A Multidisciplinary Consortium to Advance Genetic Counseling in Oncology

Lunch and Learn #2

September 28, 2021

Iowa Oncology Society

Introductions: Staff

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Background

The Iowa Oncology Society (IOS) and the Association of Community Cancer Centers (ACCC) are leading this initiative to explore gaps/barriers around hereditary genetic counseling and testing in patients with cancer and their family members.

Consortium Members

William R. Bliss Cancer Center

GENESIS

Grand River MEDICAL GROUP

Heartland ONCOLOGY & HEMATOLOGY
A DIVISION OF AMERICAN ONCOLOGY PARTNERS, P.A.

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University of Iowa Health Care

UNIVERSITY OF IOWA HOSPITALS & CLINICS
University of Iowa Health Care
Genetic Counseling

Iowa Oncology Society

Genetic Testing Approaches to Improve the Identification of Hereditary Cancer Syndromes

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University of Iowa Hospitals & Clinics

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Disclosures

I have no financial disclosures.

I am a genetic counselor employed by the Holden Comprehensive Cancer Center at the University of Iowa Hospitals & Clinics.

Objective

Review different genetic testing models that can be implemented in community clinics to improve the identification of individuals with hereditary cancer conditions.

Genetic Service Delivery Models

Physician Refers to Genetic Specialist

Physician Directly Orders Genetic Testing

Individual-Driven Testing with Third-Party MD

Physician Refers to Genetic Specialist

Criteria Met

For tips and tricks on identifying patients for genetic counseling/testing please see Lunch and Learn presentation #1

- Review resources to assist with personal and family history collection
- Discuss tips to remember when and how to order genetic counseling/testing

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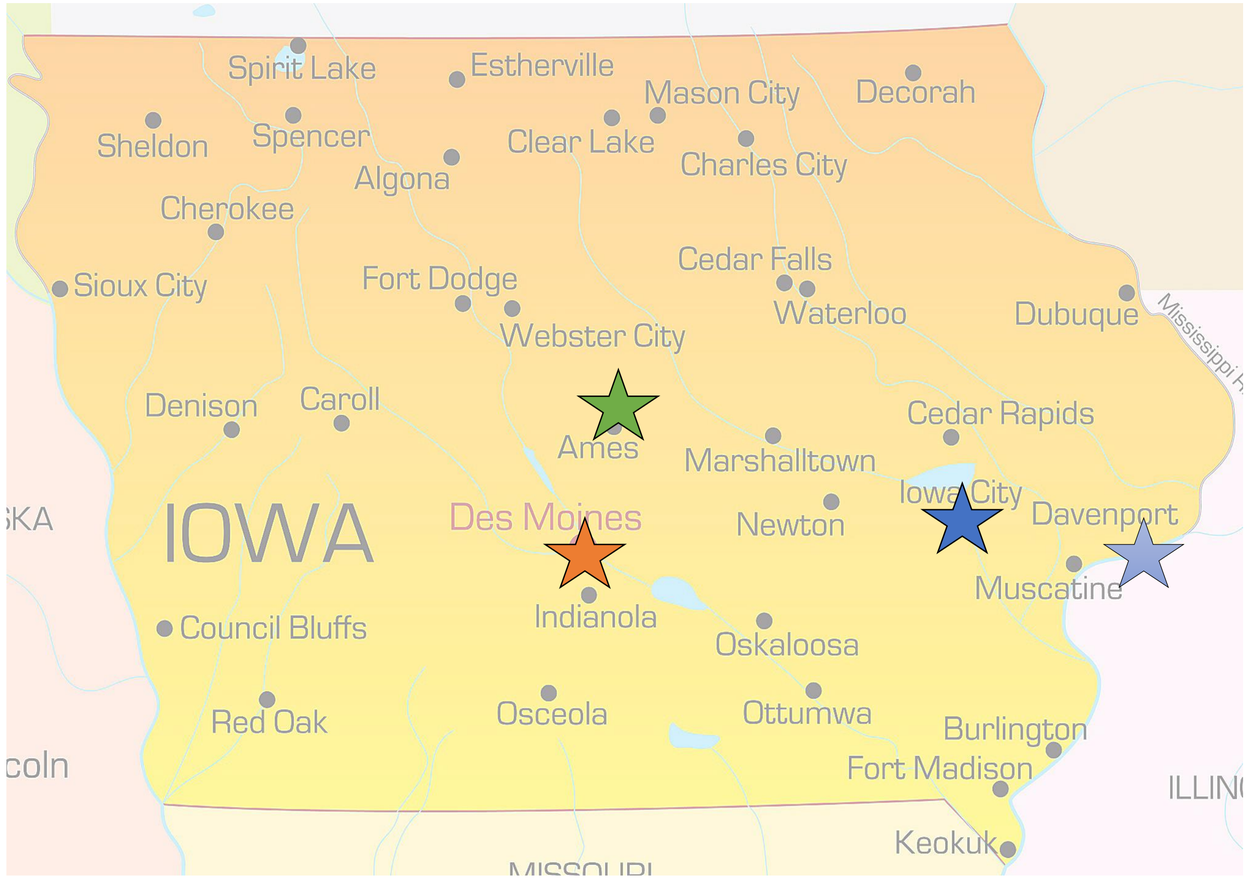
Physician Refers to Genetic Specialist

Criteria Met

- In-Person Genetic Counselors
- Referral to Provider with Genetics Training
- Partnering with a Telehealth Company

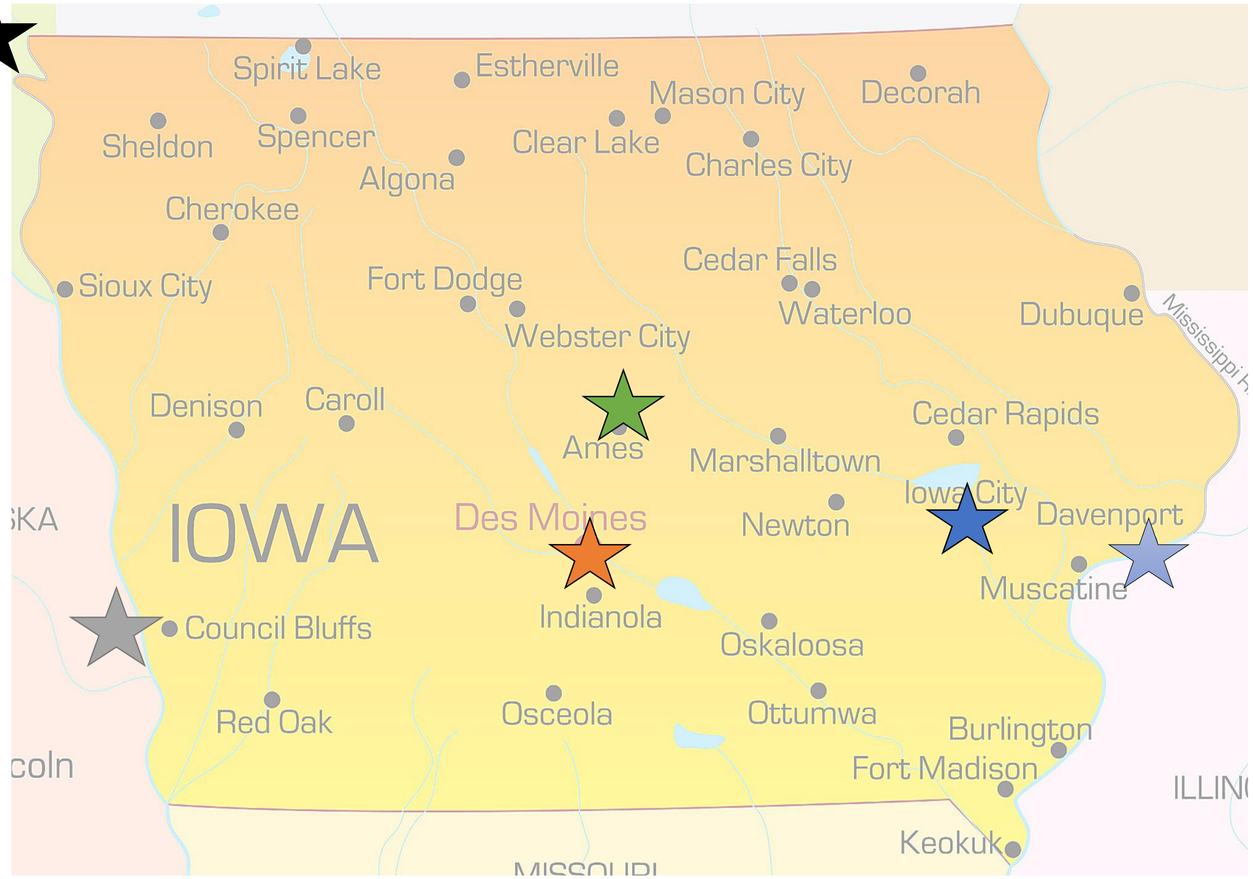
In-Person Genetic Counselors



In Iowa

- University of Iowa Health Care, Iowa city
  - Outreach clinic in quad cities
- UnityPoint Health, Des Moines
- Mercy Medical Center, Des Moines
  - Telehealth
- Mary Greeley Medical Center, Ames

In-Person Genetic Counselors

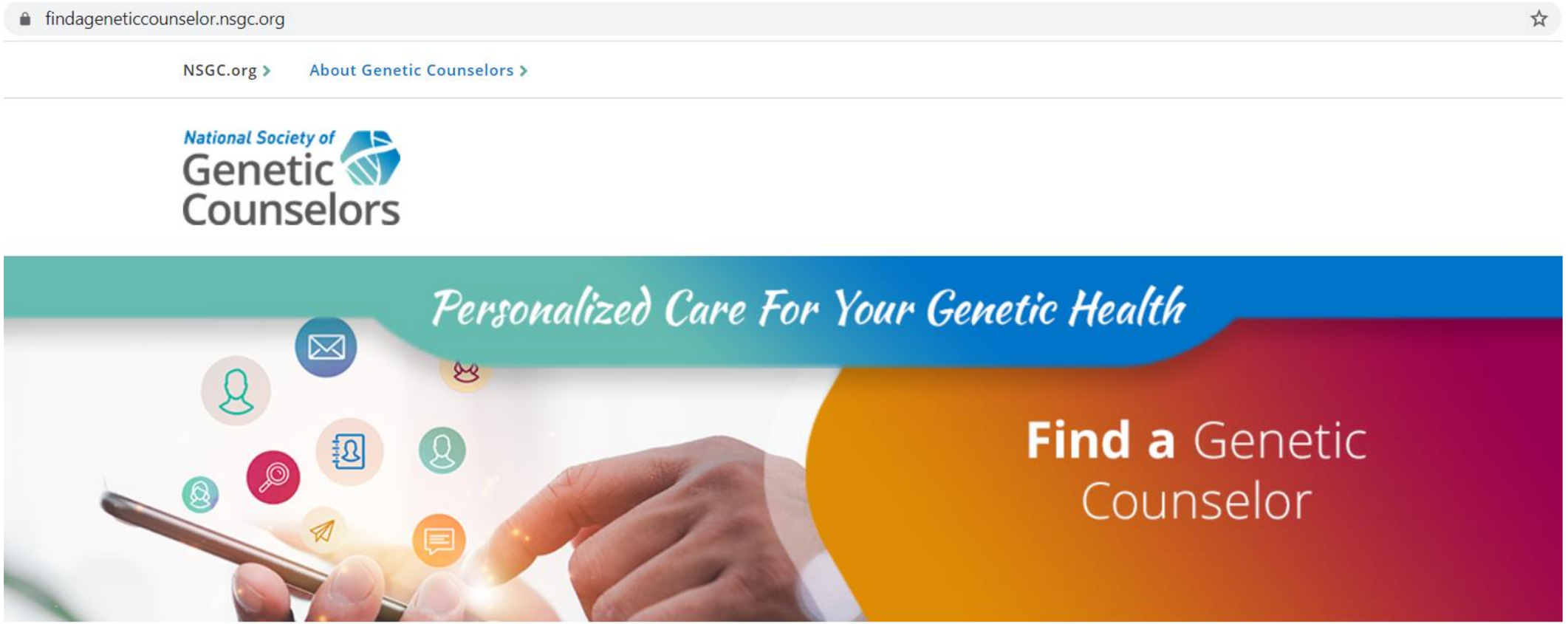


Neighboring States

- Sanford Health, Sioux Falls, South Dakota
- Avera Cancer Health, Sioux Falls, South Dakota
- University of Nebraska Medical Center, Omaha, Nebraska

- Mayo Clinic, Rochester, Minnesota
- Gundersen Health System, La Crosse, Wisconsin
- Saint Louis University, St. Louis, Missouri

In-Person Genetic Counselors



findageneticcounselor.nsgc.org/

In-Person Genetic Counselors

Benefits

- Genetic Expert
  - Collect full family and medical history, risk assessment, and genetic counseling
  - Choose the hereditary genetic testing laboratory and test to order
  - Speak with patient about cost of genetic testing and insurance coverage
  - Result disclosure, recommendations, and will place referrals to other providers when necessary
- Coordinate family testing

Challenges

- Can be hard to locate
- Distance barrier
- Patients may not understand what a genetic counselor is and choose not to go

Physician Refers to Genetic Specialist

Criteria Met

- In-Person Genetic Counselors
- Referral to Provider with Genetics Training
- Partnering with a Telehealth Company

Referral to Provider with Genetics Training

- Advanced Practice Registered Nurse can have additional genetics training
  - Advanced Genetics Nursing Certification (AGN-BC)

Benefits

- They complete the full risk assessment and help to facilitate genetic testing
- Responsible for result disclosure and recommendations
- Choose hereditary genetic testing lab and test to order
- They can offer the clinic other patient care and can complete screening

Challenges

- Can be hard to locate
- Distance Barriers
- May not be experts in all cancer areas

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Physician Refers to Genetic Specialist

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- In-Person Genetic Counselors
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Partnering with a Telehealth Company

Referral to telehealth company

Genetic counseling via telehealth

- Zoom/Skype link
- Telephone call

Company will coordinate testing

- Saliva kit
- Blood draw with mobile phlebotomy service
- Blood draw with community-based service

Company will complete post-test genetic counseling and make recommendations

Partnering with a Telehealth Company

Benefits

- Genetic Experts
  - Collect full family and medical history, risk assessment, and genetic counseling
  - Choose the hereditary genetic testing laboratory and test to order
  - Speak with patient about cost of genetic testing
  - Result disclosure and recommendations
- Patients and Providers can be anywhere in the state of Iowa
- Can integrate into clinic or hospital
- Can offer other tools for providers for patient identification

Challenges

- Cost and billing for the service
  - Will not be in network for all insurance companies
  - Not all insurance companies will consider a covered benefit
- Integration into clinic can cost money and time
- Other tools can cost more money

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Partnering with a Medical Center for Telehealth

- Contract with medical center who has genetic counselors for a certain number of telehealth hours per month

Breast Cancer Example

50 yo female diagnosed with left sided breast cancer (ER/PR positive, HER2 negative)

Patient will meet with surgeon*

Provider takes a family history

- Paternal aunt diagnosed with breast cancer at the age of 47
- Paternal grandfather diagnosed with prostate cancer at the age of 75
- Mother diagnosed with thyroid cancer at the age of 40 and colon cancer at the age of 55
- Maternal uncle diagnosed with kidney cancer at an unknown age

Meets National Comprehensive Cancer Network(NCCN) criteria for genetic testing

* In cases of breast cancer, it can be beneficial for all surgeons to be prepared to help facilitate genetic counseling/testing as all breast patients will see a surgeon. This information can also impact how a patient would like to proceed with surgery.

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Breast Cancer Example

Referral to genetic counselor who meets with patient for a full discussion and orders the test

Patient positive for a *PTEN* mutation which is consistent with a diagnosis of PTEN Hamartoma Tumor Syndrome (Cowden syndrome)

GC discusses results and future recommendations (colon, kidney, thyroid, endometrial). Breast cancer recommendations as well

*Sends surgeon-obtained results and recommendations. Can focus on breast cancer management

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PTEN Hamartoma Tumor Syndrome (Cowden Syndrome)

Cancer Risks

- Female Breast Cancer-77-85%
- Endometrial Cancer-19-28%
- Thyroid Cancer (most commonly follicular)-21-38%
- Colorectal Cancer-9-16%
- Renal Cancer-15-34%
- Melanoma-Up to 6%

Non-Cancerous Tumors/Features:

- Macrocephaly (enlarged head)
- Colorectal polyps of many types
- Lhermitte-Duclos disease (a hamartomatous brain tumor)
- Specific skin findings (trichilemmomas, acral keratoses, and papillomatous papules)
- Developmental delay and/or autism spectrum disorders

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PTEN Hamartoma Tumor Syndrome (Cowden Syndrome)

Management for Males & Females

- Annual thyroid ultrasound from time of diagnosis
- Annual physical with thyroid and skin exam from time of diagnosis
- Colonoscopy at least every 5y starting at age 35
- Consider kidney imaging (ultrasound, CT, of MRI) every 1-2 years starting at 40
- Consider psychomotor assessment in children; symptoms may require brain MRI
- Be familiar with cancer signs and symptoms

Management Specific to Women

- Breast:
  - Breast awareness at age 18
  - Clinical breast exam every 6-12 mo, starting at age 25
  - Annual mammogram AND breast MRI starting at age 30-35
  - Consider preventative mastectomy
- Uterus:
  - Watch for and promptly report abnormal bleeding
  - Consider random endometrial biopsy every 1-2 years and note that there are limitations
  - Postmenopausal women may consider transvaginal ultrasound, but there are limitations
  - Consider preventative hysterectomy when done having biological children

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Genetic Service Delivery Models

Physician Refers to Genetic Specialist

Physician Directly Orders Genetic Testing

Individual-Driven Testing with Third-Party MD

Physician Orders Genetic Test

Criteria Met

Physician speaks with patient about genetic testing

Patient consents to test

Physician or team member with the physician's team orders the genetic test and sends it to lab

Physician receives results and informs patient

Physician Orders Genetic Test

Criteria Met

Physician speaks with patient about genetic testing

Benefits

- Streamline process for patient
- Quicker turnaround for test since patient doesn't have to wait for GC apt

Challenges

- This will take additional time during clinic

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Physician Orders Genetic Test

Criteria Met

Physician speaks with patient about genetic testing

Patient consents to test

Physician or team member with the physician's team orders the genetic test and sends it to lab

<u>Challenging Step</u>- What test to order?

What Genetic Testing Company to Use?

- Different laboratories will often travel around to different clinics and pitch their product
- Not all labs are equal, and some labs will have different limitations

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INVITAE

GeneDx
DNA DIAGNOSTIC EXPERTS

myriad®
WHEN DECISIONS MATTER

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What to Look for in Genetic Testing Laboratories

- College of American Pathologists (CAP)-accredited and Clinical Laboratory Improvement Amendments (CLIA)-certified clinical diagnostic laboratory
- Laboratory Technology
  - >99% analytical sensitivity and specificity for single nucleotide variants, insertions and deletions <15bp in length, and exon-level deletions and duplications
  - Should include sequencing and deletion/duplication
  - Sanger confirmation for positives
- When was the company established and how long has the lab been doing hereditary cancer genetic testing?
  - Labs with multiple years of testing for hereditary cancer conditions have a larger database that can help with analysis
  - The lab has time to improve interpretation calls and improve billing processes

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What to Look for in Genetic Testing Laboratories

- Is RNA testing included?
  - Some labs are completing DNA AND RNA testing upfront to help with variant calls and detect splice site variants

  - Some labs offer RNA testing to selective variants when a variant of uncertain significance
  - Some labs don't offer RNA testing at all

What to Look for in Genetic Testing Laboratories

- Post-test genetic counseling
- Free family testing within a certain time period
- Programs (for a cost) to help with all steps of the genetic counseling referral and testing process
  - Can help with family history collection and risk assessments
  - Please see Lunch and Learn presentation #1 for more information on these tools

Know the Limits!

- Testing laboratories offer comprehensive panels for common hereditary cancer conditions
  - Some labs ‘comprehensive’ panels will focus on hereditary breast, ovarian, uterine, and colorectal cancer conditions
  - When an individual has a personal and/or family history of other cancers (brain cancer, blood cancers, kidney cancers, neuroendocrine tumors, etc.) some labs will not have the correct or necessary panels. These cases may be best to refer out

Physician Orders Genetic Test

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Physician speaks with patient about genetic testing

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Physician receives results and informs patient

Pancreatic Cancer Example

Medical Oncologist* meets with a 70 yo man diagnosed with pancreatic cancer

- Automatically meets NCCN criteria for genetic testing regardless of family history

Physician speaks with patient about genetic testing

Benefits of testing

- Could impact treatment and chemotherapy
- Could help family members

Provider may already be taking time to discuss somatic genetic testing

* In cases of pancreatic cancer, it can be beneficial for oncologists to be prepared to help facilitate genetic counseling/testing as all pancreatic cancer patients will see an oncologist

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Hereditary Pancreatic Cancer

- About 10% of those with pancreatic cancer have a hereditary cancer condition
  - About 50% of patients with pancreatic cancer and a hereditary cancer condition do not have a family history consistent with a specific hereditary cancer condition (Stoffel et al., 2019)
- Some Hereditary Conditions Associated with an Increased Risk for Pancreatic Cancer
  - BRCA1/2, PALB2, Familial Adenomatous Polyposis (FAP), Familial Atypical Multiple Mole Melanoma (FAMMM), Hereditary Nonpolyposis Colorectal Cancer (HNPCC) or Lynch syndrome, Hereditary Pancreatitis, Peutz-Jeghers Syndrome, Cystic Fibrosis

Pancreatic Cancer Example

Medical Oncologist* meets with a 70 yo man diagnosed with pancreatic cancer

- Automatically meets NCCN criteria for genetic testing regardless of family history

Physician speaks with patient about genetic testing → Patient consents to test → Physician or team member with the physician's team orders the genetic test and sends it to lab → Patient is positive for a *BRCA1* mutation. Oncologist can use information for treatment and refer patient's family on to a genetic counselor

* In cases of pancreatic cancer, it can be beneficial for oncologists to be prepared to help facilitate genetic counseling/testing as all pancreatic cancer patients will see an oncologist

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Genetic Service Delivery Models

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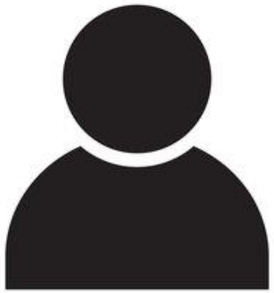
Individual-Driven Testing with Third-Party MD

Individual-Driven Testing with Third-Party MD

Criteria Met

OR



Individual reaches out to genetic testing company

Telehealth genetic counseling is performed

Patient consents to genetic testing and test is ordered through the company with a third-party MD

Patient receives results with post test counseling

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Individual-Driven Testing with Third-Party MD

Benefits

- Extra time isn't spent in clinic performing genetic counseling and testing
- Genetic experts are involved to help perform genetic counseling and facilitate genetic testing

Challenges

- Cost and billing for the service
  - Will not be in network for all insurance companies
  - Not all insurance companies will consider a covered benefit
- Results are not necessarily given to providers
  - Take extra time to get results from patients
- May be an intimidating process for patients
- May end up using a company that does not have appropriate testing

Companies That Can Complete Hereditary Genetic Testing:

INVITAE

color

Companies Not Appropriate for Hereditary Genetic Testing:

23andMe

ancestry

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Summary

Genetic Service Delivery Models

Physician Refers to Genetic Specialist

Physician Directly Orders Genetic Testing

Individual-Driven Testing with Third-Party MD

Questions?

Thank You!