

# Department of Veterans Affairs

## Preconception

### User Guide



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**Version 1.0.1**

## Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the document has been baselined.

Date	Version	Description	Author

## Artifact Rationale

A User Guide is a technical communication document intended to give assistance to people using a particular system. It is usually written by a technical writer, although it can also be written by programmers, product or project managers, or other technical staff. Most user guides contain both a written guide and the associated images. In the case of computer applications, it is usual to include screenshots of the human-machine interface(s), and hardware manuals often include clear, simplified diagrams. The language used is matched to the intended audience, with jargon kept to a minimum or explained thoroughly. The User Guide is a mandatory, increment-level document, and should be updated to reflect the contents of the most recently deployed increment.

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# **1. Introduction**

This document provides an overview of the continuous development and evolving functionality of the Preconception mobile application. Preconception care is an application that is specifically geared towards women of childbearing ages. It is a web-based application that provides Department of Veteran's (VA) clinicians with information that supports integration of preconception care into primary care visits, thereby optimizing the health of women and their children.

## **1.1. Purpose**

The User Guide is authored by Agilex/LongView International and Technology, Inc. for the purpose of capturing and describing the capabilities of the mobile application developed/to-be developed. The User Guide provides guidance and clarification regarding the functionality of the mobile application, as well as identifies the important features and familiarizes users with the navigational elements of the Preconception 1.0 application.

## **1.2. Overview**

Preconception is an important information source for VA and Non-VA providers when making clinical decisions regarding medical conditions for women veterans of childbearing ages. The application provides guidance based on birth control and reproductive history, concurrent health issues, family and genetic history and risks, vaccinations received, and lifestyle factors. The goal of this application is to identify factors that may increase risk during a future pregnancy, and identify preventative actions that may mitigate these risks based on the information provided. Additionally, the Preconception application allows VA and Non-VA Providers the opportunity to educate women's veterans about contraception and other health issues that can impact her well-being during pregnancy.

### **1.2.1. Preconception Functionality**

At a high level, Preconception provides the following capabilities:

- 1.1.1 A VA or Non-VA Provider using the Preconception application from a mobile device or website can review a module on preconception care and view current DoD/VA guidelines.
- 1.1.2 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the About tab to view application instruction, content and version number.
- 1.1.3 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Topics tab to display topics such as Reproductive Life Plan, Reproductive History, Birth Control Methods, Concurrent Health Issues, Family History, Lifestyle Factors and Risks, Medication Use and Risk Mitigation, Men and Preconception Health, and Vaccinations.
- 1.1.4 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Reproductive Life Plan to learn more about planning for, or preventing, future pregnancies.
- 1.1.5 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Reproductive History button from the Topics page to cycle through a list of medical history and guidelines in an attempt to identify factors that may increase risk during future pregnancies.
- 1.1.6 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Birth Control Methods button from the Topics page to learn more about the effectiveness of various birth control methods, and where they can be purchased.

- 1.1.7 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Concurrent Health Issues button from the Topics page to identify chronic and acute disease conditions known to impact women's general and reproductive health. This tab also provides suggestions for management of chronic health issues such as prevention counseling, testing, treatment, and coordination of care among primary and specialty care providers.
- 1.1.8 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Family/Genetic History & Risks button from the Topics page to identify and mitigate underlying risks that could increase potentially adverse outcomes for a mother or her fetus.
- 1.1.9 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Lifestyle Factors Checklist button from the Topics page to learn more about ways to improve overall health through a healthy lifestyle.
- 1.1.10 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Medication Use & Risk button from the Topics page to identify and mitigate prescription medication that can be harmful to reproductive organs and a fetus.
- 1.1.11 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Men and Preconception button from the Topics page to learn more about how a man's lifestyle and health can affect his fertility and the health of the fetus.
- 1.1.12 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Vaccinations button from the Topics page to identify which vaccinations can/cannot be given before or during pregnancy.
- 1.1.13 A VA or Non-VA Provider using the Preconception application from a mobile device or website can select the Resources tab to access relevant contact information for both patients and providers.

### 1.3. Project References

The following documentation was leveraged for the creation of this User Guide:

- Preconception Application Concept Paper

#### 1.3.1. Stakeholders Information

Type of Stakeholder	Description	Responsibilities
Business Owner(s)/Business Subject Matter Expert(s) (SME)	[REDACTED]	Monitors the progress and time lines. Provide background on current system and processes. Describe features of current systems, including known problems. Identify features of enhancement.
Customer Application Point of Contact (POC)	[REDACTED]	Provide strategic direction to the program. Elicits executive support and funding.

Type of Stakeholder	Description	Responsibilities
Internal Product Owner	[REDACTED]	Contributes to BRD development. Provides strategic direction to the product line. Ensure that the enhancements will account for current business processes and existing software capabilities. Monitors the progress and time lines.
Internal Technical Lead	[REDACTED]	Provide technical background information about the current software and requested enhancements.
Internal Product Owner	[REDACTED]	Ensure all requirements have been captured and conveyed, and overseeing the lifecycle of the Preconception app from start to finish.

### 1.3.2. Coordination

This application required extensive coordination among all parties involved. Once buy-in was obtained, and the application was approved from all necessary parties, the LongView/Agilex Product and Development teams met internally, as well as held weekly status meetings with the User and Technical SMEs to incorporate their feedback along the way.

### 1.3.3. Help Desk

Technical Help Desk support for the application shall be provided for users to obtain assistance with the mobile application.

Technical Help Desk Support	
[REDACTED]	[REDACTED]

## 1.4. Acronyms and Abbreviations

Term	Definition
BRD	Business Requirements Document
CDW	Corporate Data Warehouse
CPRS	Computerized Patient Record System
CPG	Clinical Practice Guideline
DoD	Department of Defense
EA	Enterprise Architecture
ETA	Enterprise Technical Architecture
IAM	Identity and Access Management
IOC	Initial Operating Capability
ISO	International Organization for Standardization
M.D.	Medical Doctor

Term	Definition
MDM	Mobile Device Management
OIT	Office of Information and Technology
OM	Operations and Maintenance
PDF	Portable Document Format
RTM	Requirements Traceability Matrix
SME	Subject Matter Expert
SSO	Single Sign On
UI	User Interface
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture
VPN	Virtual Private Network

## 2. System Summary

This section provides a general system overview and outlines the system uses in supporting the activities of the user and staff.

### 2.1. Dependencies

- The content displayed in this application is only accessible when connected to a secure internet connection.
- An internet connection must be established to connect to the embedded links within the application content.
- This is a read-only application containing static text. Therefore, the accuracy and relevance of the information displayed is subjective depending on when the application was last updated.
- This application will require a stable, secure, mobile platform that allows for easy access from government issued mobile devices to existing VA resources and infrastructure.
- The primary and secondary stakeholders should be available for further functional and non-functional requirements definitions as well as for user feedback during development.
- Compatibility with the security profile issued by the OneVA EA ETA-compliant MDM.
- A major dependency for successful development and implementation of this mobile application is for VA to have an OIT approved Mobile Governance Board.

### 2.2. System Configuration

Currently, no authentication is required to login to the Preconception mobile application, therefore no integration with OIT-approved mobile application access channels, such as HealthAdapter, exist. All content displayed is static text, and does not leverage a data repository.

## 2.3. Data Flows

Preconception is a web-based, read-only application displaying various modules of static text. This section is not applicable, as this application does not leverage a data repository.

## 2.4. User Access Levels

The table below outlines the different users, user responsibilities, and respective access to the system:

User	Description	Responsibilities	System Access
VA and DoD Providers including Doctors, Physician Assistants, Nurse Practitioners, and Occupational Health Providers	VA and DoD clinical care providers who have the authority to prescribe medication and medical counseling to women veterans about their OB/GYN care.	Educational resource to assess personal health and lifestyle of women veterans, and provide medical diagnoses, counseling, and recommendations based on the clinical practice guideline (CPG).	Read-Only
Nurses	VHA staff who provide a broad spectrum of care to patients, including preventative, curative, promotional, or rehabilitative health care to women Veterans regarding their OB/GYN care.	Educational resource to maintain awareness, assess personal health and lifestyle of women veterans, and provide medical counseling and recommendations based on information provided.	Read-Only
Pharmacists	VHA staff who work in pharmacies to ensure the safe and effective prescribing, distribution, and use of medications	Collaborate with care providers to help decide which antibiotic(s) will be best to prescribe for a particular patient. They will use the information obtained from the preconception application to make formulary selections (usually through a facility's Pharmacy and Therapeutic Committee)	Read-Only
Non-VA Providers including Doctors, Physician Assistants, Nurses, Nurse Practitioners, and Occupational Health Providers	Non-VHA providers and staff who provide preventative, curative, promotional, or rehabilitative health care to women Veterans regarding their OB/GYN care.	Educational resource to facilitate preventative, curative, promotional, or rehabilitative health care to women Veterans regarding their OB/GYN care.	Read-Only
System Administrators	VHA facility staff who serve as primary resources overseeing technical and functional operation of IT resources	Maintain upkeep, configuration, and reliable operation of the application as needed	Read-Only

## 2.5. Contingencies and Alternate Modes of Operation

The accessibility of this web-based application is contingent upon communication to the web and application server(s), as well as other various functional network elements and application deployments.

## 3. Getting Started with Preconception

The following section provides an overview of the system functionality from initial logon through log off of the application.

### 3.1. Logging On

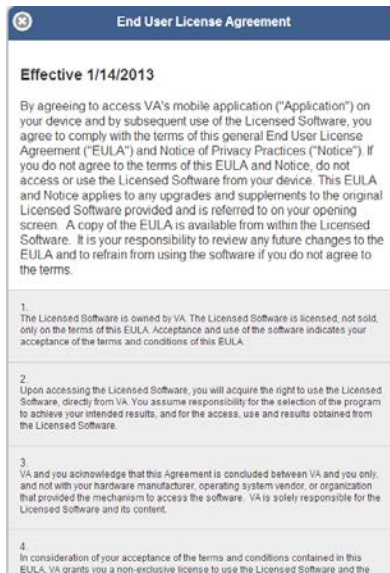
The Preconception application is a stand-alone app that requires no authentication and can be accessed from the LaunchPad using the following URL:



### 3.2. System Menu and Modules

#### 3.2.1. End User License Agreement

Upon launching the Preconception application from the LaunchPad, the user will be prompted to accept an End User License Agreement before proceeding to the home page of the application.



**Figure 3.1: Accept End User License Agreement**

Once the End User License Agreement has been reviewed and accepted, the user will be taken to the home screen. From the Home Screen, the user can select the About, Topics, or Resources module(s).

#### 3.2.2. About Module

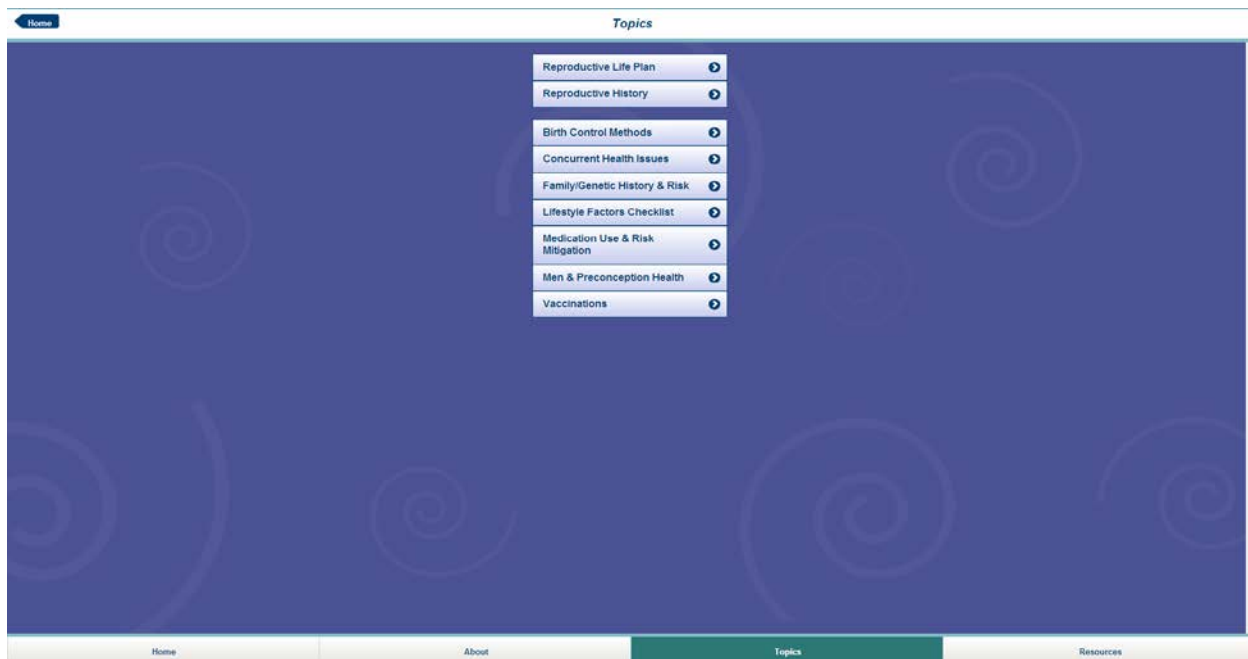
The About module displays instructional context regarding the content contained and uses of the application, as well as the version number. The About section also contains contact and reference information in the event an update or clarification is needed.



**Figure 3.2: About Module**

### 3.2.3. Topics Module

From the Topics module, the user can navigate through a list of nine (9) topics including: Reproductive Life Plan, Reproductive History, Birth Control Methods, Concurrent Health Issues, Family History/Genetics and Risks, Lifestyle Factors and Risks, Medication Use and Risk Mitigation, Men and Preconception Health, and Vaccinations. The following section outlines the content generated within each section.



**Figure 3.3: Topics Module**

#### 1.1.1.1. Reproductive Life Plan

Reproductive Life Plan provides opportunities for provider education about contraception, sexual history, and other various health issues that can impact her well-being during pregnancy.

Topics Reproductive Life Plan

Planning for pregnancy (or to prevent pregnancy) reduces adverse pregnancy outcomes and improves the health of women and their families. Other parts of well-woman care, such as taking a complete sexual history, also inform this discussion. The CDC suggests using the following open-ended questions to encourage patients to consider their reproductive wishes and plans. Discussion of your patient's answers also provides opportunities for education about contraception and other health issues that can impact her well being during pregnancy.

Would you like to have any (more) children at any time in your future?

Yes, I would like to have (more) children in the future

No, I do not wish to have (more) children in the future

**Figure 3.4: Reproductive Life Plan Module**

Reproductive Life Plan Yes: More Children

How many children would you like to have?

How long would you like to wait to become pregnant?

What birth control method do you plan to use until you are ready to become pregnant?

How sure are you that you will be able to use this method correctly all of the time?

Do you have any questions about this method or other birth control methods?

**Figure 3.5: Yes, I would like to have [more] children module**

### 1.1.1.2. Reproductive History

Reproductive History provides opportunities for provider education to help identify factors that may increase risk during a future pregnancy and actions that may mitigate these risks. Medical counseling can be provided to the woman based on the guidance provided, and information obtained, from each of the following historical topics contained on this page: ectopic pregnancy, preterm birth, second-trimester pregnancy loss, cervical surgery, known uterine anomalies, cesarean deliveries, placental abruption, intrauterine fetal demise(s), pregnancy induced hypertensive disorders, gestational diabetes, and thrombosis.

Topics Reproductive History

The goal of taking a thorough reproductive history is to identify factors that may increase risk during a future pregnancy and actions that may mitigate these risks.

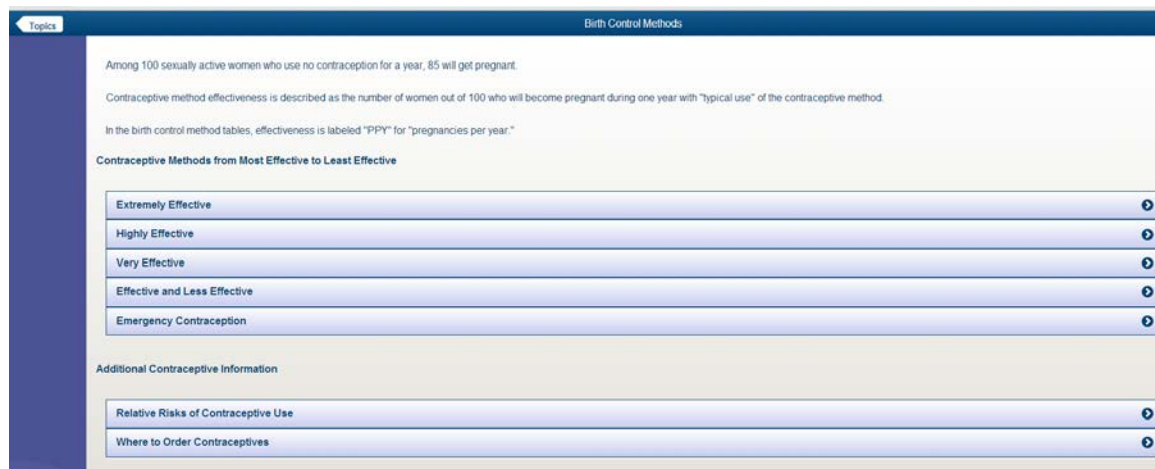
**Questions to ask:**

- History of recurrent pregnancy loss  
click to expand contents
- History of ectopic pregnancy  
click to expand contents
- History of preterm birth  
click to expand contents
- History of second-trimester pregnancy loss  
click to expand contents
- History of cervical surgery (LEEP/Cone Biopsy)  
click to expand contents
- Known uterine anomaly (fibroids, septum or other congenital anomaly)  
click to expand contents
- History of cesarean delivery  
click to expand contents
- History of placental abruption  
click to expand contents
- History of intrauterine fetal demise/stillbirth  
click to expand contents
- History of pregnancy induced hypertensive disorders  
click to expand contents
- History of gestational diabetes  
click to expand contents
- History of thrombosis  
click to expand contents

**Figure 3.6: Reproductive History Topics**

### 1.1.1.3. Birth Control Methods

The Birth Control Methods module contains a list of birth control contraceptives from most effective to least effective, as well as emergency contraceptives. This module also provides additional information regarding risks of contraceptive use, and where to obtain certain contraceptives.



**Figure 3.7: Birth Control Methods**

Close Extremely Effective

**Extremely Effective methods**

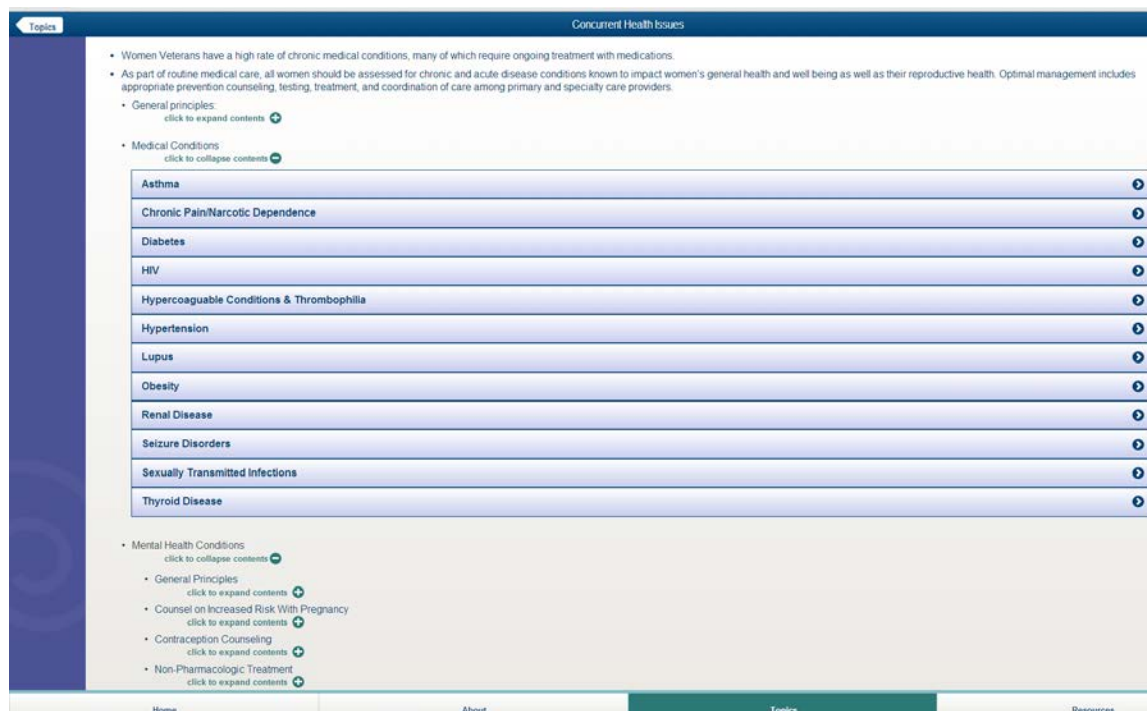
Method	PPY*	Features
Hormone implant (e.g. Nexplanon, Implanon)	<1	One rod, single insertion. Rapid return of fertility upon removal.
IUD - levonorgestrel (e.g. Mirena, Skyla)	<1	Use up to 5 years. May have lighter, infrequent, or absent menses. Rapid return of fertility after removal.
IUD - Copper T (e.g. ParaGard)	<1	Use up to 10 years. May have heavier, more painful menses initially. Rapid return of fertility after removal.
Tubal sterilization	<1	Permanent. Requires surgical procedure.
Partner's vasectomy	<1	Permanent with that partner. Ineffective with other partners.
Lactational amenorrhea for first 6 months after birth	1-2	Requires exclusive breastfeeding during first 6 months after delivery. Effectiveness declines thereafter.

\*PPY = pregnancies per year that occur among 100 women with typical use of the method.

**Figure 3.8: Extremely Effective Methods from Birth Control Methods page**

#### 1.1.1.4. Concurrent Health Issues

The Concurrent Health Issues module provides opportunities for education based on general principles and/or existing or acute medical conditions. This module helps to assess chronic and acute disease conditions known to impact women's general health, as well as their reproductive health.



**Figure 3.9: Concurrent Health Issues**

### 1.1.1.5. Family History/Genetics and Risks

The Family History/Genetics and Risks module provides a forum to understand family and genetic history of the patient. It provides an opportunity to identify, and sometimes mitigate, underlying risks that could increase potentially adverse outcomes for a mother or her fetus. This module also includes a section specific for specific ethnic populations.

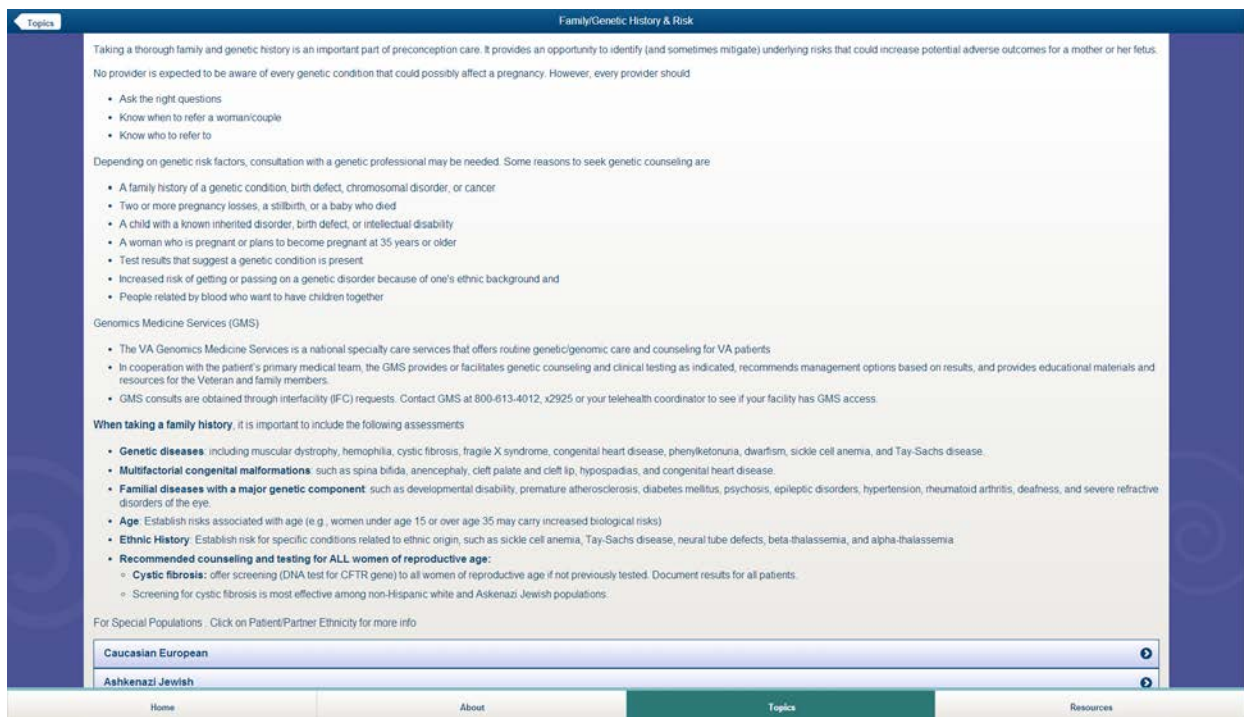


Figure 3.10: Family History/Genetics and Risks

Caucasian European									
<p>Back</p> <p>Caucasian</p> <p>Recommended counseling and testing for Special Populations</p> <table> <tr> <th>Ethnicity (patient and/or partner)</th><th>Disorder and Tests</th></tr> <tr> <td>Caucasian</td><td>Cystic fibrosis DNA test - CFTR gene</td></tr> </table> <p>Source: Solomon, et, al., "The Clinical content of preconception care genetics and genomics." AJOG, Supplement to December, 2008. S340-S344</p> <p>European</p> <p>Recommended counseling and testing for Special Populations</p> <table> <tr> <th>Ethnicity (patient and/or partner)</th><th>Disorder and Tests</th></tr> <tr> <td>European</td><td>Cystic fibrosis DNA test - CFTR gene</td></tr> </table> <p>Source: Solomon, et, al., "The Clinical content of preconception care genetics and genomics." AJOG, Supplement to December, 2008. S340-S344</p>		Ethnicity (patient and/or partner)	Disorder and Tests	Caucasian	Cystic fibrosis DNA test - CFTR gene	Ethnicity (patient and/or partner)	Disorder and Tests	European	Cystic fibrosis DNA test - CFTR gene
Ethnicity (patient and/or partner)	Disorder and Tests								
Caucasian	Cystic fibrosis DNA test - CFTR gene								
Ethnicity (patient and/or partner)	Disorder and Tests								
European	Cystic fibrosis DNA test - CFTR gene								

Figure 3.11: Caucasian European

#### 1.1.1.6. Lifestyle Factors and Risks

The modules contained within the Lifestyle Factors and Risks page provide guidance and education on healthy lifestyle indicators and how to maintain overall good health for a woman of child-bearing ages.

Lifestyle Factors Checklist	
Healthy Eating	1
Vitamin and Mineral Recommendations	2
Exercise	2
Healthy Weight	2
Alcohol Use	2
Tobacco Use	2
Drug Use	2
Intimate Partner Violence	2

**Figure 3.12: Lifestyle Factors Checklist**

**Healthy Weight**

- Women with BMI of 27 kg/m<sup>2</sup> or higher, or with BMI of 19.8 kg/m<sup>2</sup> or lower, should be advised on their health risks and the risks to future pregnancy.
- Women who are overweight or obese are at higher risk for problems before, during, and after pregnancy. Some of these issues include:
  - Infertility
  - Miscarriage
  - Stillbirth
  - High blood pressure and preeclampsia
  - Gestational diabetes
  - Complications during labor and birth
  - Venous thrombosis
  - Difficulties initiating lactation and breastfeeding
- Women with low BMI should be evaluated for possible eating disorders.

**Figure 3.13: Healthy Weight Guidance**

#### 1.1.1.7. Medication Use and Risk Mitigation

The content contained within the Medication Use and Risk Mitigation page provides education about various medicine-related risks and increases in birth defects in humans.

**Medication Use & Risk Mitigation**

Half of pregnancies in the United States are unplanned.

Many women of childbearing age have medical conditions that require ongoing or intermittent treatment with medications.

A 2010 study by a VA physician and clinical pharmacist found that 49% of women Veterans received a prescription for a medication that increases the risk for birth defects in humans; 44% of these women had no documented family planning services.

Ask patients about their use of prescription medicines, non-prescription medicines and dietary supplements.

Risk/Benefits discussions about medication-related risk must occur before pregnancy occurs.

In the embryo, development of major organ systems begins 2 to 3 weeks after conception, before a woman may know she is pregnant.

- Critical Stages of Embryonic Development  
click to expand contents

**FDA Pregnancy Categories**

The FDA pregnancy category letter alone is not enough.

Read the pregnancy subsection of labeling for each medication and/or the REPROTOX® summary (see Resource Section).

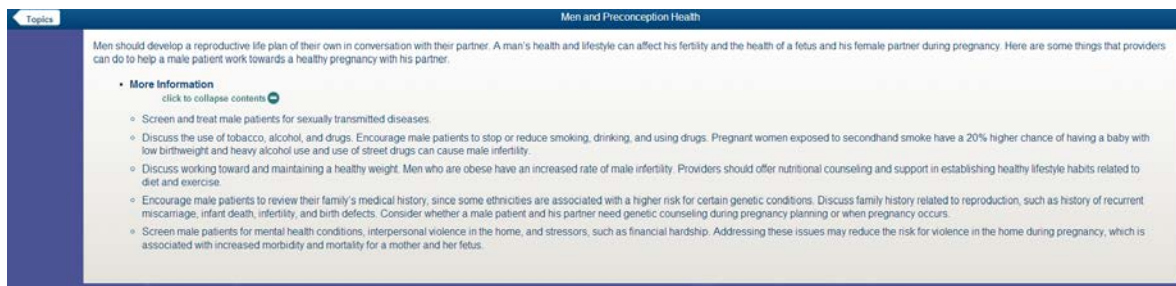
The FDA pregnancy categories describe only general differences in the reproductive risk of medications based on the types of data available (animal vs. human and studies vs. case reports) and reproductive outcomes. Some categories consider treatment benefit as well as risk.

- FDA Pregnancy Categories  
click to expand contents

**Figure 3.14: Medication Use and Risk Mitigation**

#### 1.1.1.8. Men and Preconception Health

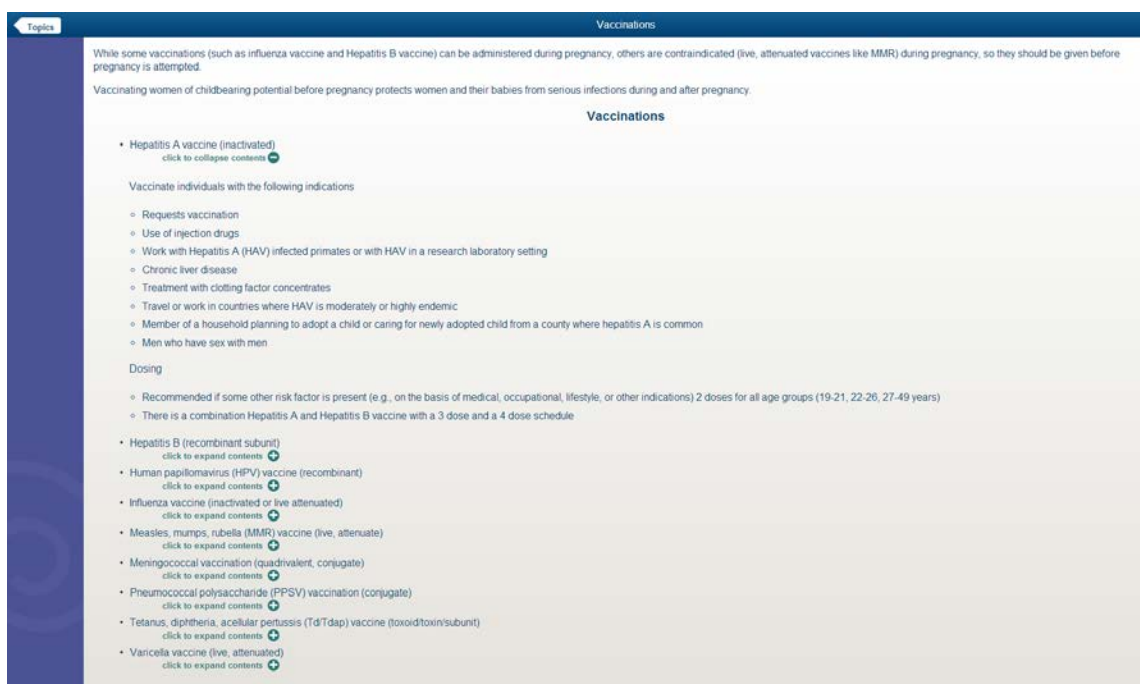
The content contained within the Men and Preconception Health provides education regarding a man's health, and how his lifestyle can affect his fertility and the health of the fetus and his female partner during pregnancy.



**Figure 3.15: Men and Preconception Health**

### 1.1.1.9. Vaccinations

The content contained on the Vaccination module provides opportunities for education regarding which vaccinations should and should not be administered before, during, and after pregnancy.



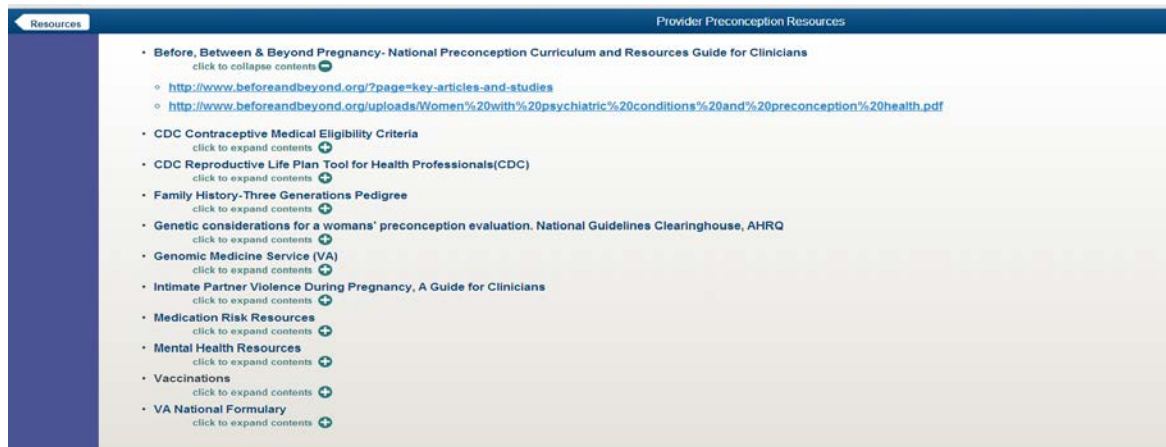
**Figure 3.16: Vaccinations**

### 3.2.4. Resources Module

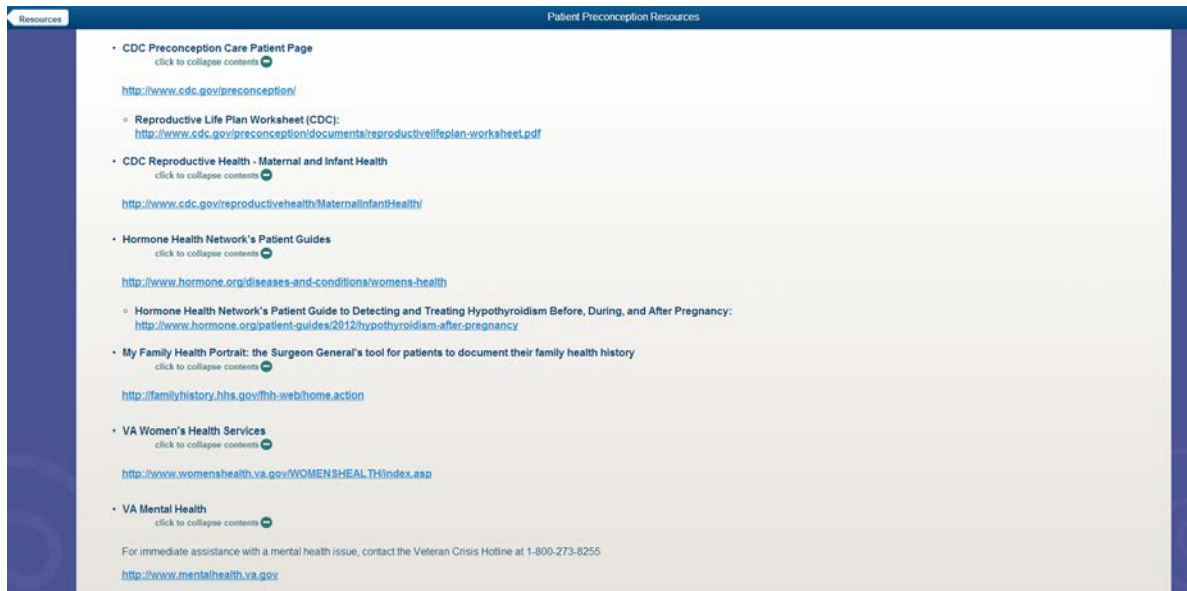
The Resources module contains provider and patient preconception resources, including links to websites from which the user is able to launch from within the application.



**Figure 3.17: Preconception Tools and Resources**



**Figure 3.18: Resources for Providers**



**Figure 3.19: Resources for Patients**

### 3.3. Changing User ID and Password

No authentication is required for this application at this time. As a result, this section is not applicable.

## 4. Troubleshooting

This application displays modules of static text. Please refer to the About section of the application for contact information regarding who to contact for updates to the text. For all technical issues, please contact the Technical Help Desk.

### 4.1. Appendix A: Preconception Remediation

Preconception remediation will address all of the 508 Compliance and Usability Fixes identified during the functional review by VA SMEs. The following items will be addressed during Preconception remediation:

- Address all 508 compliance issues so that a VA and Non-VA Provider can resize the text and viewport content within each (applicable) module of the application so that he/she can read the text from whichever approved mobile device that is being used.
- Address all 508 compliance issue(s) regarding reading order so that the title header is included in each page, and all tables have applicable table headers.
- Address all 508 compliance issue(s) to ensure off-screen and hidden content is not rendered by assistive technology so that users do not get lost or confused while navigating through a particular module.
- Address all 508 compliance issue(s) to ensure implicit list markup is avoided on each applicable module to prevent confusion for the assistive technology user.
- Address all 508 compliance issue to ensure text and images of text provide sufficient color contrast to ensure the text is legible by all users.
- Update content contained, fix spelling errors, and include appropriate version numbers to address all Usability issues identified in the functional review.