



DEVELOPING A HIGH RISK BREAST PROGRAM

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ACE Webinar
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**association of
cancer
executives**

Connecting All
Oncology Leaders

AGENDA

- Imperative for a High Risk Women's Program (HRWP)
- Defining the HRWP Model/Continuum
- Identifying and Navigating the High Risk Patient
- Genetic Counseling Considerations
- High Risk Management/Clinic Considerations
- Leveraging Technology
- Program Planning

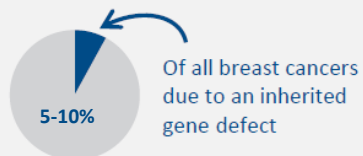
WHY IS A HIGH RISK BREAST PROGRAM IMPORTANT?

Problem Magnitude



1.2M Women in US with a history of breast or ovarian cancer still need to be tested

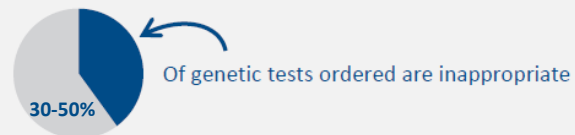
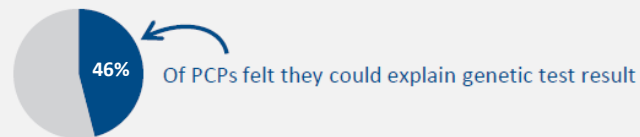
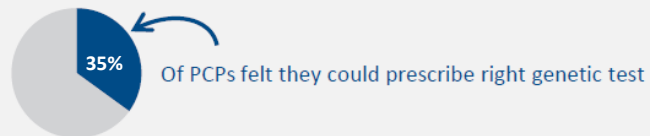
10.7M High risk women in US without a history of breast or ovarian cancer, but still need to be tested



Problem Ownership

- PCP's time and processes inadequate
- PCPs often not comfortable managing high risk patient

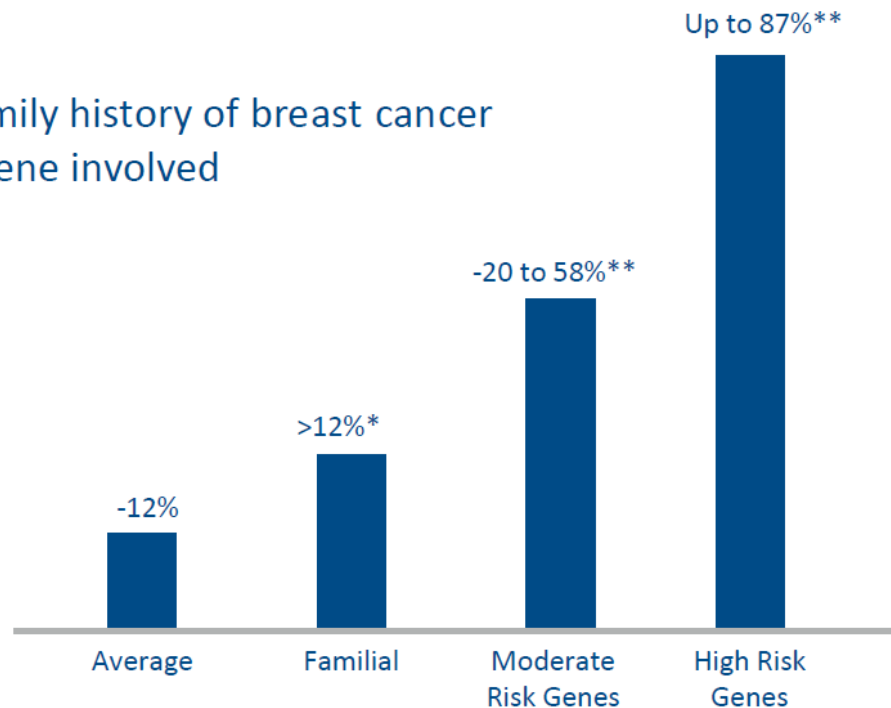
One study showed:



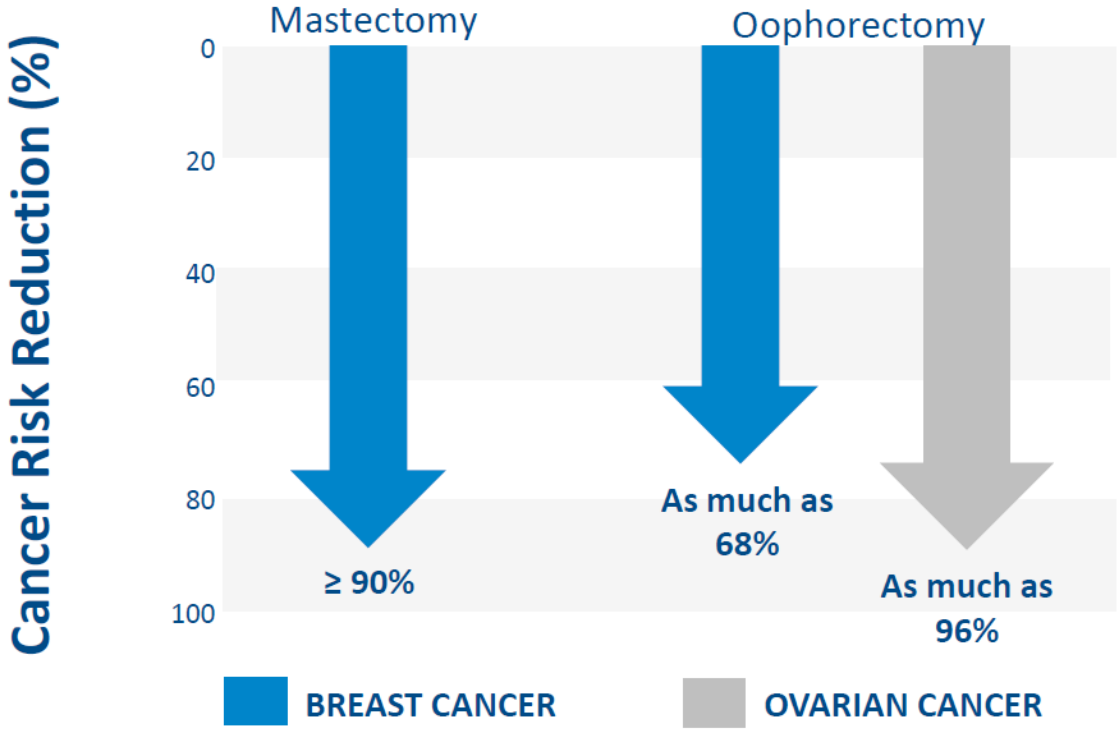
GENETIC SYNDROMES CREATE HIGHER RISK

* Specific level of risk depends on the family history of breast cancer

** Specific level of risk depends on the gene involved



IDENTIFYING RISK SAVE LIVES



BENEFITS OF PROGRAM

Patients and Providers

Preventing cancers saves lives and cost

Cancer cost avoidance avg >\$100,000 pp

Patients and providers educated about risks and recommendations

Patients tracked/navigated along continuum

Patient's care coordinated with trained providers

Program instills PCP's confidence that patients are receiving comprehensive, collaborative, multidisciplinary care



Health System

Increased volumes w/supplemental screenings, visits, interventions

Associated increased revenue

Reduction in leakage – due to navigation and genetic counseling

Opportunity to differentiate program in market

Enhanced relationships with referring providers

Ability to meet NAPBC and CoC genetics standard

BARRIERS



Woman's reluctance to engage in high risk screening



Referring physician's reluctance to support the program



Physician's perception of loss of patient volumes or control



Protocols and standards that may not be covered by insurance



Lack of IT solutions to support very manual processes



Inability to acquire genetic professionals



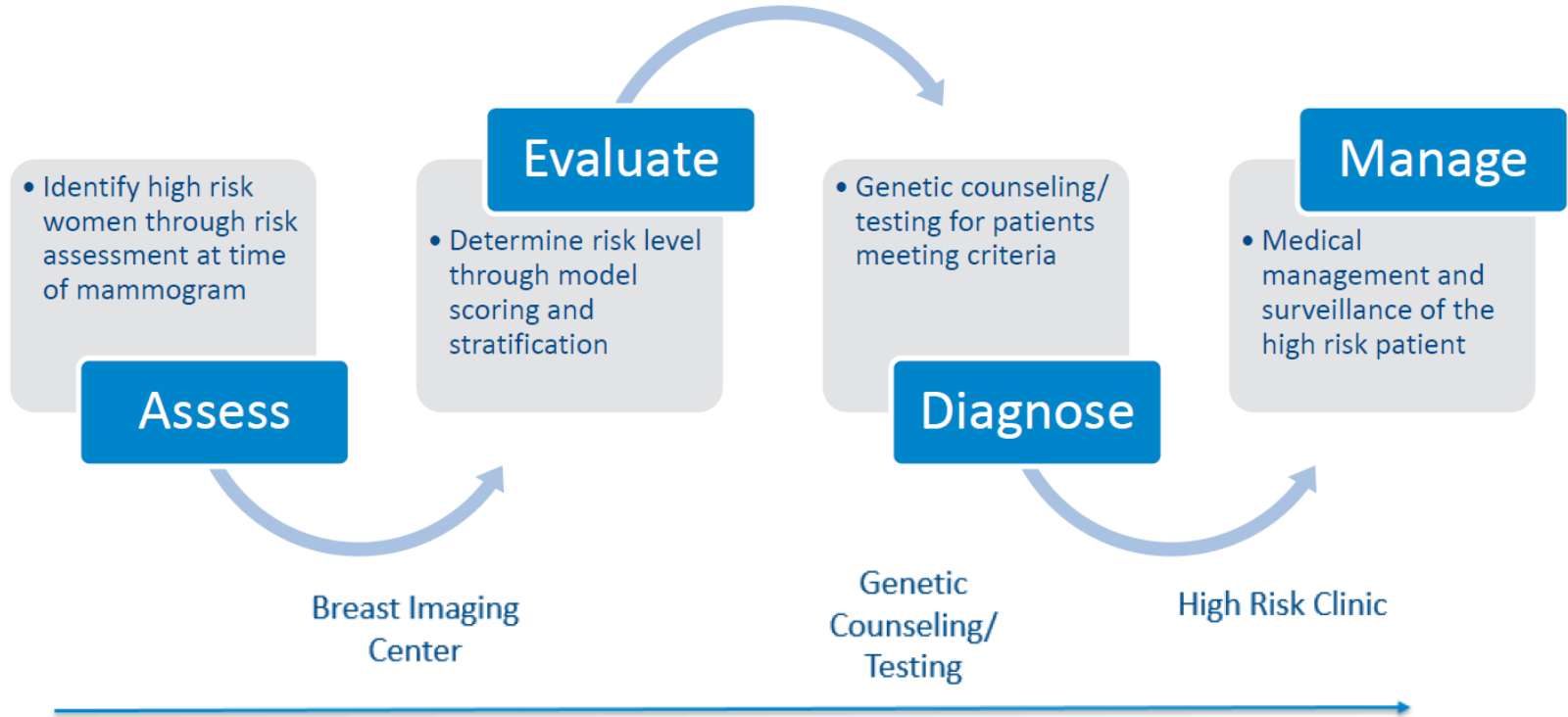
Lack of collaboration



Lack of program "ownership"

HRWP CONTINUUM

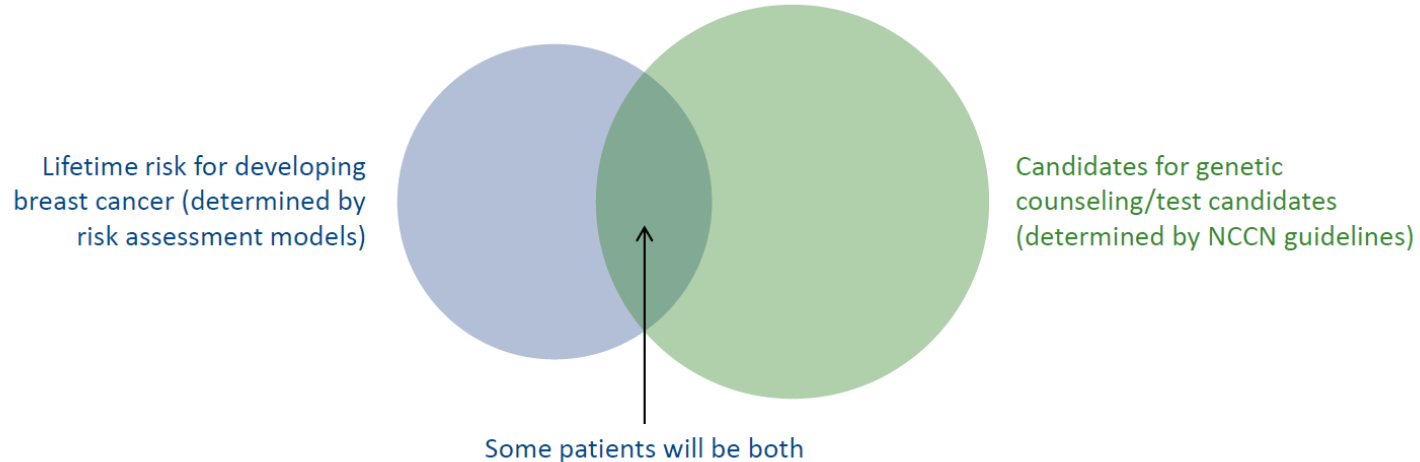
CONTINUUM OF CARE WILL DETERMINE PROGRAM MODEL/SERVICES OFFERED



IDENTIFYING THE HIGH RISK PATIENT

TWO SEPARATE CLINICAL ISSUES

- To identify women with increased 5yr/lifetime risk of breast cancer
- To identify meeting criteria for genetic evaluation



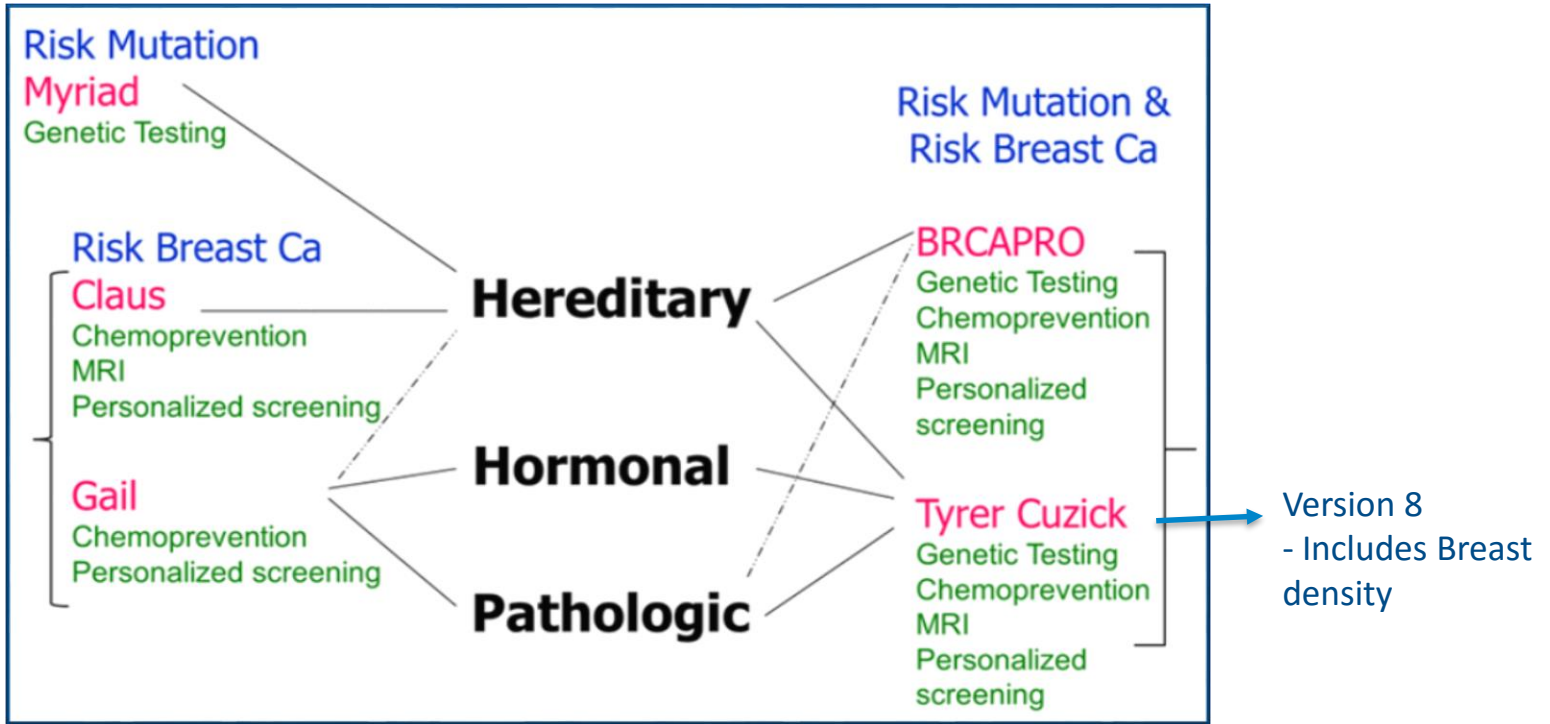


THERE ARE A NUMBER OF FACTORS ASSOCIATED WITH INCREASED RISK FOR BREAST CANCER

- Age
- Gender
- Race & Ethnicity
- Age at menarche (first period)
- Age at birth of first child
- Age at menopause
- Use of hormone replacement therapy
- High risk breast lesions
- Number of biopsies, even if benign
- DES exposure
- Radiation to the chest during childhood
- Family history
- Genetic mutations
- Breast Density
- Obesity
- Sedentary Lifestyle
- Alcohol
- Smoking



CHOOSING RISK MODELS/GUIDELINES TO USE

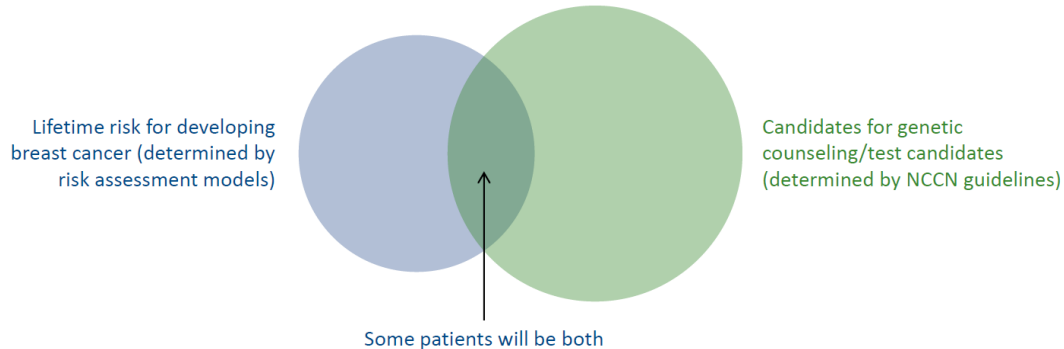


MAJOR CATEGORIES OF BREAST CANCER RISK



SARAH CANNON RISK MODELS

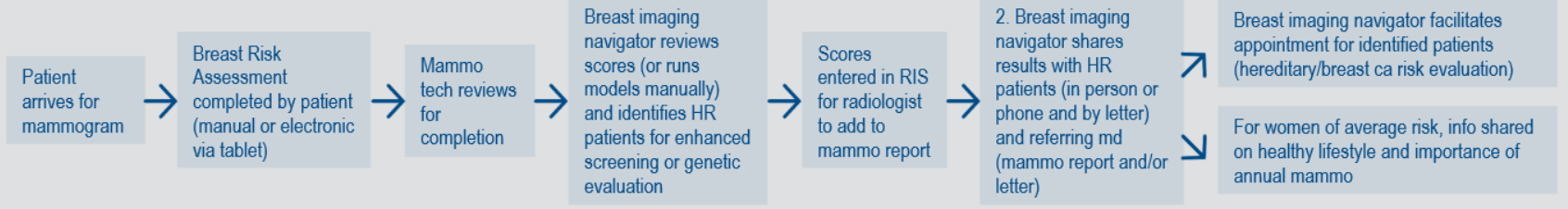
- **To identify lifetime risk of breast cancer** – Tyrer-Cuzick 8 (takes into account breast density)
- **To identify women for chemoprevention** – Gail model
- **To identify need for genetic counseling/testing** – NCCN guidelines



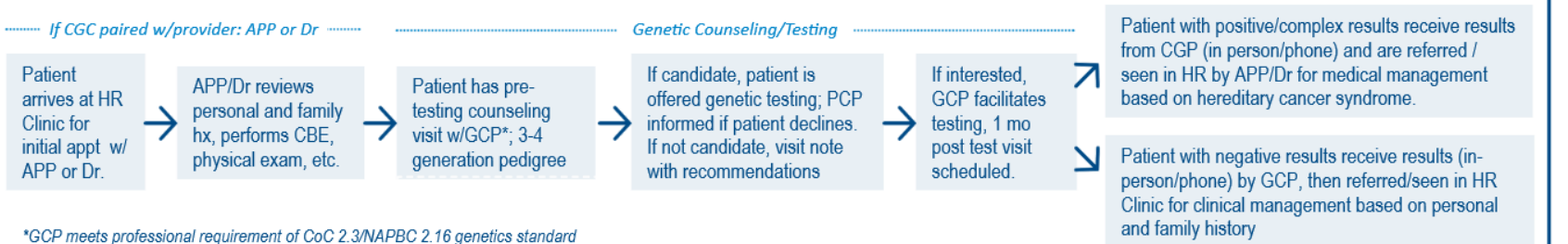
LEVERAGING TECHNOLOGY

LEVERAGING TECHNOLOGY – MANY COMPLICATED/MANUAL PROCESSES

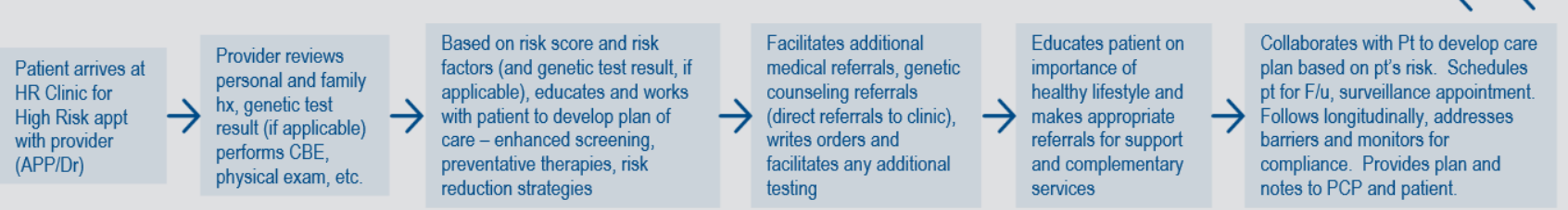
RISK ASSESSMENT - BREAST IMAGING CENTER



HIGH RISK - HEREDITARY RISK - GENETIC COUNSELING/TESTING



HIGH RISK CLINIC – HIGH RISK MANAGEMENT



COMPREHENSIVE CANCER RISK ASSESSMENT AND MANAGEMENT SOLUTIONS

- Supports all processes across the continuum
 - Risk assessment and running validated models
 - Scoring/Stratification
 - Intervention recommendations
 - Navigation
 - Genetic evaluation/testing – Pedigree mapping
 - Risk management and surveillance
 - Customizable patient and provider communications
 - Report generation

- Examples: CancerIQ, CRA Health (Hughes Risk), perhaps others

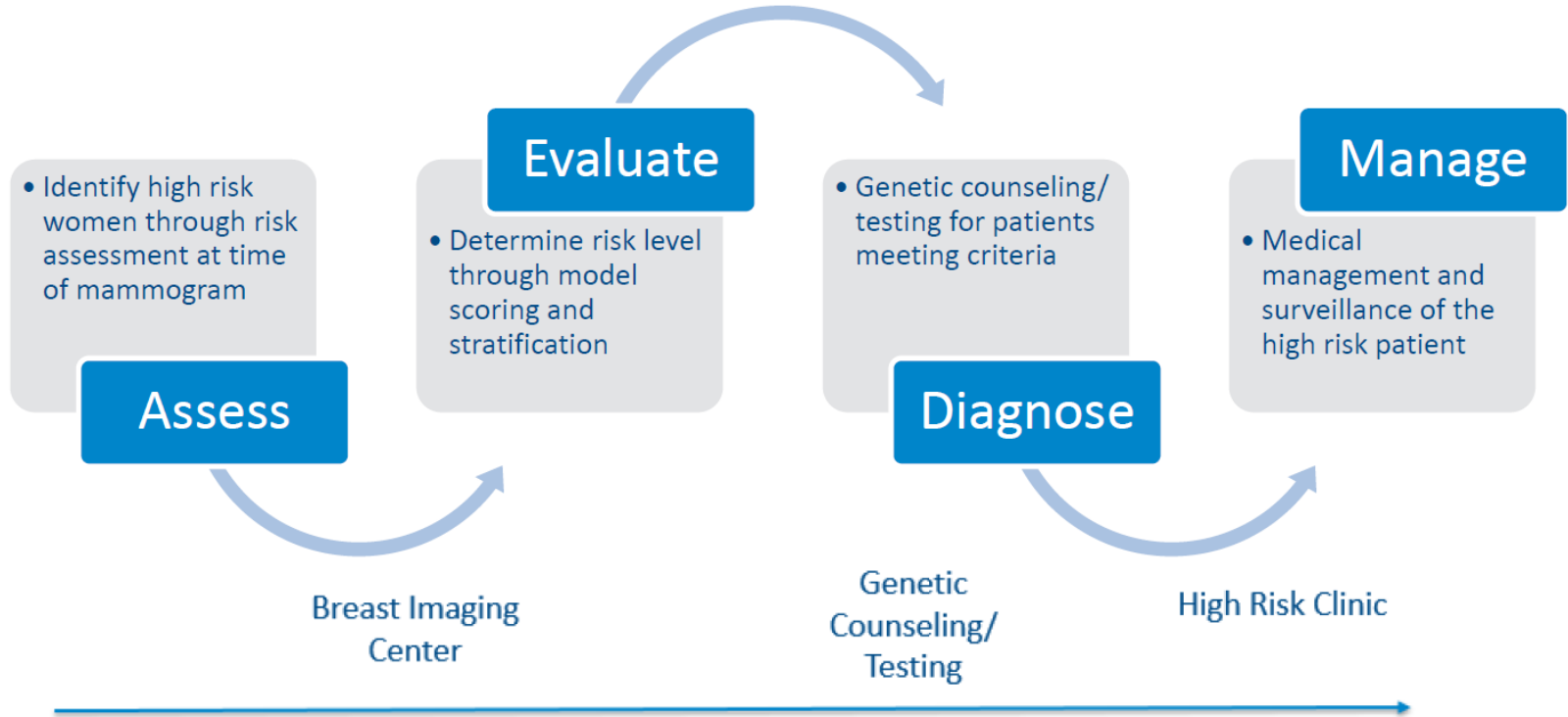
IT SOLUTIONS TO SUPPORT THE PROGRAM

- **At a minimum, ensure your mammography information system supports processes in breast imaging center:**
 - Automatic intake of patient personal and family history
 - Automatic running of selected risk models (and versions) and stratifying according to risk
 - Generation of high risk worklist for patient management and referral
 - Customization of mammography report to include risk information and recommendations



NAVIGATING THE HIGH RISK PATIENT

CONTINUUM OF CARE – LOTS OF OPPORTUNITIES FOR FRAGMENTATION



CRITICAL ROLE – BREAST IMAGING NAVIGATOR/COORDINATOR

Breast Imaging Coordinators/Navigators are...

- Breast imaging professionals
- Advocates
- Educators
- Liaisons/care coordinators
- Strategic relationship builders
- Champions for the High Risk Program

The BIC/N is a critical member of the multidisciplinary team:

- Ensures patients have access to imaging and high risk support services
- Encourages patient adherence to personalized treatment plans

BIC/N roles may vary based on facility, services and existing resources



PROGRAM IMPACT OF THE BIC/N

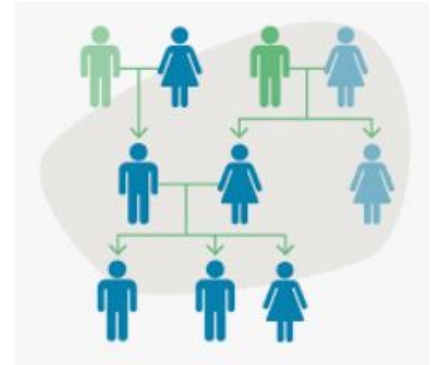
- Increase compliance for imaging and biopsy follow-up
- Improve communication with referring providers
- Streamline process for hand-off to oncology navigation team
- Improve efficiency
- Identify meaningful quality metrics, leading to improvements in continual quality improvement program
- Improve customer satisfaction and loyalty



GENETIC COUNSELING/TESTING CONSIDERATIONS

PRIMARY COMPONENTS OF GENETIC COUNSELING/TESTING PROCESS

- Risk assessment
- Pre-test counseling
- Testing to include selecting the most appropriate and cost-effective test for the patient and their family and ordering test through a high quality lab.
- Post-test counseling with results disclosure



GENETICS PROFESSIONAL – PROVIDER MODEL

CoC/NAPBC Genetics Professional Education/Training Criteria

- An American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics (ABMG) board-certified/ board-eligible and (in some states) a licensed genetic counselor
- An American College of Medical Genetics (ABMG) physician/PhD board-certified/board-eligible in clinical or medical genetics
- A Genetics Clinical Nurse (GCN), an Advanced Practice Nurse in Genetics (APNG), or an Advanced Genetics Nursing-Board Certified (AGN-BC) credentialed through the American Nurses Credential Center (ANCC)
- An advanced practice oncology nurse or Physician Assistant who is prepared at the graduate level (master or doctorate) with specialized education in cancer genetics and hereditary cancer predisposition syndromes; certification by the Oncology Nursing Certification Corporation is preferred
- A board-certified/board-eligible physician with experience in cancer genetics (defined as providing cancer risk assessment on a regular basis) employing a model that includes both pretest and posttest counseling.

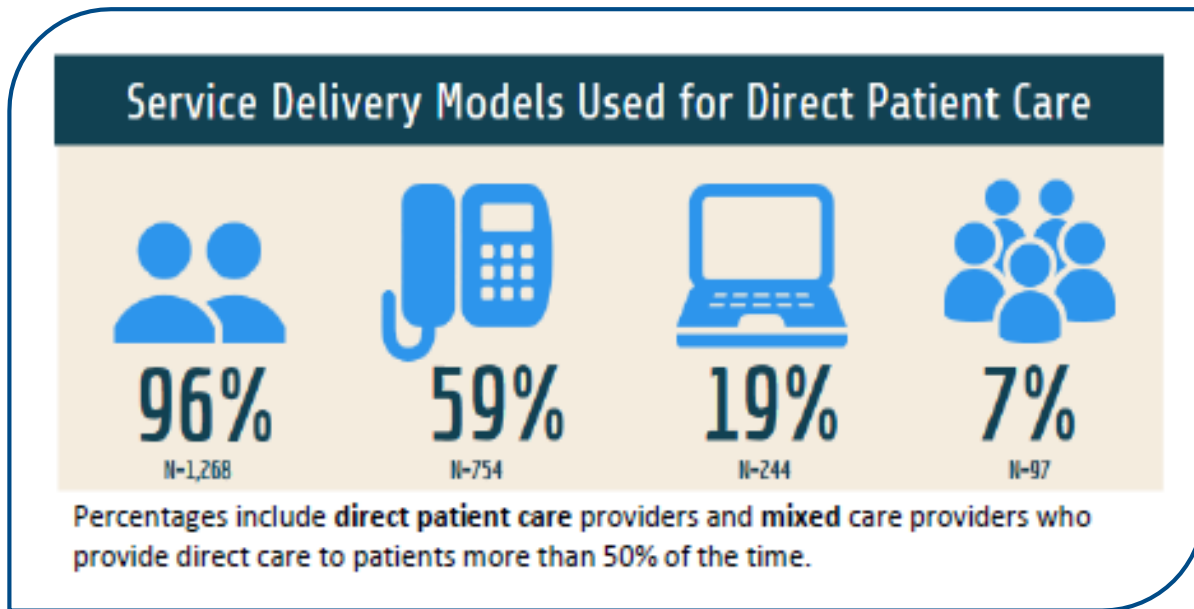


CERTIFIED GENETIC COUNSELOR RESOURCING OPTIONS

- Employ
 - High demand/Supply low, but many new training programs
- Contract locally
- Contract remotely with Genetic Counselor Extender model
 - Uses RNs/APNs with genetics training to partner with remote CGC
- Contract through genetic counseling staffing company
- Access via genetic labs – **only** tele-education, not full counseling

- *There are pros/cons of each*

SERVICE DELIVERY MODELS

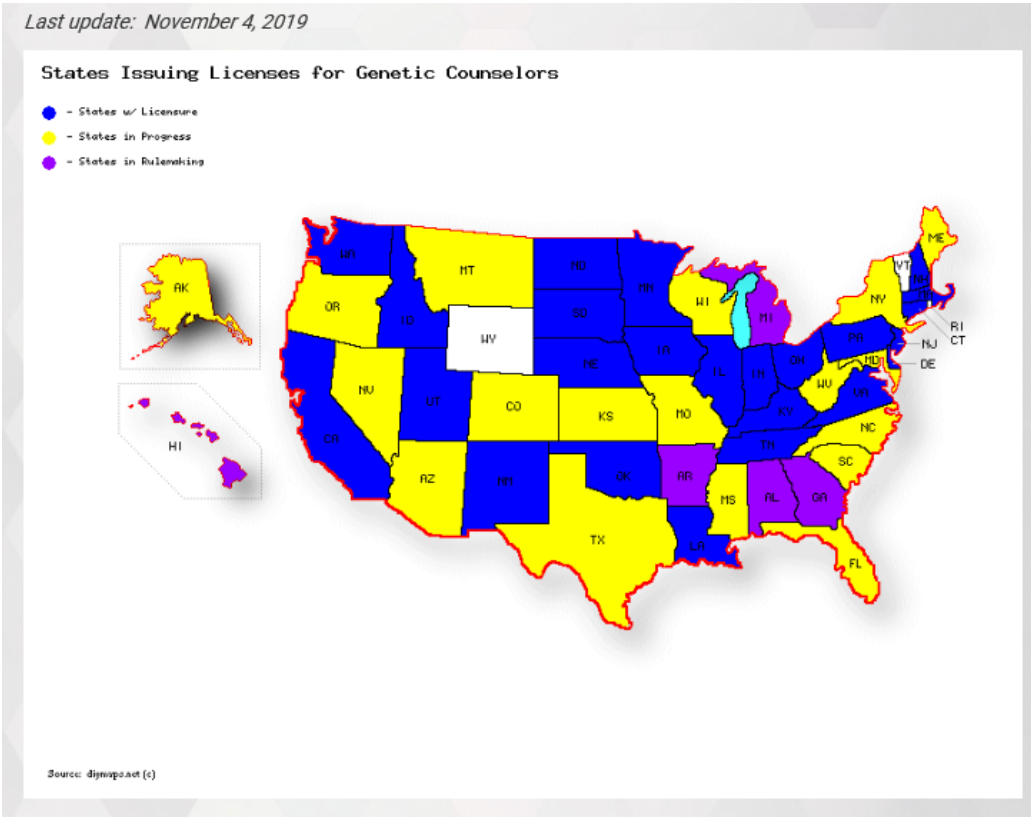


REIMBURSEMENT MAY INFLUENCE PRACTITIONER AND SERVICE DELIVERY MODELS

Genetic Counseling Provider(s)	Patient Insurance Status	Billing Method
Genetic counseling by certified genetic counselor (CGC) –	Commercial (Private)	CPT 96040, billed 1 unit for each 30 min of face to face counseling time with pt/family
	Medicare	Medicare does not recognize CGCs as providers, does not recognize CPT 96040 - E & M codes “incident to” (99XXX codes, depending on level of visit and new or established pt)
	Medicaid	Medicaid coverage is state-dependent
	Uninsured, uncovered benefit, others	Self-Pay
	<ul style="list-style-type: none"> Telephone-based: According to the National Society of Genetic Counselors, most commercial insurers are reimbursing 96040 for telephonic genetic counseling services. Check with your insurers. Check with your state Medicaid program for telephonic GC services for Medicaid patients. <ul style="list-style-type: none"> Telephone/online medical evaluation codes provided by non-physician health care professional; 98966-98969. There are a number of exclusions in using this code and many payers may not reimburse. Check with your local compliance department. Telehealth (Video-based): Telehealth for genetic counseling is currently not recognized by Medicare, even with a GT modifier. Telehealth services may be covered by Medicaid if the service location is considered rural. Check with your state Medicaid Program. 	
		<ul style="list-style-type: none"> Group Counseling: 98961-98962; For group genetic counseling
Genetic counseling by qualified APP or Physician	All Patients	E & M codes (99- codes, depending on new or established pt)

MANY STATES NOW REQUIRE LICENSURE FOR GENETIC COUNSELING

- 22 states require licensure
- 5 have passed bills and are in rule-making
- NSGC currently working with some congressional representatives on federal legislation to recognize CGCs as Medicare providers



GENETIC COUNSELING REFERRAL MODEL MAY INFLUENCE PATIENT FOLLOW THROUGH

Model	Description	% of patients referred seen by genetic counselor
Referral Model	Interested high risk patients leave screening center. A genetic specialist calls to schedule appointment with genetic counselor	8%
Point of Care Scheduling	Screening center facilitates the scheduling of appointment with genetic counselor before interested high risk patient leaves center	18%
Point of Care Counseling	Screening center provides interested high risk patient option for immediate access to genetic counselor prior to leaving center. If unable to stay, an appointment is scheduled	49%

Source: CancerIQ Observational Study. Intro to Genetic Cancer Risk Assessment Implementation

HIGH RISK MANAGEMENT/CLINIC CONSIDERATIONS

HIGH RISK MANAGEMENT/CLINIC SERVICE DELIVERY MODELS



“Bricks and Mortar”

- Designated clinic space
- Provides one-stop shop for high risk services
- Includes genetic counselor, NP/Physician
- Ideally co-located with Breast Center
- May designate Multidisciplinary High Risk Clinic Days
- Will often require administrative support
- May provide support services such as preventative education, smoking cessation, nutritional counseling, healthy lifestyle counseling, high risk support group
- Evolution from High Risk *Breast* Clinic to High Risk *Cancer* Clinic



“Virtual”

- Genetic counselors and high risk providers reside in different locations
- Patient coordination is key
- Process of identifying, navigating, referring and managing high risk patient well defined
- May increase fragmentation and duplication of services
- NP embedded in physician practice

FACTORS THAT MAY INFLUENCE HIGH RISK CLINIC MODEL

- **Local high risk services currently being provided** – is there partnership potential, or will the program compete?
- **Education/training of local providers** – is there CoC/NAPBC qualified practitioner or will one need to be recruited? Is there one available remotely?
- **Specialty of the physician champion/identified supervising physician** – will the NP be supervised by/paired with a breast surgeon, medical oncologist or PCP/OB-Gyn?
- **Space** - Is designated clinic space available or able to be built out?
- **Reimbursement**

HIGH RISK CLINIC PROVIDER MODELS

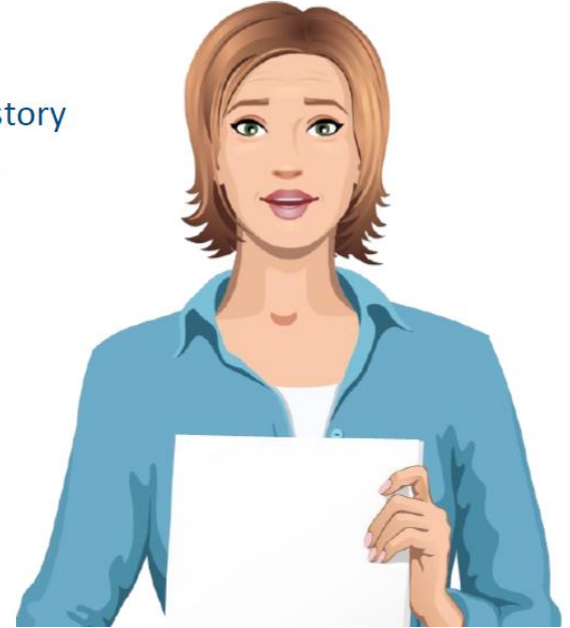
- Very dependent on providers and level of expertise available
- Ideally, a collaborative, multidisciplinary team of genetic counselor, nurse practitioner and supervising or attending physician(s).
 - Allows all practitioners to work at highest level of licensure
 - Ensures better access for patients – each provider has primary roles
 - Provides more streamlined hand-off for patients needing additional medical management or risk reduction services.



TYPICAL HIGH RISK CLINIC VISIT ACTIVITIES

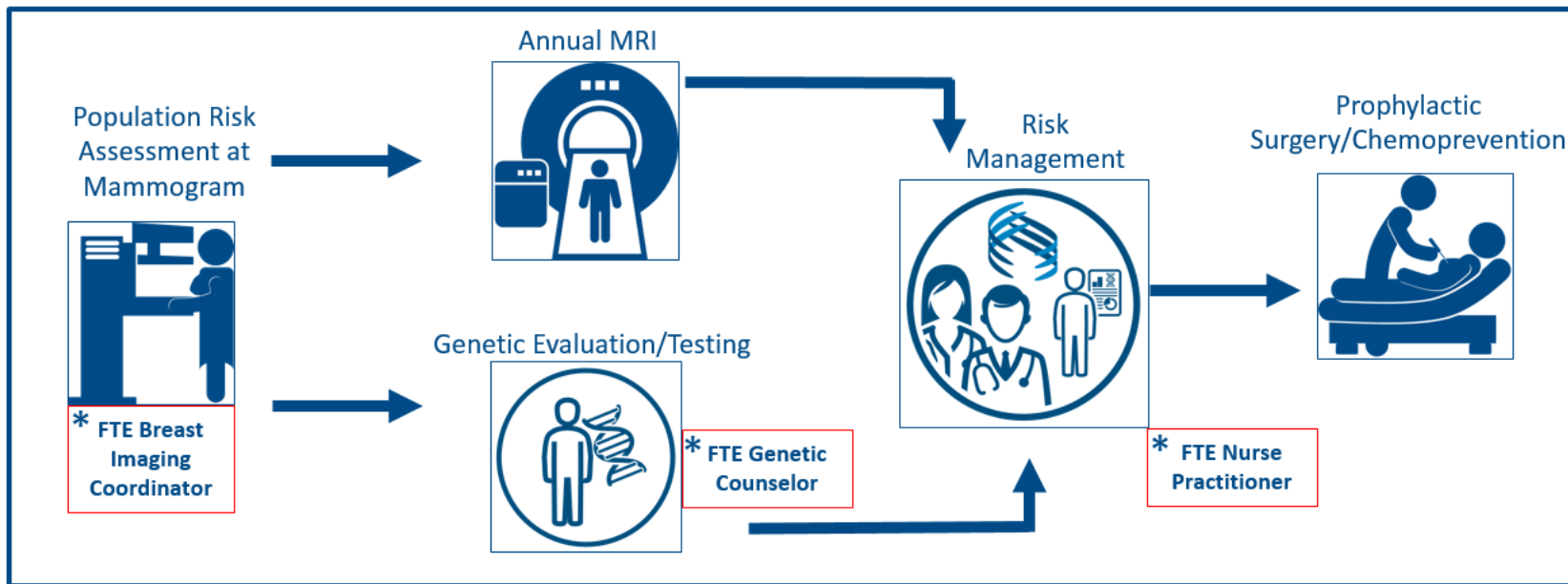


- Making appropriate referrals (including GC)
- TC, Gail, NCCN risk assessments
- Provide educational handouts
- Patient interview with detailed history
- Lifestyle modifications counseling
- Discuss intervention options
- Clinical breast/lymph node exam



BUSINESS CASE PLANNING

KEY INVESTMENTS/RESOURCES ACROSS THE CONTINUUM



IT Solution to Support Across Continuum

*Does not include any required administrative resources

PROJECTING RETURN ON INVESTMENT

Est. Operating Expenses

Staffing

FTE Breast Imaging Coordinator	\$
FTE Genetic Counselor	\$
FTE Nurse Practitioner	\$

Total

Information Technology

Comprehensive IT Solution	\$
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Total Annual Operating Expenses \$

Assumptions

Costs

- Assumes additional FTEs needed

Volumes/Revenues

- Assumes Use of Tyrer-Cuzick V 7 or 8
- Assumes use of NCCN Guidelines
(Genetic Evaluation)

10,000 Screening Mammograms
Estimate 20% will be “High Risk”**

Procedure	Estimated Eligible	Adoption Rate	Annual Volume	Net Revenue
Breast MRI	1500 (15%)			
Genetic Consults	2000 (20%)			
Prophylactic Mastectomy	20 (0.2%)			
Prophylactic BSO/Hysterectomy	20 (0.2%)			
Diagnostic F/u	110 (1.1%)			
Diagnostic BX	11 (0.11%)			
Net Revenue				
Less Operating Expenses				
Net Income				

KEY PERFORMANCE METRICS ACROSS CONTINUUM

Risk Assessment at Screening Mammography



KEY METRICS

- % of screening mammography patients completing risk assessment
- % of screening mammography patients consenting for HRWP Outcomes Study

MEASURES

- # of screening mammography patients
- # of screening mammography patients completing risk assessment
- # of screening mammography patients consenting for HRWP Outcomes Study

Supplemental Screening



KEY METRICS

- % of screening mammography patients with lifetime risk $\geq 20\%$
- % of patients in whom breast MRI screening is recommended
- % of patients who complete breast MRI and revenue

MEASURES

- # of screening mammography patients with lifetime risk $\geq 20\%$ (TC)
- # of above patients in whom breast MRI screening is included as a recommendation on the mammography report
- # of screening mammography patients with lifetime risk $\geq 20\%$ that complete breast MRI exam within 15 months
- Revenue from above MRI exams

Genetic Evaluation/ Testing



KEY METRICS

- % of screening mammography patients who are genetic counseling (GC) candidates
- % of patients in whom GC is recommended
- % of patients who complete GC

MEASURES

- # of screening mammography patients meeting NCCN criteria for GC
- # of above patients in whom GC is included as a recommendation on the mammography report
- # of screening mammography patients who are GC candidates that complete the GC visit at the center within 15 months

High Risk Consultation



KEY METRICS

- % of screening mammography patients identified as "high risk"
- % of patients in whom a high risk (HR) consult is recommended
- % of patients who complete a HR consult

MEASURES

- # of screening mammography patients that are "high risk" (in one or more of the following categories: $\geq 20\%$ TC lifetime risk, GC candidate, $\geq 2\%$ 5 year Gail risk)
- # of above patients in whom a HR consult is included as a recommendation on the mammography report
- # of "high risk" screening mammography patients that complete initial HR consult at the center within 15 months

Prophylactic Surgery/ Chemoprevention



KEY METRICS

- % of patients compliant with chemoprevention
- % of patients compliant with breast surgical consult
- % of patients compliant with GYN surgical consult

MEASURES

- # of "high risk" patients that are prescribed chemoprevention
- # of above patients that comply with chemoprevention
- # of "high risk" patients that are referred for breast surgical consult
- # of above patients that complete breast surgical consult
- # of "high risk" patients that are referred for GYN surgical consult
- # of above patients that complete GYN surgical consult

HRBP Program



- Program must achieve a minimum of "Core" level HRWP Center of Excellence
- Data related to patient experience, satisfaction, stress levels (to be included in HRWP outcomes study)

STEPS FOR DESIGNING YOUR HRBP

- ✓ Identify executive sponsor
- ✓ Identify physician champion – consider med onc or breast surgeon who will serve as supervising physician for APP
- ✓ Identify additional key stakeholders and form HRBP Workgroup– be sure to include primary care/OB-GYN!
- ✓ Define your ideal state for HRBP
- ✓ Identify what high risk services currently being provided and by whom – leverage partnerships
- ✓ Hold facilitated process mapping session to identify gaps and variances
- ✓ Perform SWOT analysis on current program and prioritize where to start
- ✓ Determine scope of services to provide and resources needed to provide them
- ✓ Determine risk assessment tool, risk model(s), clinical guidelines and protocols to use
- ✓ If possible, acquire comprehensive cancer risk assessment and management IT solution
- ✓ Map out workflow in breast imaging center
- ✓ Determine genetic counseling practitioner model and service delivery model and referral process
- ✓ Determine high risk management/clinic provider model and service delivery model and referral process
- ✓ Develop and provide community, patient and provider education and marketing
- ✓ Collect and report data to demonstrate program success and allow for continuous improvement

“To identify a woman as a carrier only after she develops cancer is a failure of cancer prevention”

- Mary-Claire King, PhD
(American Geneticist)



THANK YOU

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