Identifying Appropriate Patients in Your Practice for Hereditary Cancers with Genetic Testing

Objectives



At the conclusion of this presentation, participants should understand the following concepts related to hereditary cancer risk assessment and patient management:

- How utilizing Cancer Family History can help you optimally manage all of your patients
- Stratify patients by risk categories to determine appropriate management and screening recommendations
- Build a Hereditary Cancer Risk Assessment (HCRA) protocol for your practice

Provider Credentials

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Women's Specialty Health Centers
Director of Women's Preventive Health
Noblesville, IN

Testing since 2008
er: Speaker for Myriad Genetics

Disclaimer: Speaker for Myriad Genetics

Use of Cancer Family History



TAKE

CURRENTLY MOST PROVIDERS TAKE CANCER FAMILY HISTORY FOR:

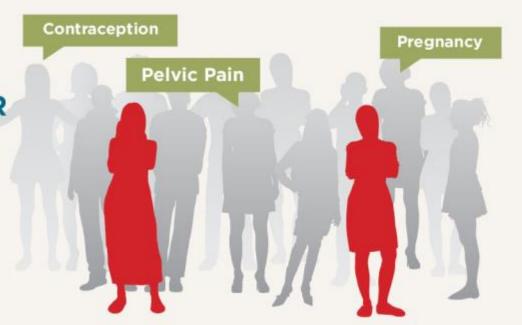
- Well-woman visits
- Hereditary cancer prevention only



UTILIZE

ACTIVELY UTILIZING CANCER FAMILY HISTORY FOR:

- All visits
- Optimal management for all patients



Patient Information

- · 36-year-old
- G2 P2
- Childbearing complete

Visit Type

Contraception consult

Visit Notes

 Patient desires permanent sterilization

Recommended Management

- Common recommendations may include:
 - Tubal occlusion (Essure®)
 - Tubal ligation
 - Vasectomy (for partner)

FAMILY HISTORY						
Relative	Cancer Site	Age Dx				
Mother	Breast	65				
Maternal Aunt	Ovarian	55				



Family history

Expected Single Syndrome Result

Breast Ca lifetime risk: >20%



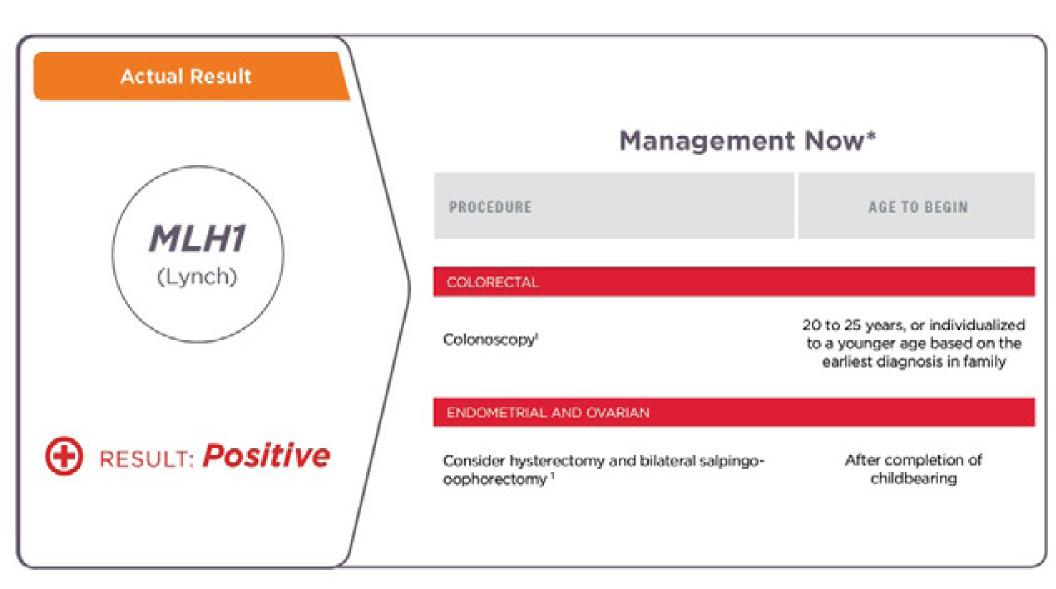
Management

Early and frequent MRI / mammograms

Management

- Earlier and frequent MRI / mammograms
- · Other increased cancer risks
- · BSO





Assessment that is too narrow can create a false sense of security and patient mismanagement





Patient Information

- 44-year-old
- G2 P2
- Childbearing complete

Visit Type

Abnormal Uterine Bleeding

Recommended Management

- Common recommendations may include:
 - Oral contraceptives
 - Mirena® IUD
 - Hysteroscopic removal of fibroids or polyp
 - Ablation

Relative	Cancer Site	Age Dx		
Father	Colorectal	62		
Brother	Colorectal	52		
Paternal Aunt	Gastric	52		





Patient Information

- 44-year-old
- G2 P2
- Childbearing complete

Visit Type

Abnormal Uterine Bleeding

Recommended Management

- Common recommendations may include:
 - Oral contraceptives
 - Mirena® IUD
 - Hysteroscopic removal of fibroids or polyp
 - Ablation

FAMILY HISTORY								
Relative	Cancer Site	Age Dx						
Father	Colorectal	62						
Brother	Colorectal	52						
Paternal Aunt	Gastric	52						



Family history

Expected Single Syndrome Result

Two First Degree Relatives:

Colon Ca

Management

Early and frequent colonoscopies



Management

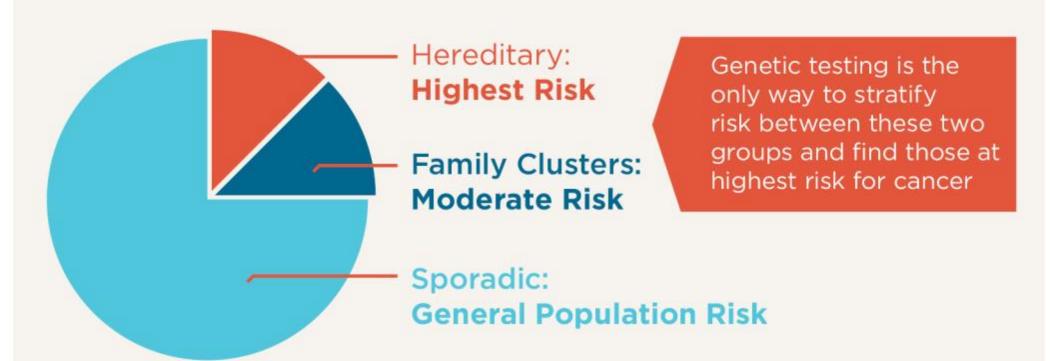
- Earlier and more frequent colonoscopies
- · Endometrial and other cancer risks
- TAH-BSO

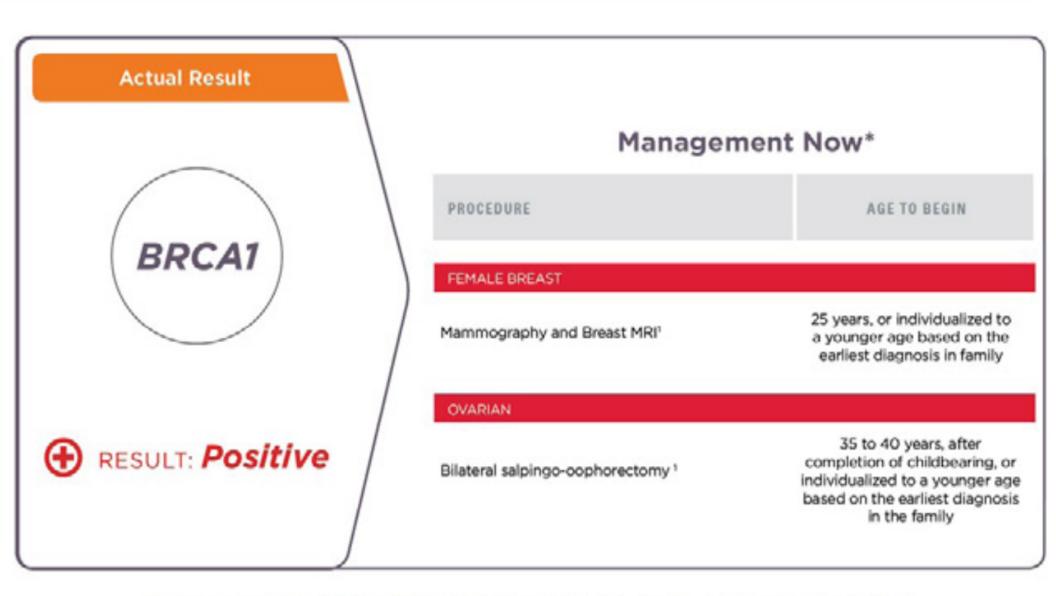


Risk Stratification



- Cancer Family History alone can help you optimize management
- Now consider if your patient is positive for a syndrome:



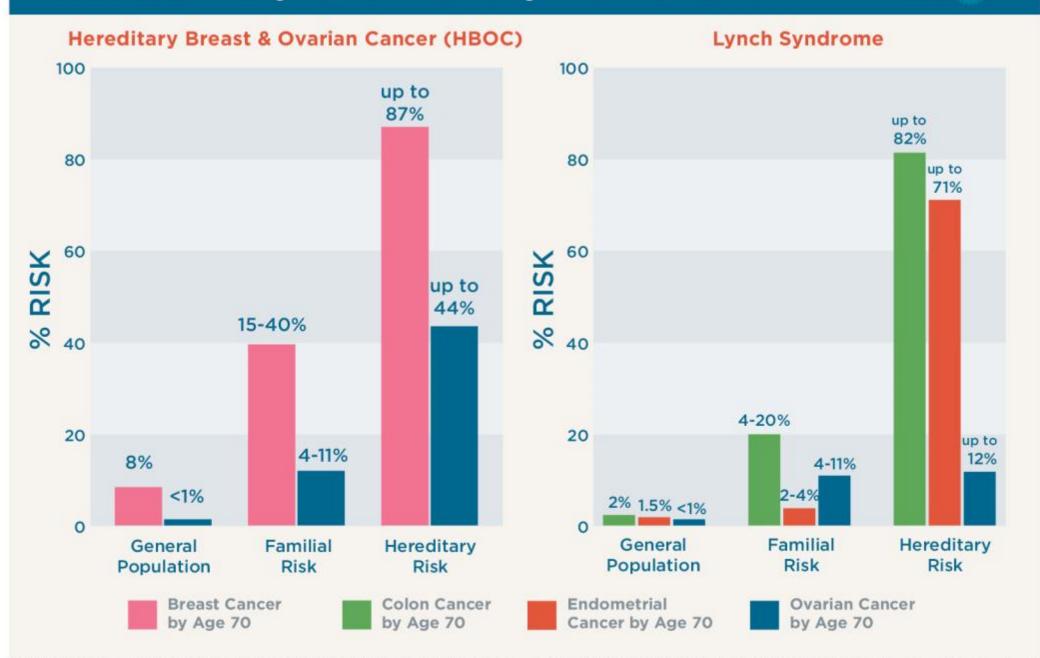


Assessment that is too narrow can create a false sense of security and patient mismanagement



Hereditary Cancer Syndromes





HBOC REFERENCES: 1. Domchek SM, et al. Br Ca Res Treat. 2010 Jan;119(2):409-14. 2. Ford D, et al. Lancet. 1994;343:692-5. 3. Struewing JP, et al. NEJM. 1997;336:1401-8. 4. Antoniou A, et al. AJHG. 2003;72:1117-30. 5. The Breast Cancer Linkage Consortium.JNCI. 1999;15:1310-6. 6. Easton DF, et al. AJHG. 1995;56:265-71. 7. King MC, et al. Science. Oct 24 2003:643-6. 8. Narod SA, Offit K. JCO. 2005 Mar 10:23(8):1656-63. 9. DevCan: Probability of Developing or Dying of Cancer Softwar;18:48. Version 6.0. Statistical Research and Applications Branch, National Cancer Institute, 2005. http://srab.cancer.gov/devcan. Assessed Jan 2010. 10. Meterdife KA, et al. Br J Cancer. 2009 Jan 27;100(2):421-5.Epub 2008 Dec 16. 11. Kauff ND, et al. AJHG. 1994;60:496-504. 15. Ford D, et al. AJHG. 1995;60:496-504. 15. Ford D, et al. AJHG. 1997;60:496-504. 15. Ford D, et al. AJHG. 199

BA. Best Practice & Research Clinical Obstetrics and Gynaecology. Vol 16. No.4, 449-68, 2002.

Do you see how CFHx impacts all patients





Today's Schedule 10:00 - Annual 10:15 - 0B Visit 10:30 - Contraception 10:45 - Problem Visit Pelvic Pain 11:00 - Problem Visit Irreg. Heavy Bleeding 11:15 - 0B Visit 11:30 - Annual 11:45 - Contraception

Active use of CFHx helps to ensure you are making optimal recommendations

- ACOG¹, USPSTF² and NCCN³ guidelines exist for Hereditary Cancer Risk Assessment
- Optimal medical recommendations for all patient visit types:
 - Well-woman visit
 - Problem visit
 - OB visit
- May increase patient safety and quality of care

Do you believe you need to utilize CFHx for every visit type to make optimal management recommendations?

Consider:

According to guidelines, patients at increased risk require more intervention visits which may include increased surveillance, chemoprevention and risk-reducing surgeries.



Hereditary Cancer Risk Assessment standard of care for every patient:

Education

- Clinical background
- Test result interpretation
- Pre and post test counseling

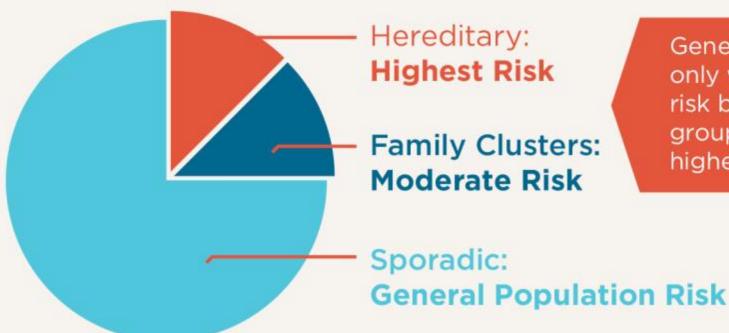
Process

- Standard protocol to efficiently assess every patient for hereditary cancer risk
- Establish management plans

Hereditary & Familial Cancer: Establishing a Protocol

A protocol should be used to efficiently stratify your patient's risk for a hereditary cancer

Steps: SCREEN, EVALUATE, DIAGNOSE, MANAGE



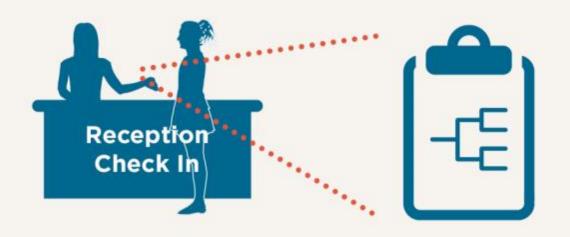
Genetic testing is the only way to stratify risk between these two groups and find those at highest risk for cancer

References:1. National Comprehensive Cancer Network Genetic/Familial High Risk Assessment: Breast and Ovarian version 1.2012. 2012(1):MS-2. 2. ACOG Practice Bulletin No. 103. Obstet Gynecol. 2009 Apr;113(4):957-66.

3. Foulkes WD. Inherited susceptibility to common cancers. N Engl J Med. 2008 Nov 13;359(20):2143-53. 4. Pharoah PD, et al. Polygenic susceptibility to breast cancer and implications for prevention. Nat Genet. 2002 May;31(1):33-6. Epub 2002 Mar 4.







WRITTEN FHQ

- Use written cancer FHQ with all patients every visit
- Remind patients to be complete and accurate when filling out FHQ, including paternal side

ACOG recommends that all women receive a family history evaluation as screening for inherited risk, this should be updated regularly.

ACOG Committee Opinion 478, March 2011

Use a Family History Questionnaire on all patients

Common He	redi	tary	uesti Can	cer	Syn	dro	mes	
atient Name:	on Hereditary Cancer Syndromes Physician: Date Completed:							
Please mark below if there is a personal relationship and age at diagnost in the aunts, uncles, and cousins.	or family hi appropriate	istory of a column.	ny of the fol Consider par	lowing cr ents, chil	ancers. If yes	i, then in ers, sister	dicate family s, grandpare	r ents,
auris, unites, and codinis.	YOU	NOR STOW	SIBLINGS/ CHILDREN		MOTHER'S SIDE	NOE STORE	FATHER'S SIDE	Mary Colle
or example: Colorectal cancer	none	-	Brether	JE yes	Aunt Causin	44 yrs 58 yrs	Grandfathe	65 yes
REAST AND OVARIAN CANCER								
Breast cancer (male or female)								
Ovarian cancer								
Breast cancer in both breasts OR multiple primary breast cancers								
Male breast cancer						1		1
Pancreatic or prostate cancer								
Are you of Ashkenazi Jewish descent?	☐ Yes ☐] No		60-1				
OLON AND UTERINE CANCER								
Uterine (endometrial) cancer								
Colorectal cancer								
Colon/rectal, uterine/endometrial, ovarian, stomach/gastric, kidney/urinary tract, billiary tract, small bowel, pancreas, brain, and sebaceous adenomas								
10 or more cumulative colon polyps								
MELANOMA								
Melanoma								
Pancreatic cancer		1				1		+
THE CANCER								
THER CANCER		-				1		1
	_			1		1		1
AVE YOU OR ANY MEMBER OF YOU	R FAMILY E	EVER HA	GENETIC '	TESTING	FOR HERE	DITARY	RISK OF CA	NCER7
☐ Yes ☐ No If yes, please	explain:							
If answered "yes", obtain copy of relati	lves test resu	iit.						
OR OFFICE USE ONLY								
Patient appropriate for further risk assessme BRACAnalysis* - A test for Hereditary Brea COLARIS* - A test for Lynch synchrome Stee COLARIS API - A test for Adenomatous For	est and Ovaria reditary Nonp	in Cancer s polyposis C	yndrome	er)	Discussed her Patient offer ID ACCEPTED Follow up ap	ed genetic	LINED	patient



EVALUATE

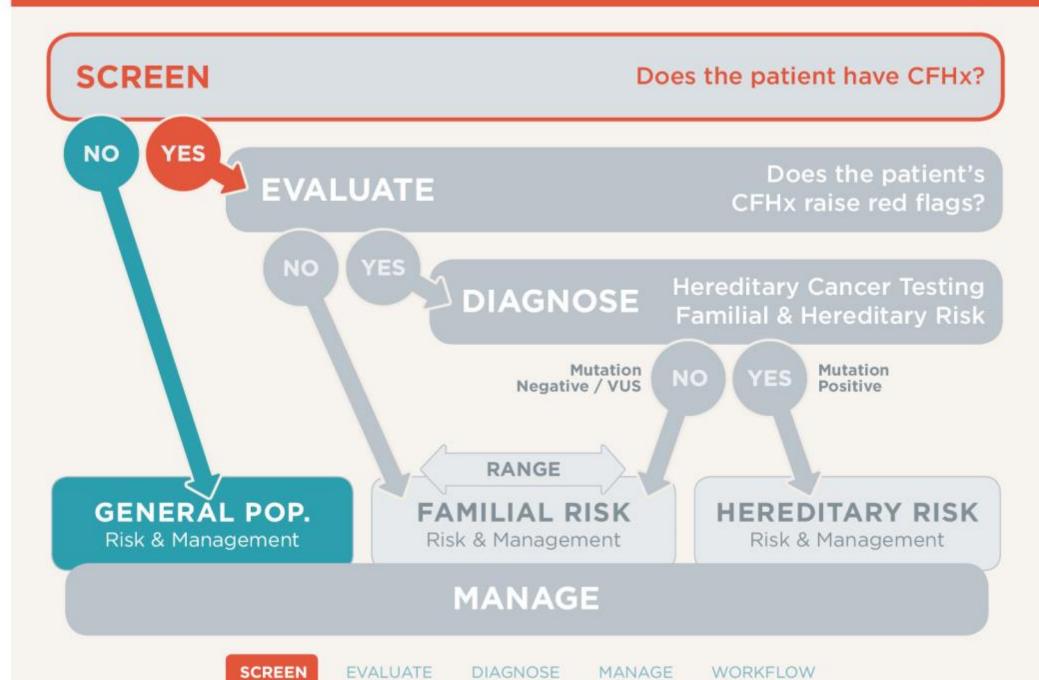
DIAGNOSE

MANAGE

WORKFLOW

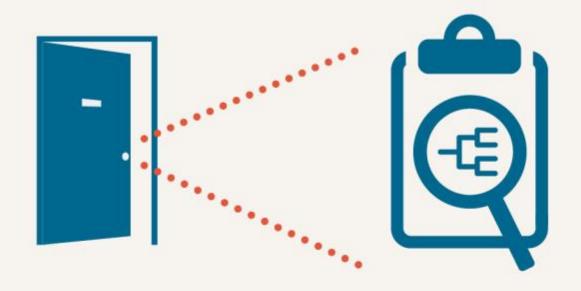
Screen













- Review all FHQs and document
- Use consistent testing criteria and evaluation methods

Red Flags

Identify Your Patients at Risk

Hereditary Breast and Ovarian Cancer (HBOC) Syndrome

An individual with, or a family history of, any of the following:

- Ovarian cancer
- Breast cancer diagnosed before age 50
- · Two primary breast cancers
- · Male breast cancer
- Triple negative breast cancer
- Ashkenazi Jewish with an HBOC-associated cancer^{tt}
- Three or more HBOC-associated cancers at any age¹
- A previously identified HBOC syndrome mutation in the family

‡HBOC-associated cancers include breast (including DCIS), ovarian, pancreatic, and aggressive prostate cancer (Gleason score of ≥7) †In the same individual or on the same side of the family. ^Close blood relatives includes first-, second-, or third-degree in the maternal or paternal lineage.

Lynch Syndrome

An individual with any of the following:

- Colorectal or endometrial cancer before age 50
- Two or more Lynch syndrome cancers at any age
- · A Lynch syndrome cancer§ with one or more relative(s) with a Lynch syndrome cancer

An individual with any of the following family histories:

- A first- or second-degree relative with colorectal or endometrial cancer before age 50
- Two or more relatives with a Lynch syndrome cancers, one before age 501
- Three or more relatives with a Lynch syndrome cancer® at any age1
- A previously identified Lynch syndrome or MAP syndrome mutation in the family

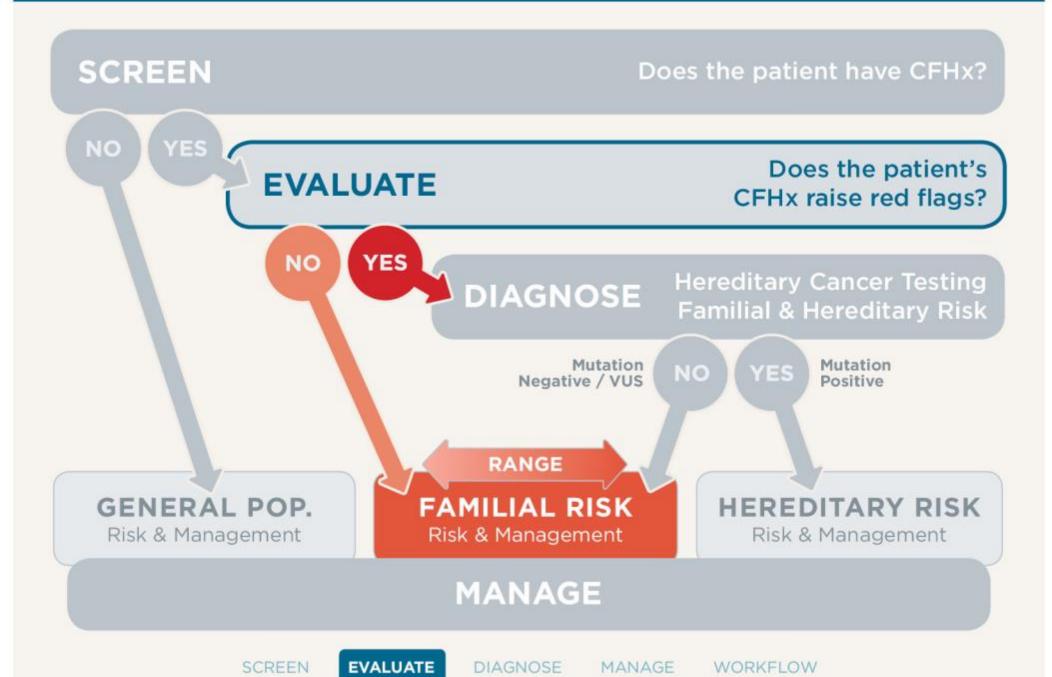
§ Lynch syndrome-associated cancers include colorectal, endometrial, gastric, ovarian, ureter/renal pelvis, biliary tract, small bowel, pancreas, brain, sebaceous adenomas. ¶Cancer history should be on the same side of the family

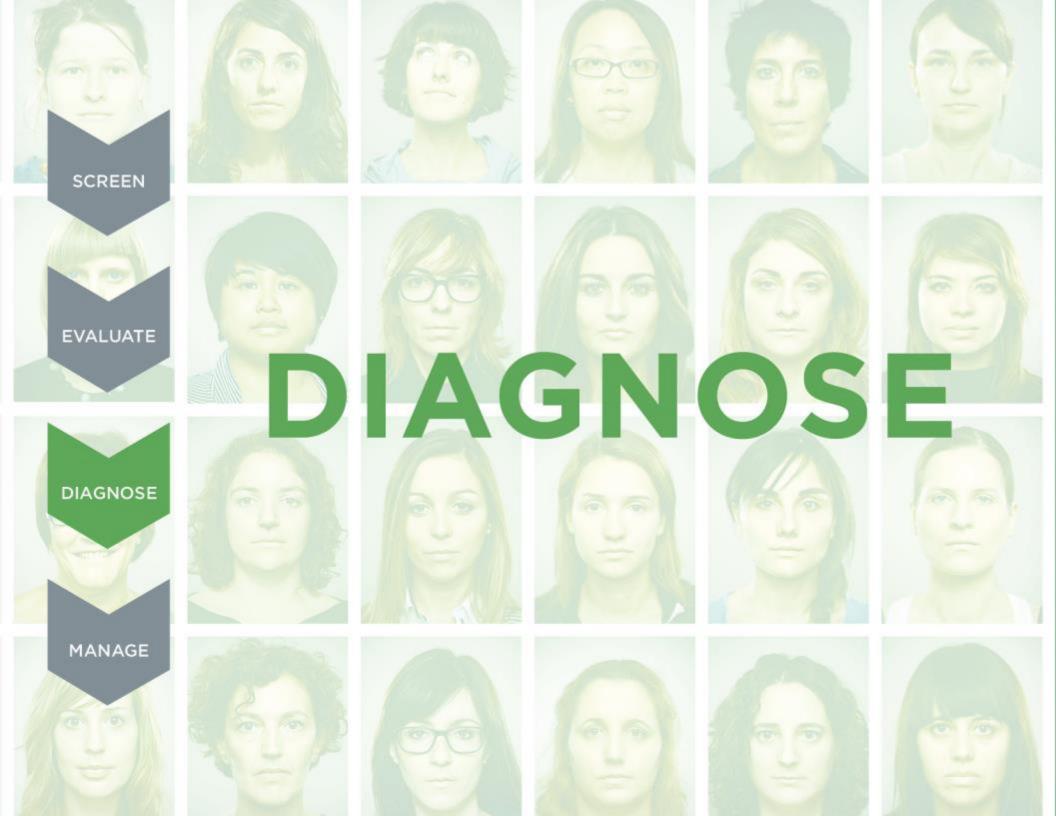
EVALUATE

MANAGE

Evaluate

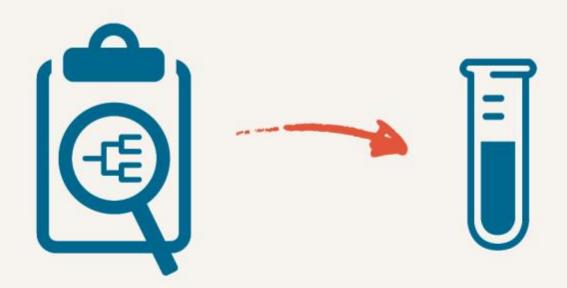






DIAGNOSE





APPLY CRITERIA

Test appropriate patients

FOLLOW UP

- Use follow-up protocol for all patients whether tested or not
- Document follow-up appropriately

What is Your Patient's Cancer Risk?



Patients per year: 4,000*

~3,600 Patients
NORMAL CANCER
FAMILY HISTORY

~400 Patients
ABNORMAL CANCER
FAMILY HISTORY (~10%)





~372 Patients FAMILIAL RISK (~93%) ~28 Patients HEREDITARY RISK (~7%)

SCREEN



DIAGNOSE

MANAGE

WORKFLOW

^{*}Approximate numbers based on general primary care practice information.

Informed Consent



If patient meets testing criteria:

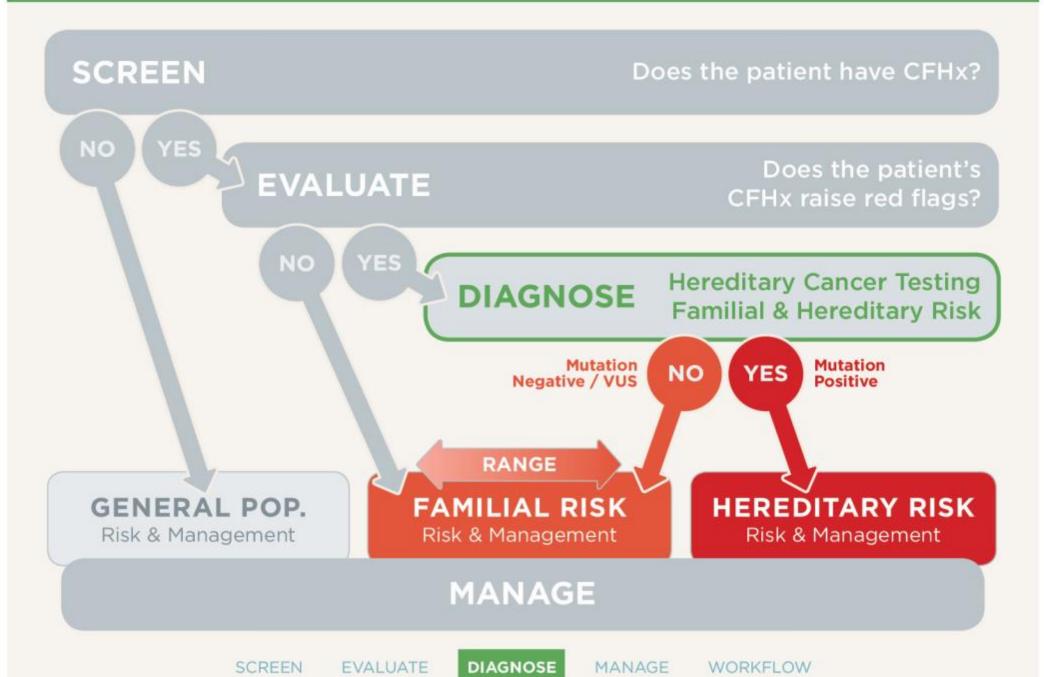
- Discuss testing with patients just as you do with other common diagnostic tests such as an abnormal pap
- Emphasize the need for a test result in order to manage the patient properly
- Gain agreement from patient
- Patient Education Videos

HBOC - http://bcove.me/v57lya6q

Lynch - http://bcove.me/oai8af1u

Diagnose

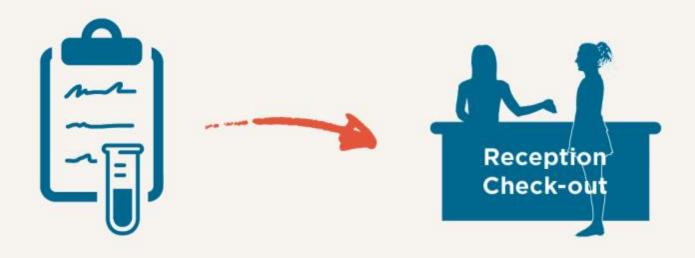






MANAGE





FOLLOW UP

- Document results & management
- Communication plan for patients and referring providers

PLAN

- Manage patients based on individualized risk
- Document individualized medical management plan
- Involve other providers as appropriate

HBOC Diagnosis/Management Options



HBOC Risk Assessment: Personal & Family History

GENERAL POPULATION

Routine Care

FAMILIAL RISK

No Mutation or VUS Empiric Care

HEREDITARY RISK

Deleterious Mutation High Risk Care

Intervention

May include: Chemoprevention such as: OCs, Tamoxifen, Raloxifene

Lifestyle: Family Planning, Diet, Exercise, Normal BMI, Avoid EtOH

Surveillance

May include: Mammogram, Breast MRI, TVUS, CA125, Skin/eye, Prostate, Pancreas

Surgery

RRBSO BPM

1) NCCN Clinical Practice Guidelines in Oncology v1.2011 Genetic/Familial High-Risk Assessment: Breast and Ovarian. Accessed at www.nccn.org 2) Wamer E, et al. Surveillance of BRCA1 and BRCA2 mutation carriers with magnetic resonance imaging, ultrasound, mammography, and clinical breast examination. JAMA. 2004;229(10):1517-25. 3) Saslow, et al. American cancer society guidelines for breast streening with MRI as as a adjunct to mammography. CA Cancer J Clin. 2007;57(2):158-89. 4) Warner E, et al. Prospective study of Breast Cancer Incidence in Women With a BRCA1 or BRCA2 Mutation Under Surveillance with and Without Magnetic Resonance imaging. J Clin Oncol. 2011;29(3):1664-9, 5) NIH Consensus Development Panel on Ovarian Cancer Covarian Cancer Covarian Cancer Centerial Cancer Genetics Studies Consortium. JAMA. 1997;277:997-9003. 7) Berchuck A, et al. Role of BRCA1 mutation screening in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME.

Lynch Diagnosis / Management



Lynch Risk Assessment: Personal & Family History

GENERAL POPULATION

Routine Care

FAMILIAL RISK

No Mutation or VUS Empiric Care

HEREDITARY RISK

Deleterious Mutation High Risk Care

Intervention

May include: Chemoprevention such as: OCs, Aspirin

Lifestyle: Family Planning, Diet, Exercise, Normal BMI

Surveillance

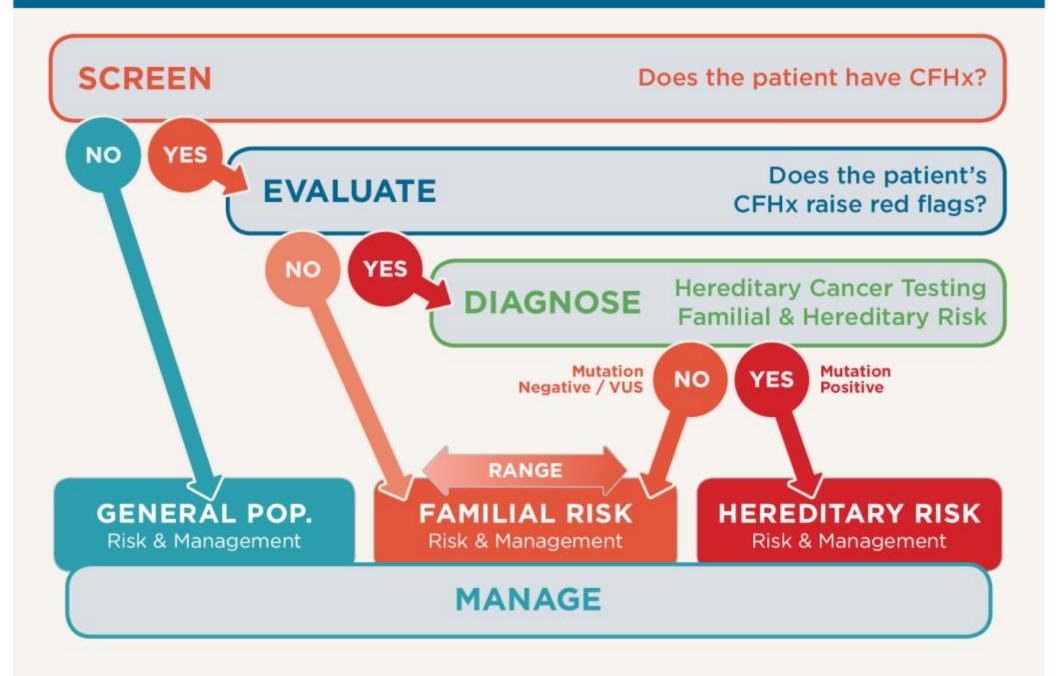
May include: More frequent clinical exams, Endometrial biopsy, Hysteroscopy, Colonoscopy, Upper endoscopy, TVUS, CA125, Renal, Neuro, Pancreas, Biliary, Skin

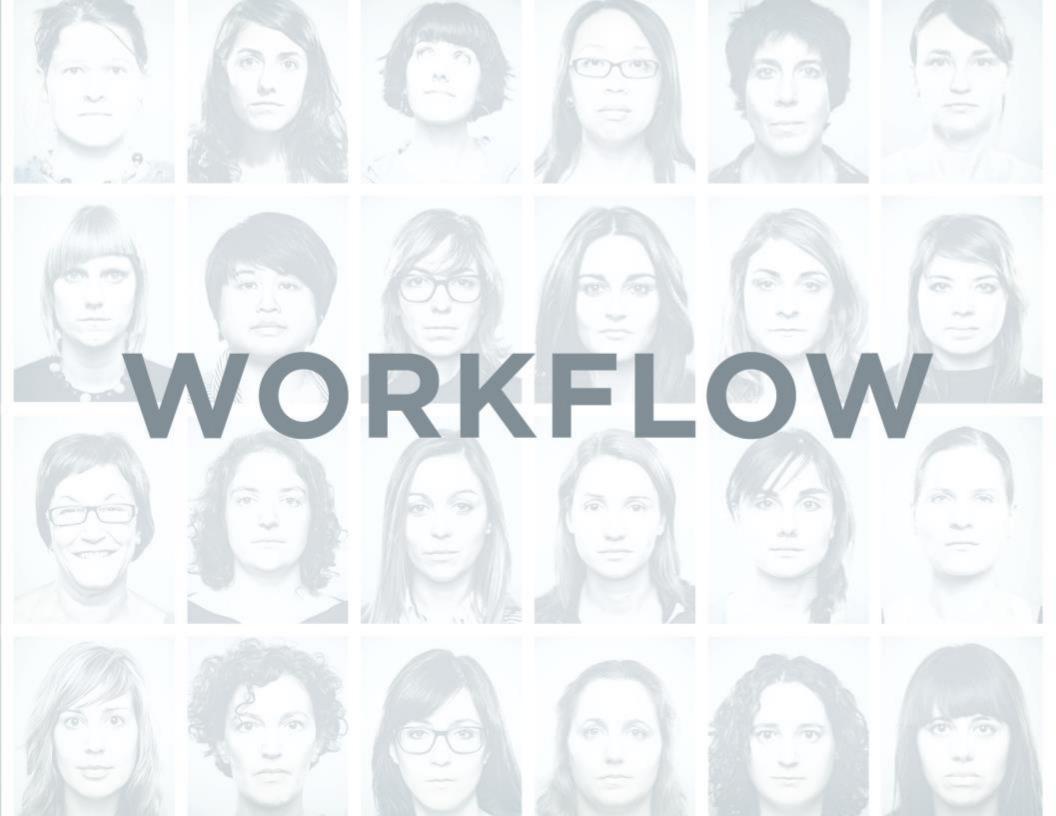
Surgery

RR Hyst+BSO RR Colectomy

1) NCCN Clinical Practice Guidelines in Oncology v1.2011 Genetic/Familial High-Risk Assessment: Breast and Ovarian. Accessed at www.nccn.org 2) Warmer E, et al. Surveillance of BRCA1 and BRCA2 mutation carriers with magnetic resonance imaging, ultrasound, mammography. Ac Cancer J Clin. 2007;57(2):75-25. 3) Sasiow, et al. American cancer society guidelines for breast screening with MRI as an adjunct to mammography. CA Cancer J Clin. 2007;57(2):75-25. 3) Sasiow, et al. American cancer society guidelines for breast screening with MRI as an adjunct to mammography. CA Cancer J Clin. 2007;57(2):75-25. 4) Warmer E, et al. Properties Sudy of Freast Cancer Incidence in Women With a BRCA2 Martin Cancer. She Properties Sudies Consortium. JAMA. 1995;273:491-497. 6) Burke W, et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II. BRCA1 and BRCA2. Cancer Genetics Studies Consortium. JAMA. 1997;277:997-1003. 7) Berchuck A, et al. Role of BRCA1 mutation screening in the management of familial ovarian cancer. American Journal of Obstetrics & Gynecology. 1996;175:738-746. 8) Robson ME. Clinical considerations in the management of individuals at risk for hereditary breast cancer. J Clin Oncol. 2005 Mart 10:23(8):956-6-63. 10) Rebbeck TR, et al. Prophylactic cophorectomy in carriers of BRCA1 on BRCA2 mutations. Nat 10:20(8):956-6-63. 10) Rebbeck TR, et al. Prophylactic cophorectomy in carriers of BRCA1 on BRCA2 mutation. JAMA. 2006;296(2):185-92. 12) Kauff ND, et al. Risk-reducing salpingo-cophorectomy for the prevention of BRCA1 and BRCA2-associated breast and gynecologic cancer: a multicenter, prospective study. J Clin Oncol. 2005;86(8):1351-7. 15) Rebbeck TR, et al. BRCA1 on BRCA2 mutation estimates associated with risk-reducing salpingo-cophorectomy in women with a BRCA1 on BRCA2 mutation. NEJM. 2002;345(195-164. 18) Hartmann LC, et al. Efficacy of bilateral prophylactic mastectomy in women with a BRCA1 on BRCA2 mutation. Carriers. J NCL 2001;345(196-165. 15) Narrod SA. (DMF K.

HCRA Process





Example Provider Workflow



Step		Responsible	Resources Available	
Gives and collects cancer Family History Questionnaire (FHQ) for every patient		• Receptionist	Family History Questionnaire Online Family History Tool	
Informs the patient on the need to fill out her/his complete cancer family history		Receptionist	Family History Reminder	
Reviews the FHQ for cancer family history		• HCP / MA	Field Based Support	
Determines and documents appropriateness of hereditary cancer testing for patient based on cancer family history		• HCP	Red Flag Card Societal Guidelines	
Counsels appropriate patient on hereditary cancer testing		• HCP	Patient Education Tools Patient Education Videos	
Collects specimen and fills out test request form		• HCP / MA	Test Kits MyriadPro.com Patient Risk Cards	
Sets up follow up appointment in weeks for results discussion		Receptionist	Results Patient Education Tool NGCN Management Guidelings	
Determines and recommends individualized management plan; follows-up with patient		• HCP	NCCN Management Guidelines MySupport360.com	

SCREEN EVALUATE DIAGNOSE MANAGE WORKFLOW