > 42 days postpartum = category 1 VTE risks in this population to consider include: age ≥ 35 years old, smoking, C-section delivery, preeclampsia, BMI ≥ 30, and postpartum hemorrhage.	Unlike estrogen-containing contraception, progestin-only methods can safely be used and are a good choice for this population as they do not increase the risk for clots, and do not decrease production of breastmilk.
	Are you currently breastfeeding?	**Breastfeeding (see also postpartum)**	There is no evidence to indicate any health risks to the infant from exposure to hormones in the breast milk. There is also contradictory and poor evidence that there is an association with milk production in women using CHC's. If there is an association with decreased milk production, it is likely only taking place when milk production is being established.	Unlike estrogen-containing contraception, progestin-only methods can safely be used and are a good choice for this population as they do not increase the risk for clots, and do not decrease production of breastmilk.
	Do you have diabetes?	**Diabetes mellitus (DM)**	This is another question that requires follow-up questioning to find out the severity and duration the patient has had diabetes. In general, only complicated diabetes + other comorbidities (i.e. nephropathy, neuropathy, retinopathy, hypertension, etc.) would be contraindicated with CHC's. History of gestational diabetes = category 1 Non-complicated diabetes = category 2 Diabetes + other comorbidity = category 3 or 4 based on severity	Similar to HTN, most forms of progestin-only contraceptives can be used regardless of comorbidities. DMPA is the exception and should not be used in patients with complicated diabetes that also have neuropathy, nephropathy, retinopathy, or vascular disease.
	Do you get migraine headaches? If so, have you ever had the kind of headaches that start	**Headaches**	Women with migraine headaches, and who also experience auras with them, are at an increased risk for strokes. Auras are not considered painful and will completely subside by the time the migraine headache starts. Symptoms of auras are neurologic and include seeing flashing lights, experiencing	Progestin-only methods can be initiated in women with migraines, at any age, and even with auras.

	with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?		numbness, smelling something that isn't there, etc. The contraindication to CHC's with migraine are only when accompanied with an aura, so it will be important to ask more about it in order to verify that her symptoms include those for auras. Additionally, if any woman who previously did not get migraines with auras, but starts to after starting on a CHC should stop taking it. Any woman with bad headaches, or headache that are getting worse should also be evaluated by and referred to her PCP.	
	Are you being treated for inflammatory bowel disease?	**Inflammatory Bowel Disease**	Patients with inflammatory bowel disease (IBD) have a small but increased risk for VTE that is associated with disease severity. Therefore, if a woman answers "yes" to having IBD, the pharmacist will need to find out if it is mild or severe before prescribing a CHC. Women whose IBD is more severe or active may be getting surgeries with immobility, using corticosteroids or experiencing vitamin deficiencies and/or fluid depletion. • Mild IBD = category 2 for CHCs • Severe, active or extensive IBD = category 3 for CHCs	The US MEC gives POP's and DMPA a category 2 in women with IBD and it would be appropriate for a pharmacist to prescribe these methods. Pharmacists should keep in mind, however, that women with IBD can sometimes end up on long-term therapy with corticosteroids which, like DMPA, can cause bone mineral density loss. In this case it would be appropriate to counsel on the additional risk and recommend they be followed closely by their provider.
	Do you have high blood pressure, hypertension or high cholesterol?	**Hypertension** **History of high blood pressure during pregnancy**	Hypertension and hyperlipidemia are cardiovascular disease (CVD) risk factors that increase the risk for experiencing a heart attack. In most cases, these would be looked at in the presence of other CVD risks. Hypertension should looked at individually, and pharmacists should take a blood pressure (BP) reading prior to initiating or continuing CHC's since BP that is $\geq$ 140/90 mmHg is considered a category 3 or 4. Systolic BP of 140-159 mmHg or diastolic BP of 90-99 mmHg = category 3 Systolic BP $\geq$ 60 mmHg or diastolic BP of $\geq$ 100 mmHg = category 4 It should be kept in mind that hypertension is diagnosed from getting at least 2 high BP readings on 2 different days, so getting 1 high reading does not mean that the patient has hypertension. And in fact, the pharmacist can choose to retake the BP after the patient has had a chance to sit for a while. If it is still high, then it is advised to not prescribe CHC's. Women with a known history of hypertension that is being controlled by medications have a lower risk of CVD, but there is not enough evidence yet to say that she also has a lowered risk while on CHC's. Some providers feel comfortable enough to prescribe CHC's under this condition, but pharmacists should refer these women as the US MEC still puts them at a category 3.	Most progestin-only methods are safe to use in these patients. However, DMPA does have a category 3 risk in the US MEC and should be avoided in women with very high BP $\geq$ 160/100 mmHg or vascular disease.
	Have you ever had a stroke, heart attack or been told that you had any heart disease?	**Peripartum Cardiomyopathy**	Any known past medical history of a blood clot is a category 4 contraindication to receiving CHC's.	In most cases, this is a complicated patient and would need to be referred. If there is a patient with this type of history, the US MEC should be referenced for their eligibility. It may be ok to start a POP, but not to continue, and DMPA should not be given.

	Have you ever had a blood clot?	**Multiple risk factors for arterial CVD** **Ischemic heart disease** **Valvular heart disease** **Stroke** **Known thrombogenic mutations** **DVT and PE** **Superficial venous disorder**	The previous question does not address some of the less common clots that include DVT, pulmonary embolism, or other clots occurring throughout the body. Any history of ac lot is a category 4 contraindication to CHC's.	This questions would depend on the type of clot they've had, so would require follow-up questioning. Once you know what type of blood clot it was, you can reference the more specific category in the MEC. Stroke and CVD have their own questions, but this question will help you determine if the patient has a history of DVT or PE. For this population, it is safe to use progestin-only methods including DMPA.
	Have you ever been told by a medical professional you are at risk of developing a blood clot?		It is hard to ask about a genetic disorder that can increase the risk for clots, so this question attempts to get at this and any other risks for clots. Some versions of the self-assessment questionnaire asked about family history in an attempt to get at a genetic link but it is very possible that the patient could say that her parent or grandparent experienced an MI or stroke, etc. but this does not mean that she is at an increased risk for it. This is because most clots are "provoked" or happen when other risk factors or circumstances, (like immobility), are present.	Pharmacists should analyze the answer, and compare to the US MEC if there are questions. Likely, the patient is safe to take a progestin-only contraceptive.
	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?		Immobility dramatically increases the risk of experiencing a clot, especially in the deep veins of the legs. Surgery is not the only place that immobility can happen, but would also apply to a patient that is in a wheelchair, which is something that the pharmacist can observe. US MEC categories regarding surgery include: Major surgery + prolonged immobility = category 4 Major surgery without prolonged immobility = category 2	Progestin-only methods are safe to use in this population.
	Will you be immobile for a long period?	**See categories in cell directly above** **Multiple Sclerosis**	Immobility is a VTE risk factor and CHC's should be avoided in this population. If a patient answers "yes" to being immobile, it should prompt the pharmacist to ask more questions about the type and duration of immobility. Also keep in mind that there are disease states like multiple sclerosis (MS) that can cause immobility.	Immobility is a risk for VTE and the primary concern is for estrogen-containing methods of contraception. Progestin-only methods would be appropriate to use in this population but pharmacists should be aware that the immobility could be caused by a condition that might have restrictions to progestin-only method use.
	Have you had bariatric surgery or stomach reduction surgery?	**History of bariatric surgery**	This risk only applies to oral contraceptives since some forms of bariatric surgery induce malabsorption, and can cause lowered serum levels of OC's making them ineffective. Not all kinds of bariatric surgery cause malabsorption, so if a patient answers "yes" to this question, the pharmacist should consult the US MEC. Additionally, when there are no other risk factors present, the transdermal patch or ring would be appropriate and would be a category 1.	For POP's this may be a concern if the surgery causes malabsorption. This is not a problem though for the other progestin-only methods, including DMPA and the implant.
	Do you have or have you ever had breast cancer?	**Breast disease & Breast cancer**	Many breast cancers are hormone sensitive, and many advance more quickly with the presence of hormones: exogenous estrogen or progestin should not be given. Therefore, having current breast cancer is a category 4, and a history of breast cancer is a category 3.	As with estrogen, any hormones can exacerbate active breast cancer or cause recurrence of cancer. MEC categories are also the same where having current breast cancer is a category 4, and a history of breast cancer is a category 3.

	Have you had a solid organ transplant?	**Solid organ transplant**	Hopefully this population of women are being closely followed by a PCP or a transplant team. It is also important for this population to be on highly effective contraception because they are at an increased risk for adverse health events as a result of pregnancy. For the most part, this population are ok to receive CHC's, but there is a case report of a woman developing cholestasis associated with CHC use and when experiencing complications. Therefore, if she has complications or graft failure, she should not use a CHC. The US MEC has broken down solid organ transplants into 2 CHC categories based on complications: • Complicated: graft failure, rejection, etc. = category 4 • Uncomplicated = category 2	DMPA and POP's are safe to use in this population.
	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	**Viral Hepatitis** **Cirrhosis** **Liver tumors** **Gallbladder disease** **History of cholestasis**	Liver issues are only a problem if they are severe. For mild cirrhosis, benign tumors or a carrier of hepatitis are all either a category 1 or 2. The patients that should not be prescribed CHC's include: • Severe cirrhosis = category 4 • Malignant or hepatocellular benign liver tumors = category 4 • Acute hepatitis = category 3 or 4 depending on the severity A history of gallbladder disease and that is not symptomatic is a category 2. When symptoms are present, then it is a category 3 and should not be prescribed CHC's, but referred to her PCP for other options.	Both progestins and estrogens are metabolized by the liver, and so patients with severe, decompensated cirrhosis or liver tumors should not use any hormone-containing contraceptive methods. This does not include patients with mild cirrhosis. Estrogen appears to play a bigger role in causing gallbladder disease, and using progestin-only methods are safe to use in this population.
	Do you have lupus, rheumatoid arthritis, or any blood disorders?	**Systemic lupus erythematosus** **Rheumatoid arthritis** **Blood conditions and anemia**	Rheumatic diseases include rheumatoid arthritis, but also systemic lupus erythematosus (SLE). If rheumatoid arthritis is the only condition present, then the US MEC puts her at a category 2, and it would appropriate to prescribe a CHC. The main reason to ask this question is to determine whether the patient has SLE, particularly if she also has antiphospholipid antibodies. This puts patients at a higher risk of clots that include heart attack, stroke, and VTE. Therefore, the first step to take if a patient answers "yes" to this question would be to find out if she has a clot history of any of these, and then follow the instructions and categories related to those. If the patient knows that she does not have antiphospholipid antibodies, no clot history, and no other risk factors are present, (i.e. CVD, smoking, diabetes, etc.) then it would be fine to prescribe CHC's. The following list comes from the US MEC and can be referred to when assessing the risks for this patient population. SLE: • Positive antiphospholipid antibodies = category 4 If the patient knows that she has SLE, but does not know if she has antiphospholipid antibodies, then it would be appropriate to err on the conservative side, assume that she is a category 4 and refer her to her PCP. • Severe thrombocytopenia = category 2 • Immunosuppressive treatment = category 2 • None of the above = category 2	While progestins do not carry the same risks for clots, some conditions are higher risk than others, and progestins should still be avoided. Therefore, patients who are positive for having anti-phospholipid antibodies should not take progestins or DMPA. It should also be avoided in women who have severe thrombocytopenia, and DMPA should be avoided in women taking long-term corticosteroids (because of the risk for bone fractures).

			• Rheumatoid arthritis = category 2 SLE does fit in with blood disorders, but keep in mind that there are other blood disorders that can increase the risk for clotting or refer the patient to her PCP.	
	Do you take medications for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	**Epilepsy** **Tuberculosis** **HIV Antiretroviral therapy** **Anticonvulsant therapy** **Antimicrobial therapy** **Supplements**	Some medications induce the metabolism of CHC's making hormone blood levels decrease to where they are no longer effective. One additional thing to think about is that some of the medications that have an interaction can also cause birth defects (i.e. phenytoin and topiramate) so for a woman with one of these medications she would still need a highly effective birth control. Some medications that interact with CHC's include: • Phenytoin • Carbamazepine • Topiramate • Oxcarbazepine • Lamotrigine • Rifampin (TB medication) • Barbiturates • Fosamprenavir (when not boosted with ritonavir)	DMPA does not lose effectiveness when given with interacting medications, and therefore can safely be given to women on these medications as it is a category 1 in the US MEC. Other progestin-only methods should be checked first as POP's generally do interact and should not be given to women on these medications.
	Do you have any other medical problems or take any medications, including herbs or supplements?		Just one last chance to capture anything that the questionnaire might have missed. If there is ever a question on what the category for a medical problem is, the pharmacist should consult the US MEC. This question also asks her about herbs or supplements because there was concern that St. John's Wort can interact with CHC's. However, the CDC has recently clarified the supplement by giving it a category 2 in the MEC.	Again, analyze the answer and refer to the US MEC for any clarifications.

CHC: Combined Hormonal Contraceptive **POP: Progestin Only Pill** **DMPA: Depot Medroxyprogesterone Acetate**