Hormone Replacement Therapy: Clinical Decision Support System

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Clinical Decision Support Systems

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Introduction

Background information

Fifty million American women age fifty and older face the decision whether or not to use hormone replacement therapy (HRT) for the treatment of menopausal symptoms. Indications for hormone replacement therapy vary considerably with clinical indicators unique to each patient. Risk and benefits including coronary artery disease (CAD), stroke, breast cancer, colorectal cancer and osteoporosis are significant factors to consider when making a determination whether or not to use HRT. Over the past two decades as more studies are reported and recommendations are modified, HRT for menopausal and postmenopausal women has raised much controversy and uncertainty even among the most astute practitioner.

Much of the information women gain regarding menopause and treatment modalities comes from the media. This information is often incomplete and not tailored to the individual patient. Women need to be fully informed about the transient nature of menopausal symptoms, the risk and benefits of hormone therapy, as well as the non -pharmacological therapies that are available. With so many factors influencing the decision on which treatment to use if any, the primary care setting would be the ideal place for a clinical decision support (CDS) tool to be implemented.

This paper outlines a CDS tool that can be implemented to facilitate the discussion and decisions around HRT as treatment for menopausal symptoms. In this model, the patient will provide the physicians their preferences regarding HRT via an initial survey. In addition, different assessment tools will provide data that will feed into the Clinical Decision Support System (CDSS). This information will be analyzed by the physician with input from the CDSS in an effort to provide a customized treatment plan for the patient, tailored to their preferences, risk, and benefits.

Intervention Selection and Workflow Opportunities

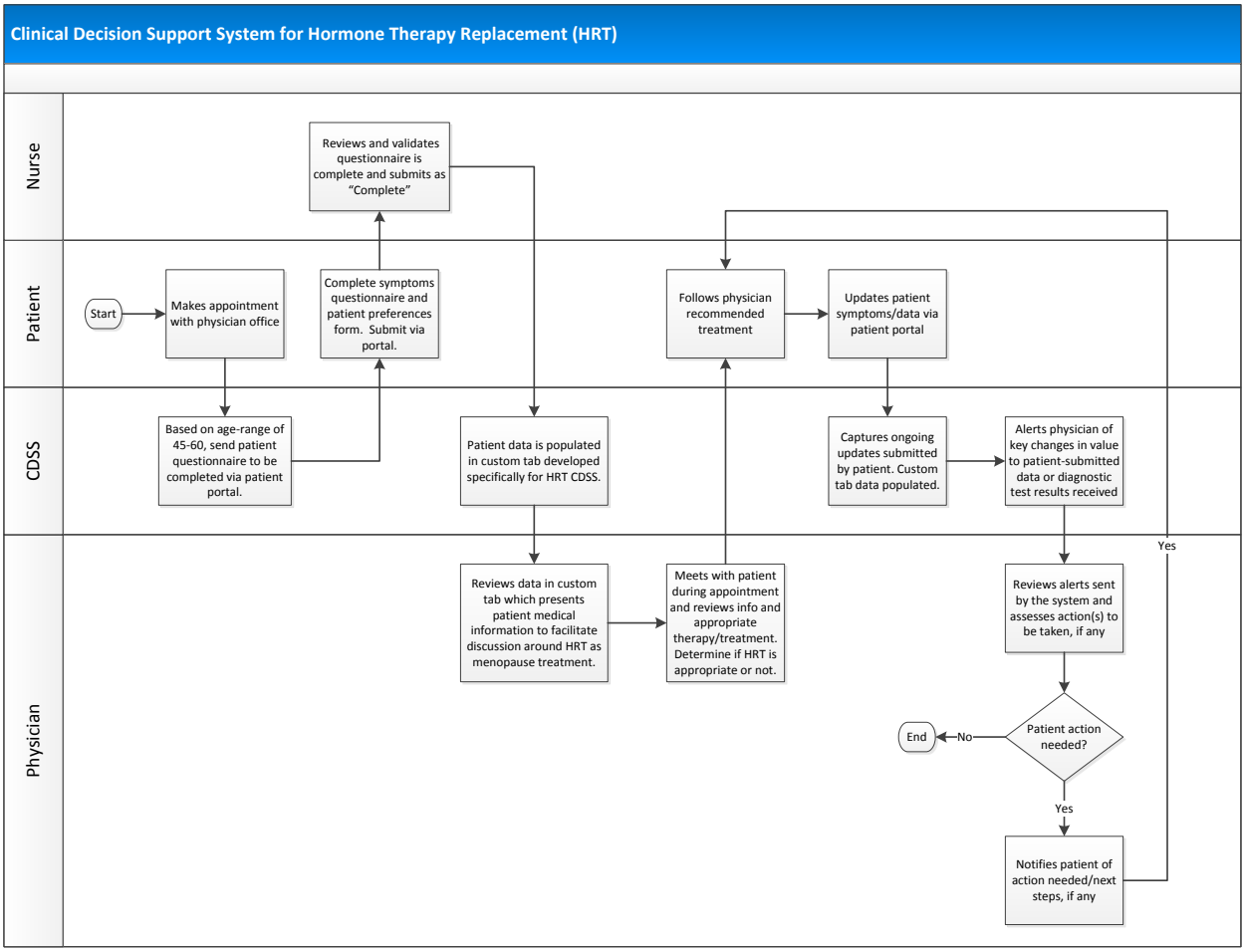
Two main areas will provide information for the CDSS. First, the data gathered from the patient and second, the information gathered from the physician. The workflow process will

begin with the patient prior to their appointment with the primary care physician. In order to individualize treatment, personal health information must be gathered from the patient including symptomatology with patients rating each symptom according to severity, patient preferences, past medical history, including risk factors and a quality of life assessment. The information from the physician will include data from the patients EHR, clinical exam, diagnostic test, and risk assessment, clinical trial data.

This alteration in the workflow patterns moves the data collection from the patient rushing to fill out forms in the waiting area to the patients home allowing them time to carefully consider their responses. Preferably this is completed online so the data will be received by the MD's office and integrated directly in to the patient's EHR and the Decision Support System. The physician will have a report to evaluate summarizing the patient's information, chief complaints and concerns prior to their appointment. Analyzing this information may trigger a recommendation for lab test that can be performed prior to the appointment, which will ultimately make the patient –physician interaction more productive.

On the appointment date the workflow will be improved since much of the information is already in the EHR and CDSS. After clinical examination by the physician, pertinent data will again be incorporated directly on to the EHR and CDSS. With all the relevant data at hand the MD may review with the patient options regarding treatment by analyzing risk, benefits, expected outcomes and possible side effects. Included in the EHR is the patient's insurance information, which will allow for immediate determination of the cost of therapy to the patient dependent on their policy. If a pharmacologic intervention is decided upon, with the ability to use E-prescribing, the patient may pickup their medication on the way home from their appointment. The patient may receive an individualized treatment plan printed from the physician and a copy will be e-mailed as well. There will be triggers set for the patient at set intervals to their e-mail to evaluate the effectiveness of the treatment, sending this feedback to the MD for alterations if needed. This streamlined workflow process including the patient preferences, EHR integration, medication reconciliation has assisted the physician in providing Safe, Timely, Effective, Efficient and Patient Centered care aligning with the goals from the IOM (IOM 2001).

Below is a cross-functional (swim-lane) diagram illustrating the outlined process.



Goals and Objectives

The HRT CDSS has the following broad organizational goals, mid-level goals, and measurable objectives:

1. Improved patient education and empowerment
    a. Patients use the CDSS to enter their menopausal symptoms
        i. Percentage of patients who use the patient portal to enter their information prior to the office visit.
        ii. Percentage of patient who use the patient portal to track their menopausal symptoms on a daily/weekly/monthly basis, measured at a 3-month milestone, 6-month milestone, and a 1- year milestone.
    b. Patients comply with ordered tests

        i. Percentage of patients who comply with follow up care: screenings for breast cancer, hypertension, osteoporosis, and colorectal cancer.

2. Improved staff access to clinical information
    a. Physicians use the CDSS to access the latest HRT research results
        i. Number of physician accesses to HRT knowledge base.
3. Improved patient-centered care delivery
    a. Menopausal symptom treatment is tailored to individual patient needs, preferences, and risk factors
        i. Percentage of care plans generated from use of the CDSS.
4. Improved compliance with published clinical guidelines
    a. Physicians follow the HRT Clinical Guidelines adopted by the organization
        i. Percentage of women for whom bone-density tests are ordered.
        ii. Percentage of women for whom CVD risk is assessed.
        iii. Percentage of women on HRT for relief of menopausal symptoms whose doses are decreased over time as symptoms abide.
        iv. Percentage of women who remain on HRT for up to 1 year, up to 2 years, up to 3 years, and beyond 3 years.

Stakeholders

Stakeholders for a Hormone Replacement Therapy (HRT) CDSS implemented in a private practice primary care physician group fall into three main categories (Osheroff J.A. et. al., 2012). These categories include governance, implementation and project management, and end-users.

1. Governance: Sets strategy and allocates resources.
2. Implementation and Project Management: Develops, deploys, and monitors CDS interventions.
3. End Users and Related Positions: Performs patient care activities affected by the CDS system (CDSS).

The three main stakeholder categories have the following roles:

1. Governance

a. Executive sponsor: Sets strategy and priority, and allocates resources.
b. Oversight Management Team: Defines, deploys, and monitors CDS interventions.

2. Implementation and Project Management
    a. CDS Team: Implement the interventions, measurement capabilities, and knowledge management capabilities of the CDSS.
        - Clinical leader: Provides clinical expertise for evaluating and implementing potential interventions.
        - Practice Manager/Nursing leader: Provides workflow expertise for proposed interventions.
        - Technical IT Experts: Implement the CDS software and integrations with other systems.
        - Project Manager: Manages the project schedule and deliverables.
3. End Users and Related Positions
    a. End Users
        - Patients: Become educated in risks/benefits of HRT, closely monitor and document menopausal symptoms, comply with care recommendations.
        - Physicians: Use the CDS intervention, present treatment options to the patient, strive to understand the patient's preferences, use professional judgment when applying guidance provided by the CDS tool.
        - Nurses: Use the CDS intervention, collect and enter patient information if not directly entered by patient, train patient to use the CDS tool.
    b. Subject matter experts: Review knowledge base for content. Includes recommendations from the American Association of Obstetricians and Gynecologists (AAOG). NCI, NAMS
    c. EHR vendor: Provides interface specifications for EHR, collaborates with CDS Team for integration of EHR and CDSS.
    d. Champion: Helps ensure the interventions meet the needs of the organization and are successfully adopted, builds support within the user community for the CDSS.

e. Pharmacist: Consults on drug formularies for HRT, provides recommendations on drugs and drug combinations for HRT.
f. Clinical thought leaders: Advise CDS Team on value of proposed interventions, and how to measure success.
g. Legal counsel: Advises CDS Team on liability associated with use of CDSS.
h. Risk management representative: Evaluates safety risks introduced into the current care delivery system by the use of the CDSS.
i. Quality representative: Audits the implementation deliverables for compliance with safety-critical software standards and best practices.
j. Regulatory representative: Evaluates the CDSS for the need to file for approval with regulatory agencies.
k. Office staff: Consults on current workflows and the effects of the intervention on the workflows.

Change Management Plan

Implementing the HRT CDSS will require a solid change management plan to ensure success both for the implementation as well as for the end-user adoption. Below are some critical components of the change management plan designed for the HRT CDSS.

- Implementation of the HRT CDSS will introduce changes in workflows and processes in the primary care physician office. The patient schedules her appointment online through a patient portal, and completes a questionnaire prior to the office visit. If the questionnaire has not been fully completed, then the office administrator contacts the patient to get the additional information. This is a new workflow introduced by the CDS intervention. The interaction between the nurse and the patient during the office visit is affected because the nurse no longer has to question the patient and enter the patient's information. Using the custom "HRT CDS" tab of the EHR, the physician has ready online access to the patient's medical record during the visit, including all lab test results, medication history, chief complaint, problem list, previous diagnoses, and patient preferences for treatment. The physician also has easy access to relevant Clinical Practice Guidelines for treating menopausal symptoms with HRT, along with risk calculations specific for the given patient. Ready access to this

information enables the physician to be more precise in his treatment of the patient since the risk information is tailored to the individual patient.

- Many, if not most unintended consequences can be anticipated and planned for by performing a Risk Analysis with a cross-functional team during the design phase of the project. Risks are classified according to probability of occurrence, and severity. Risk control measures are then identified to mitigate the risks. If and when an unintended consequence occurs after system deployment, the proposed mitigation can be implemented.
- The effects of unintended consequences can be minimized by frequently communicating project status with everyone who will be affected by the intervention. This facilitates stakeholder buy-in and active participation, which in turn fosters a higher level of cooperation and shared ownership in solving problems that occur after launch.
- Training users so that they are prepared for the changes can mitigate effects on workflow. Prior to implementation, a detailed workflow analysis will be performed with the users' input and participation. This should result in workflow optimization to achieve efficiencies. Of particular importance for the success of the intervention is the willingness of the patient to routinely document her symptoms in the patient portal. To address this, the CDS Team will develop a patient training packet to be used by the physician during the initial office visit.
- The CDS Team will frequently engage with stakeholders throughout the project, demonstrating prototypes or screen shots of the intervention, and discussing the resulting changes to the workflows. The team will emphasize the positive impact and benefits resulting from the intervention so that users become invested in making the implementation successful. The team will explain the rationale behind all workflow changes so that the users understand them. Human factors assessment will be done at several points during the implementation, and user feedback will be solicited and addressed. Champions from the end user group will be engaged from the beginning of the project so that they can model desired end user behavior.
- The CDS Team will conduct User Acceptance Testing with representative users. All users will be trained. Information about modifications to the workflow will be communicated again to the stakeholders just prior to launch. Users will be reminded of the goals of the project, the changes to the workflows and processes, the benefits that can be expected, and the channels that are available for feedback (Osheroff J.A. et. al., 2012).

- Prior to launch, a readiness assessment will be conducted to determine if stakeholder interests are aligned.

System Design

Intervention (Content) Specification

Hormone Replacement Therapy CDSS Specification

The HRT CDSS is going to be implemented in a medium-sized physician office with 30+ primary care physicians, 5 nurses, and a staff of 4 back-office administrators.

The physician office uses the Allscripts Professional (Pro) EHR applications. The modules implemented include the Allscripts Practice Management Software, the Allscripts Pro Clinical System, and the Allscripts Patient Portal. The Surescripts pharmacy solution is implemented and integrated with the EHR's e-prescribing software and facilitates the direct submission of patient prescriptions to the patient's preferred pharmacy as well the download of patient's historical meds and insurance beneficiary information. The practice also has a subscription to the Elsevier FirstConsult solution for decision support reference and various other free clinical content sites such as PubMed. Lastly, the office recently purchased a license for Quest Diagnostics' Care360 software which allows for electronic lab ordering to the Quest Lab facilities, immediate results download and various physician/patient alerts for managing patient lab tests.

The HRT CDSS is designed to leverage the physician office's existing technology solutions. Below is an outline of the process and how the CDSS intervention is designed to work.

1. Patient calls the physician office (or logs on to the patient portal to do self-service scheduling) to make an appointment with her primary care doctor. The scheduled appointment is saved in the system and based on the patient's age, the EHR automatically tags the patient record for follow-up.

2. For female patients within the age range of 45-60, the physician office EHR is set up to automatically send the patient a questionnaire to gather additional information in preparation for the office visit.

3. Patient receives a secure-email via the patient portal. The email has a link to a custom questionnaire. The questionnaire asks the patient to go through a list of symptoms and rate each one based on severity. See My Symptom Tracker diagram below.

My Symptom Tracker

		Rank your symptoms 0-4 , 4 being severe, zero being none						
		Severe	Mild	Moderate	None	My Symptom Score	Intervention	Change in symptom score
Week 1	Anxiety							
	Bladder issues							
	Bleeding							
	Bloating							
	Burning or dry mouth							
	Decrease sex interest							
	Excessively tired							
	Headaches							
	Hot Flashes							
	Irritability							
	Night sweats							
	Palpitations							
	Trouble remembering things							
	Skin changes							
	Sleep problems							

4. Patient accesses this secure questionnaire on the patient portal, completes it, and submits the form. In addition to the questionnaire, the patient is also presented with additional forms including Patient Preferences, Risk Assessment, and Quality of Life forms. The patient preferences help define what the patient values are in terms of the given risks and benefits of undergoing HRT.

5. The office administrator is notified via an alert (email) that the patient submitted the questionnaire and reviews it for completeness. If any key items were left blank, or additional information is needed, the office administrator makes a call to the patient for additional follow-up.

6. Once the questionnaire is finalized, the office administrator marks the questionnaire as ‘Complete’, which facilitates a process in the back-end of the Allscripts EHR, and the

patient data from the questionnaire (all built as structured data) populates a custom tab built specifically for patients dealing with (potential) menopause.

7. When the patient presents at the office for the appointment, the physician reviews the data in the EHR custom tab and makes an assessment based on the patient symptoms and physical exam. This data is entered into the EHR and the custom tab.

8. The physician at this point may prescribe certain medication to alleviate the patient symptom(s). The EHR system's e-prescribing tool is used and the prescription is electronically sent to the patient's preferred pharmacy for pick-up on the way home.

9. If needed, additional lab and diagnostic tests are also ordered via the EHR using an order set. The patient is reminded via secure email that an upcoming diagnostic appointment exam is coming up. When the test results are returned, the EHR data is updated and applicable information is also updated in the custom tab.

10. Given the additional results captured in the EHR, the physician does another assessment of the patient case. He utilizes FirstConsult and the office-approved Clinical Practice Guidelines. One treatment option available for the physician to vet is the Hormone Therapy Replacement. Given the data captured on the patient in the EHR, the physician determines whether the patient is a candidate for HRT or not.

11. The physician contacts the patient and recommends next steps for treatment plan. Part of the discussion is a review of the patient preferences. A tool such as the Quality of Life table (shown below) that outlines the various impacts of HRT on a patient, can be used for this discussion.

Quality of Life & Patient Preferences Assessment Tool

Table Acronyms Key:

- QOL- Quality of life
- SQOL- Sexual quality of life
- HQOL-Health quality of life
- HT- Hormone therapy
- ET- Estrogen therapy
- PT- Progesterone therapy
- EPT- Estrogen and progesterone therapy

Categories	Symptoms	Affects	Route/Type	Notes
Vasomotor symptoms	• Hot flashes • Night sweats	QOL	• ET • EPT	Reduces symptoms by 80%
Vaginal symptoms	• Related to vulvar and vaginal atrophy	SQOL	• ET	Moderate to severe symptoms
Sexual function	• Dyspareunia	SQOL	• ET Vaginal • ET Oral	HT may be effective in relieving dyspareunia
Urinary Health	• Urge incontinence due to vaginal atrophy • Chronic urinary tract infections	QOL	• Local ET • Vaginal ET	Systemic HT- May worsen symptoms or Provoke stress incontinence
Weight Change in BMI	Weight gain during menopause	HQOL/EQOL	• None	No effective HT for Weight gain during menopause
Quality of Life (QOL)		QOL	• HT	• No product is approved for enhancing QOL • HT can improve QOL – better sleep, mood. Only in symptomatic women
Osteoporosis	Risk of fractures	HQOL	• HT	• RCT- HT decreases osteoporotic fractures in postmenopausal women even if they have osteoporosis • Many systemic HT are approved for long-term tx form women with osteoporosis • Start early
Breast Cancer	Breast Cancer	HQOL	• ET • EPT	• No increase risk of cancer after 7.1 yrs. of use (all age groups) • Use > 3-5 yrs. breast cancer increase •
After Breast Cancer		HQOL	• EPT • ET	• Conflicting studies • Observational studies suggest

				EPT is save and possibly beneficial • Overall thought is ET use post breast ca is not safe •
Ovarian Cancer	Ovarian cancer	HQOL	• EPT	• Use for 5.6 yrs. no increase in ovarian cancer • Conflicting data • Observational data suggest increase risk with HT • Epidemiologic studies show no association
Endometrial cancer	Endometrial cancer	HQOL	• HT • ET • EPT	• HT in general is not recommended for women with endometrial cancer • ET in women with an intact uterus increase risk of ca (the risk persist even after discontinuation • EPT for women with a uterus taking HT
Coronary artery disease	CAD	HQOL	• ET	• May reduce CHD risk when initiated in younger and more recently menopausal women. • Women who initiated HT> 10yrs after menopause are at increase risk of CAD • Women who initiated within 10 yrs. have lower risk. • Observational studies suggest longer duration of HT use is associated with reduced risk of CHD and related mortality
Misc			• SSRI • Herbal treatments • Bio-identical hormones (BHT)	• Selective reuptake serotonin inhibitors have been shown to reduce vasomotor symptoms (hot flashes) • Herbal- questionable efficacy • BHT are custom compounds providing different dosages and routes of administration. They are not approved by the FDA and have not been tested for safety and efficacy

12. If no treatment plan changes are defined, the physician asks the patient to schedule a return visit within a certain period of time for follow-up and monitoring. In the interim,

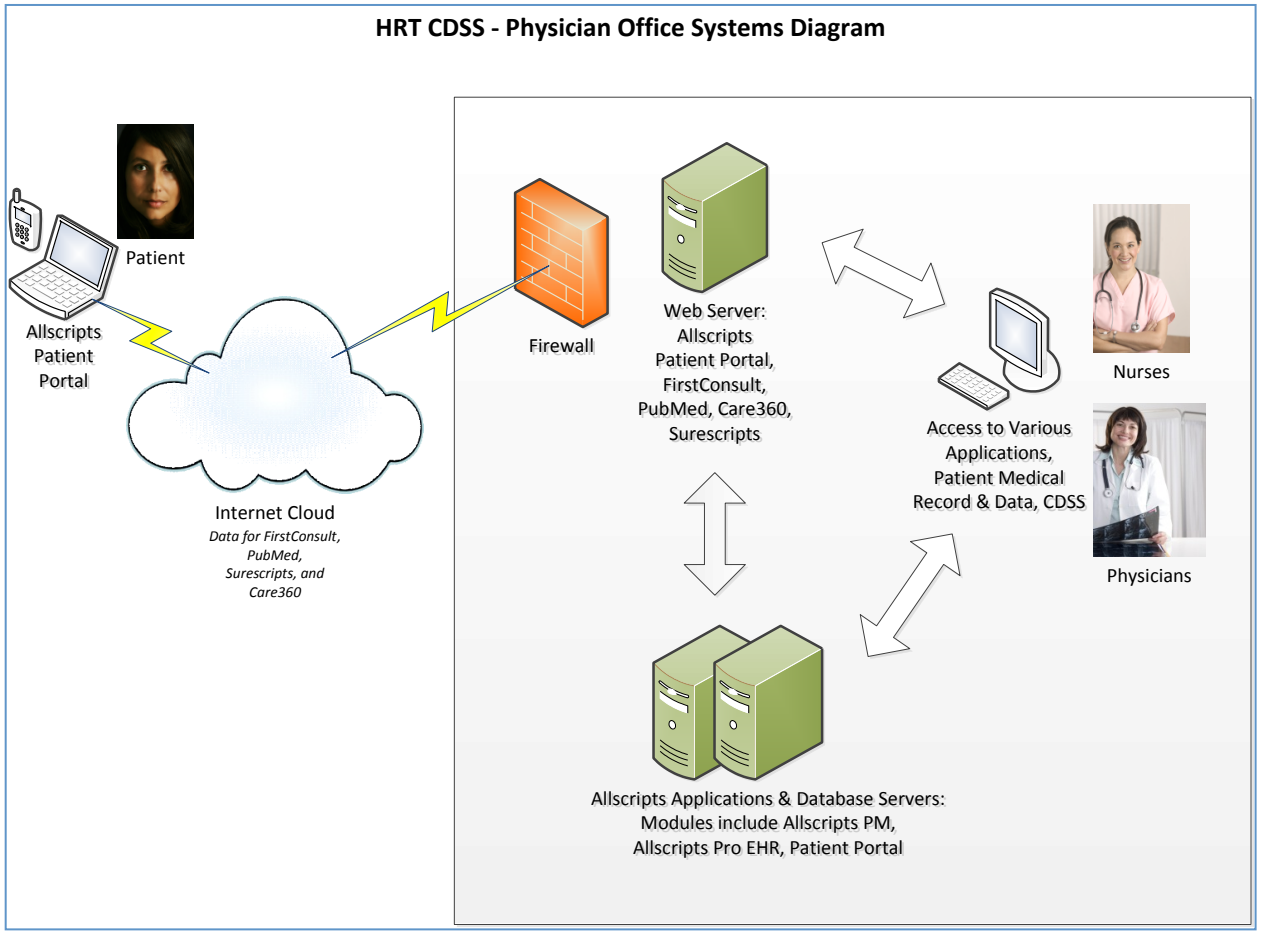
the patient can utilize the patient portal to securely communicate with the physician office regarding any dramatic changes in the patient's status or symptoms.

13. Based on updates made to the patient data in the custom tab, the physician can generate a trend report and make further assessments on the patient case.

The custom tab implemented in the Allscripts EHR application facilitates the CDSS intervention by capturing the appropriate and up-to-date data on the patient and presenting this data to the physician in a manner that is organized and helps promote the proper treatment options, one of which is the Hormone Therapy Replacement. The CPG's used in this process as well as other clinical content from FirstConsult and other sources are reviewed by the physician office on an annual basis ensuring that the treatment options and treatment plans are adjusted/updated accordingly.

System Architecture

Below is a technical system architecture diagram for the physician office's application solutions. The Internet plays a key role not only in the delivery of the patient data to the office EHR system and thus CDSS, but it also provides for additional data sources such as PubMed and FirstConsult.



Information Systems Inventory

Below is a table that includes the major applications being utilized in the physician office and how each plays a component in the CDSS solution.

Hormone Replacement Therapy - Information System Inventory

System Name/Type	CDS-related Functionality	Information Types	System Users and Usage	Notes
Financial/Administrative				
Allscripts PM (Practice Management/Billing Software)	Patient insurance coverage validation for various treatment types	Visit reason/symptoms (ICD-10)	Physician office administrators, Nurses	
Clinical Records and Patient Management				
Allscripts Pro EHR	Documentation templates (e.g. patient assessment)	Visit diagnosis (ICD-10)	Primary care physicians, Nurses	Some data exchange capabilities with nearby hospital facility. CCD download in PDF format.
	Order entry	Problem lists (ICD-10)		
	Relevant data display	Medication lists (NDC)		
	Alerts	Visit notes (Free text)		
Allscripts Patient Portal	Patient online portal for patient questionnaire and data entry; Test results review	Symptoms/Problem lists (ICD-10)	Patients, Primary Care Physicians, Nurses	Secured online email communications
Clinical Content				
American College of Obstetricians and Gynecologists	Updated gynecological recommendations and medical literature		Primary Care Physicians	
Elsivier FirstConsult (Quick reference CDS site)	Evidence-based medical information site	Diagnosis (ICD-10)	Primary care physicians, Nurses	Subscription-based clinical content access
PubMed	Medical literature		Primary care physicians, Nurses	
Departmental Data Management (External 3rd Party Solutions)				
Quest Diagnostics Care360	Electronic lab orders and results	Lab test orders and results (LOINC)	Primary care physicians, Nurses, Patients	Electronic lab results available via mobile and internet
	Results alerts			
	Patient test reminder			
	Patient education resources			
Surescripts	Electronic prescription writer	Medication lists and drug formularies (NDC)	Primary care physicians, Nurses	Connections to subscribing pharmacies and

				payers
	Patient medication history			
	Insurance benefits eligibility			
Physician Office Hardware/Equipment/Networking/Misc				
Local Area Network (LAN)			Primary care physicians, Nurses, Physician office administrators	
Office Workstations			Primary care physicians, Nurses, Physician office administrators	
Workstations on Wheels (WOWs)			Primary care physicians, Nurses, Physician office administrators	
Internet Connectivity			Primary care physicians, Nurses, Physician office administrators	
ObjectsPlus Programming Toolset			IT Programmer, Consultants	Use to develop custom tab for CDSS

Solution Vendor Links:

Allscripts PM - http://www.allscripts.com/en/solutions/ambulatory-solutions/rcm/show1/practice-management.html
Allscripts Professional EHR - http://www.allscripts.com/en/solutions/ambulatory-solutions/ehr/Show/ProductSelect/AllscriptsProfessionalEHR/Overview.html
Allscripts Patient Portal - http://www.allscripts.com/en/solutions/ambulatory-add-ons/allscripts-patient-portal/features.html
FirstConsult - http://www.firstconsult.com/php/332221470-69/home.html
Care360 - http://www.questdiagnostics.com/home/physicians/testing-services/specialists/primary-care-physicians.html
Surescripts - http://www.surescripts.com/
ACOG - http://www.acog.org/

User Interface

There are two user interaction points with the CDSS: the patient portal and the HRT tab of the EHR.

Inputs

1. Through the patient portal, patients complete an online symptom questionnaire, including patient preference, risk assessment and quality of life input forms.
2. Through the patient portal, patients routinely enter data in the My Symptoms Tracker browser window.
3. Through the HRT tab nurses enter missing patient information.

Outputs

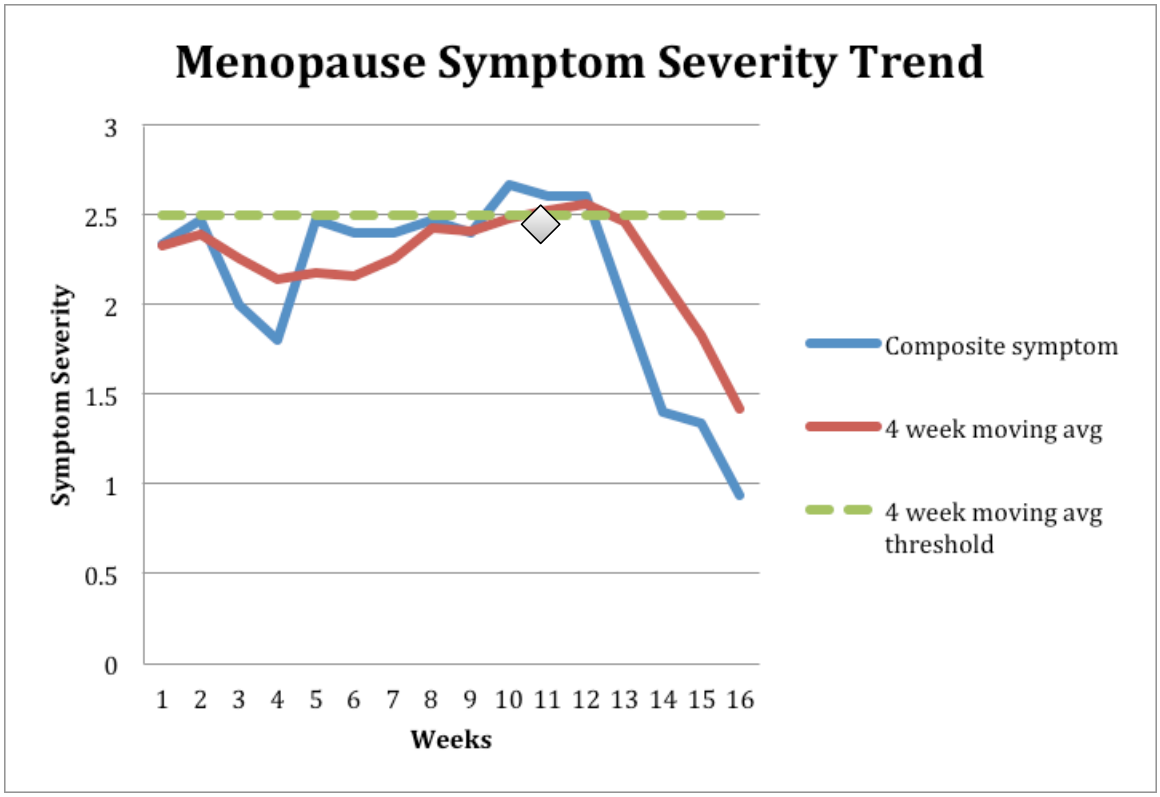
1. Through the HRT tab, physicians view patient data.
2. Through the HRT tab, physicians access risk calculators.
3. Through the HRT tab, physicians access Clinical Practice Guidelines.
4. Through the HRT tab, physician view patient symptom trend graphs.

Due to the imprecise nature of using HRT to relieve menopausal symptoms, the HRT CDSS does not provide specific treatment recommendations. Instead it aggregates all of information about the patient, the patient's risk factors, and the Clinical Practice Guidelines that the physician needs to determine treatment.

The following is a detailed description of the patient symptom trend graph. As the patient enters symptom severities weekly, the CDSS graphs the severity of each symptom, as well as a composite symptom, representing all symptoms. Four-week and eight-week moving averages are calculated on each individual symptom as well as on the composite symptom.

The CDSS has a Boolean logic editor interface which allows the physician to specify rules for triggering alerts based on thresholds set for any combination of individual symptoms, composite symptom or moving averages. Markers for intervention events are included in the trend graph.

In the example below, the threshold for the 4-week moving average for the composite symptom was set to a severity value of 2.5. When the 4-week moving average crossed the threshold (week 11), an alert was triggered. The physician evaluated the alert and elected to adjust the patient's therapy. In the weeks following the therapy adjustment, the symptom severity started trending down.



Usability testing will be performed iteratively throughout the project, starting with prototype screenshots. Users will be asked to interact with the CDSS to follow a defined script representing a typical user action. They will be asked to "think aloud" during the interaction, and will be videotaped. The CDS Team will review the videotapes and modify the user interfaces as necessary to attain the optimal user experience. After deployment, users will be surveyed to ascertain their satisfaction with the ease of use of the system, and any necessary changes will be implemented in the next revision.

Knowledge Engineering

Knowledge Acquisition

Risk benefit ratio's must be analyzed when determining whether to use HRT, when to begin therapy, how long to take and what route to use. The patient's baseline risk and starting age of therapy affect the net benefit risk ratio. There are several different models one may use to evaluate risk. We will use these models to calculate patient's risk associated with each disease process.

1. **Coronary Artery Disease and Stroke risk Assessment:**
   Farmington Heart Study Model
   - Risk factors- age, cholesterol, HDL, systolic blood pressure, diabetes, smoking, atrial fibrillation
   - High risk= 3 risk factors
   - Low risk = 0 risk factors

2. **Breast Cancer Risk Assessment**
   The National Cancer Institute Breast Cancer Risk Assessment Tool is considered the most authoritative and accurate model
   - Is a tool designed for the health care professional to identify and calculate risk factors for breast cancer
   - It is not intended for women who already have breast cancer
   - Women with strong family histories and breast cancer mutations BRACA1 or BRACA2 will require more specific methods of identifying risk.

3. **Osteoporosis Risk Assessment**
   - There are several different models to determine this risk factor, we chose the model used by the Women's Health Initiative, since the criteria did not include expensive bone density test. The result where shown to have a predicative value similar to models using this test. This would allow us to have more complete data.
   - Eleven key risk factors are included
   - Age, self reported health, weight, height, self reported physical activity, history of fracture after age 50, current smoking, current use of corticosteroids, treated diabetes.
4. **Colon Cancer**
   - 10 observational studies have shown a decrease risk of colon cancer
   - There are no published clinical trial data about HRT and colon cancer or polyps.
5. **Quality of life**
   - The Utian Quality of Life Scale will provide the healthcare provide numerical data summarizing QOL issues as well as assigning categories

- Occupational QOL
- Health QOL
- Emotional QOL
- Sexual QOL
- Total QOL

6. **My Symptoms Tracker**
    - Web based patient tracking system to monitor symptom acuity and track interventions

Knowledge Representation

There are no clear-cut recommendations for HRT use in menopausal women. The reason for this is that most studies regarding HRT are observational studies and trial data cannot be used to extrapolate information and make recommendations for all women. One large RCT (Randomized Controlled Trial) was the WHI, however this study was limited to only one formula for estrogen therapy (ET) and estrogen and progesterone therapy (EPT) and one route (orally). In addition, this study evaluated women with a mean age of 63, 10 years past typical age of menopause. The information we will use for this CDSS will come from a variety of expert sources, notably the American Academy of Obstetrics and Gynecology, (AGOC), The North American Menopause Society (NAMS), and the National Cancer Institute (NCI).

Knowledge Inference

An analysis of the initial risk assessments along with the physicians clinical exam with be evaluated and algorithms developed identifying risk factors. Once Identified the CDSS will compare risk factors, patient's age, history and symptoms to provide informed options analyzing the risk and expected benefits.

Knowledge Maintenance

Our risk analysis methods came from the NAMS, NCI and they are periodically modified as new data is presented, we will follow the status, making updates and modifications as needed. Additional information will come from the patient surveys, which will be collected via the patient portal from the physician's office. The CDSS committee of experts will evaluate new

studies, knowledge and or recommendations as they emerge. The committee will meet quarterly to review and evaluate the system. If changes are to be made to the system, the cloud-based architecture will allow for easy updates.

Evaluation

Are there competitor models or systems? How do they compare?

HRT decision aids have been tested in the past. One example of this was done at the University of Ottawa in Ontario, Canada in 1999 (O'Connor et al). The decision aid was a self-guided decision aid. It involved a 40-minute audiotape that walked the patient through a booklet that discussed the following items:

1. The benefits and risks of HRT
2. A walkthrough of an exercise that helped the patient define their values (preferences)

The review of these two topics helped guide the patient towards the best decision for their own particular case. The results of the test were that 1) most patients felt more informed after going through the decision aid process, and 2) the majority of the patients, however, did not change their original, baseline decision.

The decision aid above can be a valuable tool to add to the HRT CDSS. The advantages of the HRT CDSS over decision aids is that 1) it incorporates patient data elements that are already captured in the physician office EHR system which allows for a more comprehensive view of the patient case, 2) it includes interaction with the physician who can provide additional guidance to the decision making process, and 3) it is a tool that is dynamic and allows for views and decisions to be adjusted/updated based on new data elements being provided.

Verification and Validation

System verification will include testing of all functional and computing environment performance requirements. The CDSS will be exercised with data sets of simulated data to test all boundary conditions, the happy path through the workflows, and all of the exception paths.

The over reaching goal of this CDSS is to educate and empower women to become partners with their physician as they transition though the natural phase of life called menopause. The question becomes how do we validate we are indeed achieving these goals. Early in the development process we designed performance measures tailored to the different areas of the CDSS from patient registration through entire process. One key metric is whether patient portals triggers are evaluated and followed up on by the provider. If any recommendations arise from this process, the result is the patients QOL will improve while considering risk factors unique to that patient. System validation will include measuring the stated goals and objectives of the project.

Additionally, a user validation will be conducted to ensure that the user needs and requirements have been satisfied by the system design and implementation.

Finally, the implementation of the CDSS will be evaluated against the CDS Five Rights model stating that (AHRQ, n.d.):

- the “right information” must be presented
- to the “right person”
- in the “right CDS intervention format”
- through the “right channel”
- at the “right time in the workflow”

Discussion

There were three key assumptions made during the project. The first assumption is that patients will be willing to use the patient portal to enter the severity of their symptoms on a regular basis. The second assumption is that patients are technology literate and have access to a computer or mobile device. The third assumption is that clinical end users will find the system useful enough and easy enough to use, that they will be willing to use it. Although end users were involved in the design of the user interface, there is no guarantee of user adoption. Given these assumptions, a limitation of the CDSS is that it should be targeted to primary care practices that serve an educated, somewhat affluent patient population.

A major shortcoming of the model is that it depends on patients entering symptom severity information. A future improvement would be the integration of the CDSS with a body

area network (BAN) of sensors that can automatically sense symptom severity while the patient is sleeping and communicate the information to the system. Some of the sensor technology exists today, but other technology would need to be developed.

Another major shortcoming is that the CDDS does not provide specific recommendations for treatment, but rather provides focused information targeted to a specific patient, so that the physician has the information he needs to make treatment decisions. A randomized prospective double blind controlled trial (RCT) encompassing all the risk factors, the different therapies available, the time of initiation and duration of treatment, patient preferences, patient demographics etc. would be the most effective way to generate evidence for the CDSS. "Evidence based medicine is the process of systematically reviewing appraising and using clinical research findings to aid the delivery of optimal clinical care to patients (Hill. A., Spittlehouse, C., 2009)". The literature shows that EBM is used to provide the physician and patient information on HRT and menopause, yet as discussed earlier in the paper the process of determining the treatment for a particular patient is multifactorial and there is no RCT addressing all of these factors unique to each patient. Thus the CDSS will gather the data on best practices from these studies and use them as pieces of the puzzle to determine the best options for each individual patient. This shortcoming, however, could be an advantage when considering the medical and legal risks associated with CDSSs that recommend specific therapy.

A Proof of Concept system could be implemented and piloted. An area needing additional consideration is the integration of the knowledge sources and risk calculators with the system, and the effective presentation of that information to the user.

Appendix A

Coronary Artery Disease and Stroke Risk Assessment Tool

Age		
Gender		
Total cholesterol		
HDL		
Smoker		
Systolic Blood pressure		
Are you taking medication for BP		

Breast Cancer Risk Assessment Tool

Does the women have a medical history of any breast cancer	
What Is her age	
What was the women's age at the time of her 1st menstrual period	
What was the women's age at the time of her first live birth of a child	
How many of the women's 1st degree relatives (mother, sister, daughter) have had breast cancer	
Has the women ever had breast biopsy	
• How many breast Biopsies has the women had	

• Has the women had at least one breast biopsy with atypical hyperplasia?	
What is the women's race	
• What is the sub race /ethnicity	

QOL Assessment Tool

Utian Quality of Life Scale (UQOL)

Please rate the degree to which you agree with the following statements, as they apply to you *within the past month*. Be sure to *answer every question!* Please circle your answer using the following 5-point scale:

1 Not true of me	2	3 Moderately true of me	4	5 Very true of me

1. I am able to control things in my life that are important to me.	1	2	3	4	5
2. I feel challenged by my work.	1	2	3	4	5
3. I believe my work benefits society.	1	2	3	4	5
4. I am not content with my sexual life.	1	2	3	4	5
5. I am content with my romantic life.	1	2	3	4	5
6. I have gotten a lot of personal recognition in my community or at my job.	1	2	3	4	5
7. I am unhappy with my appearance.	1	2	3	4	5
8. My diet is not nutritionally sound.	1	2	3	4	5
9. I feel in control of my eating behavior.	1	2	3	4	5
10. Routinely, I engage in active exercise three or more times each week.	1	2	3	4	5
11. My mood is generally depressed.	1	2	3	4	5
12. I frequently experience anxiety.	1	2	3	4	5
13. Most things that happen to me are out of my control.	1	2	3	4	5
14. I am content with the frequency of my sexual interactions with a partner.	1	2	3	4	5
15. I currently experience physical discomfort or pain during sexual activity.	1	2	3	4	5
16. I believe I have no control over my physical health.	1	2	3	4	5
17. I am proud of my occupational accomplishments.	1	2	3	4	5
18. I consider my life stimulating.	1	2	3	4	5
19. I continue to set new personal goals for myself.	1	2	3	4	5
20. I expect that good things will happen in my life.	1	2	3	4	5
21. I feel physically well.	1	2	3	4	5
22. I feel physically fit.	1	2	3	4	5
23. I continue to set new professional goals for myself.	1	2	3	4	5

Utian Quality of Life Scale (UQOL) Scoring Summary

Instructions: Each of the four subscales of the UQOL is represented by a unique color, as shown below. Sum the circled responses by color and enter the sum in the scoring summary section at the bottom of the page.

1.	I am able to control things in my life that are important to me.	1	2	3	4	5
2.	I feel challenged by my work.	1	2	3	4	5
3.	I believe my work benefits society.	1	2	3	4	5
4.	I am not content with my sexual life.	5	4	3	2	1
5.	I am content with my romantic life.	1	2	3	4	5
6.	I have gotten a lot of personal recognition in my community or at my job.	1	2	3	4	5
7.	I am unhappy with my appearance.	5	4	3	2	1
8.	My diet is not nutritionally sound.	5	4	3	2	1
9.	I feel in control of my eating behavior.	1	2	3	4	5
10.	Routinely, I engage in active exercise three or more times each week.	1	2	3	4	5
11.	My mood is generally depressed.	5	4	3	2	1
12.	I frequently experience anxiety.	5	4	3	2	1
13.	Most things that happen to me are out of my control.	5	4	3	2	1
14.	I am content with the frequency of my sexual interactions with a partner.	1	2	3	4	5
15.	I currently experience physical discomfort or pain during sexual activity.	5	4	3	2	1
16.	I believe I have no control over my physical health.	5	4	3	2	1
17.	I am proud of my occupational accomplishments.	1	2	3	4	5
18.	I consider my life stimulating.	1	2	3	4	5
19.	I continue to set new personal goals for myself.	1	2	3	4	5
20.	I expect that good things will happen in my life.	1	2	3	4	5
21.	I feel physically well.	1	2	3	4	5
22.	I feel physically fit.	1	2	3	4	5
23.	I continue to set new professional goals for myself.	1	2	3	4	5

Scoring Summary

	Lower QoL -2SD	-1SD	Mean	+1SD	Higher QoL +2SD
Occupational QoL	13	19	25	31	35
Health QoL	11	16	21	26	31
Emotional QoL	12	16	20	24	28
Sexual QoL	0	4	8	12	15
Total QoL	48	61	74	87	100

Instructions: Means for each factor, along with standard deviations above and below the mean, are shown above. After summing each factor, mark with an "X" roughly where the patient's score falls along each continuum. These marks will provide a graphic summary of the patient's QOL score on each factor and for the scale as a whole.

Appendix B: Performance Measures

Performance Measures: Related to Data Collection from Patients

Phase 1 Registration

Number of patients given information to log onto patient portal
% of patients given information on patient portal who register within one week
Number of patients registered on patient portal
Number of patients who fill out history forms before appointment on pt portal
Number of triggers from history forms before patients appointment

Phase 2 Triggers Results

Number of interventions ordered as a result of trigger per week
% of patients who log onto portal who access info tabs per week
% of patients who update symptoms per week
Number of trigger alerts per week as a result of change in My Symptom Score/week

Phase 3 Follow up contact

Number of contacts per week, patients with trigger alerts
Number of contacts as a result of trigger with in 72 hours/week
Number of contacts as a result of trigger greater than 72 hours/week
Number of unsuccessful attempts to contact patient after trigger

Phase 4 Interventions

Number of interventions as a result of contact resulting from trigger/week(Intervention may include phone consult per RN or MD)
Number of treatment modifications as a result of triggers/week
% of patients who had contact whose symptom scores improved within 4 weeks
% of patients who had contact whose symptom scores remained unchanged within 4 weeks
% of patients who had contact whose symptom scores declined with in 4 weeks

Measures related to data obtained and accessed from the CDSS

Number of logons to CDSS per week by MD
Number of interventions recommendation considered from CDSS
Number of times MD access HRT database resources
% of care plans developed/ # of patients entered into CDSS

References

AHRQ, (n.d.), Approaching Clinical Decision Support in Medication Management, http://healthit.ahrq.gov/images/mar09_cds_book_chapter/CDS_MedMgmnt_ch_1_sec_2_five_rights.htm

Barrett-Connor, E., & Stuenkel, C. A. (2001). Hormone Replacmetn Therapy (HRT): Risk and Benefits. *Innternational Journal of Epidemeiology , 30* (3), 423-426.

Christianne L. Roumie, M., Eric L. Grogan, M., William Falbe, P., Joseph Awad, M., Theodore Speroff, P., Robert S. Dittus, M. M., et al. (2004). A Three-Part Intervention To Change the Use of Hormone Replacement Therapy in Response to New Evidence. *Annals of Internal Medicine , 141* (2).

E Løkkegaard, A. T. (2003). Relation between hormone replacement therapy and ischaemic heart disease in women: prospective observational study. *BMJ , 326* (22).

Evidence Based Medicine Interventions. (n.d.), Institute of Medicine. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century Released:.* Consensus.

Hill. A., Spittlehouse, C., (2009). What is Critical Appraisal: Evidence Based Medicine. http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/What_is_critical_appraisal.pdf

Keating, N., Cleary, P., & Wells, G. (19999). Use of Hormone Replacement Therapy by Postmenopausal Women in the United States. *Annals of Internal Medicine , 130* (7).

Lorenzi, N., & Riley, R. T. (2000). Managing Change: An Overview. *JAMIA , 7*, 116-124.

Machens, K., & Schmidt-Gollwitzer, K. (2003). Issues to debate on the Womenn's Health Initiaitve (WHI) study. Hormone replacment therapy: and Epidemiological dilemma? *Human Reproduction , 10*, 1992-9.

National Cancer Institute. (n.d.). *Breast Cancer Risk Assessment Tool.* Retrieved 5 2012, from http://www.cancer.gov.bcrisktool/.

NIH. (n.d.). *The Heart Truth - Lower Heart Disease Risk Menopausal Hormone Therapy and Heart Disease*. Retrieved 5 2012, from http://www.nhlbi.nih.gov/educational/hearttruth/lower-risk/hormone-therapy.htm

O'Connor, A., & Wells, G. (1998). A Decision Aid for Women Considering Hormone Therapy after Menopause:Decision Support Framework and Evaluation. *Elsevier Patient Education and Counseling , 33*, 267-279.

Osheroff, J. A. *Improving Outcomes with Clinical Decision Support: An Implementer's Guide.* Chicago, Il: HIMSS.

Rookus, M. A., & Van Leeuwen, F. E. (2003). Breast Cancer and hormone-replacement Therapy :The Million Women Study. *The Lancet , 362* (9392), 1330.

Rossouw JE, A. G. (2002). Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results From the Women's Health Initiative randomized controlled trial. *JAMA , 288* (3), 311-33.

U.S. Preventive Services Task Force. (2002). Postmenopausal Hormone Replacemetn Therapy For Primary Prevention of Chronic COnditions: Recommendations and Rational. *Annals of Internal Medicine , 137* (10).

Utian, W. H., Ianata, J. W., Kingsberg, S. A., Schluchter, M., & Hamilton, J. C. (2002). The Utian Quality of Life (UQOL) Scale: Development and Validation of an instrument to quantify quality of through and beyond menopause. *Menopause , 9* (6), 402-410.