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# DEVELOPING A HIGH RISK WOMEN'S PROGRAM

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**No Disclosures**

Association of Cancer Executive 25th Annual Meeting, January 27, 2019

## AGENDA

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

## SARAH CANNON PROGRAM GOAL

*To develop a program using evidence-based pathways for identifying women who are at increased risk for cancer, then providing personalized management, risk reduction and surveillance.*

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# IMPERATIVE FOR A HIGH RISK WOMEN'S PROGRAM (HRWP)

## MAGNITUDE OF PROBLEM

| | |
|---|---|
| 1st | Breast CA most common cancer in the US |
| 2nd | 2nd leading cause of cancer deaths among women |
| 15-20% | Of all breast cancers associated with a family history |
| 5-10% | Of all breast cancers due to an inherited gene defect |
| 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 |
| 90% | Of women in the US needing testing have yet to be identified |

## OWNERSHIP OF PROBLEM

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

| | |
|---|---|
| 35% | Of PCPs felt they could prescribe right genetic test |
| 46% | Of PCPs felt they could explain genetic test result |
| 30-50% | Of genetic tests ordered are inappropriate |

Source: http://informeddna.com/research/117-genetic-counseling-connecting-patients-to-the-power-of; Oncology Roundtable interviews and analysis.

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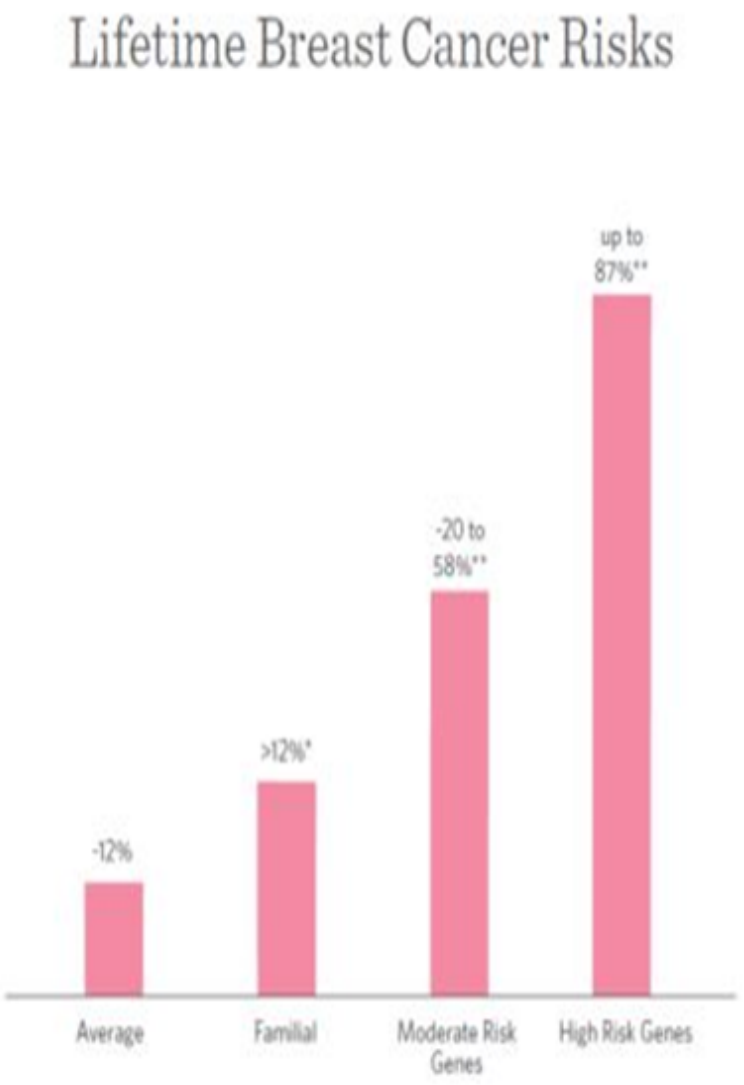
## IDENTIFYING GENETIC RISK

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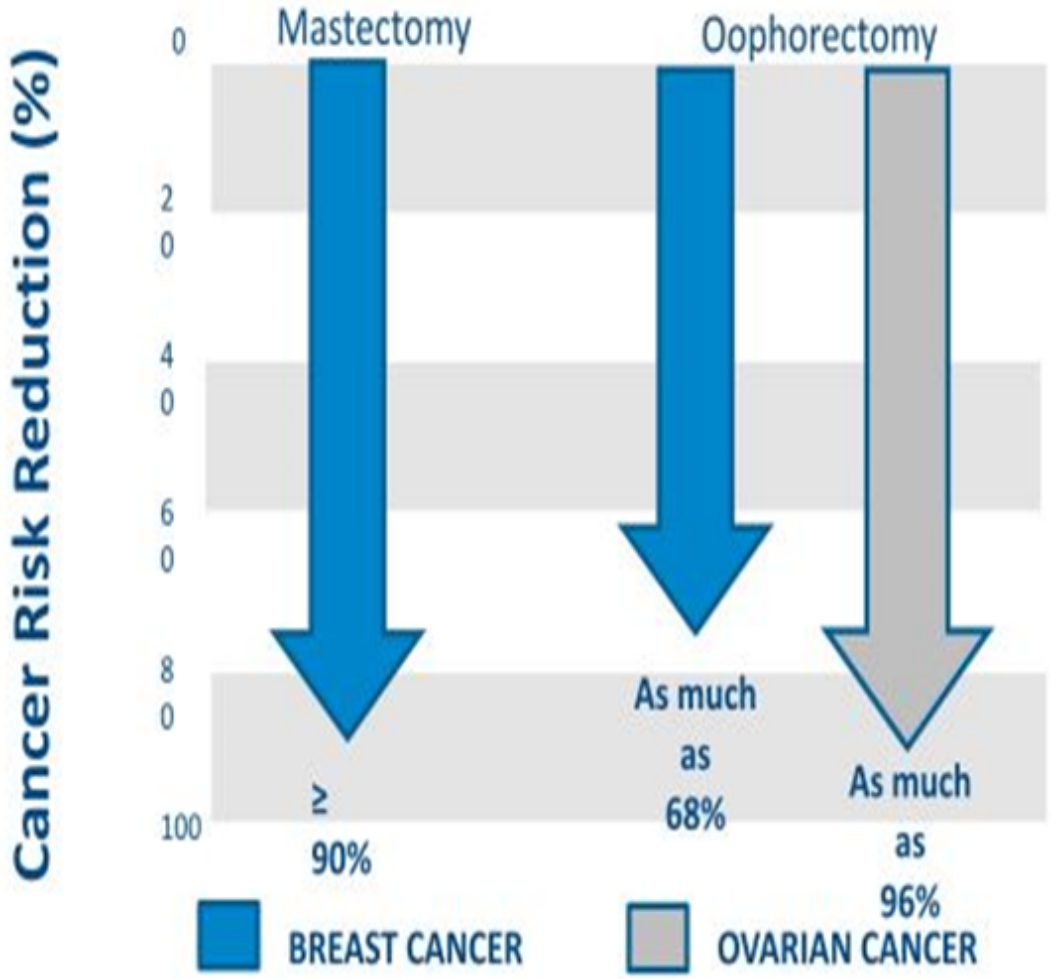
Source: Ambry Genetics

## OPPORTUNITY TO SAVE LIVES

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Reference combined by: Myriad Genetic Laboratories, Inc.

## BENEFITS OF PROGRAM

### Patients and Providers

- Preventing cancers saves lives and cost
  - Cancer cost avoidance Avg >$100,000 pp
- Patients and providers become educated about risks and recommendations
- Patients get tracked/navigated along continuum
- Patient's care is coordinated with access to trained providers
- Program instills PCP's confidence their 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 genetic standard

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## BARRIERS

- Woman's reluctance to engage in high risk screening
- Referring physician's reluctance to support the program
- Physician's perception of threat of loss of patient volumes or control
- Protocols and standards that may not be covered by insurance
- Lack of IT solutions to support the very manual processes of program
- Inability to acquire genetic professionals due to shortage in field
- Lack of collaboration between imaging, oncology, women and children's services and physicians
- Lack of program "ownership" – identified leader

# HRWP MODEL

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# MODELS BUILT AROUND CRITICAL POINTS IN HIGH RISK BREAST CARE

| Targeting Patients for Screening | Determining Optimal Screening Modality | Genetic Testing and Counseling | Ongoing Risk Management |
|---|---|---|---|
| • Awareness campaigns<br>• Education about screening and genetic testing guidelines<br>• Mobile mammography | Pre-screening questionnaires to determine lifetime risk and optimal screening modality | • Pre-testing counseling to determine eligibility and inform patient's choice<br>• Ordering tests<br>• Counseling patients about their test results and risk management options | • Health and wellness programs<br>• Recommendations for different/more frequent screenings<br>• Prophylactic surgery<br>• Chemoprevention |

Source: Oncology Roundtable interviews and analysis

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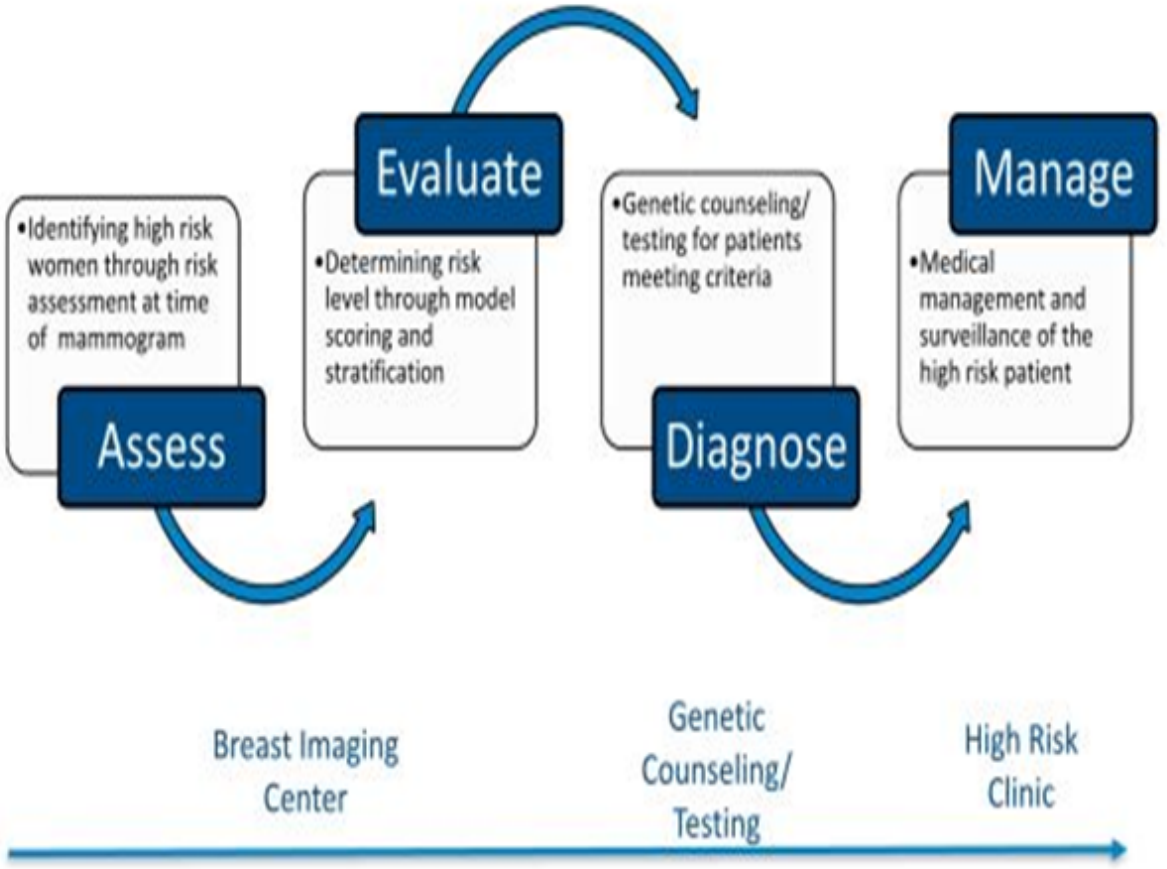
# CONTINUUM OF CARE WILL DETERMINE PROGRAM MODEL

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## HRBP MODELS

- HRBPs vary significantly
- Popular: NP-run clinics
  - Advanced Genetics Nursing Certification through COH
  - NCBC/COH – Breast Cancer Risk Assessment Certification in development
- Evolution of "Cancer Risk and Genetics Center"
- Will need to determine your "must have's"

**Community hospital-based programs offer more concentrated services, have smaller patient volumes**

*Spectrum of high-risk breast programs, by hospital type, 2008*


| Hospital | 450-bed, government-owned academic medical center (AMC) Section VI | 350-bed, not-for-profit teaching hospital Section IV | 350-bed, not-for-profit minor teaching hospital Section V | 250-bed, not-for-profit community hospital Section III |
|---|---|---|---|---|
| Annual volumes | • 400 to 500 new patients<br>• 600 to 700 breast exams<br>• 350 tissue samples | • 360 to 480 new patients<br>• Volumes growing by 10 percent monthly | 440 patient appointments in 2007 | • 133 new patients<br>• 244 follow-up visits<br>• 600 total enrolled patients |
| Services | • Cancer risk counseling and education<br>• Clinical trials<br>• Community outreach<br>• Experimental imaging services<br>• Genetic counseling<br>• Genetic testing<br>• Screening services<br>• Second opinion services | • Breast cancer screening<br>• Clinical breast exams<br>• Education<br>• Genetic counseling<br>• Genetic testing (outsourced)<br>• Imaging services | • Breast care navigator<br>• Education<br>• Genetic counseling<br>• Genetic testing<br>• Support groups | • Breast imaging<br>• Clinical breast exams<br>• Education<br>• Genetic counseling<br>• Genetic testing |
| Space | 3,000 square feet of dedicated space within breast center | • One office and one exam room dedicated to the high-risk program<br>• Plans to add a dedicated administrative office | • Dedicated space within the cancer center, including:<br>• Office for each genetic counselor<br>• Meeting room for conducting patient education and counseling | • One office and four exam rooms shared with breast center staff<br>• Administrators would like to acquire dedicated space |
| Staff | • 9 dedicated full-time equivalents (FTEs)<br>• Breast oncologist serves as medical director<br>• 12-person advisory board | • 3 dedicated FTEs<br>• Pathologist and radiologist serve as co-medical directors<br>• 4-person advisory board composed of the following specialists:<br>• Breast surgeon<br>• Oncologist<br>• Pathologist<br>• Radiologist | • 3.5 dedicated FTEs, including 1 medical director<br>• No advisory board | • 3.6 dedicated FTEs<br>• 2 breast surgeons oversee the program, but are not dedicated staff members<br>• No advisory board |

Source: Advisory Board interviews, April 2008

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## DEFINING STANDARDS ALONG CONTINUUM

- Patient populations to identify
- Leadership structure
- Diagnostic technology
- Risk assessment and stratification
- Genetic counseling and testing
- High risk management/clinic services
- Providers and navigators
- Pathways/guidelines
- Support and prevention services
- Clinical research opportunities

# IDENTIFYING AND NAVIGATING THE HIGH RISK PATIENT

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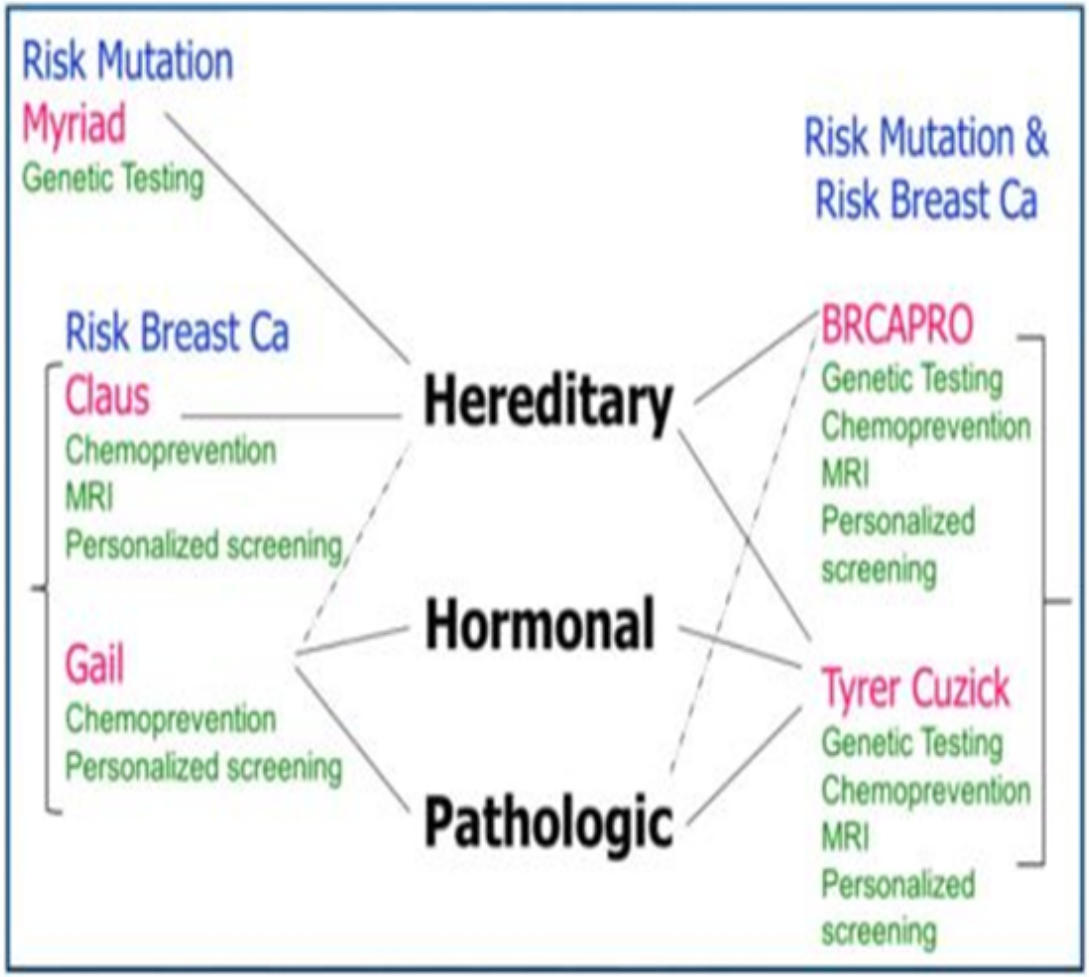
## ASSESSING FOR RISK – 2 SEPARATE CLINICAL ISSUES

- **The risk of breast cancer over time** – which will help inform the need for chemoprevention, MRIs, earlier mammography screening and additional risk-based screening.

- **The risk of genetic mutation** – which will help inform the need for genetic counseling and testing.

# CHOOSING RISK MODELS/GUIDELINES TO USE




*Source: Hughes, K. Many breast cancer risk models: Which one is accurate? Jan 22, 2016.*

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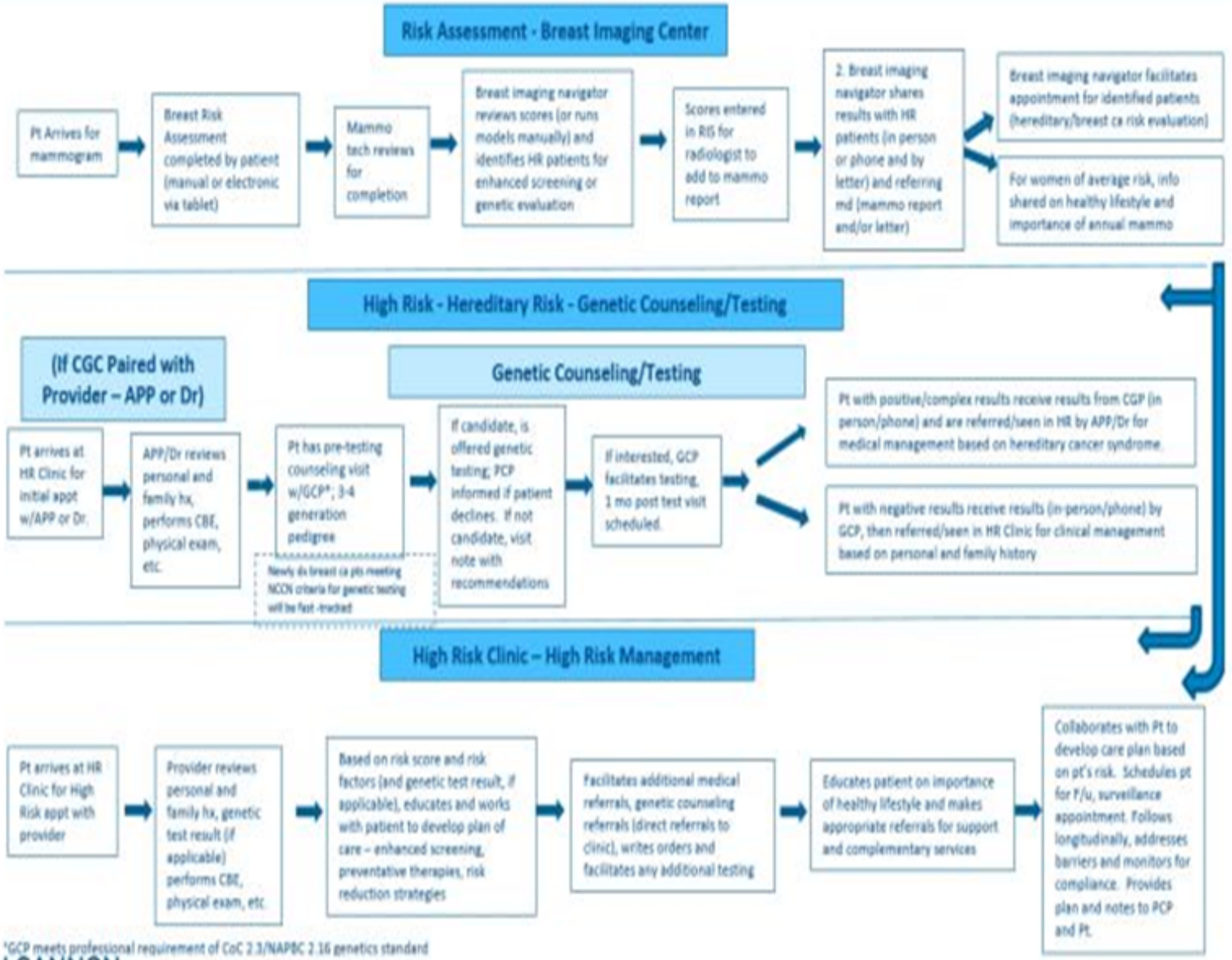
## SC RISK MODELS

- **To identify lifetime risk of breast cancer** – Tyrer-Cuzick (minimum v6; prefer v7 or 8 (takes into account breast density))
- **To identify women for chemoprevention** – Gail model
- **To identify need for genetic counseling/testing** – NCCN guidelines

# LEVERAGING TECHNOLOGY – MANY COMPLICATED/MANUAL PROCESSES




*GCP meets professional requirement of CoC 2.3/NAPBC 2.16 genetics standard

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## IT SOLUTIONS TO SUPPORT THE PROGRAM

- **At a minimum, ensure your mammography information system/RIS 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

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## 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

## CRITICAL ROLE – BREAST IMAGING NAVIGATOR/COORDINATOR

- Typically an RN or advanced mammography technologist
- Facilitates the high risk program activities within the breast imaging center
- Educates patients regarding risk results
- Communicates with patients and providers
- Facilitates appropriate referrals
- Key to ensuring patients don't fall through the cracks
- Key to reducing leakage
- ROI is predicated on this position in place

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# GENETIC COUNSELING/TESTING CONSIDERATIONS

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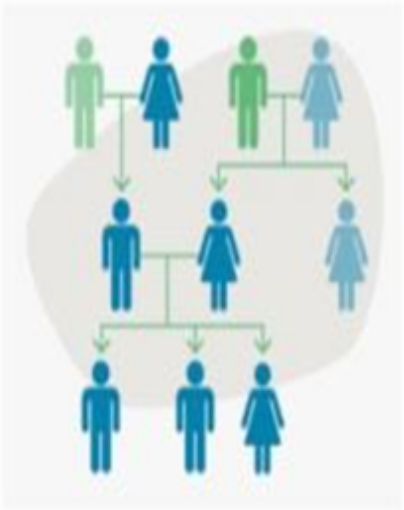
## PRIMARY COMPONENTS OF GENETIC COUNSELING/TESTING PROCESS

- 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



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# 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.

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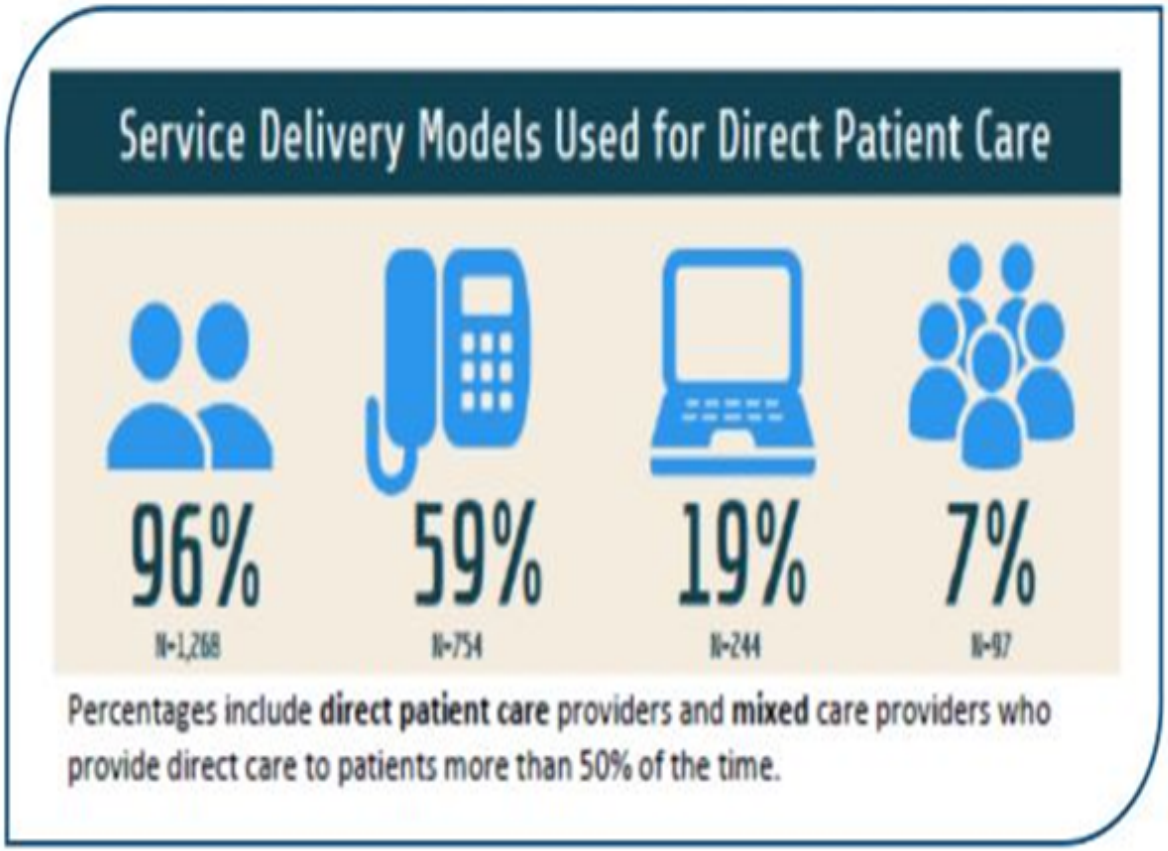
Source: 2018 NAPBC Standards Manual, Standard 2.16

## 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

- *There are pros/cons of each*

## SERVICE DELIVERY MODELS






*Source: National Society for Genetic Counselors Professional Status Survey, 2018*

# 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<br>- 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 |
| | • **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.<br>o **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. | |
| | • **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) |

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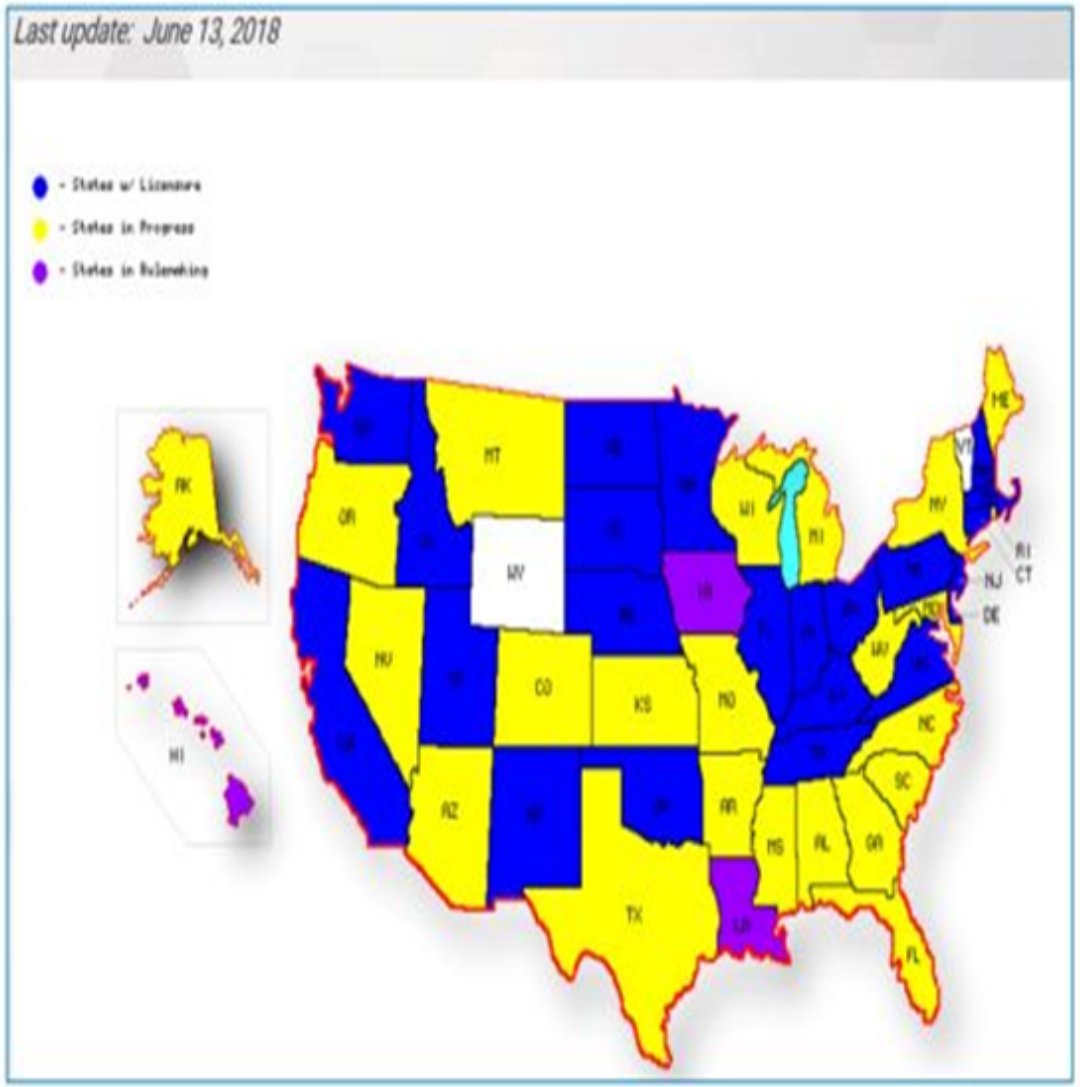
**This is not meant to be an exhaustive list, but rather frequent codes and processes that may be used for genetic counseling billing/reimbursement. There are numerous considerations for each billing method.*

# MANY STATES NOW REQUIRE LICENSURE FOR GENETIC COUNSELING

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




Source: National Society of Genetic Counselors website

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# 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

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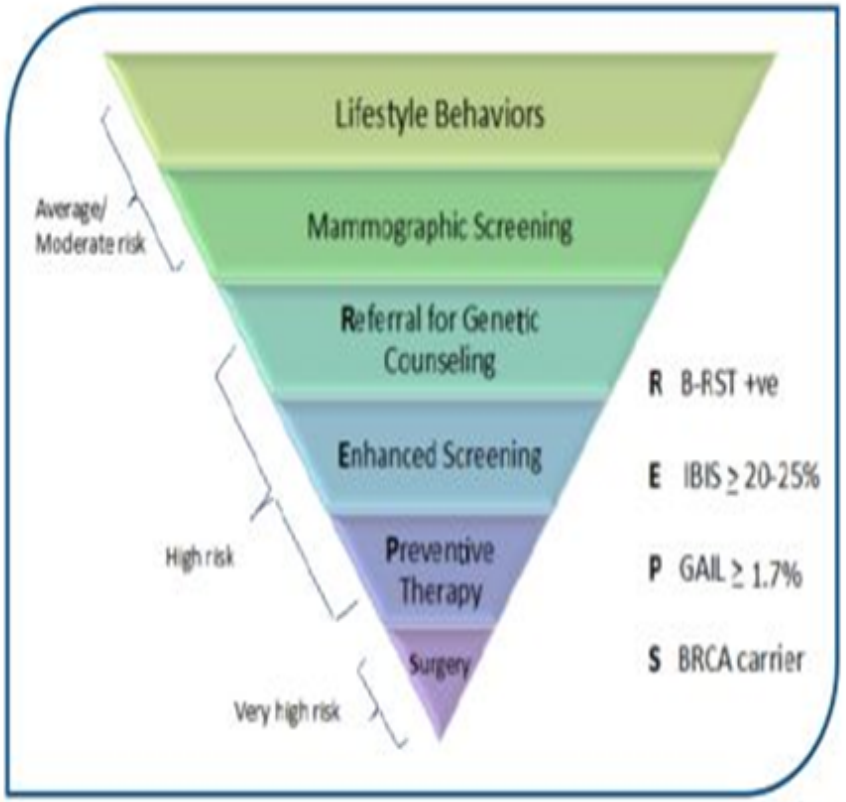
## HIGH RISK MANAGEMENT

- Risk level determines intervention options and providers involved
- Focused on the education, medical management and surveillance of high risk patient




*Source: Pruthi, S. et al. Assessing and managing women at increased risk for breast cancer.*

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# 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

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## 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.

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# PROGRAM PLANNING

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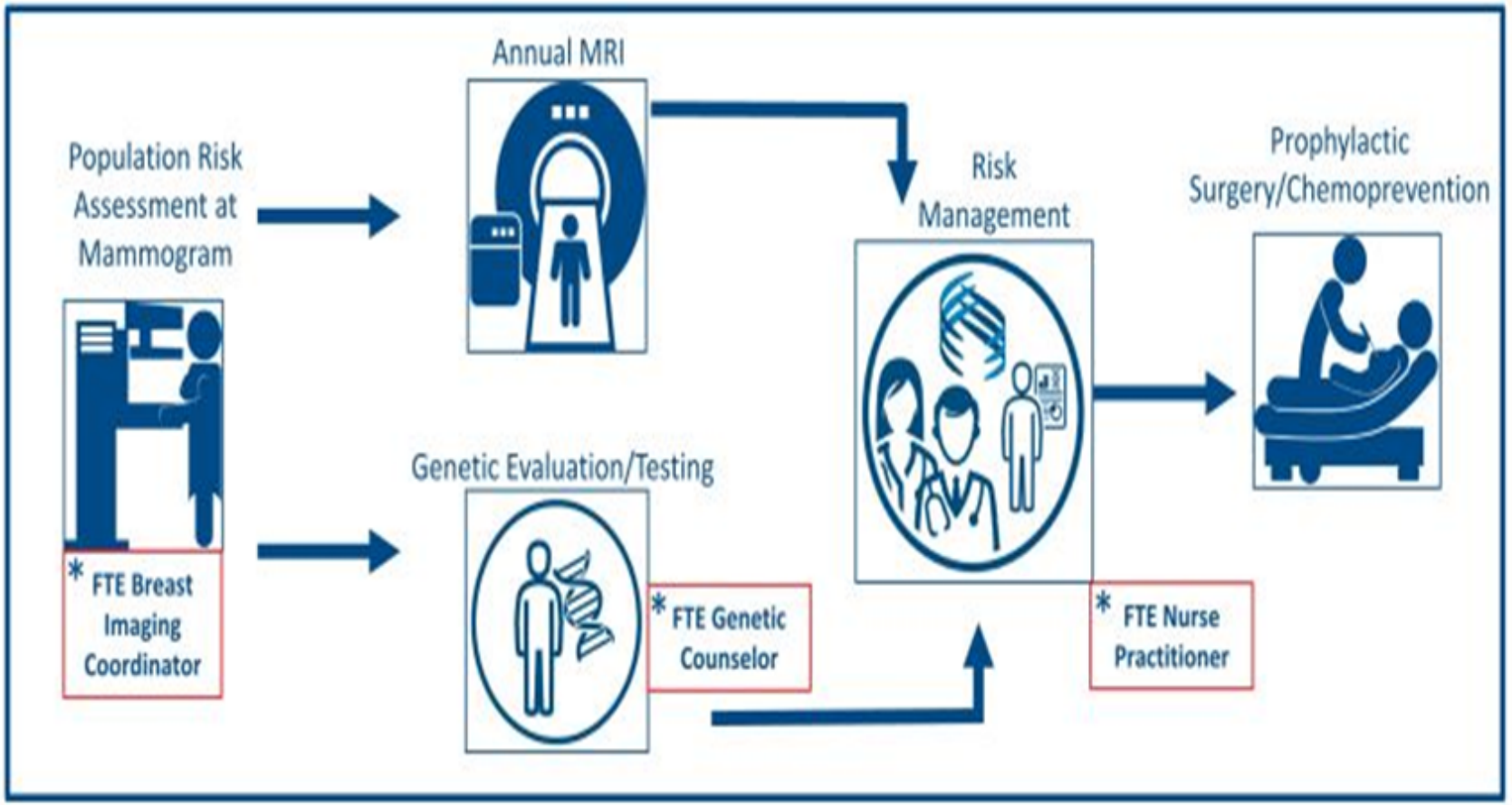
# KEY INVESTMENTS ACROSS CONTINUUM




*Does not include any required administrative resources or capital equipment, such as MRI

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# PROJECTING RETURN ON INVESTMENT

## Operating Expenses

**Staffing**

| | |
|---|---|
| FTE Breast Imaging Coordinator | $77.000 |
| FTE Genetic Counselor | $86,500 |
| FTE Nurse Practitioner | $104,000 |
| **Total** (Benefits not included) | **$267,500** |

**Information Technology**

| | |
|---|---|
| Comprehensive IT Solution | **$35,000** |

**Total Annual Operating Expenses $302,500**

## 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** | |

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*Does not include additional revenues from Ultrasounds, or other screening/diagnostic, treatment procedures or E & M visits
**High Risk is defined as meeting NCCN guidelines for genetic evaluation and/or having ≥20% Lifetime risk via TC v7, 8

# 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 ≥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 ≥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 ≥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: ≥20% TC lifetime risk , GC candidate, ≥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

## HRWP 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 HRWP

- ✓ 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 HRWP Planning Team – be sure to include primary care/OB-GYN!
- ✓ Define your ideal state for HRWP
- ✓ 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
- ✓ If possible, acquire comprehensive cancer risk assessment and management IT solution
- ✓ Determine risk assessment tool, risk model(s), clinical guidelines and protocols to use
- ✓ Map out workflow in breast imaging center
- ✓ Determine genetic counseling practitioner model and service delivery model
- ✓ Determine high risk management/clinic provider model and service delivery model
- ✓ 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)

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Source: King MC, Levy-Lahad E, Lahad A: Population-based screening for BRCA1 and BRCA2.JAMA 312:1091-1092, 2014

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# THANK YOU

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