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The Cancer Institute of HCA Healthcare

The Case for Community-Based, High Risk Women's Cancer Programs

Dax Kurbegov, MD

Vice-President, Physician in Chief of Clinical Programs

THE STORY

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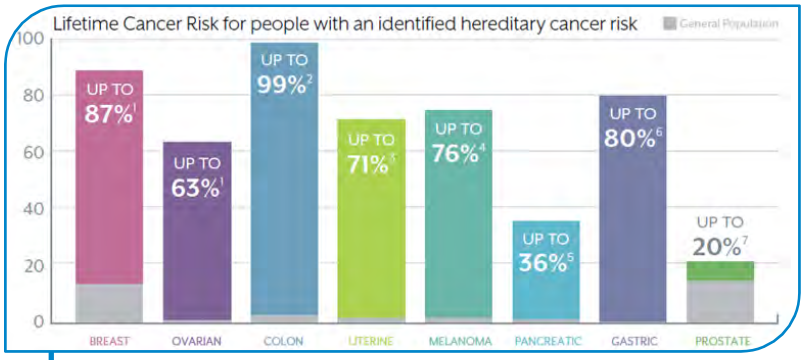
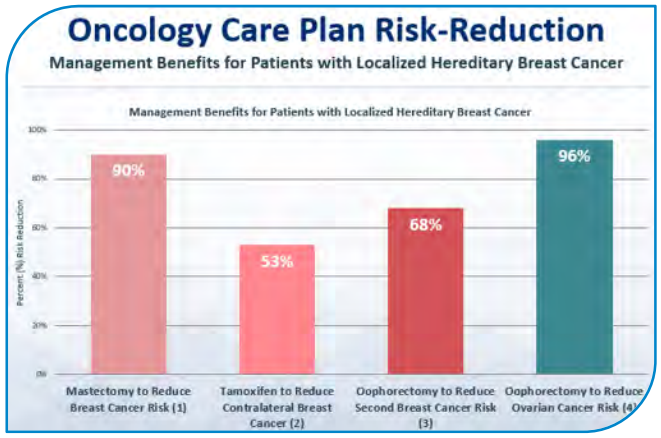
SAM'S STORY

- 36 year old, lives in Denver
- Obsessed with friends, family, Orange Theory and health living

- Sister diagnosed with breast cancer and BCRA positive at age 38; first cancer diagnosis in their family
- Prompted Joy to get tested; came back BRCA positive
- Understanding her increased risk for breast cancer, opted for a prophylactic bilateral mastectomy
  - Tissue results showed pre-cancerous changes
  - She is so grateful she got identified before it became cancer

- A HRWP can establish a woman's relationship for a lifetime





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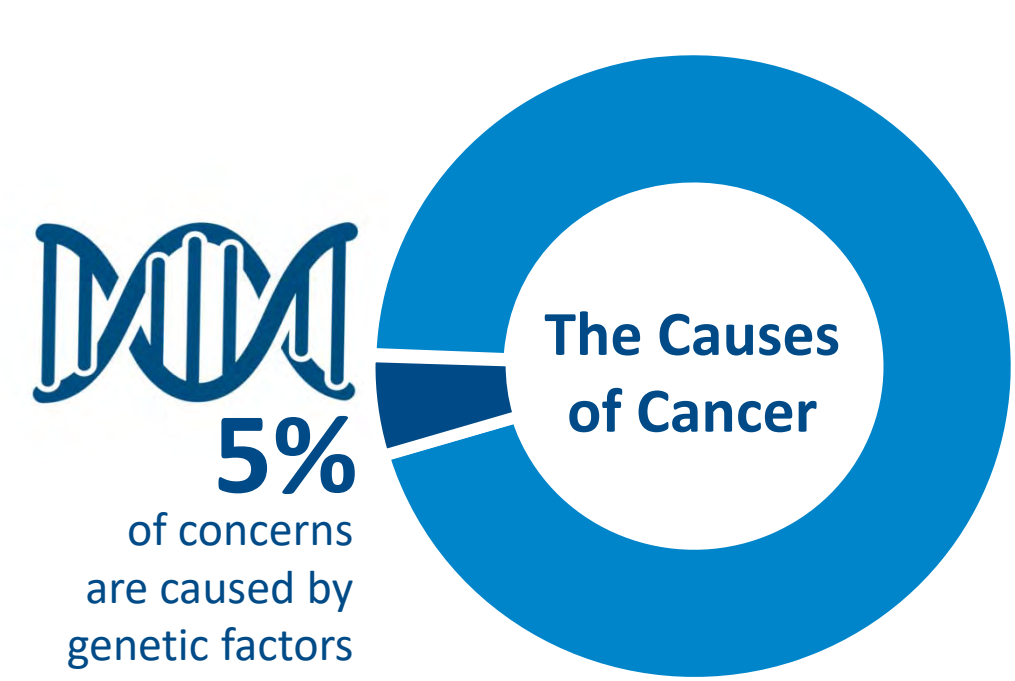
NURTURE VERSUS NATURE – CANCER OVERALL



5%
of concerns are caused by genetic factors

95%
of concerns are caused by environmental or lifestyle factors

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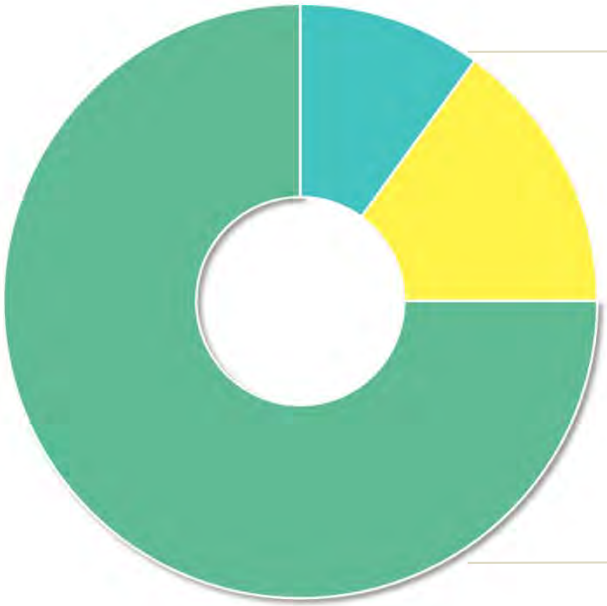
HEREDITY AND BREAST CANCER RISK



5-10% Hereditary

Inherited pathogenic gene mutation

15-20% Familial

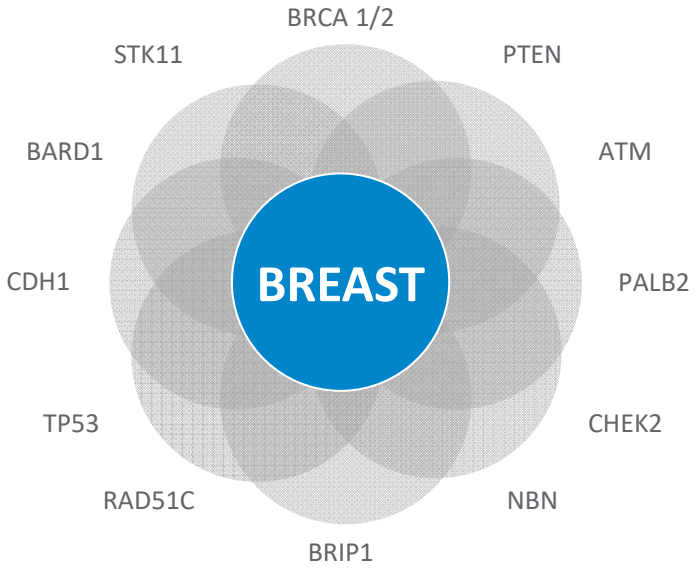
Combined environmental and genetic factors

70-80% Sporadic

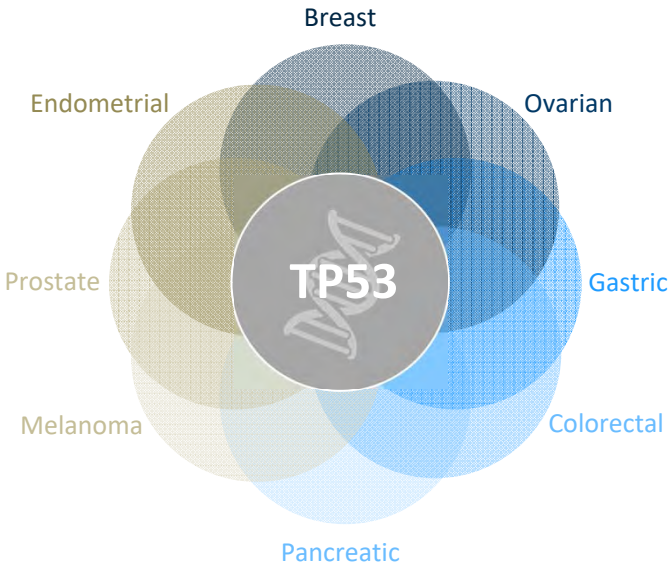
Non-inherited spontaneous development

GENES AND CANCER RISK

Genetic Overlap



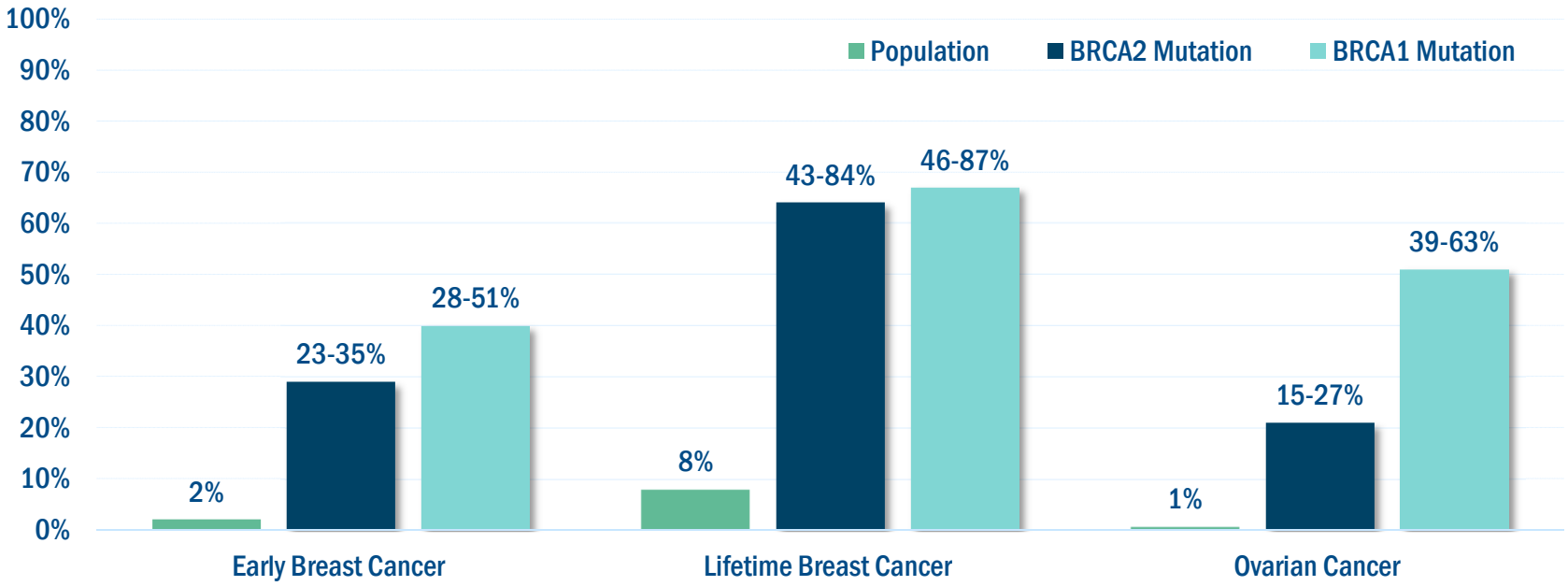
Multiple genes can increase the risk of a single cancer



Multiple cancers can be associated with a single gene

Myriad Genetics

BRCA AND RISK OF WOMEN'S CANCERS



Courtesy of CancerIQ

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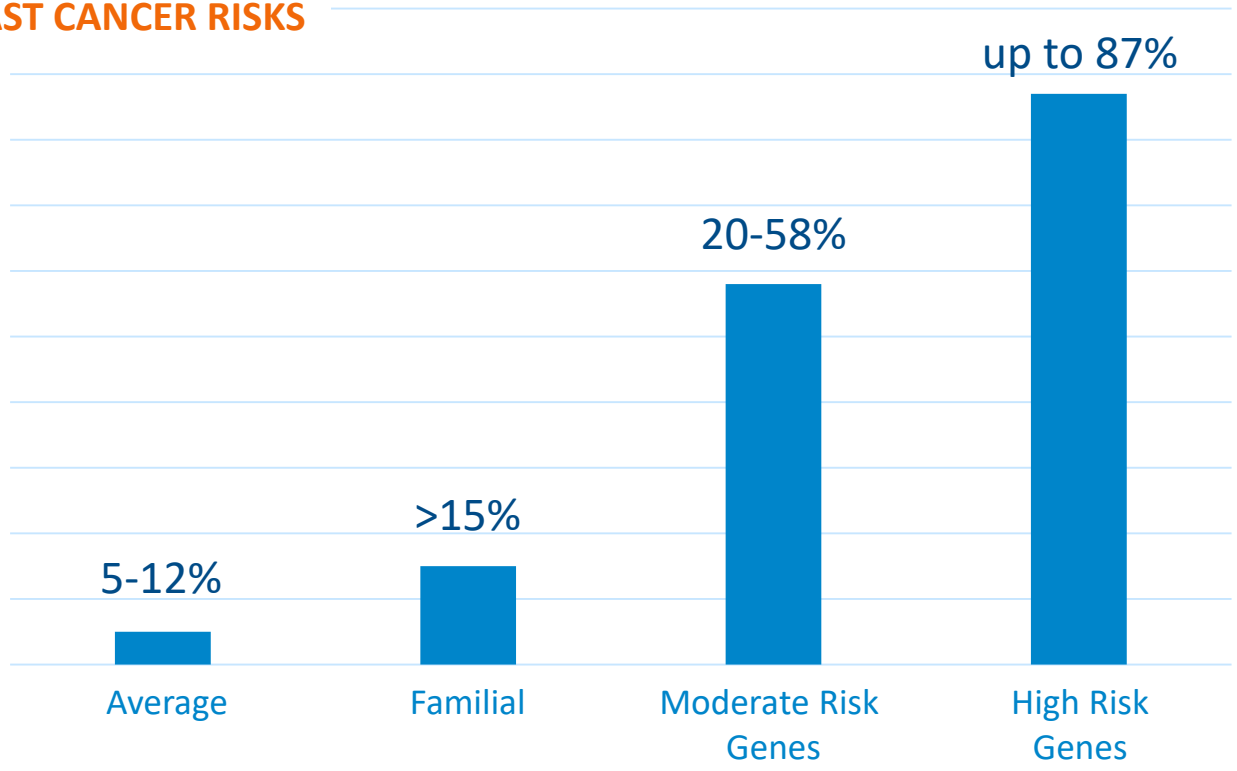
WOMEN WITH GENETIC SYNDROMES ARE AT MUCH HIGHER RISK

LIFETIME BREAST CANCER RISKS



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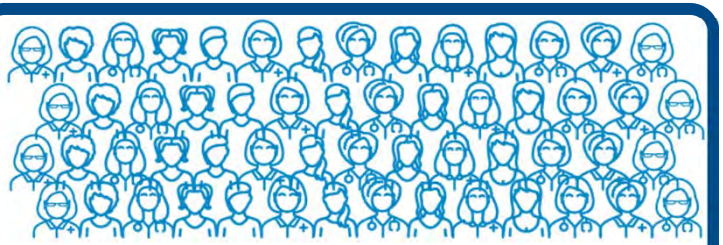
Source: Ambry Genetics

WHY COMMUNITY HEALTH CARE MUST ADDRESS THIS ISSUE



MAGNITUDE OF PROBLEM

1st	Breast CA most common cancer in the US
2nd	2nd leading cause of cancer deaths among women
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 these high-risk women have yet to be identified**

OWNERSHIP OF PROBLEM

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

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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THE PROGRAM

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HCA'S OPPORTUNITY – SOURCED BY CLINICAL EXPERTS

Advisory committee participants

+50

- Genetic counselors
- Administrators
- Navigators
- 21 Engaged Physicians

(Gyn Oncs, Med Oncs, Radiologist, Surgeons, PCPs)

Across 8 Markets

Working groups Developing Best Practices

13

- Risk Assessment model
- Genetic counseling models
- Workflows
- Guidelines/Pathways

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Patient

Patient Identification and Coordination
- No standardized comprehensive risk assessment strategy in place
- Variable access to genetic counseling and genetic testing
- Marked gaps in care coordination

Strategy
- No markets have *all* components/processes of a comprehensive program
- Subject matter expertise is extremely limited
- Most markets are actively investing in high risk women's programming
- High fragmentation of care; outmigration

Technology
- Highly manual, labor-intensive processes
- Spreadsheets, sticky notes to track patients

Finance
- No clear understanding of needed investments
- No clear understanding of ROI opportunities
- Multiple markets pursuing disparate technical solutions

HRWP ADVISORY COMMITTEE

Name	Position/Specialty	Location	Workgroup Member
Stephanie Graff, MD	Chair, Breast Med Onc	Kansas City	X
Teresa Heckel, MBA	Project Director	SC Corporate	Lead
Alex Sardina, MD	Med Director, Solis	Solis National	X
Amy Casseri	VP Women & Children Services	HCA Corporate	
Arlene Garcia-Soto, MD	Gyn Oncologist	Dallas	
Beth Anglin, MD	Breast Surgeon	Dallas	
Brittany DeBerry, MD	Breast Surgeon	San Antonio	
Cherylle Hayes, MD	Breast Rad Oncologist	N. Florida	X
Chirag Parghi, MD	Breast Radiologist	Houston	Phys. Champion
Cliff Deal, MD	Breast Surgeon	Richmond	X
Colleen Johnson, RN	Oncology Director	Kansas City	X
Dax Kurbegov, MD	VP, Physician-in-Chief	SC Corporate	
Debbie Kelly, RN, BSN, OCN	Breast Navigation Manager	Houston	Lead
Denise Yardley, MD	Breast Med Oncologist	Nashville	X
Dhatri Kodali, MD	Breast Med Onc Oncologist	Houston	Phys. Champion
Emily Gentry, RN	Navigation Director	Dallas	X
Ethel Randall, MBA	RVP, Oncology Leader	Dallas	X
Holli Dilks, PhD	Dir of Personalized Medicine	SC Corporate	X
John King, MD	Breast Radiologist	Nashville	
Jonathan Tinker	RVP, Oncology Leader	Richmond	
Julie Shisler	Dir Clinical Operations	Solis, Addison, TX	Lead
Justin Boatsman, MD	Breast Radiologist	San Antonio	X
Kamadi Camp	Clinical Programs Director	SC Corporate	
Kelly Johnson, MS, RN, APNG	Oncology Director	Denver	X
Kelly Winkler, NP	HRBP Nurse Practitioner	Kansas City	Lead
Kevin Drake, MBA	Director, Cancer Applications	SC Corporate	Lead
Kristen Daniels	ARVP Women's Health	HCA Corporate	Lead
Laura Hafertepen, DO	Breast Surgeon	Denver	Phys. Champion

Name	Position/Specialty	Location	Workgroup Member
Lindsey Reed, RN	Navigation Director	Kansas City	X
Lisa Morris LaPerriere, RN	Navigation Director	Nashville	X
Lora Barke, MD	Breast Radiologist	Denver	Phys. Champ
Mary Freivogel, MS, CGC	CGC, Sr Director Operations, ISJ	Denver	Lead
Micah Mcarthur, MSN, RN, OCN	Cancer Program Manager	SC Corporate	
Molly Lund, MS, CGC	Sr Genetic Counselor	Kansas City	Lead
Nicole Centers, RN, BSN, OCN,	Navigation Director	N Florida	Lead
Nikki DeLano, MSN, RN, ONN	Cancer Program Manager	SC Corporate	
Reena Vashi, MD	Breast Radiologist	Houston	X
Richard Geer, MD	Surg Onc, Physician-in-Chief	SC Corporate	
Sheryl Walker, MS, CGC	Certified Genetic Counselor	Dallas	Lead
Sidney Clevinger, MD	Primary Care Physician, CMO	N. Florida	X
Stephanie Miller, MD	Breast Surgeon	Denver	Phys. Champ
Stephen Rose, MD	Breast Radiologist, CMO Solis	Solis	
Susan Kemp	VP - STRIC, Breast Imaging	San Antonio	X
Susie Ulloa, RN	Breast Navigator	N Florida	
Timothy Dudley, MD	Primary Care Physician, CMO	Denver	X
Wesley Fox, MBA	Imaging Director	Charleston	Lead

Additional Contributors

Name	Position/Specialty	Location
Erin Copeland	Cancer Market Director/PPR	Kansas City
Jessie Perez	Sr Business Analyst, IT	SC Corporate
John Roll	Oncology IT Manager	SC Corporate
Kim Akel	Dir Phys. and Comm. Relations/PPR	Austin
Samantha Maxwell	Dir Marketing/Communications	SC Corporate
Stacy Tuckwell, MHA	Sr. Director Oncology/PPR	Denver

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SOLUTION: SARAH CANNON/HCA HIGH RISK PROGRAM MODEL

PROGRAMMATIC BUILD

- Assess Current State
- Playbook/Toolkit
- Resources (Breast imaging coordinator, genetic counselor, high risk provider)
- Technology
- Pilot(s)

OUTCOMES STUDY/DATA

- Risk Model Evaluation
- Patient Experience/ Satisfaction
- Program Quality
- Program Growth

INFORMATION TECHNOLOGY

- Automate Key Processes
- Physician Communication
- Patient Communication
- Support Workflow

Key Program Components

- Systematic risk assessment process in place
- Proper validated risk model
- Proper pedigree mapping, genetic counseling and testing
- Proper resourcing
- Comprehensive workflows to support care management
- Proper surveillance
- Integrated model and reporting across enterprise

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HRWP – COMPREHENSIVE BEST PRACTICES, TEMPLATES, AND TOOLS

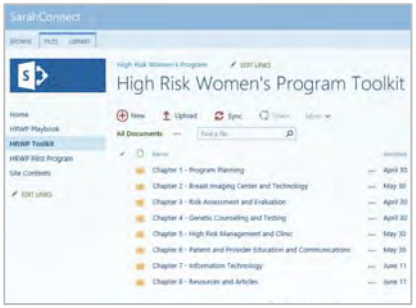
Phase I

- Engage Physicians and care team
- Develop HRWP Playbook – comprehensive document outlining all components of a high risk program
- Develop HRWP Toolkit – repository of tools, documents, resources for program planning and implementation

Engagement and Define Infrastructure/Best Practices

Play Book

Toolkit



Phase II

- Establish Steering Committee for operational oversight - Establish business plan imperatives
- Share best practices nationally
- PILOT programmatic build and Technology
- Define Genetic counseling models
- Prove technology
- Design HRWP Outcomes Research Study

Assessment

GAP Analysis

Pilot

Measure and Report

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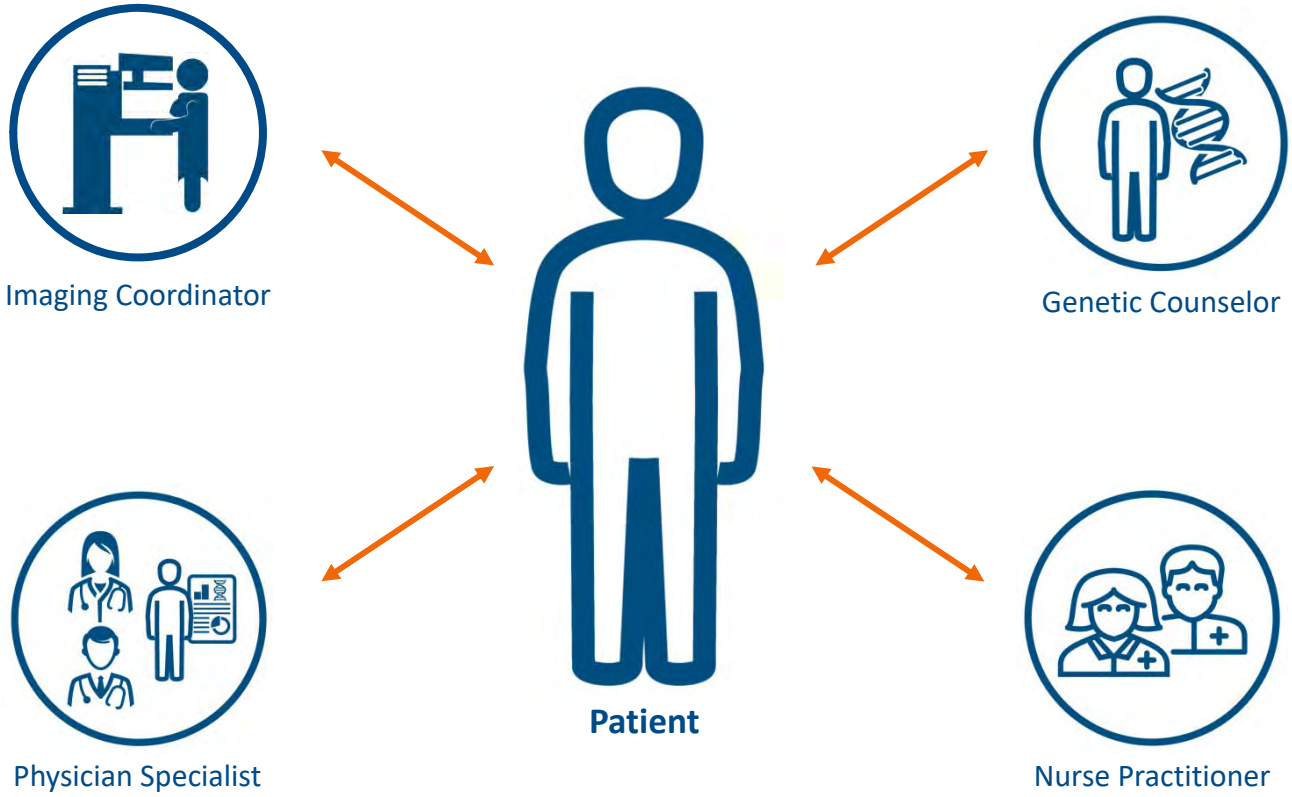
ESSENTIAL MEMBERS OF A HIGH RISK ECOSYSTEM



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THE VALUE OF A GENETIC COUNSELOR AS A CORE RESOURCE

	Mayo[a]	ARUP[b]
Data Collection Time Frame	3 month period	21 month period
Order Modification %	8% (n=5504)	26% (n=~2080)
Noted Modifications	Modified/improved (~ 55%) Canceled misorders (38%)	Modified/improved (34%) Canceled misorders (61%)
Average yearly cost savings for 1 laboratory client	$779,060	$576,000

[a] Katrina E. Kotzer, Jacquelyn D. Riley, Jessie H. Conta, Claire M. Anderson, Kimberly A. Schahl, McKinsey L. Goodenberger, Genetic testing utilization and the role of the laboratory genetic counselor, Clinica Chimica Acta, Volume 427, 1 January 2014, Pages 193-195, ISSN 0009-8981,

[b] Miller CE, Krautscheid P, Baldwin EE, Tvrdik T, Openshaw AS, Hart K, LaGrave D. 2014. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. Am J Med Genet Part A 9999:1–8.

SERVICE DELIVERY MODELS

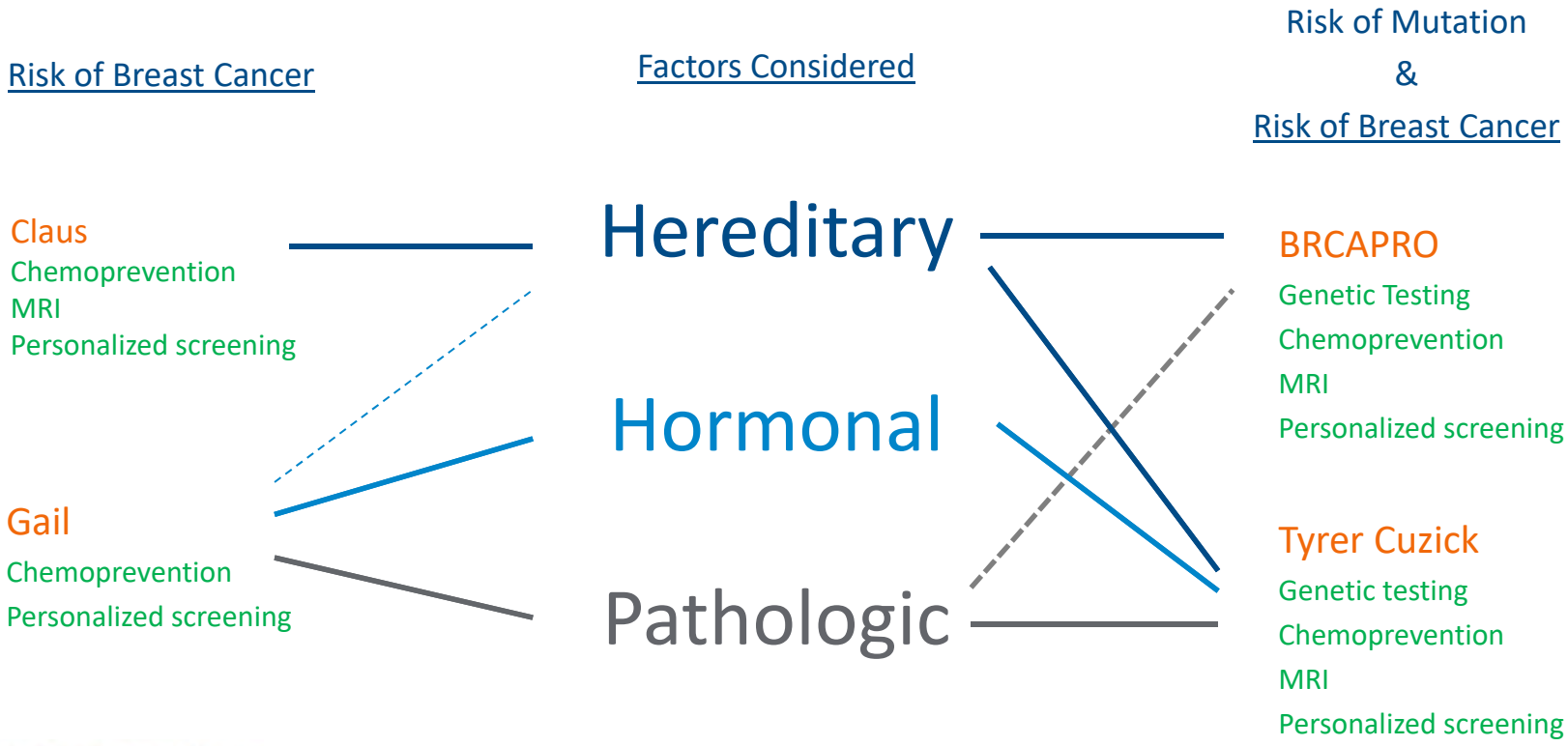
In-Person	• Genetic Counseling is provided in-person. Follow up and results disclosure may occur by telephone of other means.
Telephone	• Genetic Counseling is provided remotely by telephone. The telephone call may be supplemented by written, online or other resources.
Group	• Patients are educated in a group setting by a genetic counselor, which may be followed by individual assessment, counseling etc.
Telegenetic	• Genetic Counseling is provided remotely using videoconferencing.

Cohen S, et.al. J Genet Couns. 2012 Oct;21(5):645-51.

CERTIFIED GENETIC COUNSELING RESOURCING OPTIONS

GC Model	Employ	Contract Locally	Contract Remotely	GC Extender	Genetic Lab
Description	Employed FT or PT by facility	Contracted to provide services locally in market (Independ./Company)	Contracted to provide services via phone/video (Usually company)	CGC is paired with trained NP (APP) to "extend" use of remote CGC (Company)	CGCs on staff. Most can only provide post-test counseling pts. Some provide pre-test "tele-education"
Potential Advantages	-Full team integration -Able to use across market -In-person encounters	-Full team integration -Able to use across market -In-person encounters	-Usually easier option if small volume, as building program -Usually good coverage, may include off hours -Lots of companies now	-Allows more judicious use of GC -Useful with low volumes -Builds skills of NP -Lower cost than employed CGC	-No cost to patient or facility for counseling -Fast, easy access to CGC -May provide free access to an IT solution (Some solutions are lab-owned)
Potential Limitations	-Single CGC may feel lack of peer support, no coverage -Turnover of CGC may cause gap in services	-May also work for competitor -Turnover risk if GC independent	-Not integrated with team -May lack access for provider consultations with a CGC -May be more expensive for facility and patients, depending on fee model -Less control of quality	-GC not fully integrated with team, but better than remote contracted -GC encounters are all remote -Will still need IT solution -Will need to figure out documentation/EMR access -Turnover of NP may cause gap	-Need to have local staff to facilitate process -Not integrated with local team, all services remote -Functionally restricts facility to working with a single lab/vendor
Consider When…	Best option – PT or FT	Unable to hire and/or strong, local option exists	No strong local option exists and unable to hire	-A trained NP resource is available	-Unable to hire, while building program; pilot to build program
Notes	• Expensive • Hard to find • Harder to keep	• May be more expensive • Rare option	• High variation in fee structures Highly dependent on volume	• Fee structure variable, usually per supported NP	• No cost to patient or facility • Least control

BREAST CANCER RISK ASSESSMENT TOOLS



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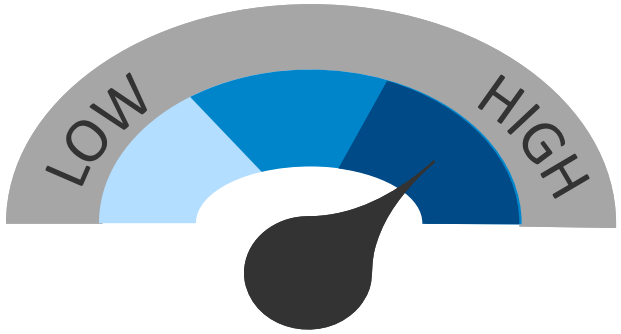
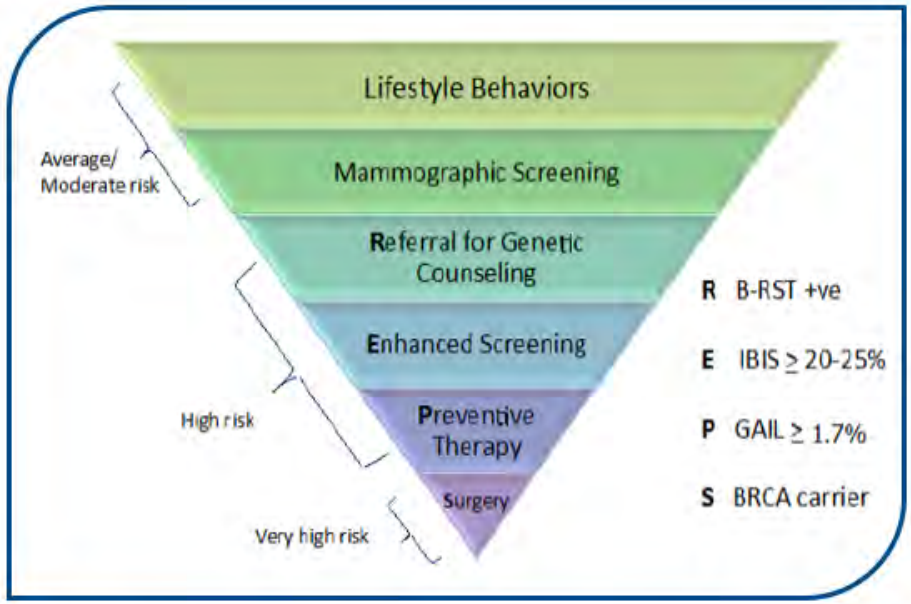
CATEGORIES OF RISK SIMPLIFIED

- **5 year risk**
  - Determined by Gail model
- **Lifetime risk**
  - Determined by TC model
- **Mutation risk**
  - NCCN guidelines



HIGH RISK INTERVENTIONS PRIMARILY DETERMINED BY LEVEL OF RISK IDENTIFIED



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

ACR Appropriateness Criteria is utilized to determine the appropriate enhanced imaging study based on the risk level, including which patients would meet criteria for MRI. NCCN® guidelines are utilized for determining the appropriate medical management/risk reduction strategies for the high risk woman.

INTERVENTIONS: ELEVATED *5 YEAR RISK*

- Drives consideration of chemoprevention strategies with tamoxifen or aromatase inhibitor
  - Tamoxifen used in premenopausal /postmenopausal women
  - Aromatase inhibitors only used in postmenopausal women
- Trials have demonstrated a benefit for chemoprevention if woman's 5 year risk >1.67%.
- Benefits must be weighed against non-trivial medication side-effects.
- The 2-3% risk range may have an equivocal risk/benefit ratio.

INTERVENTIONS: ELEVATED *LIFETIME RISK*

- A lifetime risk of breast cancer of 20% or greater by Tyrer-Cuzick is considered high-risk.
- Women in this category qualify for annual MRI screening in addition to mammography.
- MRI and mammogram can be preformed at the same time or staggered every 6 months, depending on patient and provider preference

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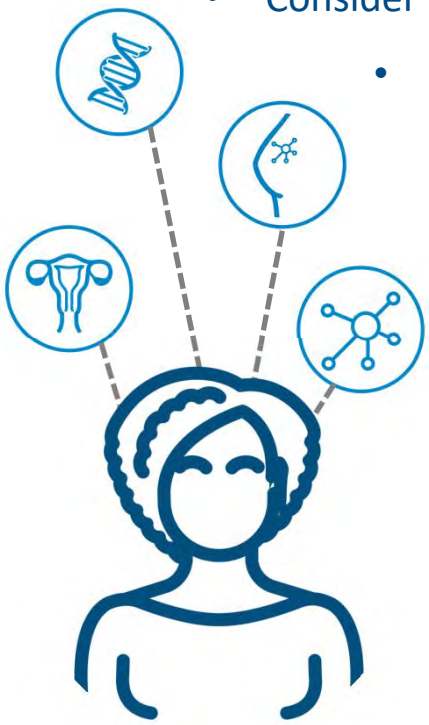
INTERVENTIONS: *BRCA MUTATIONS*



- Consider risk-reducing surgery to reduce risk of cancer (mastectomy and oophorectomy)
  - For those foregoing or delaying surgery, consider increased surveillance including MRI/mammogram annually
    - Data for chemoprevention are limited
      - NASBP P-1 found a reduction in breast cancer risk for BRCA2 carriers but not BRCA1
      - BRCA2 mutations more often associated with estrogen receptor expressing breast cancer than BRCA1
    - Other genetic mutations:
      - Depending on mutation, risk reducing surgery with mastectomy or oophorectomy may be indicated
      - Women with mutations should receive genetic counselor support, medical management, enhanced surveillance ongoing at high risk appointments

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GOOD CARE = GOOD BUSINESS

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CLINICAL EFFECTIVENESS AND COST EFFECTIVENESS WELL ESTABLISHED

- Genetic testing cost-effective in high risk populations
- Preventative strategies are clinically effective and cost effective in women carrying a mutation
- Women assume that their healthcare providers are assessing and advising them of their risk status
- Women want “well-care” not just “sick-care”
- Recent literature suggests that even more broad testing might be cost-effective

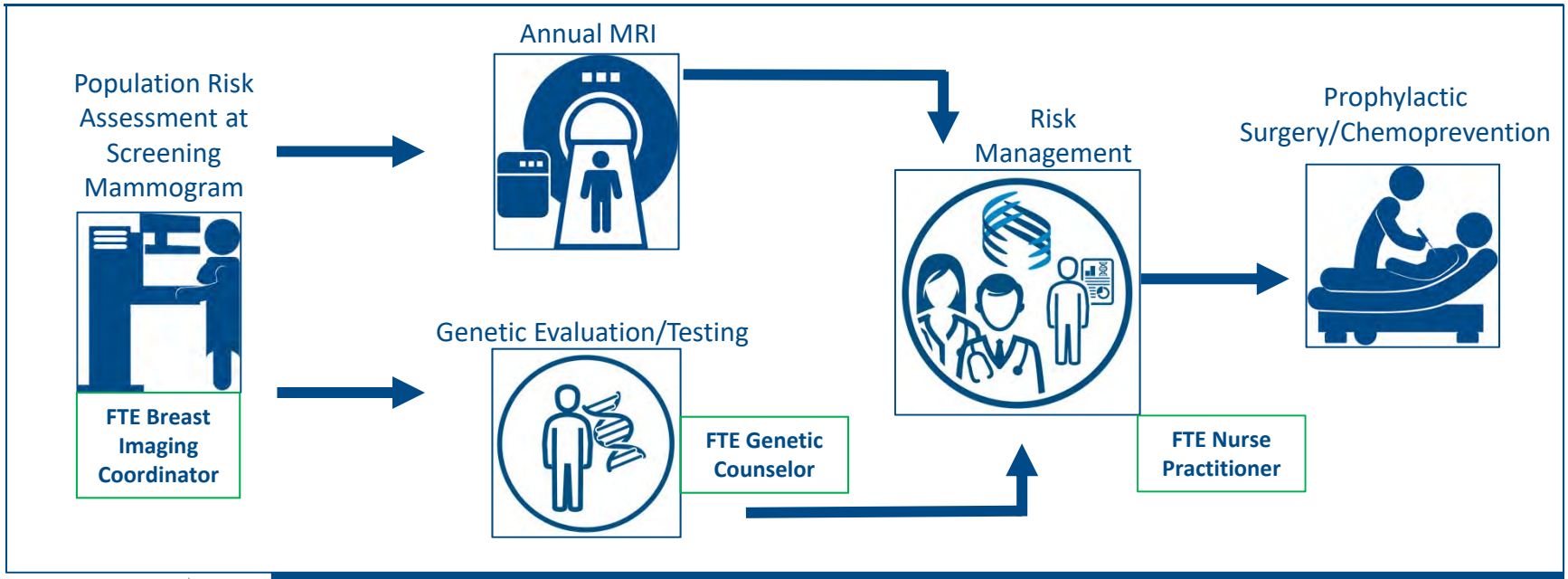
Anderson K, et al. Cost-effectiveness of preventive strategies for women with a BRCA1 or BRCA2 mutation. Annals of Internal Medicine 2006; 164(6): 397-407.

EM Ozanne, et al. Cost-effectiveness of genetic testing for BRCA1 and BRCA2 mutations. Cancer Res 2009;69(2 Suppl):Abstract nr 6100.

Ranjit Manchanda, et al. Cost-effectiveness of Population-Based BRCA1, BRCA2, RAD51C, RAD51D, BRIP1, PALB2 Mutation Testing in Unselected General Population Women. JNCI J Natl Cancer Inst (2018) 110(7): djx265

Additional references: NCCN, USPSTF

SUSTAINABILITY OF HIGH RISK PROGRAMS



10,000

Screening Mammos

Risk Coordination	Genetic Evaluation	Annual MRIs	Risk Management	Prophylactic Surgeries	Year 1 Estimated Net Revenue Opportunity
20% high risk = 2,000	20% eligible = 2,000	15% eligible = 1,500	20% eligible = 2,000	.20% eligible = 20	**$ 1.0M**

Financial Proforma represents the financial opportunity for a high performing, comprehensive HRWP using 50% Commercial Payer Mix.
*Does not include additional revenues from Ultrasounds, or other screening procedures or E & M visits
**Estimated based on use of Tyrer-Cuzick v7, 8 and NCCN Guidelines for Genetic Evaluation

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"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

THANK YOU

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