Breast Cancer Risk Assessment: Genetics, Risk Models, and Screening

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Hall-Perrine Cancer Center

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Disclosure-

I DO NOT HAVE any relevant financial interest with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by or used on patients, this does not include providers of clinical services directly to patients.

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Guidelines for Cancer Genetic Assessment

- National Comprehensive Cancer Network (NCCN)
  - Breast and/or Ovarian Cancer Genetic Assessment (Version 1.2018)
    - Available online www.nccn.org and iPhone app (NCCN Guidelines for Smartphone)
    - Last updated 10/2017
      - Updated 3 times in 2017

- American College of Medical Genetics and Genomics
- National Society of Genetic Counselors
  - A practice guideline from the American College of Medical Genetics and Genomics and the National Society of Genetic Counselors: referral indications for cancer predisposition assessment
    - Publication available online: www.ncbi.nlm.nih.gov/pubmed/25394175

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National Comprehensive Cancer Network Guidelines (NCCN) Version 1.2018

Breast and/or Ovarian Genetic Assessment (not an inclusive list):

Close blood relative: includes- first-; second-; and third-degree relatives

- Known mutation in a cancer gene within the family (any gene mutation)
- Diagnosis of ovarian cancer (personal history or close relative with history of)
- Diagnosis of breast cancer- early age onset (≤45 years)
- Diagnosis of two breast primaries (synchronous or asynchronous)
- Diagnosis of metastatic prostate cancer radiographic evidence or biopsy-proven (new indication- on 2017 updated guideline)
- Breast cancer diagnosis at any age **and**
  - ≥1 close relative with breast cancer ≤50 years
  - ≥1 close relative with invasive ovarian cancer at any age
  - ≥2 close relatives with breast cancer, prostate cancer (metastatic or Gleason score ≥7) and/or pancreatic cancer at any age
  - Pancreatic cancer at any age
  - From a population at increased risk (founder mutations of Ashkenazi Jewish population)

National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian (Version 1.2018). https://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf. Accessed 1.29.2018.

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National Comprehensive Cancer Network Guidelines (NCCN) Version 1.2018

- An individual with no personal history of cancer but with:
  - A close relative with any of the following:
    - A known mutation in a cancer susceptibility gene within the family
    - ≥2 breast cancer primaries in a single individual
    - ≥2 individuals with breast cancer primaries on the same side of the family with at least one diagnosed ≤50 years
    - Ovarian cancer
    - Male breast cancer
  - First- or second-degree relative with breast cancer diagnosed ≤45 years

National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian (Version 1.2018). https://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf. Accessed 1.29.2018.

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National Comprehensive Cancer Network Guidelines (NCCN) Version 1.2018

- An individual with a personal and/or family history of three or more of the following (especially if diagnosed age ≤50 years and can have multiple primary cancers in the same individual):
  - Breast cancer
  - Pancreatic cancer
  - Prostate cancer (Gleason score ≥7 or metastatic)
  - Melanoma
  - Sarcoma
  - Adrenocortical carcinoma
  - Brain tumors
  - Leukemia
  - Diffuse gastric cancer (lobular breast cancer)
  - Colon cancer
  - Endometrial cancer
  - Thyroid cancer (Follicular and/or multifocal)
  - Kidney cancer (multifocal)
  - Dermatological manifestations (Cowden syndrome)
  - Macrocephaly (58 cm in adult women and 60 cm in adult men)
  - Hamartomatous polyps of GI tract

National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian (Version 1.2018). https://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf. Accessed 1.29.2018.

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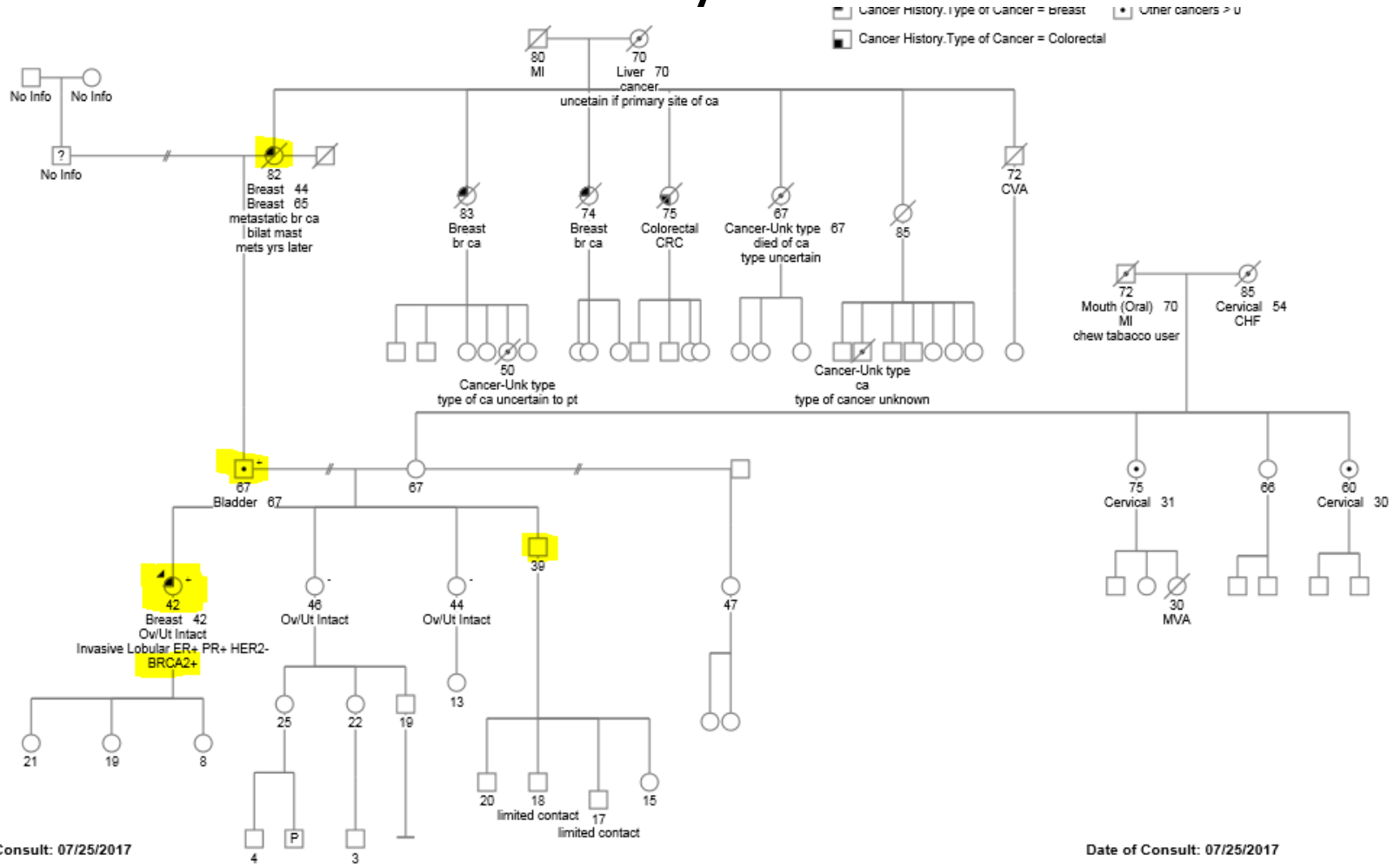
Limited Family Structure

Fewer than 2 first- or second-degree female relatives surviving past age 45 years



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Family Medical History

- Importance of obtaining family history
  - Need more information than “Is there a family history of breast cancer?”
- Three generational history preferred
  - Patient’s children, siblings, parents, aunts, uncles, and grandparents
  - Maternal AND Paternal sides of the family
  - Family ancestry (Ashkenazi Jewish descent)
- Detailed family history
  - Type of cancer
  - Age of diagnosis
  - Unilateral or bilateral cancer
- Challenges of obtaining family history
  - Many…
- Tools to gather family history
  - EPIC/myChart forms
  - Paper forms
    - FORCE printable: (http://www.facingourrisk.org/understanding-brca-and-hboc/publications/documents/FamilyMedicalHistoryChart.pdf)

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FORCE Family History Form

Know Your Family Medical History

This Knowledge Can be Life-Saving

Please fill in the name and type of cancer of each family member affected.

	Breast, Ovarian, Male Breast, Pancreatic or Prostate Cancer	Age Diagnosed
Yourself		
Sons/Daughters		
Sisters		
Brothers		
Mother's Side:		
Mother		
Grandmother		
Grandfather		
Aunts		
Uncles		
Cousins		
Father's Side:		
Father		
Grandmother		
Grandfather		
Aunts		
Uncles		
Cousins		

Have you or any family member had:

1. ☐ ovarian or fallopian tube cancer at any age?
2. ☐ breast cancer at age 50 or younger?
3. ☐ more than one breast cancer diagnosis?
4. ☐ both breast and ovarian cancer?
5. ☐ triple negative breast cancer?
6. ☐ Eastern European (Ashkenazi) Jewish ancestry and a history of breast or ovarian cancer
7. ☐ male breast cancer

Have more than one member on the same side of the family had:

1. ☐ breast cancer?
2. ☐ ovarian or fallopian tube cancer?
3. ☐ prostate cancer?
4. ☐ pancreatic cancer?

If you answered yes to any of these items, see a genetics expert and contact FORCE now.
For more information on talking to your family, visit facingourrisk.org/familyhistory.

FORCE Facing Our Risk of Cancer Empowered
Fighting Hereditary Breast and Ovarian Cancer

Toll-free Helpline: 866-288-RISK (7475)
info@facingourrisk.org www.facingourrisk.org

Have you or any family member had:

1. ☐ ovarian or fallopian tube cancer at any age?
2. ☐ breast cancer at age 50 or younger?
3. ☐ more than one breast cancer diagnosis?
4. ☐ both breast and ovarian cancer?
5. ☐ triple negative breast cancer?
6. ☐ Eastern European (Ashkenazi) Jewish ancestry and a history of breast or ovarian cancer
7. ☐ male breast cancer

Have more than one member on the same side of the family had:

1. ☐ breast cancer?
2. ☐ ovarian or fallopian tube cancer?
3. ☐ prostate cancer?
4. ☐ pancreatic cancer?

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Who to refer for cancer risk assessment:

Personal history or family history of:

- Early age onset cancer (eg. breast under age 45)
- More than one primary cancer in an individual (bilateral breast cancer)
- Cancers occurring in multiple generations on the same side of the family
- Cluster of cancers consistent with specific cancer syndromes (eg. breast with ovarian; colon with endometrial; pancreatic with melanoma)
- Rare cancers with or without additional cancers in a family (retinoblastoma; adrenocortical carcinomas)
- Unusual presentation of cancer (male breast cancer)
- Uncommon tumor histology (medullary thyroid cancer)
- Geographic or ethnic populations known to be at risk due to founder effect (Ashkenazi Jewish heritage)

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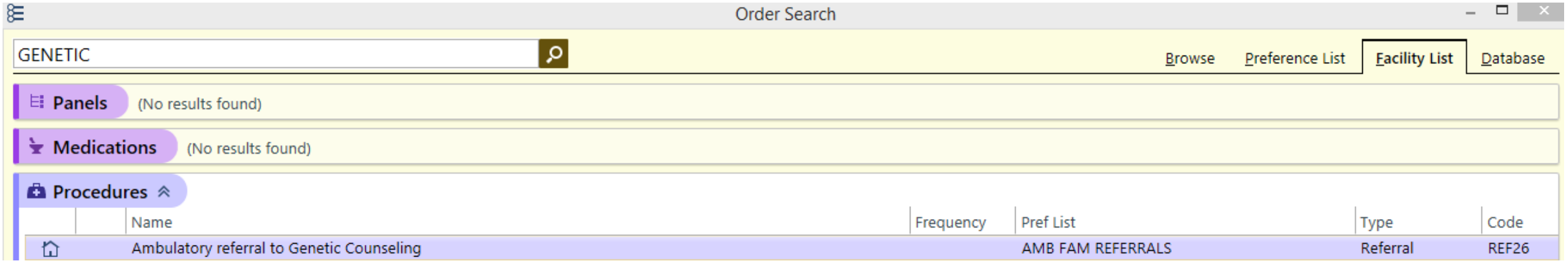
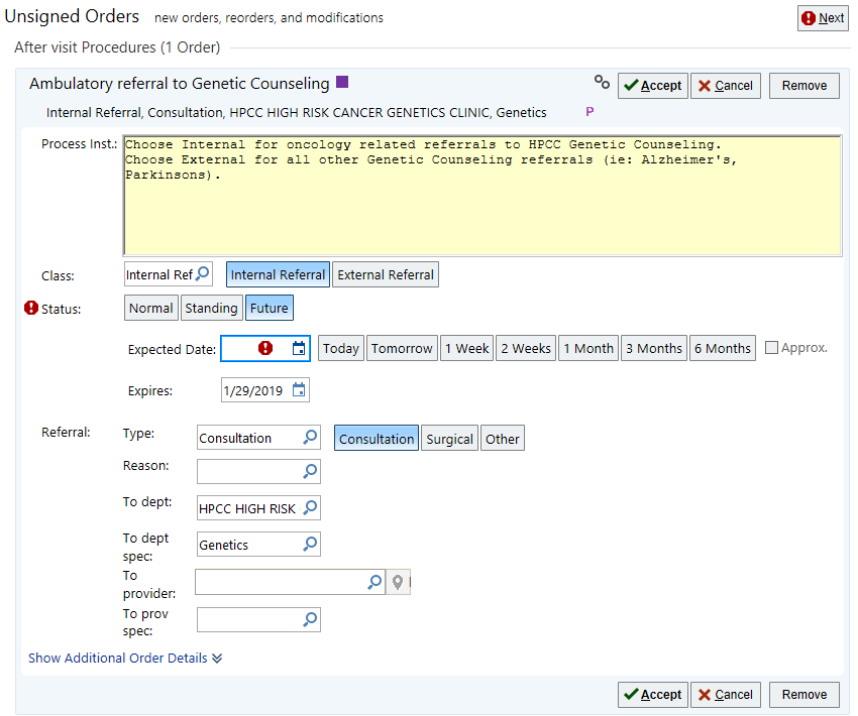
EPIC Referral:



Ambulatory referral to Genetic Counseling: Internal



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Breast Cancer Risk Assessment

Breast Cancer Risk Models:

Gail Model

BRCAPRO

Claus Model

Tyrer-Cuzick Model (IBIS)

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Breast Cancer Risk Assessment

Gail Model:

- A computerized tool that estimates a woman's 5 year and lifetime risk of developing breast cancer to age 90
- Also called the National Cancer Institute (NCI) Breast Cancer Risk Assessment Tool. (NIH…Turning Discovery Into Health, 2016)
- www.cancer.gov/bcrisktool/
- Not to used for women with breast cancer history (Invasive or DCIS) or history of LCIS

- Does not take into account paternal family history
- Inputs: mostly non-genetic risk factors (11 data points)
  - Age
  - Race (white, African American, Hispanic, Asian American, Native American or Alaska Native) with sub race
  - Ages at menarche and first live birth
  - First degree relatives with breast cancer
  - Previous breast biopsy
    - Takes into account AH but not LCIS

Culver, J., Lowstuter, K. & Bowling, L. (2006, 2007). Assessing Breast Cancer Risk and BRCA1/2 Carrier Probability. *Breast Disease*. 27, 5-20.

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Breast Cancer Risk Assessment

BRCAPRO

- Estimates for breast and ovarian cancer based on the likelihood that a person carries a BRCA1/2 mutation
- 5 year risk and lifetime risk to age 85
- Located through U.T. Southwestern Medical Center (CancerGene) http://www4.utsouthwestern.edu/breasthealth/cagene/
- Risk estimates tend to be much lower than other models

- Inputs
  - Both affected and unaffected individuals up to second degree relatives
  - Breast and ovarian cancer history
  - Male breast cancer
  - Bilateral breast cancer
  - Breast pathology (invasive vs DCIS)
  - Oophorectomy status
  - Ethnicity (white, black, Hispanic, Asian, Native American)
- Data entry- enter pedigree and numerous data points
- Does not account for:
  - Non-hereditary risk factors
  - Non-BRCA1/2 risk elements (will underestimate risk in breast-cancer only families)

Culver, J., Lowstuter, K. & Bowling, L. (2006, 2007). Assessing Breast Cancer Risk and BRCA1/2 Carrier Probability. *Breast Disease*. 27, 5-20.

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Breast Cancer Risk Assessment

Claus Model

- A risk model for familial risk of breast cancer in a large population-based, case-control study conducted by the Centers for Disease Control
- Based on data from the Cancer and Steroid Hormone Study (4,730 cases and 4,688 controls aged 20-54 years).
- 5 year risk and lifetime risk to age 79
- iPhone app: BRisk (City of Hope)

- Provides age-specific risk estimates of breast cancer in women with a family history.
- Inputs
  - Incorporates maternal and/or paternal 1st and 2nd degree relatives and adjusts risk based on age at diagnosis.
  - Easy to use iPhone app
- Does not incorporate:
  - Family size
  - Ethnic background
  - Non-genetic risk factors
  - More than two affected family members

Culver, J., Lowstuter, K. & Bowling, L. (2006, 2007). Assessing Breast Cancer Risk and BRCA1/2 Carrier Probability. *Breast Disease*. 27, 5-20.

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Breast Cancer Risk Assessment

Tyrer-Cuzick Model (Version 8)

- Incorporates probability of BRCA1/2 mutation, the likelihood of a low penetrance gene mutation, and personal risk factors.
- Available at (download program):
  - http://www.ems-trials.org/riskevaluator/
- 5 year and lifetime risk for breast cancer to age 80
- Tends to be the highest estimated risk of breast cancer
- User friendly printable output

- Inputs (18+ data points)
  - Age
  - Age at menarche
  - Parity
  - Age at first livebirth
  - Age at menopause
  - History of Atypical hyperplasia or LCIS
  - Height
  - Weight
  - Family history
    - Age of family members
    - Age of diagnosis of affected family members
    - Number of paternal and maternal aunts
    - Number of sisters
    - Number of daughters
    - Affected male family members and cousins

Culver, J., Lowstuter, K. & Bowling, L. (2006, 2007). Assessing Breast Cancer Risk and BRCA1/2 Carrier Probability. *Breast Disease*. 27, 5-20.

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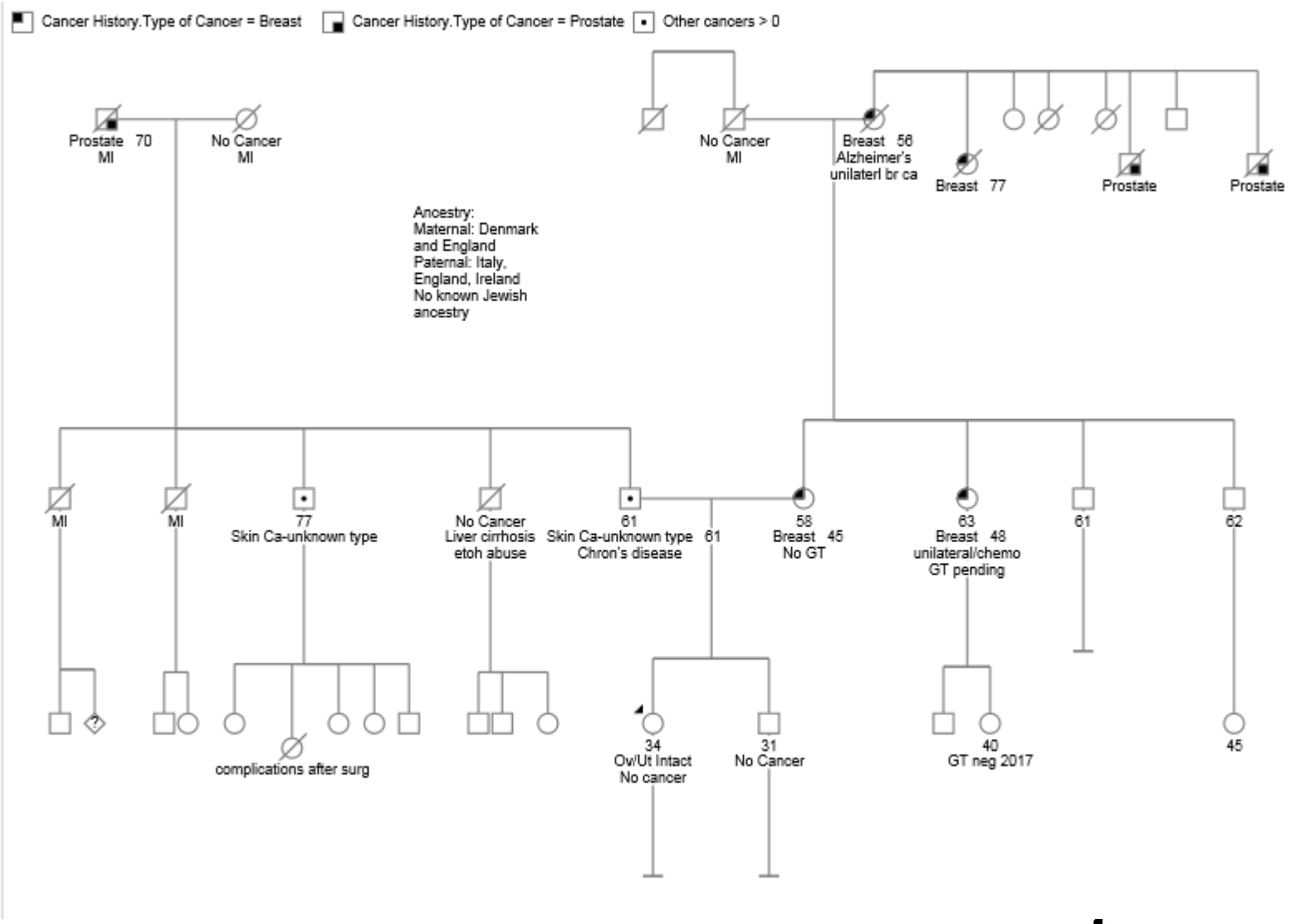
Case Study#1

- 34 y/o female- premenopausal (Mirena IUD), nulliparous
- Unaffected by cancer
- Mammogram: 12/2017- baseline- extreme breast density; BIRADS 1-negative
- Family history:
  - Mother- age 45
  - Maternal aunt- age 48
  - Maternal grandmother- age 56
- Limited Paternal Structure
- Genetic testing of affected family members



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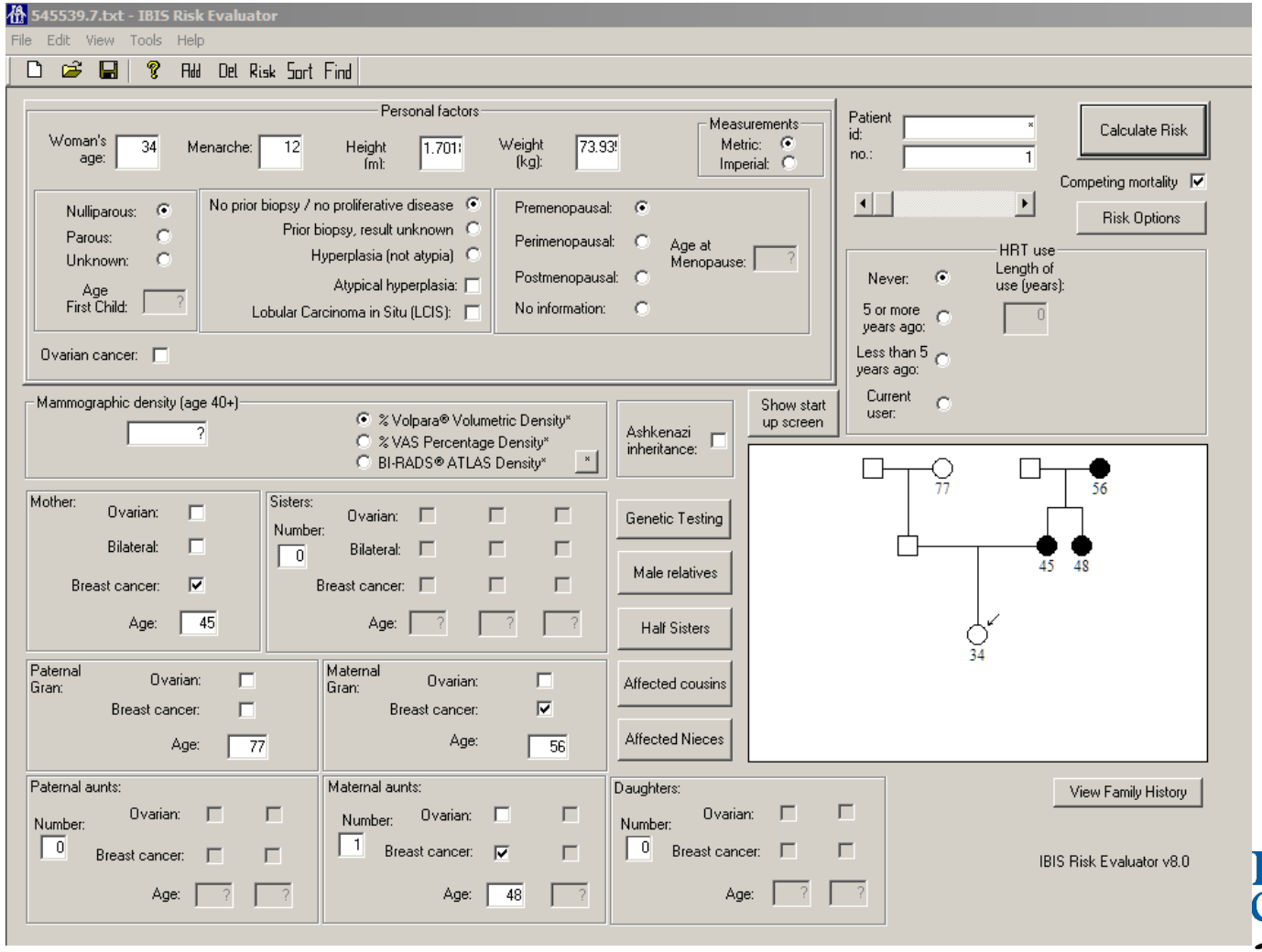
Case Study #1

Tyrer-Cuzick Model Version 8: Input



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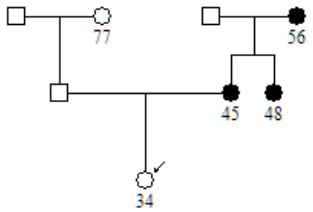
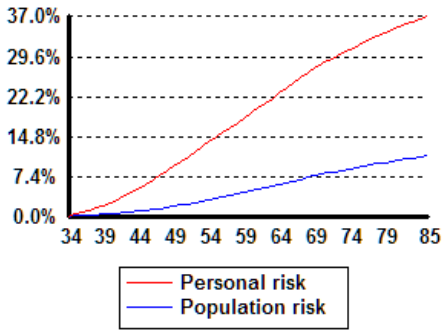
Case Study#1

Tyrer-Cuzick Model Version 8: Output

Print Preview

ID: *	Competing mortality projection
Age is 34-yrs.	Risk after 5 years is 1.9%.
Age at menarche 12-yrs.	5 year population risk is 0.3%.
Nulliparous.	Lifetime risk is 36.7%.
Premenopausal.	Lifetime population risk is 11.1%.
Height is 1.7018 m.	Probability of a BRCA1 gene is 3.01%.
Weighs 73.9352 kg.	Probability of a BRCA2 gene is 4.79%.
Never used HRT.	





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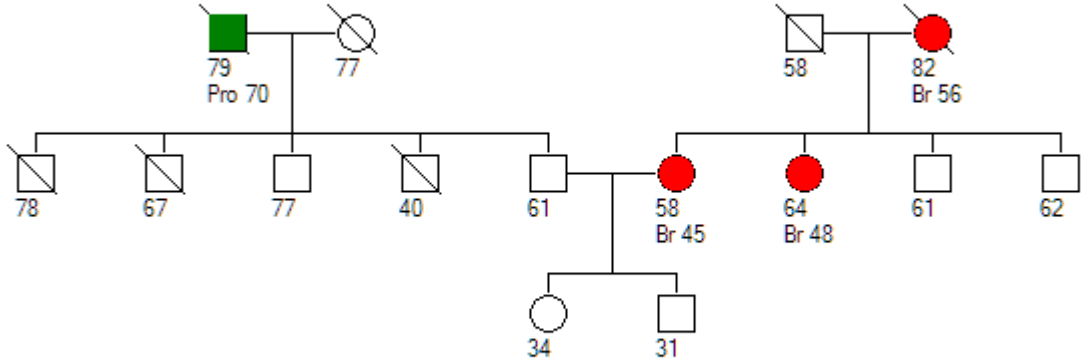
Case Study #1



CaGene6 Local BayesMendel 2.0-813 R 2.15.2

Mutation Probabilities

BRCA1		**MLH1**	
BRCAPRO	0.0142	MMRPRO	0.0001
BRCA2		**MSH2**	
BRCAPRO	0.0272	MMRPRO	0.0001
Any BRCA		**MSH6**	
BRCAPRO	0.0414	MMRPRO	0.0001
		Any MMR	
p16		MMRPRO	0.0002
MELAPRO	0.0000	**Pancreas Gene**	
		PANCPRO	0.0038

Cancer Risks 5-Year Lifetime

Breast		
Gail	0.005	0.191
Chen	NA	NA
Claus	0.017	0.318
BRCAPRO	0.005	0.136
Ovarian	0.000	0.029
Colorectal	0.000	0.033
Endometrial	0.000	0.019
Melanoma	0.002	0.021
Pancreas	0.000	0.013

Output Manager Gail Chen Claus BRCAPRO MMRpro MELAPRO PANCPRO

Gail Model: 0.5% 5 year risk and 19.1% lifetime risk
Claus Model: 1.7% 5 year risk and 31.8% lifetime risk
BRCAPRO: 0.5% 5 year risk and 13.6% lifetime risk

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National Comprehensive Cancer Network Guidelines (NCCN) Breast Cancer Screening and Diagnosis (Version 1.2017)

- Women who have a lifetime risk >20% as defined by models that are largely dependent on family history:
  - Clinical encounter every 6-12 months
    - To begin when identified as being at increased risk
    - Referral to genetic counseling
  - Annual screening mammogram
    - To begin 10 years prior to the youngest family member but not less than 30 years
      - Consider tomosynthesis
  - Recommend annual breast MRI
    - To begin 10 years prior to the youngest family member but not less than age 25 years
  - Consider risk reduction strategies
  - Breast awareness

National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis (Version 1.2017). https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf Accessed 1.29.2018

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Case Study #1

- Discuss risk tolerance regarding breast cancer risk
- Recommendations:
  - Await genetic test results of affected family member (aunt); mother declined
    - If positive- consider genetic testing for known gene mutation or panel test
    - If negative- consider genetic testing using gene panel
  - Consider implications of genetic testing
  - Breast cancer screening
    - Clinical encounter every 6-12 months
    - Annual mammogram- encouraged use of 3D mammogram
    - Recommend annual breast MRI
      - Discussed benefits and limitations of breast MRI
        - Most research based on BRCA mutation carriers
      - Benefit: earlier stage of breast cancer; additional screening tool; breast density
      - Limitations: high sensitivity and low specificity (higher false-positive findings); impact on survival not established; cost (EFY funds); can not detect microcalcifications; IV contrast; tolerance of MRI

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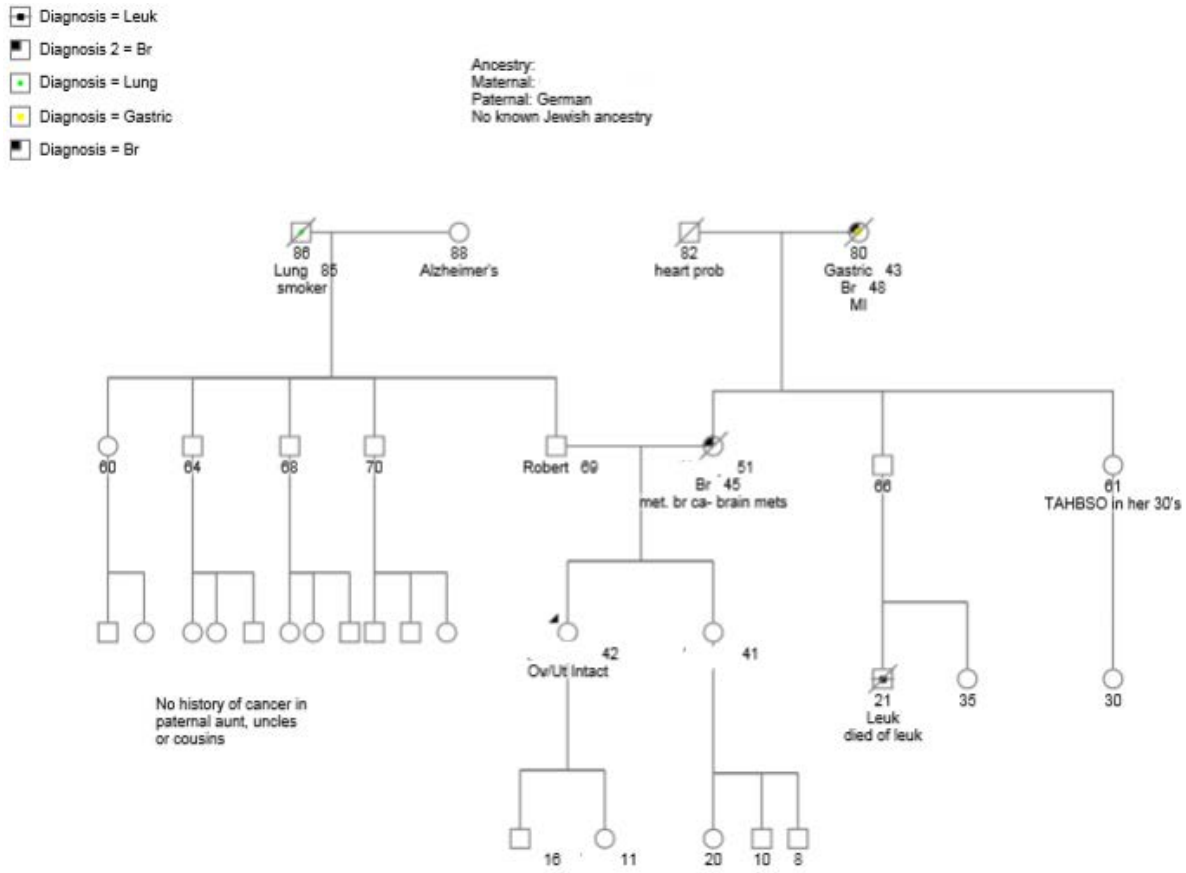
Case Study #2

- 42 y/o female unaffected by cancer
- Premenopausal- on OCP for menorrhagia- referred by GYN- considering hyst
- Last mammogram in 2015 (seen in 1/2017)- follow-up with US and breast MRI for cysts/fibrocystic changes
- Family history:
  - Mother age 45
  - Maternal grandmother age 48
- No family members had genetic testing



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Case Study #2

Breast Cancer Risk Assessment Model	5-Year Breast Cancer Risk	Lifetime Risk of Breast Cancer (Age 70)
BRCAPRO	0.8%	11.4%
Tyrer-Cuzick v7	2.1%	24.3%
Claus	1.0%	11.6%
BOADICEA	1.9%	14.2%
Gail	1.4%	19.6%

Patient decided to proceed with genetic testing.

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Case Study #2

BRCA1/2 Analyses with CancerNext

RESULTS	
BRCA2	Pathogenic Mutation: c.9357_9360delAATT
SUMMARY	

POSITIVE: Pathogenic Mutation Detected

BRCA2 Associated Cancers and Risks:

Cancer Type	General Population Risk	Mutation Risk: BRCA2
Breast (by age 70)	12%	40%-84%
Second Primary Cancer in Breast	2% within 5 years	10.8% within 5 years
Ovarian (by age 70)	1%-2%	16%-27%
Male Breast Cancer	0.1%	Up to 8.9%
Prostate	6% through age 69	<39%
Pancreatic	1.50%	2%-7%
Melanoma	1.6%	Elevated risk

Patient elected to have:

- Bilateral risk reduction mastectomy with immediate reconstruction
- Bilateral risk reduction slapingo-oophorectomy with hysterectomy

Cascade testing for family members:

- Father tested negative
- Sister and maternal family members

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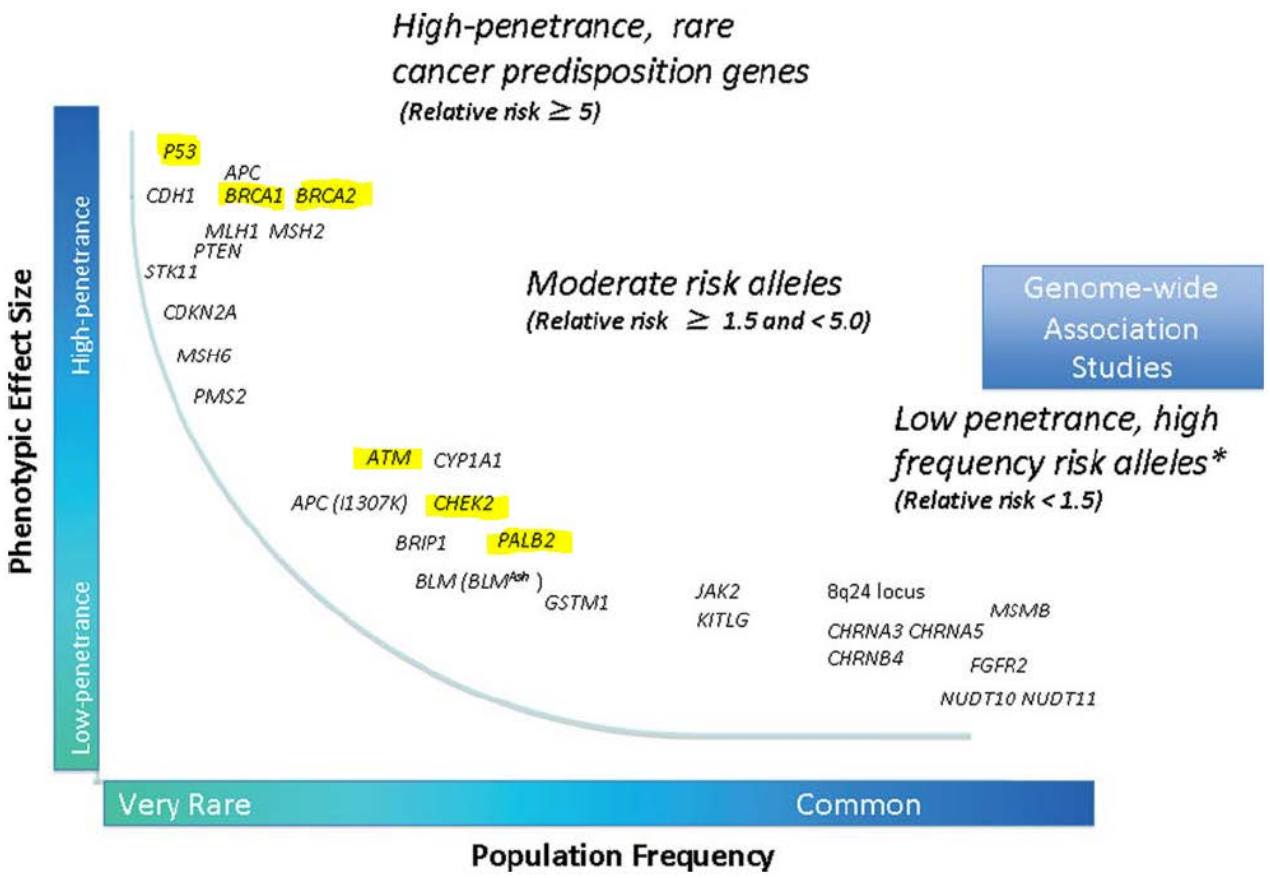
High Penetrance vs Moderate Penetrance Gene Mutations



Penetrance of Gene Mutations:

- High risk vs moderate risk
- Informative genetic test results
- Clinical utility
- Actionable results
- Evolution of genetics

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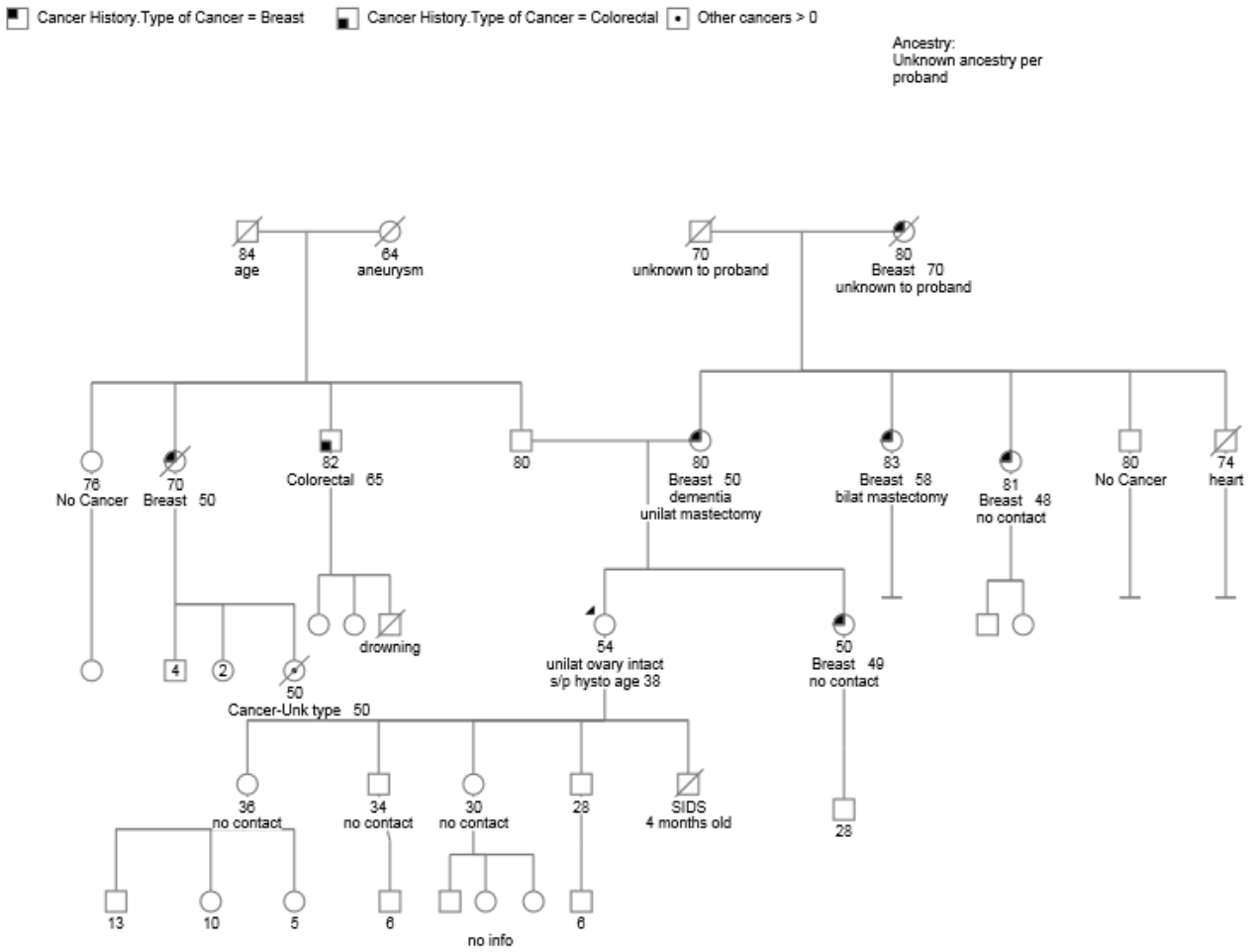
Case Study #3

- 54 y/o female- unaffected by cancer
- Post-menopausal
- Last mammogram: 1/2018 BIRADS: 1 negative with heterogeneous breast density
- Family history:
  - Sister: age 49
  - Mother: age 50
  - MGM: age 70
  - 2 maternal aunts: age 58 and 48
- No family members have had genetic testing



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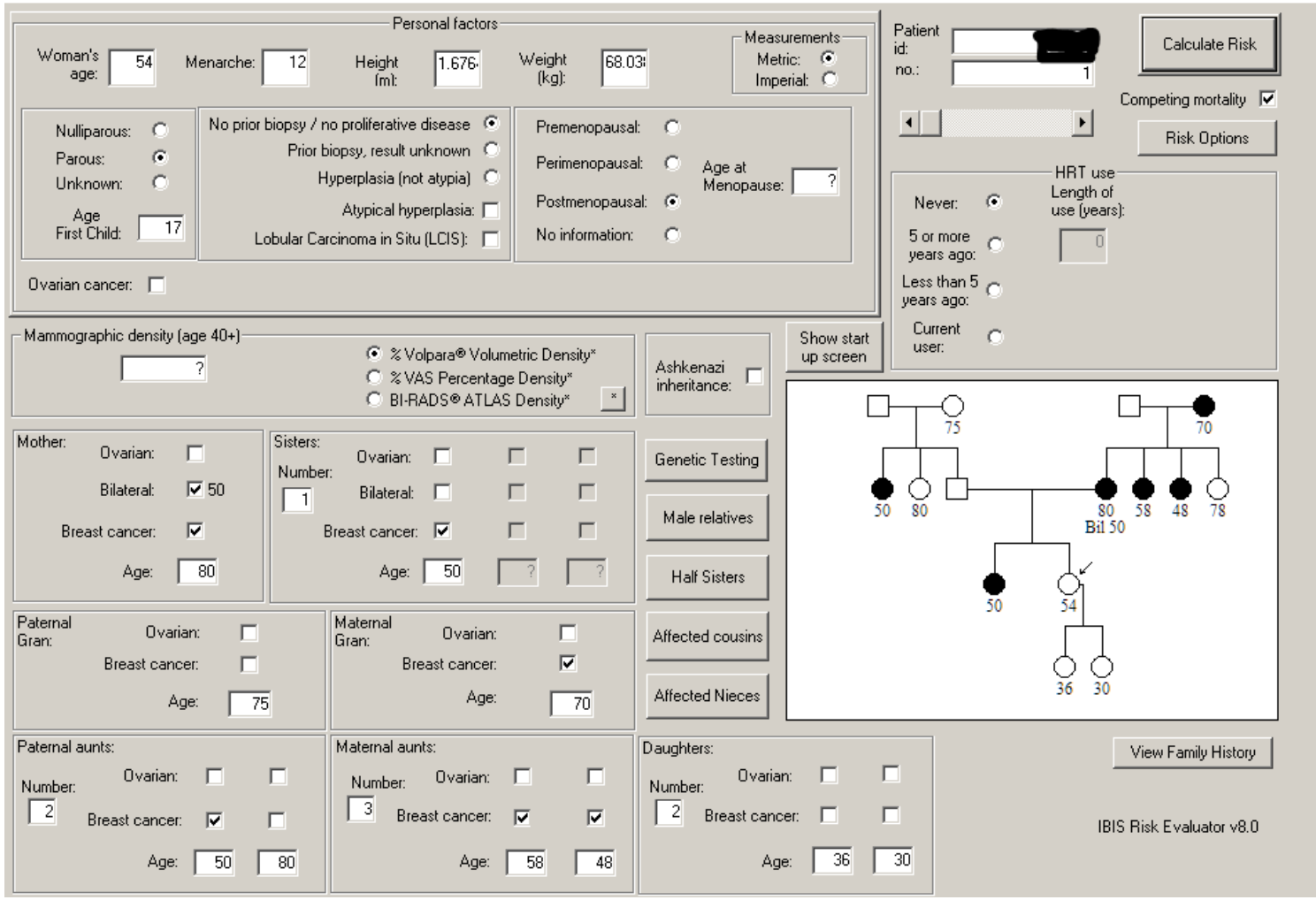
Case Study #3



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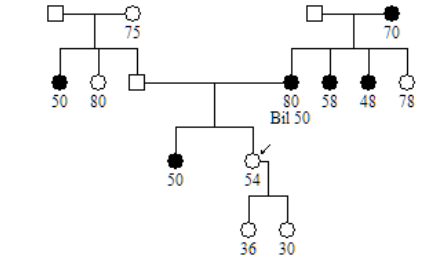
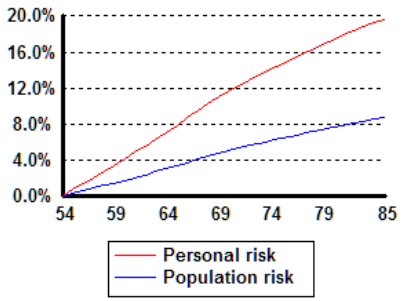
Case Study #3

Tyrer-Cuzick (version 8.0)
No breast density indicated
Lifetime risk: 19.5%

ID: [redacted]
Age is 54-yrs.
Age at menarche 12-yrs.
Age at first birth 17-yrs.
Age at menopause unknown.
Height is 1.6764 m.
Weighs 68.0385 kg.
Never used HRT.

Competing mortality projection
Risk after 5 years is 3.3%.
5 year population risk is 1.4%.
Lifetime risk is 19.5%.
Lifetime population risk is 8.6%.
Probability of a BRCA1 gene is 0.53%.
Probability of a BRCA2 gene is 1.87%.





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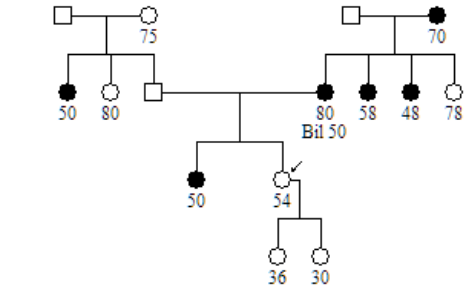
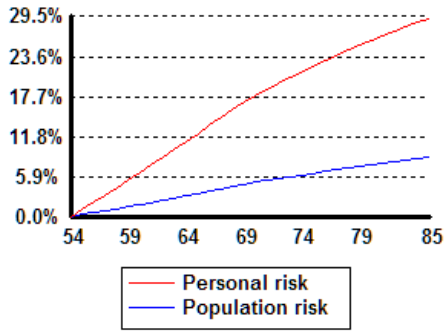
Case Study #3

ID: [redacted]
Age is 54-yrs.
Age at menarche 12-yrs.
Age at first birth 17-yrs.
Age at menopause unknown.
Height is 1.6764 m.
Weighs 68.0385 kg.
Never used HRT.
BI-RADS® density d (extrem. dense)

Competing mortality projection
Risk after 5 years is 5.2%.
5 year population risk is 1.4%.
Lifetime risk is 29%.
Lifetime population risk is 8.6%.
Probability of a BRCA1 gene is 0.53%.
Probability of a BRCA2 gene is 1.87%.





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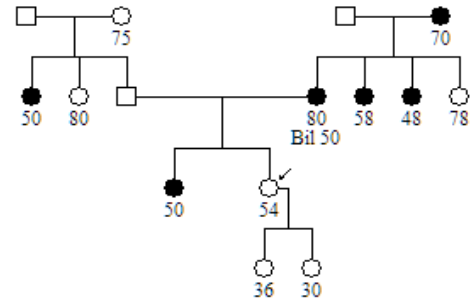
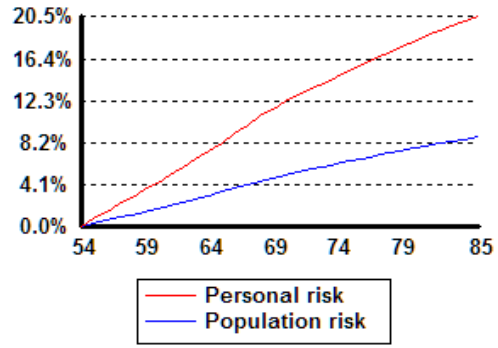
Tyrer-Cuzick (version 8)
Extreme breast density:
Lifetime risk: 29%
Heterogeneous breast density:
Lifetime risk: 20.4%

ID: [redacted]
Age is 54-yrs.
Age at menarche 12-yrs.
Age at first birth 17-yrs.
Age at menopause unknown.
Height is 1.6764 m.
Weighs 68.0385 kg.
Never used HRT.
BI-RADS® density c (heterogeneous)

Competing mortality projection
Risk after 5 years is 3.5%.
5 year population risk is 1.4%.
Lifetime risk is 20.4%.
Lifetime population risk is 8.6%.
Probability of a BRCA1 gene is 0.53%.
Probability of a BRCA2 gene is 1.87%.





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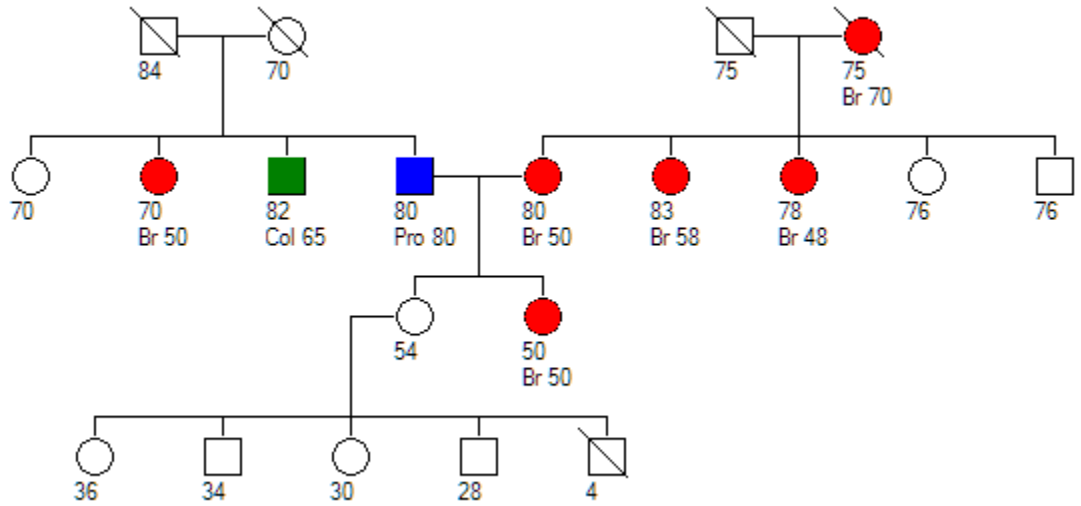
Case Study #3



CaGene6 Local BayesMendel 2.0-813 R 2.15.2

Mutation Probabilities

BRCA1		**MLH1**	
BRCAPRO	0.0024	MMRPRO	0.0001
BRCA2		**MSH2**	
BRCAPRO	0.0151	MMRPRO	0.0001
Any BRCA		**MSH6**	
BRCAPRO	0.0175	MMRPRO	0.0000
p16		**Any MMR**	
MELAPRO	0.0000	MMRPRO	0.0002
		Pancreas Gene	
		PANCPRO	0.0022

Cancer Risks	5-Year	Lifetime
Breast		
Gail	0.054	0.338
Chen	NA	NA
Claus	0.042	0.178
BRCAPRO	0.015	0.102
Ovarian	0.002	0.016
Colorectal	0.002	0.031
Endometrial	0.002	0.017
Melanoma	0.002	0.014
Pancreas	0.000	0.013

Gail Model: 5.4% 5 year risk and 33.8% lifetime risk
Claus Model: 4.2% 5 year risk and 17.8% lifetime risk
BRCAPRO: 1.5% year risk and 10.2% lifetime risk

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Case Study #3

Patient elected to proceed with genetic testing.

Genetic test results:

RESULT: NEGATIVE - NO CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

Note: "CLINICALLY SIGNIFICANT," as defined in this report, is a genetic change that is associated with the potential to alter medical intervention.

ADDITIONAL FINDINGS: VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

GENE	VARIANT(S) OF UNCERTAIN SIGNIFICANCE	INTERPRETATION
APC	c.1589T>C (p.Val530Ala) (aka V530A (1589T>C))	**UNCERTAIN CLINICAL SIGNIFICANCE** There are currently insufficient data to determine if these variants cause increased cancer risk.
MLH1	c.14C>T (p.Ala5Val) (aka A5V (14C>T))	

Recommendations:

- Uninformative genetic test results (variants of uncertain significance)
- Discuss risk tolerance regarding risk for breast cancer
- Manage breast cancer risk based upon family history (over 20% lifetime risk for breast cancer)
  - Breast cancer screening
    - Clinical encounter every 6-12 months
    - Annual mammogram- encouraged use of 3D mammogram
    - Recommend annual breast MRI

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Genetic Testing

- Commercial laboratories perform test and interpretation (positive, negative, VUS)
- Covered by most health insurance if patient meets genetic testing criteria for BRCA1/2
  - Medicare will not pay for genetic testing if **not** affected by cancer
- Majority of patients pay $0 (80%)
- Affordable options for pre-payment (not submitted to insurance)
  - $250.00 for gene panel test
- No cost for cancer risk assessment and genetic counseling at Mercy Medical Center/ Hall-Perrine Cancer Center

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Summary:

- Identifying patients for cancer risk assessment/ genetic testing
  - Young age diagnosis ≤45-50 years
  - Ovarian cancer
  - Two primary breast cancers
  - Male breast cancer
  - Family history of three or more cancers associated with hereditary breast and ovarian cancer
- Breast Cancer Risk Assessment Models
  - All models are not created equal
  - Wide range of breast cancer risk based on family history and model used for calculation
- Breast Cancer Screening
  - Greater than 20% lifetime risk calculated using breast cancer risk model
  - Individualized tolerance of breast cancer risk varies
  - Annual mammogram and breast MRI- benefits and limitations

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