Implementation Stages

Pre-Implementation	Implementation	Post-Implementation
• **Identify current practice patterns**	• Assess implementation integrity (used as intended)	• Assess acceptance and satisfaction for stakeholders
• **Identify barriers & facilitators**	• Assess implementation exposure (used at intervention sites)	• Assess clinical impact for all stakeholders
• **Assess feasibility**	• Identify explanations and solutions for low integrity or intensity	• Adapt and finalize implementation strategy
• **Establish implementation plan**	• Modify implementation plan	• Assess impact of final implementation strategy

Adapted from Smith J, editor. Evaluation Methods in Implementation Research: An introduction. Implementation Science Meeting; 2010.

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Implementation Outcomes

Outcomes	Measure	Source
Model Reach	Representativeness of patient population to general population	Recruitment data (# enrolling / # invited); SES and demographics compared to overall population; compare across clinical settings and institutions
Effectiveness	see Domains of Measures and Outcomes Table	
Model Adoption	Representativeness of clinics agreeing to participate	Recruitment data on clinic settings and characteristics as compared to general clinic settings at the institution; % of providers opting out and their characteristics compared to overall provider population in the clinics; formative evaluations on reasons for opting out
Implementation Integrity	% time intervention used as intended	Formative evaluations, study coordinator tracking patient through steps in the model (ex. MeTree™ ™ log-in vs completion), adaptations to the model, patient and provider FAQs derived during implementation, % time providers review CDS output
Implementation Exposure	% time intervention used	Formative evaluations, study coordinator tracking patient through steps of the model
Maintenance and Sustainability	Cost to Implement Cost/Effectiveness	• EHR Administrative data for utilization • Formative evaluations (clinic resource needs, successful elements for each setting, factors association with long-term adoption or not), • % adoption at study end • costs/disease prevented, early stage detected, or visits avoided

Pre-implementation Steps

SITES

- Clinic data collection forms
- Site physician and IT champions
- Site visits
- IRB approval
- Qualitative interviews
- ORCA survey

MANAGEMENT

- Coordinating Center
- Educational Materials
- Patient portal
- Coordinator portal
- IRB approval
- Data Use Agreements

Sites continued

- Clinic data collection forms
    - Demographics to monitor recruitment compared to baseline clinic pop
    - Adjust for implementation and effectiveness outcomes

- Site Visits (Goals)
    - Review study flow, recruitment, and monitoring
    - Discuss Provider preparation
    - Obtain buy-in from clinics and administrators
    - Informal interviews of clinic staff and administrators to gather details about each clinic environment
    - Identify key barriers to implementation and develop solutions
    - Work with IT to establish an initial report-EMR integration plan
    - Completing study regulatory materials

Sites continued

- IRB approval
  - Duke, Essentia approved
  - MCW one hospital approved, second hospital pending
  - Air Force pending

- Qualitative interviews
  - 20 minutes long
  - Every clinic: 1 provider champion, scheduler, administrator & nurse
  - Implementation measures related to environment and staff
  - Taped and transcribed

- Organizational Readiness to Change Survey (ORCA)
  - All providers, nurses, and administrators at every clinic
  - Electronically administered through Qualtrix

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