

Centura Health Cancer Network



GENETIC COUNSELING AND TESTING

POSITION STATEMENT

It is the position of Centura Health that genetic testing for inherited disorders should occur in the context of comprehensive risk assessment and counseling by a trained/experienced genetics professional, such as a board certified genetic counselor.

This position supports best patient care practices and assures that:

- Patient receives pre and post test counseling;*
- Appropriate genetic testing is ordered;*
- Test results are interpreted by a health professional with expertise in clinical genetics;
and*
- Test results are applied in the context of evidence-based practices.*

BACKGROUND STATEMENT

Advances in genetic testing options have made testing for inherited conditions more accessible. As a result, Genetic and genomic testing lab representatives have recently approached Centura Health providers and recommended test practices that do not meet the standards set forth by national guidelines and consistent with the mission of Centura Health to provide quality and cost-effective healthcare .

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GENETIC COUNSELING AND TESTING: STANDARDS OF CARE

The following is a summary of national guidelines for risk assessment and genetic testing from leading healthcare professional organizations and agencies.

ORGANIZATION	Pre and Post Test Counseling	“Genetic Counseling” or “Genetic Counselor”*	Recommends provided by health care Professional with expertise/ education in genetics	Defines elements of informed Consent
National Comprehensive Cancer Network (NCCN)	X	X	X	
National Cancer Institute , Cancer Genetics Risk Assessment and Counseling PDQ	X	X	X	X
United States Preventive Services Task Force (USPSTF)	X	X		
American College of Medical Genetics and Genomics (ACMG)		X		X
American Society of Clinical Oncology (ASCO)	X	X	X	X
Oncology Nursing Society (ONS)	X		X	
American College of Surgeons Commission on Cancer (CoC)	X	X	X	X
National Accreditation Program for Breast Centers (NAPBC)	X	X	X	X
American Society of Breast Surgeons (ASBS)		X		X
American College of Obstetricians and Gynecologists(ACOG) and Society of Gynecologic Oncologists(SGO)		X	X	
American Academy of Family Practitioners (AAFP)	X	X		
American Academy of Pediatrics (AAP)		X	X	

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*Some states have instituted licensure for genetic counselors. In those states the term “genetic counselor” refers only to a licensed provider. Colorado is in the process of considering licensure.

REFERENCES:

http://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf

<http://www.cancer.gov/cancertopics/pdq/genetics/risk-assessment-and-counseling/HealthProfessional/page1>

<http://www.uspreventiveservicestaskforce.org/uspstf05/brcagen/brcagenrs.htm>

http://www.acmg.net/AM/Template.cfm?Section=Policy_Statements&Template=/CM/HTMLDisplay.cfm&ContentID=7530

Robson ME et al. American Society of Clinical Oncology Policy Statement Updated: Genetic and Genomic Testing for Cancer Susceptibility 2010.28(5) 893-901.

<http://www.ons.org/Publications/Positions/Predisposition/>

<http://www.facs.org/cancer/coc/programstandards2012.pdf>

<http://napbc-breast.org/standards/2013standardsmanual.pdf>

https://www.breastsurgeons.org/statements/PDF_Statements/BRCA_Testing.pdf

ACOG Practice Bulletin No. 103: Hereditary Breast and Ovarian Cancer Syndrome
Obstetrics & Gynecology: 113 (4) 957-966

Lancaster JM et al Society of Gynecologic Oncologists Education Committee statement on risk assessment for inherited gynecologic cancer predispositions. Gynecologic Oncology_2007 107(2):159-62.

http://www.aafp.org/online/etc/medialib/aafp_org/documents/clinical/CPS/rcps08-2005.Par.0001.File.tmp/October2012SCPS.pdf

<http://www2.aap.org/visit/cmte18.htm>

Lubin IM et al. Ordering molecular genetic tests and reporting results: practices in laboratory and clinical settings. J Molecular Diagnostics 2008. 10(5)459-468.

Bierly KL et al. Adverse events in cancer genetic testing. The Cancer Journal 2012. 18(4)303-309.

Tenner and Helft. Genetic testing in cancer: ethical issues. Oncology 26 (5) 2012.
<http://www.cancernetwork.com/gastrointestinal-cancer/content/article/10165/2065567>

APPENDIX #1:

Background /Summary: Adverse Events & Practices in Cancer Genetic Testing

Competency in genetics and genomics remains limited across all healthcare disciplines with the exception of genetic specialists [NCI PDQ]. The majority of medical professionals have little practical training in genetics [Bierly]. Non-geneticist health professionals admit a lack of basic knowledge about genetic testing, or confidence in interpreting familial patterns of disease [Tenner & Heft]

Genetics professionals are experts in family history analysis, genetic testing, and genetic test interpretation. Referral to genetics professionals is recommended by many health care professions when considering genetic testing. Documented, unintended harms to patients tested by health care providers without education and expertise in genetics include:

- Wrong genetic test ordered, and a diagnosis missed [Bierly].
- Wrong genetic test ordered, increasing patient's out of pocket cost [Bierly].
- Inadequate pretest counseling [Bierly].
- Inadequate post-test counseling about family risks[Bierly].
- Incorrect interpretation of results as negative [Bierly].
- Incorrect interpretation of results as mutation positive [Bierly].
- Insufficient health care provider familiarity with complex ethical, legal and psychosocial issues in genetic testing [Bierly].
- Inadequate information supplied to testing lab [Lubin].
- Inadequate post-test results notification [Lubin].
- In some non-genetic practices, non-medical professionals, such as secretaries, fill out test requisition forms and provide genetic test results to patients. [Lubin].

APPENDIX #2

ASCO Elements of Informed Consent

1. “Information on the specific genetic mutation(s) or genomic variant(s) being tested, including whether the range of risk associated with the variant will impact medical care.
2. Implications of a Positive and Negative Result.
3. Possibility that the test will not be informative.
4. Options for risk estimation without genetic or genomic testing.
5. Risk of passing a gene variant to children.
6. Technical accuracy of the test including, where required by law, licensure of the testing laboratory.
7. Fees involved in testing and counseling and for Direct To Consumer (DTC) testing, whether the counselor is employed by the testing company.
8. Psychosocial implications of test results (benefits and risks).
9. Risks and protections against genetic discrimination by employers or insurers.
10. Confidentiality issues, including for DTC testing companies, policies related to privacy and data security.
11. Possible use of DNA testing samples in future research.
12. Options and limitations of medical surveillance and strategies for prevention after genetic or genomic testing.
13. Importance of sharing genetic and genomic test results with at-risk relatives so that they may benefit from this information.
14. Plans for follow-up after testing.”

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APPENDIX #3

Attach Commission on Cancer and NAPBC Standards' Manuals on Genetics.