

Disclosures

• I have no conflicts of interest to disclose.



Objectives

- The participant will be able to:
 - Identify the main purposes of clinical practice guidelines
 - Describe the processes by which practice guidelines are established
 - Summarize the roles genetic counselors have played in establishing various practice guidelines



Clinical Practice Guidelines (CPGs)

The Institute of Medicine defines clinical practice guidelines as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"

• Clinical Practice Guidelines We Can Trust, IOM 2011



INGC AEC 2017 Robert Pilarski

Practice Guidelines - Two Components

- The foundation is a <u>systematic review</u> of the research evidence bearing on a clinical question, focused on the strength of the evidence on which clinical decision-making for that condition is based.
- A <u>set of recommendations</u>, involving both the evidence and value judgments regarding benefits and harms of alternative care options, addressing how patients with that condition should be managed, everything else being equal



Purposes of Clinical Practice Guidelines

- Generally intended for use by healthcare providers to improve patient care.
- Also used by Insurers to set policies on payment for care.
- Used by administrators to set criteria to assess performance and care delivery.
- Lawyers may use in malpractice cases.



National Guideline Clearinghouse CPG Criteria

(Agency for Healthcare Research and Quality)

- Are produced <u>under the auspices</u> of a medical specialty association, relevant professional society, public or private organization, government agency or health care organization or plan
- Are based on a <u>systematic review</u> and grading of the evidence [by a panel of experts]
- Contain systematically developed <u>recommendations</u> intended to optimize patient care and assist health care practitioners and patients to make decisions about appropriate health care
- Contain an <u>assessment</u> of the benefits and harms of recommended care and alternative care options.



Guidelines, Recommendations, and Consensus Conferences, Oh My!

There are various ways in which practice and policy are set, and this talk will address GC involvement in both official "practice guideline"-setting groups and other groups and organizations making recommendations affecting genetic practice, whatever they are called.



Why get involved?

It provides an opportunity to influence genetics practice, and the role of genetic counselors in that practice, at a national level.

(It also looks really great on your resume, helps you get recognized as an expert, and opens up opportunities for further involvement.)



GENETIC COUNSELOR

NSGC Evidence-Based Practice Guidelines



Ways of Getting Involved

- 1. NSGC-specific practice guidelines
- 2. As a GC-expert on a national guidelines panel.
 - NCCN High Risk cancer guidelines
 - Huntington Disease Association guidelines
 - Heart Failure/ACMG guidelines
- 3. As an official NSGC representative to a guidelines panel
 - Commission on Cancer
 - NAPBC
- 4. As an NSGC or expert-GC representative on groups established to influence genetics practice.
 - Institute of Medicine



10

NSGC Practice Guidelines Committee

- Oversees development of NSGC's evidence-based practice guidelines.
- Accepts suggestions for new guidelines from the membership.
- Follows the criteria of the National Guidelines Clearinghouse
- Has developed a manual to assist in guideline development
 - Systematic review group
 - Guideline writing group
- Includes a period for NSGC member comment
- · Requires COI Disclosure



12

NSGC Practice Guidelines Address:

- Recommended use of specific genetic information in healthcare, such as:
 - Referral practices
 - Disease screening
 - Predictive testing
 - Disease diagnosis
 - Treatment
- Access to, assessment of, or delivery of, genetic counseling services



INDIANA NETWORK OF GENETIC COUNSELORS

NSGC Practice Guidelines in Development

- Epilepsy
- Hypertrophic Cardiomyopathy
- Telegenetics

NSGC Practice Resources

(Less rigorous. Address genetic counseling best practices but do not require evidence-based recommendations)

- Alzheimer Disease
- Down syndrome



Current NSGC Practice Guidelines

- Cancer Predisposition Evaluation
- Consanguinity (Reaffirmed 2014)
- Cystic Fibrosis
- Fabry Disease
- Fragile X Syndrome
- Pedigree Nomenclature (Reaffirmed 2014)
- Prenatal Screening



GC experts on national guidelines panels



Involvement as a GC Expert

- Serving as an individual genetic counselor with specific expertise in an area/issue:
 - NCCN High Risk Breast/Ovarian (multiple GCs) and High Risk Colon Cancer (Heather Hampel) Guidelines
 - ACMG Recommendations for Reporting Incidental Findings (Kelly Ormond, Julianne O'Daniel)
 - HD Society of America's "Genetic Testing Protocol for Huntington's Disease" (Robin Bennet, Allison Daley, Mara Sifry-Platt)
 - ACMG/Heart Failure Society joint practice resource/guideline on Hypertrophic Cardiomyopathy (in development) (Ana Morales)

INDIANA NETWORK OF GENETIC COUNSELORS

17

NCCN Guidelines

- Intended to document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes.
- Their development is an ongoing and iterative process, which is based on a critical review of the best available evidence and derivation of recommendations by a multidisciplinary panel of experts in the field of cancer.
- Intended to assist in the decision-making process of individuals involved in cancer care—including physicians, nurses, pharmacists, payers, patients and their families...

INDIANA NETWORK OF GENETIC COUNSELORS

National Comprehensive Cancer Network

- Not-for-profit alliance of 27 leading cancer centers.
- Established in 1995 to develop and institute standards of care for cancer treatment.
- Develops resources for the numerous stakeholders in the health care delivery system.
 - "NCCN recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers."



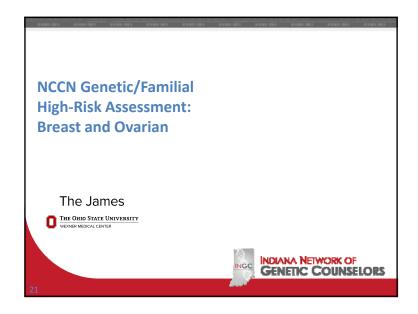
18

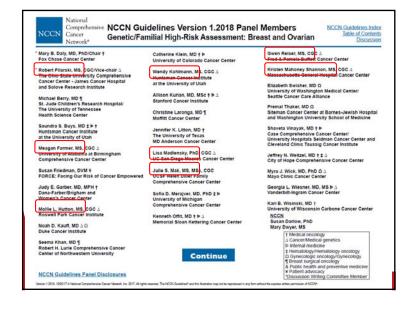
NCCN Guidelines - Started in 1996

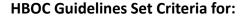
- Treatment of Cancer by Site (30)
 - Covers 97% of cancers affected patients in the US
- Supportive Care (11)
- Detection, Prevention & Risk Reduction (6)
 - Genetic: Colorectal Cancer Screening
 - Genetic/Familial High-Risk Assessment: Breast and Ovarian (first published in 1999)



20



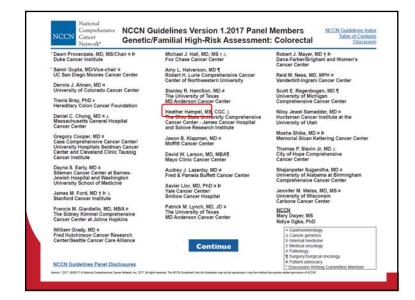




- Who to refer for genetic evaluation and counseling.
- · Who should get genetic testing.
- Clinical management of individuals with gene mutations
- Clinical management of individuals with a clinical diagnosis/presentation.

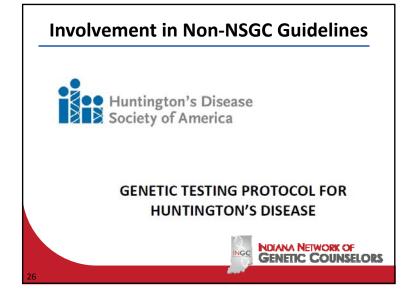
Many insurance companies base their coverage for cancer genetic testing and cancer screening on NCCN guidelines.





ACMG POLICY STATEMENT Genetics in Medicine ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing Robert C. Green, MD, MPH¹², Jonathan S. Berg, MD, PhD³, Wayne W. Grody, MD, PhD⁴6, Sarah S. Kalia, ScM, CGC¹, Bruce R. Korf, MD, PhD², Christa L. Martin, PhD, FACMG³, Amy L. McGuire, JD, PhD³, Robert L. Nussbaum, MD¹³, Julianne M. O¹Daniel. MS. CGC¹. Kelly F. Ormond, MS. CGC¹. Heidi L. Rehm, PhD, FACMG²¹. Michael S. Watson, PhD, FACMG¹¹, Marc S. Williams, MD, FACMG¹⁴ and Leslie G. Biesecker, MD¹⁵ Genetics in Medicine 2013;15:565-574









Commission on Cancer

Cancer Risk Assessment and Genetics Testing Standard



INDIANA NETWORK OF GENETIC COUNSELORS

Background

- 2009 CoC members were charged with updating the standards (last update 2004)
- Chair of this committee specifically believed that onsite genetic counseling should be a requirement at any CoC accredited cancer program
- Goals in creating the standard:
 - Differentiate cancer risk assessment/genetic counseling (CRA/GC) and genetic testing (GT)
 - Identify the minimum essential elements needed when performing a CRA/GC and GT
 - Identify who at a CoC-accredited institution is qualified to perform CRA/GC and GT

 DOWN TO THE TOWN OF GENETIC COUNSELORS

Commission on Cancer (CoC)

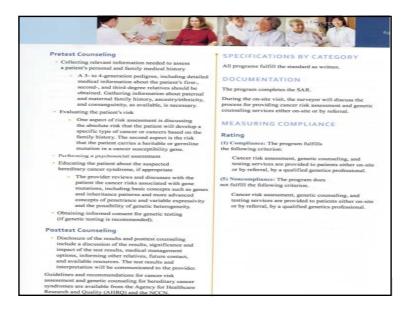
- Consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard-setting, prevention, research, education, and the monitoring of comprehensive quality care.
 - Comprised of 100 individuals with a mix from ACoS and 50+ Member Organization affiliates
 - 70% of all cancer pts receive care at CoC accredited institution (~1500 institutions in US and Puerto Rico)
 - NSGC has been a member organization since 2004



Cancer Risk Assessment and Genetic Counseling

 S 2.3 Cancer risk assessment, genetic counseling, and testing services are provided to patients either on site or by referral, by a qualified genetics professional







- Primary national organization providing accreditation to Breast Centers:
 - "Accreditation by the National Accreditation Program for Breast Centers (NAPBC) is granted only to those centers that have voluntarily committed to provide the highest quality care to patients with diseases of the breast. Each center must undergo a rigorous evaluation and review of its performance and compliance with the NAPBC standards."
- NAPBC accreditation is highly sought after by Breast Centers.





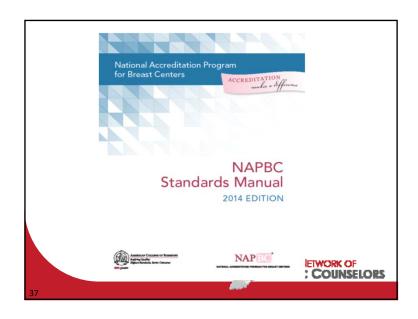
NAPBC Board Member Organizations

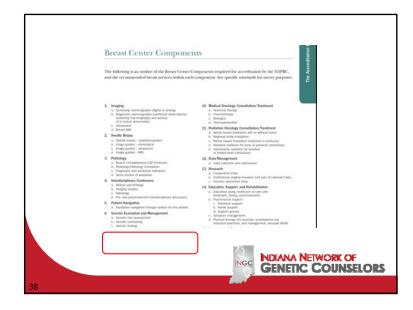
- American Board of Surgery (ABS)
- American Cancer Society (ACS)
- American College of Radiology Breast Imaging Commission (ACRBIC)
- American Cancer Radiology Imaging Network (ACRIN)
- · American College of Surgeons (ACoS)
- American Institute for Radiologic Pathology (AIRP)
- American Society for Radiation Oncology (ASTRO)
- American Society of Breast Disease (ASBD)
- American Society of Breast Surgeons (ASBS)
- American Society of Clinical Oncology (ASCO)
- American Society of Plastic Surgeons (ASPS)
- Association of Cancer Executives (ACE)
- Association of Oncology Social Work (AOSW)
- College of American Pathologists (CAP)
- National Cancer Registrars Association (NCRA)
- National Consortium of Breast Centers (NCBC)
 National Consortium of Consortium (NCBC)
- National Society of Genetic Counselors (NSGC)
- Oncology Nursing Society (ONS)
 Society of Breast Imaging (SBI)

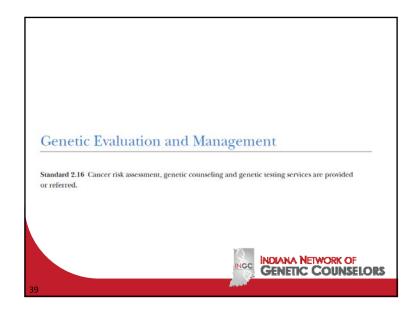
Society of Surgical Oncology (SSO)

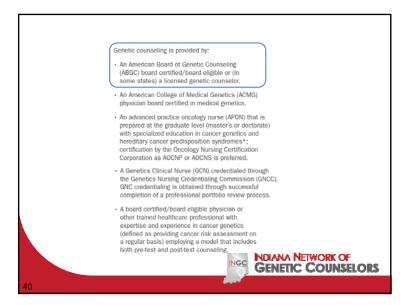


-









NSGC or expert GC representative on groups established to influence genetics practice.



INDIANA NETWORK OF GENETIC COUNSELORS

Involvement in Policy Guidelines

Institute of Medicine/National Academy of Sciences Roundtable on Genomics and Precision Health

- Focuses on examining issues in genomics with various stakeholders at the national level.
- Holds public workshops to illuminate specific issues
- Does not specifically set guidelines.
- Cathy Wicklund, MS, CGC



Involvement in Policy Guidelines

US Dept of HHS Secretary in 1999 established the Secretary's Advisory Committee on Genetic Testing (SACGT).

- Chartered to help the department formulate policies on the development, validation and regulation of genetic tests, particularly DNA-based diagnostics.
- Members were selected from nearly 200 nominees who have distinguished themselves in the areas of genetic testing, medical genetics, genetic counseling, primary health care, public health, clinical laboratory management, diagnostic technology, ethics, law, psychology, social sciences, and patient/consumer advocacy.
- NSGC rep was Ann Happ Boldt, MS, CGC



Conclusions

- Practice guidelines and similar documents play important roles in setting policy and practice standards, determining who participates in that practice, and whether insurance will cover it.
- Genetic counselors can and should play an essential role in the process of setting genetics practice guidelines.
- There are multiple ways and levels at which counselors can participate in this process.



11

So How do I Get Involved?

- Develop expertise.
- Be aware of policy and practice developments in your field.
- Volunteer!

