Improving Access to Genetic Counseling and Testing

Nancy Harris, VP Oncology, Sharp HealthCare

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Genetic Counseling Challenges

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2019
Genetic/Familial High-Risk Assessment: Breast and Ovarian

NCCN Guidelines Index
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Discussion

BREAST AND OVARIAN MANAGEMENT BASED ON GENETIC TEST RESULTS[a-d]

The inclusion of a gene on this table below does not imply the endorsement either for or against multi-gene testing for moderate-penetrance genes.

Gene	Breast Cancer Risk and Management	Ovarian Cancer Risk and Management	Other Cancer Risks and Management
PALB2	**Increased risk of breast cancer** • Screening: Annual mammogram with consideration of tomosynthesis and breast MRI with contrast at 30 y[a] • RRM: Evidence insufficient, manage based on family history	**Unknown or insufficient evidence for ovarian cancer risk**	Unknown or insufficient evidence
	Comments: Counsel for risk of autosomal recessive condition in offspring.		
PTEN	**Increased risk of breast cancer** • See Cowden Syndrome Management	**No increased risk of ovarian cancer**	See Cowden Syndrome Management
RAD51C	**Unknown or insufficient evidence for breast cancer risk**	**Increased risk of ovarian cancer** • Consider RRSO at 45–50 y	N/A
	Comments: Counsel for risk of autosomal recessive condition in offspring. Based on estimates from available studies, the lifetime risk of ovarian cancer in carriers of pathogenic/likely pathogenic variants in *RAD51C* appears to be sufficient to justify consideration of RRSO. The current evidence is insufficient to make a firm recommendation as to the optimal age for this procedure. Based on the current, limited evidence base, a discussion about surgery should be held around age 45–50 y or earlier based on a specific family history of an earlier onset ovarian cancer.		
RAD51D	**Unknown or insufficient evidence for breast cancer risk**	**Increased risk of ovarian cancer** • Consider RRSO at 45–50 y	N/A
	Comments: Based on estimates from available studies, the lifetime risk of ovarian cancer in carriers of pathogenic/likely pathogenic variants in *RAD51D* appears to be sufficient to justify consideration of RRSO. The current evidence is insufficient to make a firm recommendation as to the optimal age for this procedure. Based on the current, limited evidence base, a discussion about surgery should be held around age 45–50 y or earlier based on a specific family history of an earlier onset ovarian cancer.		
STK11	**Increased risk of breast cancer** • Screening: See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal • RRM: Evidence insufficient, manage based on family history	**Increased risk of non-epithelial ovarian cancer** • See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal	See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal
TP53	**Increased risk of breast cancer** • See Li-Fraumeni Syndrome Management	**No increased risk of ovarian cancer**	See Li-Fraumeni Syndrome Management

Footnotes on GENE-5

RRM: Risk-reducing mastectomy
RRSO: Risk-reducing salpingo-oophorectomy

Fast pace of genetic discoveries…

Changing guidelines...

Ability of clinicians to keep pace…

Insurance coverage and co-pays

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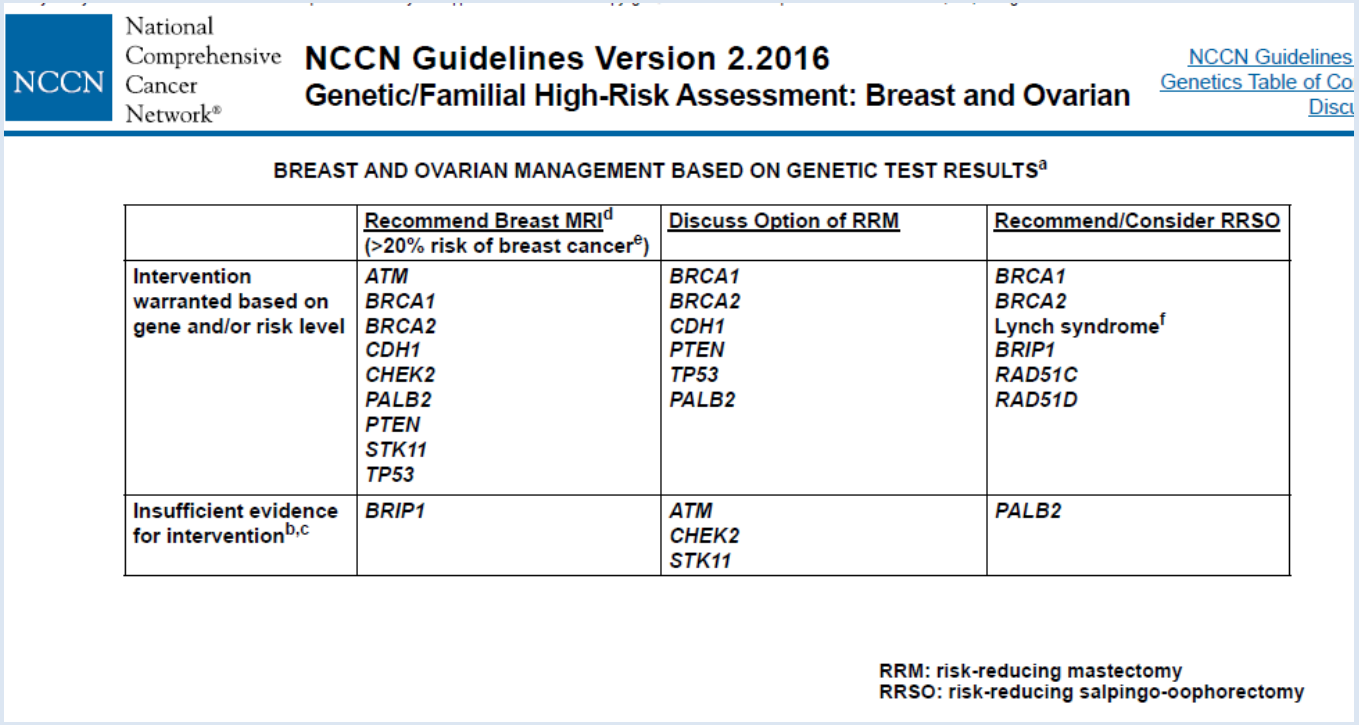
NCCN Guidelines for Care Management: 2016

Breast and Ovarian Hereditary Risk



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NCCN Guidelines Version 2.2016
Genetic/Familial High-Risk Assessment: Breast and Ovarian

NCCN Guidelines
Genetics Table of Co
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BREAST AND OVARIAN MANAGEMENT BASED ON GENETIC TEST RESULTS[a]

	Recommend Breast MRI[d] (>20% risk of breast cancer[e])	Discuss Option of RRM	Recommend/Consider RRSO
Intervention warranted based on gene and/or risk level	*ATM* *BRCA1* *BRCA2* *CDH1* *CHEK2* *PALB2* *PTEN* *STK11* *TP53*	*BRCA1* *BRCA2* *CDH1* *PTEN* *TP53* *PALB2*	*BRCA1* *BRCA2* Lynch syndrome[f] *BRIP1* *RAD51C* *RAD51D*
Insufficient evidence for intervention[b,c]	*BRIP1*	*ATM* *CHEK2* *STK11*	*PALB2*

RRM: risk-reducing mastectomy
RRSO: risk-reducing salpingo-oophorectomy

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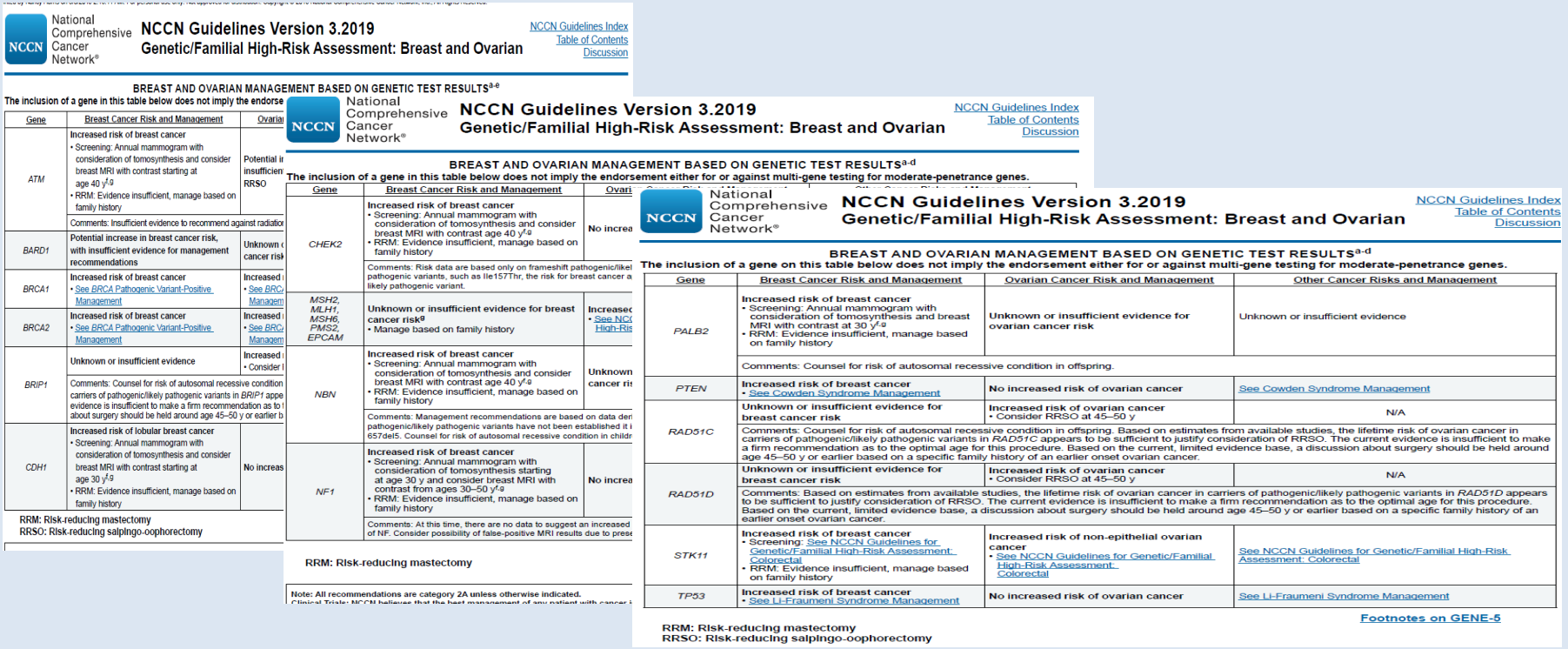
NCCN Guidelines for Care Management: 2019

Breast and Ovarian Hereditary Risk



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Genetic/Familial High-Risk Assessment: Breast and Ovarian

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Footnotes on GENE-5

RRM: Risk-reducing mastectomy
RRSO: Risk-reducing salpingo-oophorectomy

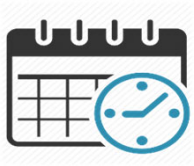
The Cancer Centers of Sharp

- 4500 new cancer cases per year across system
  - 875 breast; 400 CRC; 160 pancreas; 90 Ovarian;
  - 135 High Risk Breast (Dx ≤ age 50 and/or Triple Negative)
- Onsite Genetic Counseling services provided at 2 of 3 Cancer Center locations
- Breast, General, Gyn Onc and Neuro-Oncology Tumor Boards supported by Genetic Counselors

Sharp HealthCare Cancer Genetics Program – History

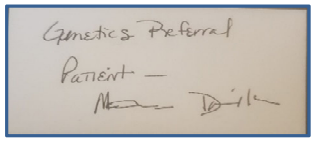
August 2009:
Program Initiated w/ 0.2 FTE Cancer Genetics Counselor; Minimal Consultation Service

Focused program development initiated

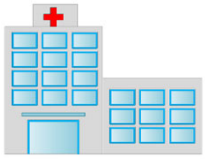


Scheduling
Appointments in Outlook

2015 Staffing
0.8 FTEs GC



Referrals
Variable – even back of business cards



Single cancer center location

Reports
Word documents; no templates

EMR Documentation
Not in EMR; Concerns with patient privacy

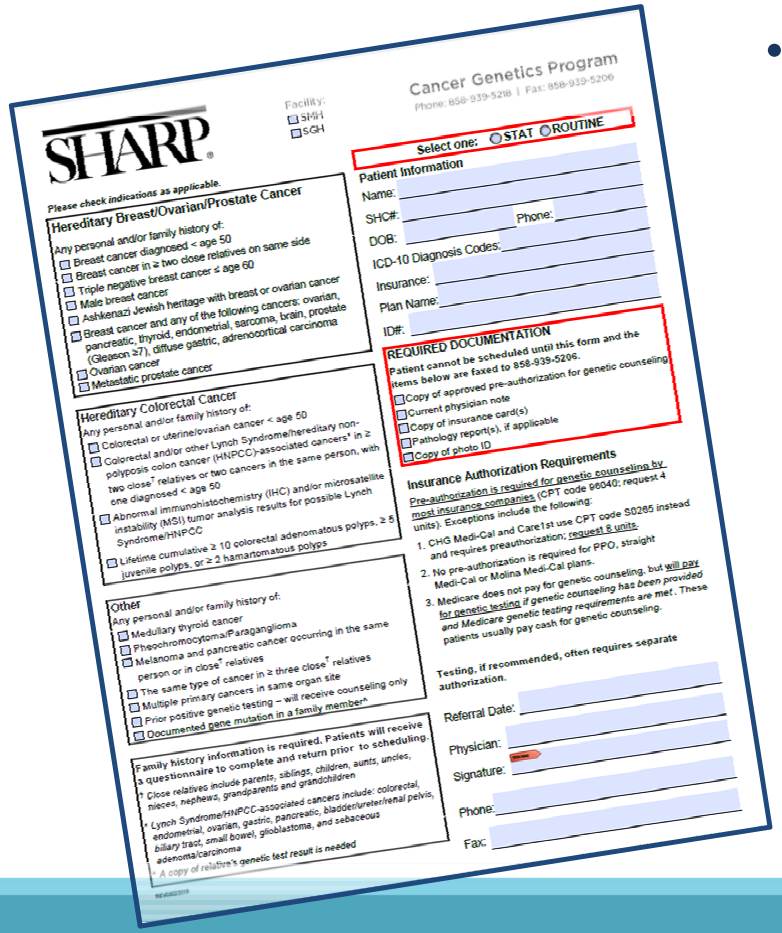
2016 Counselor Added; Still Many Patients Not Seen

	2015	2016 (1/1/-11/30/ 2016	2016 Annualized	% Increase 2016 over 2015
Referrals	476	726	792	60%
Consults	233	356	388	61%
Percent Not Seen	51%	48%	48%	
GC FTEs	0.8 FTEs	0.93 FTEs (avg. over period)	1.20 FTEs (avg. over period)	66%

* **Genetic Counselor added in March 2016.**

Additional Strategies to Address Access

#1 Need for Referral Streamlining



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Facility: ☐ SHH ☐ SCH

Cancer Genetics Program
Phone: 858-939-5218 | Fax: 858-939-5206

Please check indications as applicable.

Hereditary Breast/Ovarian/Prostate Cancer
Any personal and/or family history of:
- ☐ Breast cancer diagnosed < age 50
- ☐ Breast cancer in ≥ two close relatives on same side
- ☐ Triple negative breast cancer < age 60
- ☐ Male breast cancer
- ☐ Ashkenazi Jewish heritage with breast or ovarian cancer
- ☐ Breast cancer and any of the following cancers: ovarian, pancreatic, thyroid, endometrial, sarcoma, brain, prostate (Gleason ≥7), diffuse gastric, adrenocortical carcinoma
- ☐ Ovarian cancer
- ☐ Metastatic prostate cancer

Hereditary Colorectal Cancer
Any personal and/or family history of:
- ☐ Colorectal or uterine/ovarian cancer < age 50
- ☐ Colorectal and/or other Lynch Syndrome/hereditary non-polyposis colon cancer (HNPCC)-associated cancers* in ≥ two close† relatives or two cancers in the same person, with one diagnosed < age 50
- ☐ Abnormal immunohistochemistry (IHC) and/or microsatellite instability (MSI) tumor analysis results for possible Lynch Syndrome/HNPCC
- ☐ Lifetime cumulative ≥ 10 colorectal adenomatous polyps, ≥ 5 juvenile polyps, or ≥ 2 hamartomatous polyps

Other
Any personal and/or family history of:
- ☐ Medullary thyroid cancer
- ☐ Pheochromocytoma/Paraganglioma
- ☐ Melanoma and pancreatic cancer occurring in the same person or in close† relatives
- ☐ The same type of cancer in ≥ three close† relatives
- ☐ Multiple primary cancers in same organ site
- ☐ Prior positive genetic testing – will receive counseling only
- ☐ Documented gene mutation in a family member^

Family history information is required. Patients will receive a questionnaire to complete and return prior to scheduling.

† Close relatives include parents, siblings, children, aunts, uncles, nieces, nephews, grandparents and grandchildren

* Lynch Syndrome/HNPCC-associated cancers include: colorectal, endometrial, ovarian, gastric, pancreatic, bladder/ureter/renal pelvis, biliary tract, small bowel, glioblastoma, and sebaceous adenoma/carcinoma

^ A copy of relative's genetic test result is needed

Select one: ○ STAT ○ ROUTINE

Patient Information
Name:
SHC#: Phone:
DOB:
ICD-10 Diagnosis Codes:
Insurance:
Plan Name:
ID#:

REQUIRED DOCUMENTATION
Patient cannot be scheduled until this form and the items below are faxed to 858-939-5206.
- ☐ Copy of approved pre-authorization for genetic counseling
- ☐ Current physician note
- ☐ Copy of insurance card(s)
- ☐ Copy of photo ID
- ☐ Pathology report(s), if applicable

Insurance Authorization Requirements
Pre-authorization is required for genetic counseling by most insurance companies (CPT code 96040; request 4 units). Exceptions include the following:
1. CHG Medi-Cal and Care1st use CPT code S0265 instead and requires preauthorization; request 8 units.
2. No pre-authorization is required for PPO, straight Medi-Cal or Molina Medi-Cal plans.
3. Medicare does not pay for genetic counseling, but will pay for genetic testing if genetic counseling has been provided and Medicare genetic testing requirements are met. These patients usually pay cash for genetic counseling.

Testing, if recommended, often requires separate authorization.

Referral Date:
Physician:
Signature:
Phone:
Fax:

- Design/Implementation of Referral Form
  - ✓ Guidance on appropriate referrals
  - ✓ Stat or routine referral indicated
  - ✓ Complete insurance information needed
  - ✓ Downloadable, editable PDF for high volume practices
  - ✓ Completion required for efficient information gathering
- Knowledgeable RN or Allied Health Professional as Point Person in High Volume Practices
  - ✓ Single point for referrals, review and triaging
  - ✓ Advocate for workflow support and troubleshooting
- Relationship Development with Referring Practices – Trust

#2 Staffing Enhancements

High performing Administrative Assistant coordinating FHQ completion, scheduling and tracking (1.0 FTE)

- Ensure completion of referral form/information from referring physician office; Enter referral information into genetics software
- Referred patient introduction to Genetics Program and secure email address for FHQ completion
- Schedule stat patients; coordinate timely FHQ completion, tablet or short form if needed
- Monitor FHQ patient progress; answer questions; Contact patient 3 times if FHQ not started or incomplete; notify physician if unsuccessful
- Schedule patients upon FHQ completion; Reschedule patients if needed
- Preview FHQ information to ensure complete for “Do Not Qualify” patients – ensure nothing is missing that may change risk status
- Coordinate authorization verification process with Patient Access Services
- Mail reports to patients who prefer hard copy information
- Answer general questions; Support meeting coordination and general administrative tasks

Staffing Enhancements, con't

Additional Administrative Support (2nd individual; 0.8 FTE)

- Conduct most of general phone contact with patients for securing emails and FHQ completion
- Organize faxed referrals for review
- Assist with completion of referral forms

Genetics Student Support (Part time support as available with studies)

- Genetics projects to review records to make sure complete
- Assist with preparation for records clean-up in preparation for going paperless
- Serve to establish pipeline to meet future counselor needs

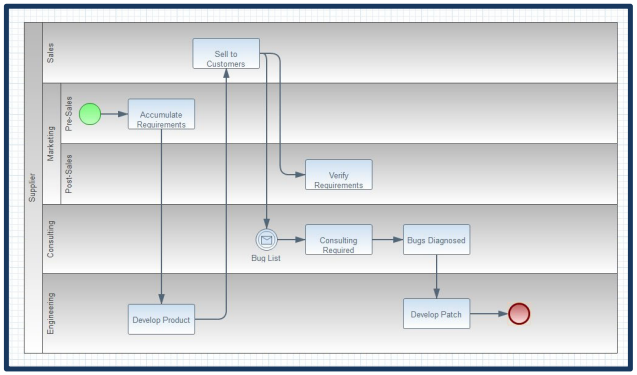
Increase Hours of Part Time Genetics Counselors

- Both 0.5 part time counselors increased time to 0.6 FTE to expand visit capacity

3 Process Improvement Strategies

Diagram Process

- Clarify roles
- Reduce steps
- Combine activities for efficiencies



Collaborate with Managed Care

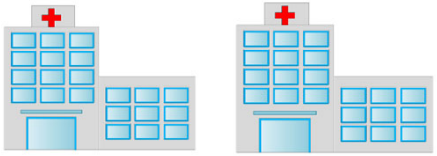
- Secure access to authorization portals to monitor status of approvals and decrease notifications and improve appointment/testing timeliness
- Increase number of counseling units to include both initial and results sessions

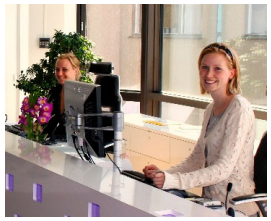
Garner Trust Through Pilots and Relationship Building

- Increase information access in referring physician charts
- Pilot GC test authorization requests rather than asking referring physician to secure

#4 Expand Geographic Sites for Patient Convenience

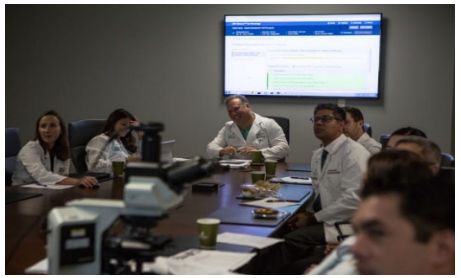
- Increase Access Points to 2 Sites





- Secure assistance for office space, patient reception, administrative support for results delivery

- Site support with tumor board participation and access for curbside consults and questions, and



- Cultivate physician and staff relationships

#5 Genetics-Specific Software Support

First Round of Genetics Software

- Selected national product over home grown product
- Implemented selected product - Product automated several tasks, but found significant limitations

Reviewed 2nd Software Product Identified Later (CancerIQ)

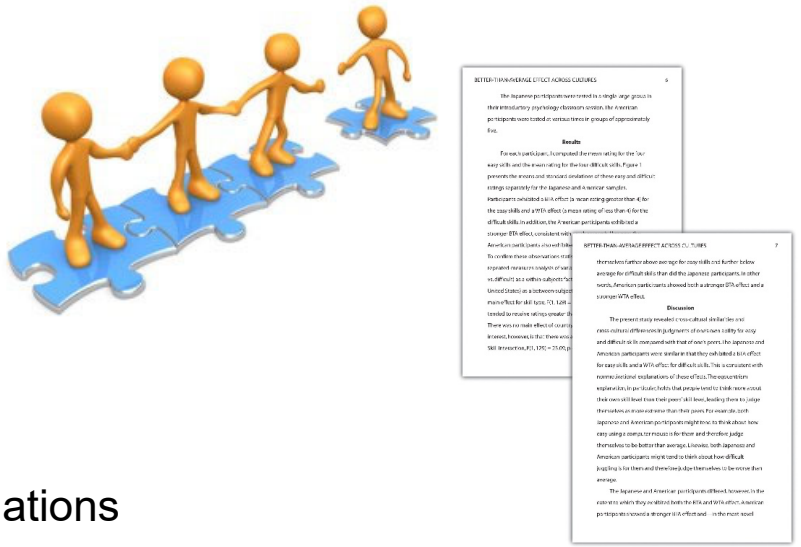
- Much more rigorous product review
  - 61 elements of operational product functionality and support evaluated
  - Information Technology and Consumer-Facing Technology reviews completed as well

Genetics IT Project Strategic Goals

1. Standardization of Consultation and Results and Recommendations Reports
2. Reduction of Genetic Counselor time spent in pre-visit and report preparation
3. Increase number of patient consults seen

Drive Efficiencies through IT Automation and Standardization

- Family Health Questionnaire (FHQ)
  - ✓ Online or by Tablet; English and Spanish
- Patient Communication (Emails)
  - ✓ Auto generated as reminders for FHQ completion
- Provider Communication
  - ✓ Incomplete Referral Form
  - ✓ Patient Contact Attempts
- Report Templates (Patient and Provider)
  - ✓ Initial Consult, Disclosure/ Results and Recommendations
- *Smart Text* Terms/Definitions/Care Management Recommendations
  - ✓ Hyperlinked definitions/explanations of terms, results, care management recommendations



CancerIQ Experience:

Supports Program Goals for Access, Quality and Operational Efficiency

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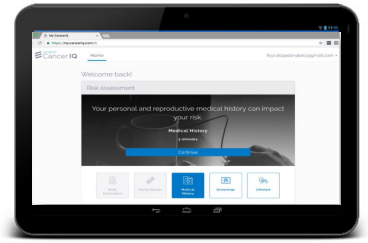
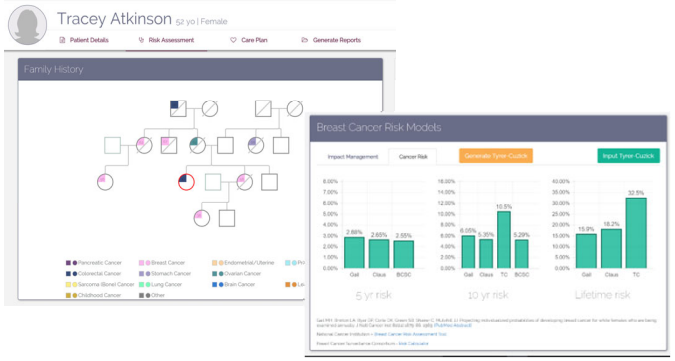
CancerIQ Attributes: A Program Perspective

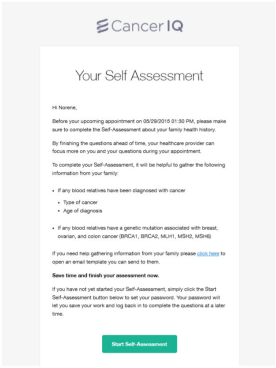


Family Health Questionnaire (FHQ)

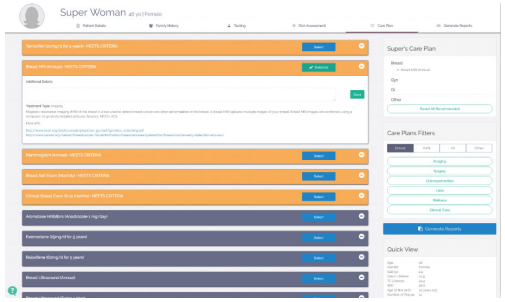
- English and Spanish
- Online and Tablet



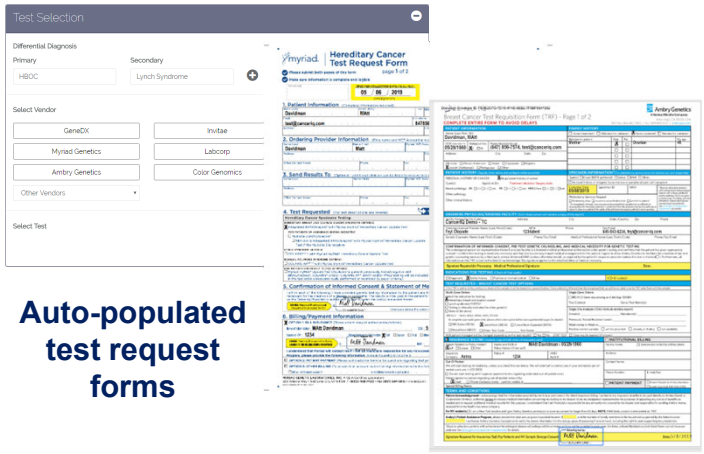
FHQ generated risk assessments and pedigrees



Auto-generated patient reminders for FHQ completion

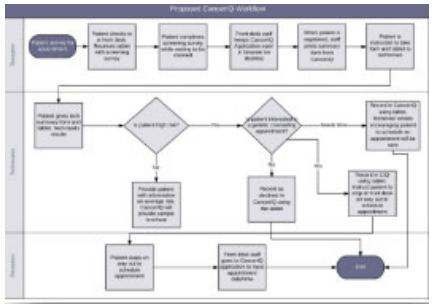


NCCN care management guidelines



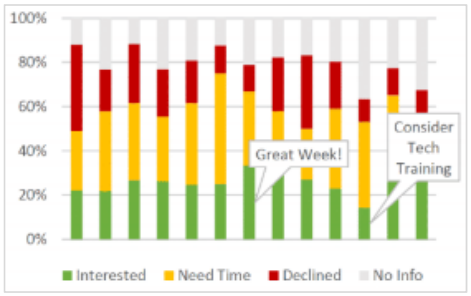
Auto-populated test request forms

CancerIQ Attributes: A Program Perspective

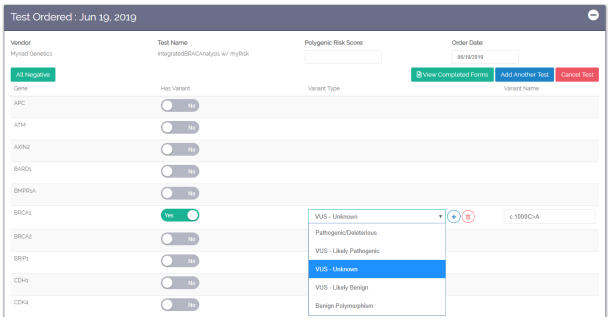


Solutions to meet specific program workflow needs

True partnership – collaborative, responsive, continuously improving



Weekly summary reports of program performance



VUS tracking capability for future patient and physician updates

In Progress

- Completion of Cerner FHIR (Fast Healthcare Interoperability Resources) integration approval process
- Improvements in data tracking and management
- Electronic genetic counselor signature capability

Evidence-Based Care Embedded in CancerIQ

Empiric Risk Models

Breast Cancer Risk:

- ✓ Gail
- ✓ Claus
- ✓ Tyrer-Cuzick v.7
- ✓ Tyrer-Cuzick v.8
- ✓ BCSC
- ✓ Myriad-Frank

Colon Risk:

- ✓ PREMM5
- ✓ PREMM1,2,6 (deprecated)

Risk Guidelines

Genetic Referral/Counseling Guidelines

- ✓ NCCN Hereditary Breast and Ovarian
- ✓ NCCN Hereditary Colorectal Cancer
- ✓ USPSTF Breast

Genetic Testing Guidelines

- ✓ NCCN
- ✓ USPSTF
- ✓ SGO
- ✓ ASBrS

Care Management Guidelines

- ✓ NCCN

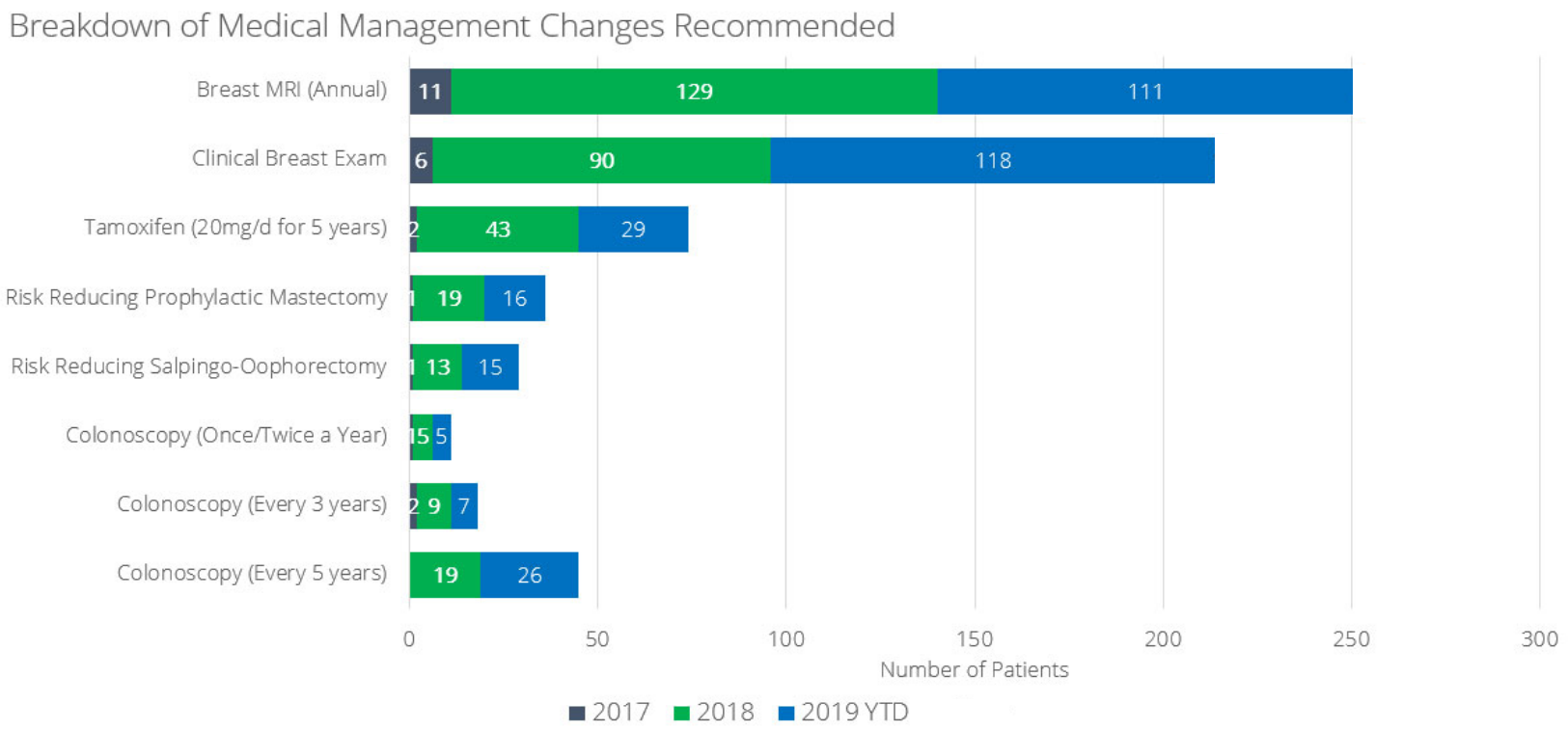
NCCN National Comprehensive Cancer Network®

U.S. Preventive Services TASK FORCE

THE AMERICAN SOCIETY OF Breast Surgeons

SGO Society of Gynecologic Oncology

Performance Visibility/Patient Care Impact



CancerIQ Reports for Monitoring and Improvement

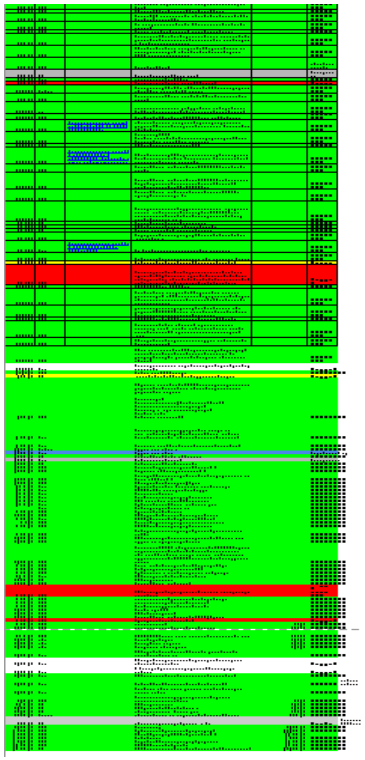
Weekly Report

- **Visit Volume**
  - ✓Initial
  - ✓Follow-up
- **Appointment Summary**
  - ✓Patients added to CIQ
  - ✓Appointments added to CIQ
  - ✓No Shows and Reschedules
- **% FHQs completed online**
- **Patients Tested**
- **% of Patients Seen and Tested (Testing Uptake)**
- **Patients Meeting MRI Eligibility (Tested Negative)**
- **Recommended Changes in Medical Management Summary**

Quarterly Administrative Report

- **Metrics Overview**
- **Product Updates**
- **Goals for Upcoming Quarter**
- **Product Request Status**

Sharp CIQ Product Requests (121 to Date)



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Genetics IT Project Strategic Goals – Achieved!

1. Standardization of Consultation; Results and Recommendations Reports

Standardized Communication

- Standard patient and physician report templates for Consultation and Results/Recommendations Reports
- Standard language for risk, pathogenic mutations and VUS explanations
- Standard physician communication regarding patient status if nonresponsive

2. Reduction of Genetic Counselor time spent in report preparation

Productivity Results

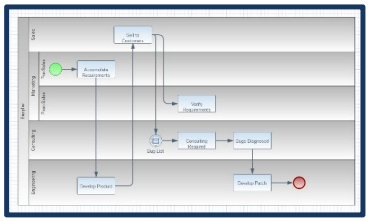
- Pre-Implementation of CancerIQ: average preparation time per patient = 4.5 hours
- Current preparation time per patient (average) = 2.5 hours

✓**Savings of 44.4% preparation hours per patient**

3. Increase the number of patient consults seen

Approximately *350 more patients seen with existing Genetic Counselors!*

Lessons Learned with Software Implementation



1. ***Develop a step by step workflow diagram***
    a) Document each action to be completed by staff in the workflow process
    b) Use document as a cheat sheet to reinforce training
    c) Reference for role clarification and responsibility assignments
    d) Highlight key steps to double check to ensure task completion/ report generation
    e) Identify opportunities to streamline the workflow even further
2. ***Consistently use standard notations and designated locations for critical information***
    a) Ease of tracking patient and results status;
    b) Operations tracking for report turn around times, patient appointment wait times
    c) Communication among team members
3. ***Routinely review steps in process to ensure all staff members are following established workflow and using software in a standard manner***

Additional Improvements Since CancerIQ *Go Live*

- Reports now in Sharp HealthCare EMR
- Appointments scheduled in Cerner Ambulatory module
- **Stats for affected patient treatment decisions**
- High Risk Breast Referrals tracked in Sharp Breast Dashboard

Future Goals and Considerations

- ***Paperless in 2020***
- Increased Program Support and Counseling Staff
- Expanded use of CancerIQ Modules
- Telegenetics
- Expansion to 3rd Cancer Center
- Further EMR Integration
- Additional Genetics integration in Quality Dashboards

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Program Financial Considerations

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Downstream revenue from non-Capitated patients*

- Increased screening frequencies
- High risk screening codes/reimbursement replacement for routine screenings
- Replacement of routine screening modalities with complex modality screening (breast MRI replacing mammography)
- Prophylactic surgeries

Cancer Genetics Program

SHARP®

Care Management Recommendation	Volume (Nov 2017-Dec 2018)
Annual breast MRI screenings	152
Risk-reducing mastectomy	24
Risk-reducing salpingo-oophorectomy	16
Colonoscopy once/twice a year	6
Colonoscopy every 3 years	11
Colonoscopy every 5 years	23

**Depends on organization ownership of revenue streams*

Staff Efficiency Dollars vs Additional Capacity Impact

Staff Efficiency Calculation

- ✓ "Expense reduction" per patient using GC salary time savings (example: 2 hrs/pt)
- ✓ Able to calculate salary savings to see a greater number of patients with same staffing level
- ✓ Not applicable as a viable staff reduction approach due to growing demand for GC services

Increased Opportunity for Favorable Financial Impact

- ✓ Additional GC patients seen due to increased capacity
- ✓ Additional downstream revenue from additional patients
- ✓ Additional averted capitation costs from future/subsequent cancer treatment with screening/prevention measures realized

* Depends on organization ownership of revenue streams or associated population financial risk

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Averted or Reduced Cost of Future/Subsequent Cancers

- **Averted expense to health plans and those with financial risk for capped populations**
  - ✓ Cost of diagnostic work-up
  - ✓ Treatment costs
  - ✓ Provider expense
  - ✓ Surveillance monitoring expense
- **The number of averted new primary cancers in high risk patients can be significant. Many have 2-3 primaries before risk assessment/counseling efforts initiated.**
- **With changes in care management implemented based on counseling and/or testing recommendations, future cancers are likely to be diagnosed at an earlier stage and are less costly to treat.**

Averted Expense Example

Evaluation of Sharp breast cancer patients diagnosed in 2017 included those who were:

- Triple negative at <= age 60, or
- Any breast cancer at <= age 50.

Estimated potential financial impact for IP/OP *hospital expense* for just 1 subsequent cancer dx per patient. *(Does not include all drugs, MD fees, or ongoing surveillance expense)* ***Understated overall expense of total care.***

Averted expense to health plans: $ 5.5M (Net Revenue)

Averted cost for capped patients: $ 2.5M (Direct Expense)

Patient population is mixed so impact is in between.

Estimated cost of routine breast panel testing and counseling for same population = less than $500,000.

Genetics Counseling and Risk Assessment

	2015	2016	2017	2018	% Increase over 2017	% Increase over 2015
Referrals	476	800	1100	1174	7%	147%
Not Seen (Declined; 3 attempts to complete FHQ, Couldn't afford)				392		
Appointments Scheduled in Following Year (New and Disclosure)				373		
Appointments (Consult and Disclosure)	233	406	633	807	27%	246%
GC FTEs	**0.8**	**1.2**	**1.8**	**2.0**	**0%**	**1.2 FTEs**
Patients Tested				599		
Pathogenic Mutation				175	**29% of Patients Tested +**	
VUS Present				141	**24% of Patients Tested +**	
Negative Results (Called)				283		

76.3% of Patients Seen are Tested

Expected Positive Rate for Mutations: 5-10% nationally

Questions?

Thank you!

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