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Hereditary Prostate Cancer:

The Ins & Outs of Genetic Testing

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University of Chicago High Risk & Advanced Prostate Cancer (UCHAP) Clinic

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ALL Cancer is Genetic!!!

Only a small percentage is hereditary

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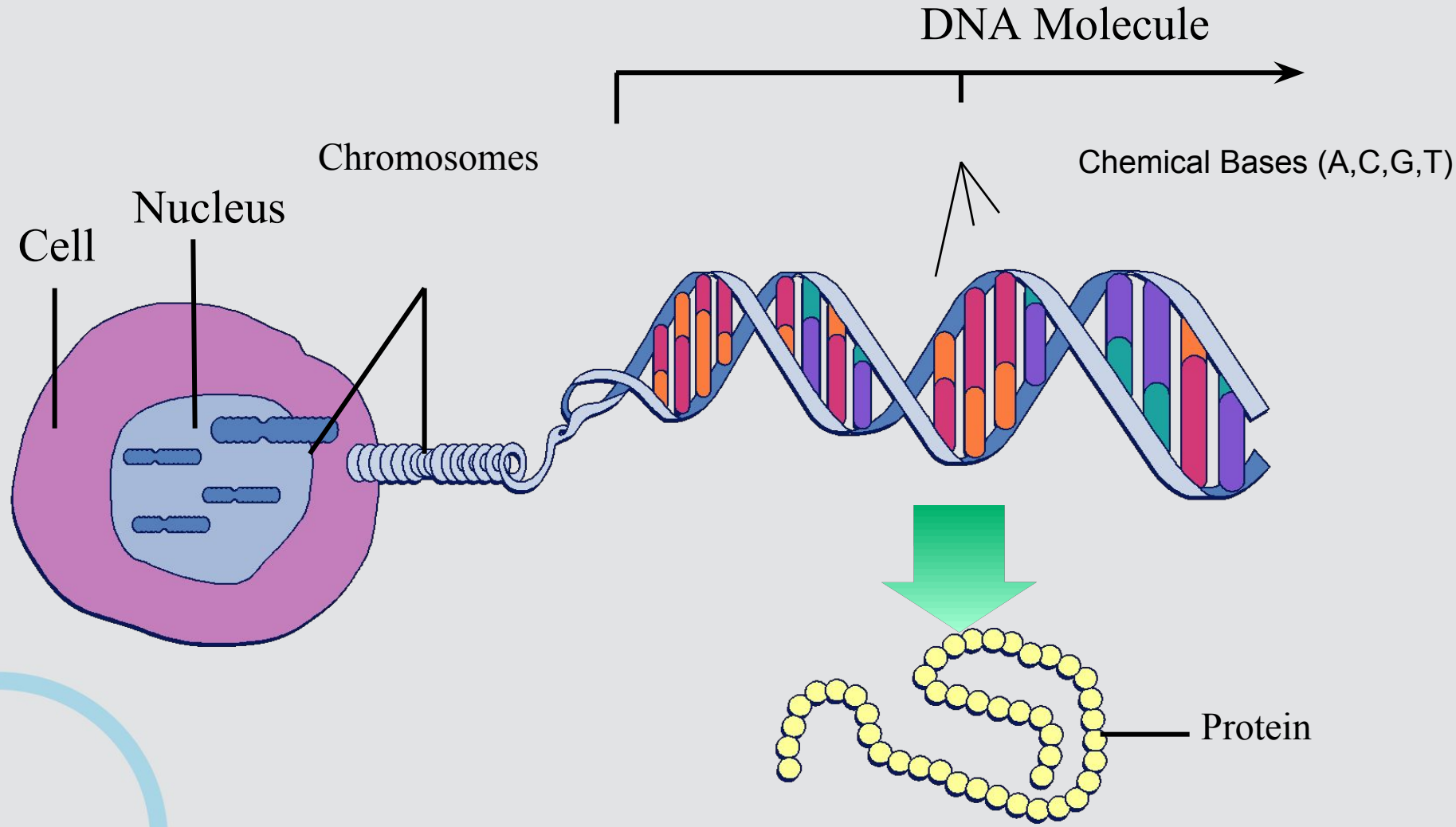
All Cancer is Genetic



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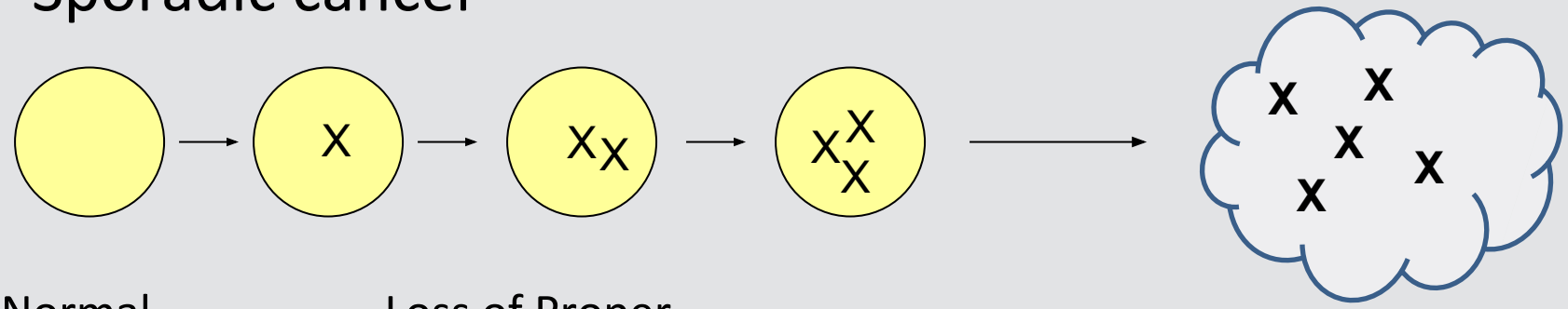
How Cancer Forms

Sporadic cancer

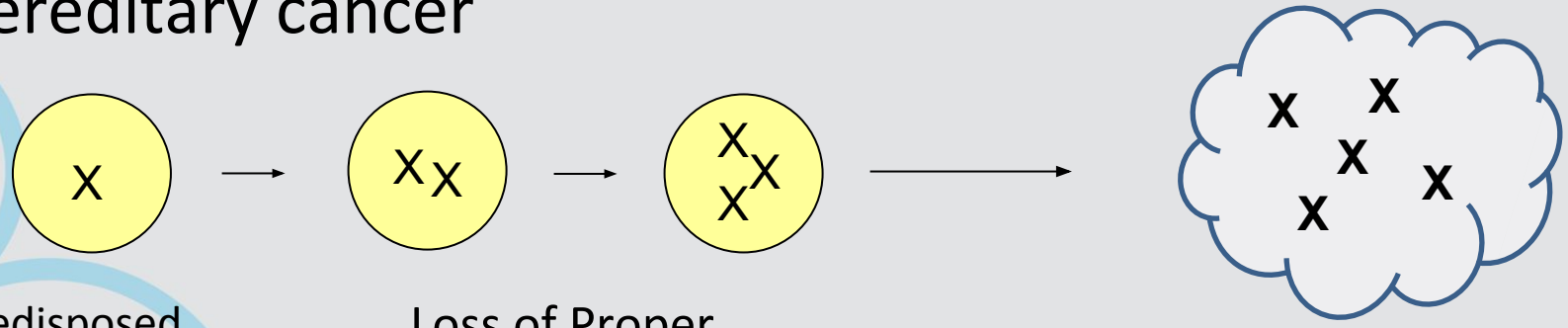


Normal Cell

Loss of Proper Growth Control

Tumor Develops

Hereditary cancer



Predisposed Cell

Loss of Proper Growth Control

Tumor Develops

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Prostate Cancer

Approximately 1 in 7 (14%) of men will be diagnosed with prostate cancer at some point in their lives

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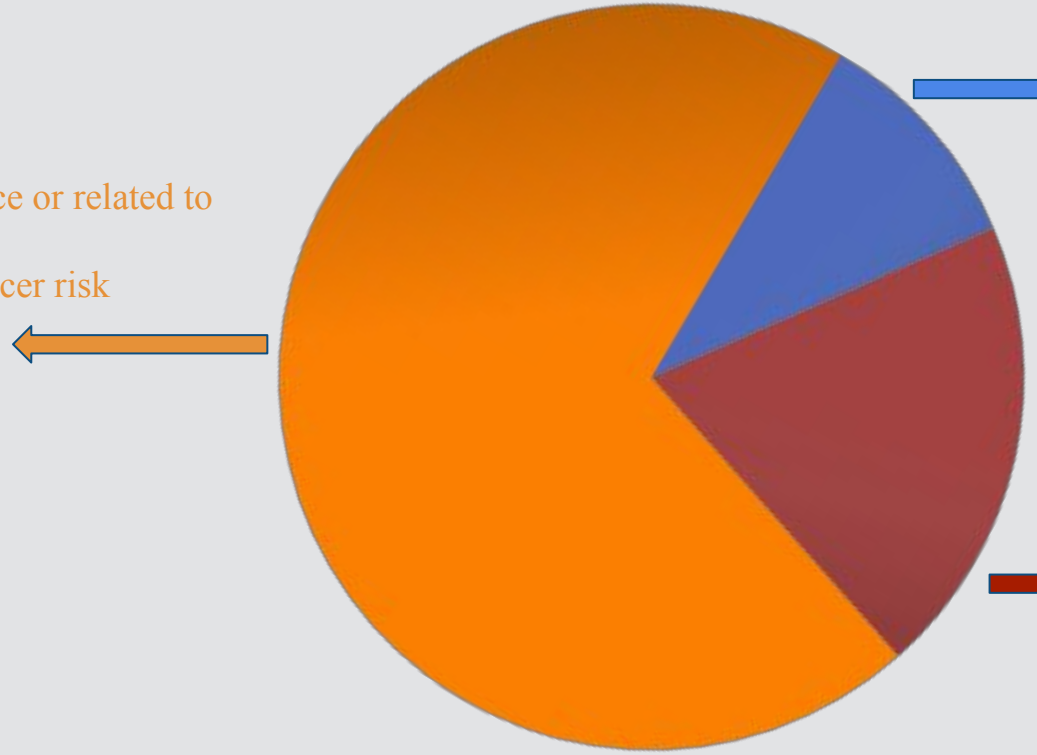
Prostate Cancer

Hereditary (5-12%)
- Gene Mutation is inherited in family
- Significantly increased cancer risk



Sporadic (70%)
- Cancer occurs by chance or related to environmental factors
- General population cancer risk

Familial (20%)
- Multiple genes and environmental factors may be involved
- Some increase in cancer risk

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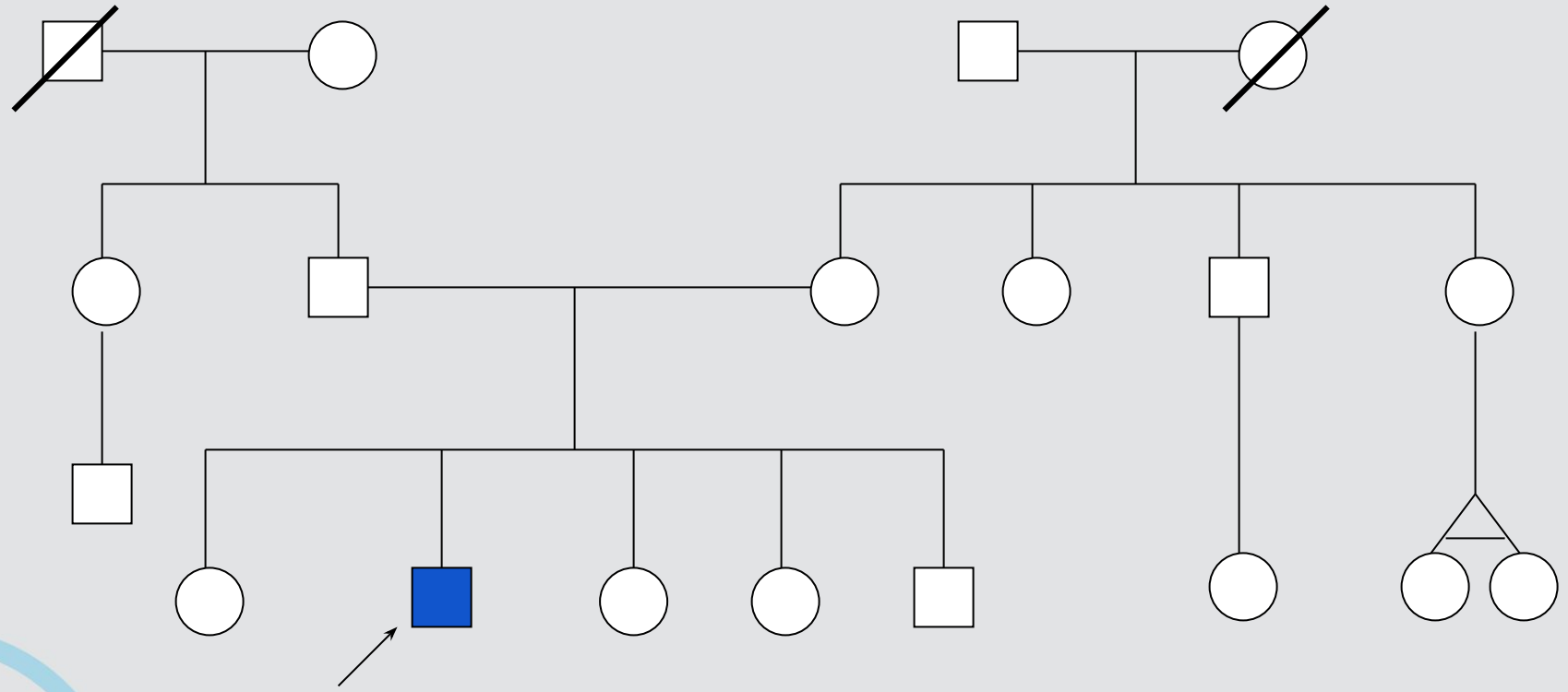
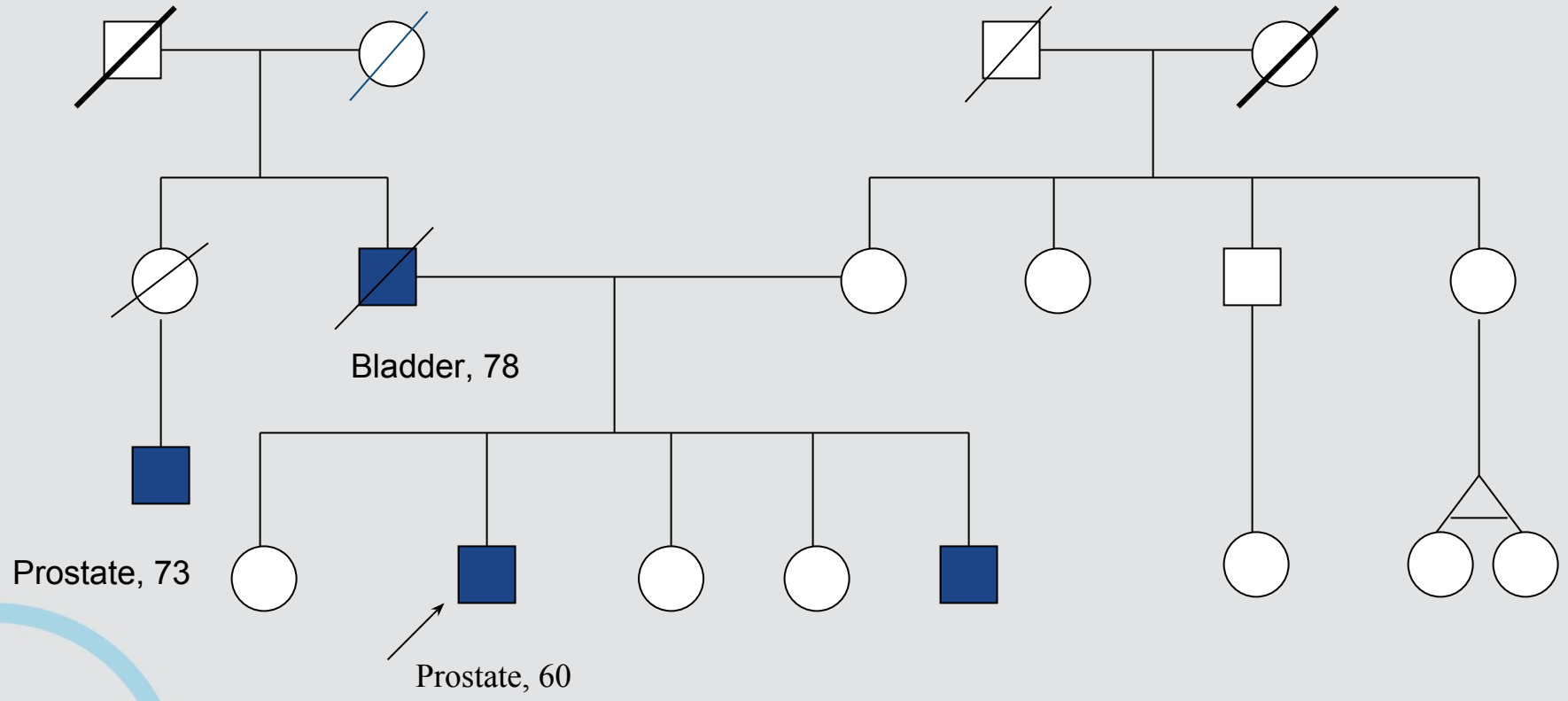
Sporadic Prostate Cancer



Prostate, 60

Familial Prostate Cancer



Hereditary Prostate Cancer

Risk Factors/Clues

- Younger age of onset
- High grade disease (Gleason score ≥ 7)
- Multiple family members with the same type of cancer
- Multiple generations with cancer
- Clustering of certain types of cancer
  (i.e. prostate/breast/ovarian/pancreatic)
- Ashkenazi Jewish ancestry

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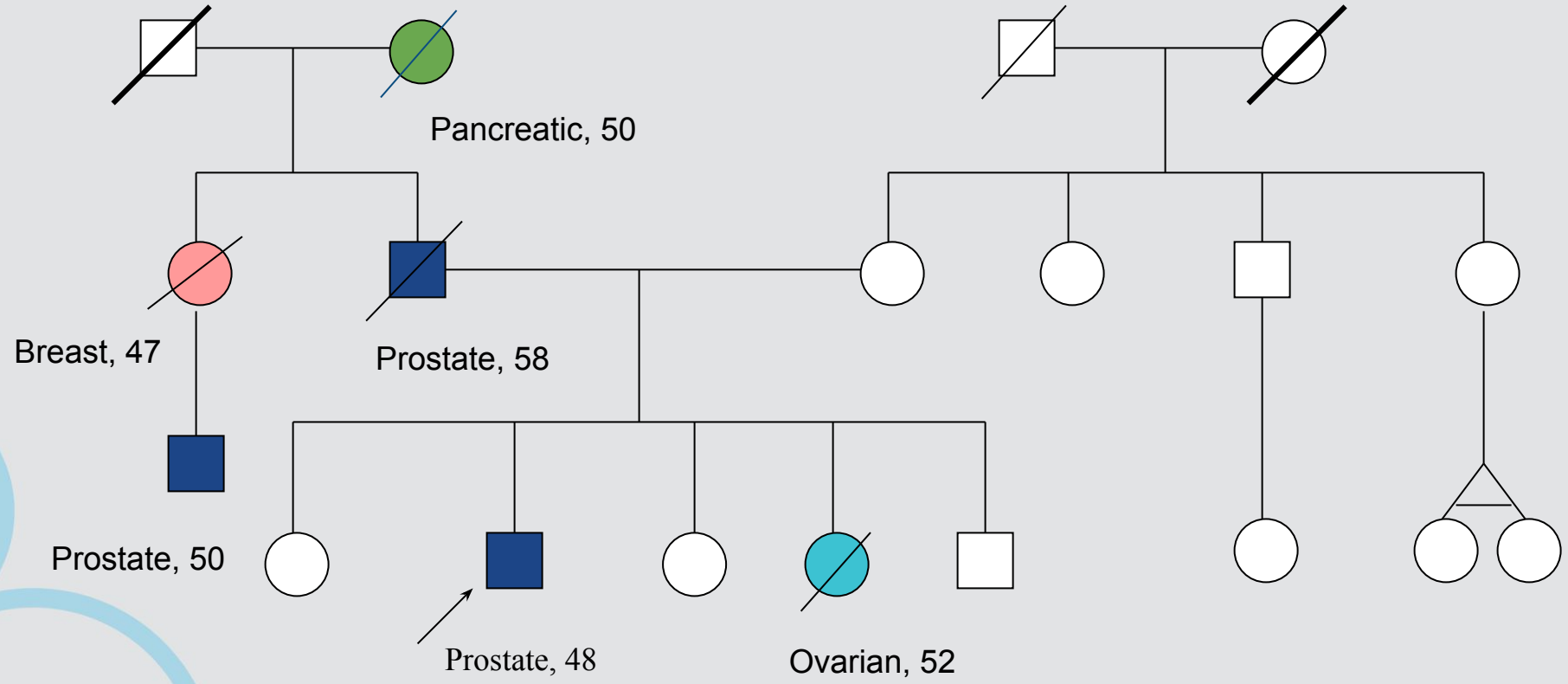
Hereditary Prostate Cancer



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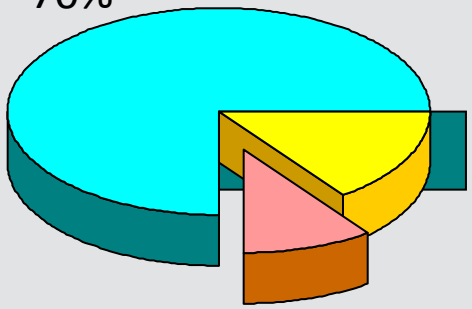
Hereditary Prostate Cancer

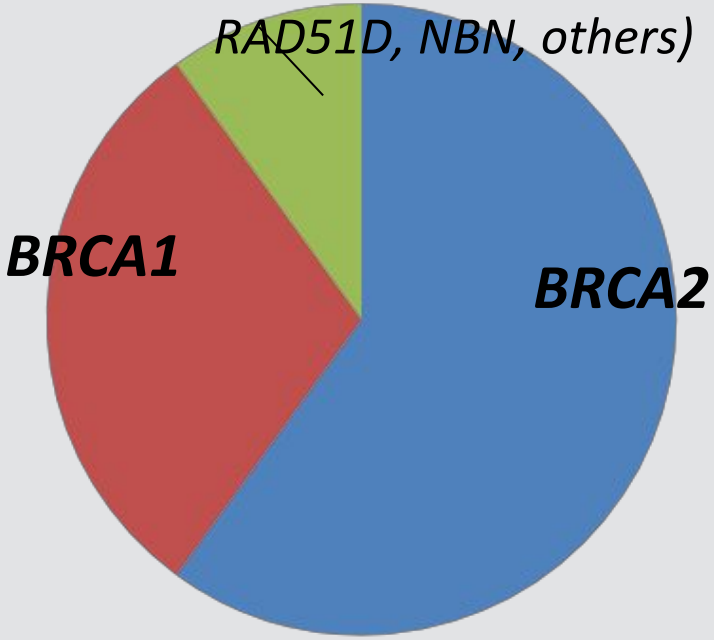
Sporadic ~70%



Familial ~15-20%

~5-12% Hereditary

Other genes/unknown
(*HOXB13, ATM, CHEK2, PALB2, RAD51D, NBN, others)*



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Prostate cancer genes

Gene	Syndrome	Chromosome	Estimated Risks	Clinical characteristics	Other cancer types
BRCA1	HBOC	17q	RR=1.82 <65 y; no inc risk >65y	Earlier onset	Breast, ovarian
BRCA2	HBOC	13q	RR=4.65; 7.33 <65y	Poorer survival	Breast, ovarian, pancreatic
HOXB13	Familial prostate ca	17q; recurrent mutation G84E (Caucasian)	OR=4.07 OR=8.41 ≤ 55y OR=7.19 with fam hx	Earlier onset, familial	None
Mismatch repair (MMR) genes	Lynch syndrome	*MLH1, MSH2, MSH6, PMS2, EPCAM*	RR=2.11-3.67	Not available	Colorectal, duodenal, uterine, ovarian,
ATM	Ataxia-telangiectasia	11q	HR=2.3	Increased in metastatic cohort	Breast, pancreatic, colon (hets)
CHEK2	CHEK2-associated cancer syndrome	22q	OR=1.9-2.3 OR=2.7 with fam hx	Not available	Breast, colon, thyroid
TP53	Li-Fraumeni syndrome	17p	RR=0.5-4.90	Not available	Breast, brain, sarcoma, leukemia, etc.
NBN/NBS1	Nijmegan breakage syndrome	8q	OR=2.5 (675del5) OR=3.1 <60y	Not available	Breast
PALB2	Fanconi anemia; PALB2-associated cancer	16p	Not available	Not available	Breast, pancreatic
RAD51D	RAD51D-associated cancer	17q	Not available	Not available	Ovarian

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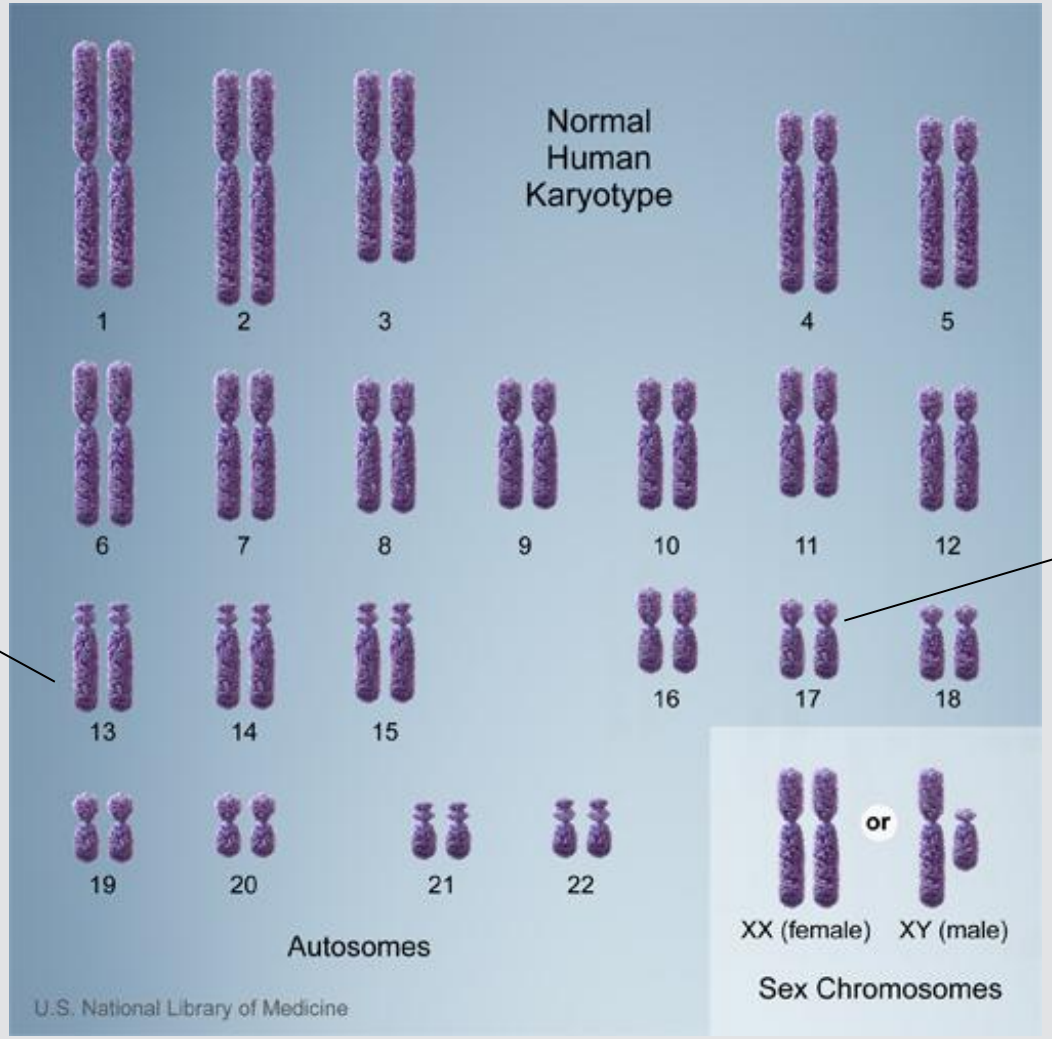
BRCA2 (13q)

BRCA1 (17q)



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Nationally Recognized Testing Criteria

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NCCN Guidelines Version 3.2019
BRCA-Related Breast and/or Ovarian Cancer Syndrome

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BRCA1/2 TESTING CRITERIA[a,b]

Meeting one or more of these criteria warrants further personalized risk assessment, genetic counseling, and often genetic testing and management.
Testing of an individual without a cancer diagnosis should only be considered when an appropriate affected family member is unavailable for testing.

- Individual from a family with a known *BRCA1/2* pathogenic/likely pathogenic variant, including such variants found on research testing[b]
- Personal history of breast cancer[c] + one or more of the following:
  - Diagnosed ≤45 y
  - Diagnosed 46-50 y with:
    - An additional breast cancer primary at any age[d]
    - ≥1 close blood relative[e] with breast cancer at any age
    - ≥1 close blood relative[e] with high-grade (Gleason score ≥7) prostate cancer
    - An unknown or limited family history[a]
  - Diagnosed ≤60 y with:
    - Triple-negative breast cancer
  - Diagnosed at any age with:
    - ≥1 close blood relative[e] with:
      - breast cancer diagnosed ≤50 y; or
      - ovarian carcinoma;[f] or
      - male breast cancer; or
      - metastatic prostate cancer;[g] or
      - pancreatic cancer
    - ≥2 additional diagnoses[d] of breast cancer at any age in patient and/or in close blood relatives
  - Ashkenazi Jewish ancestry[h]
- Personal history of ovarian carcinoma[f]
- Personal history of male breast cancer
- Personal history of pancreatic cancer[i]
- Personal history of metastatic prostate cancer[g]
- Personal history of high-grade prostate cancer (Gleason score ≥7) at any age with
  - ≥1 close blood relatives[e] with ovarian carcinoma, pancreatic cancer, or metastatic prostate cancer[g] at any age or breast cancer <50 y; or
  - ≥2 close blood relatives[e] with breast, or prostate cancer (any grade) at any age; or
  - Ashkenazi Jewish ancestry[h]
- *BRCA1/2* pathogenic/likely pathogenic variant detected by tumor profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis
- Regardless of family history, some individuals with an *BRCA*-related cancer may benefit from genetic testing to determine eligibility for targeted treatment[j]
- An individual who does not meet the other criteria but with ≥1 first- or second-degree blood relative[k] meeting any of the above criteria. The significant limitations of interpreting test results for an unaffected individual should be discussed.

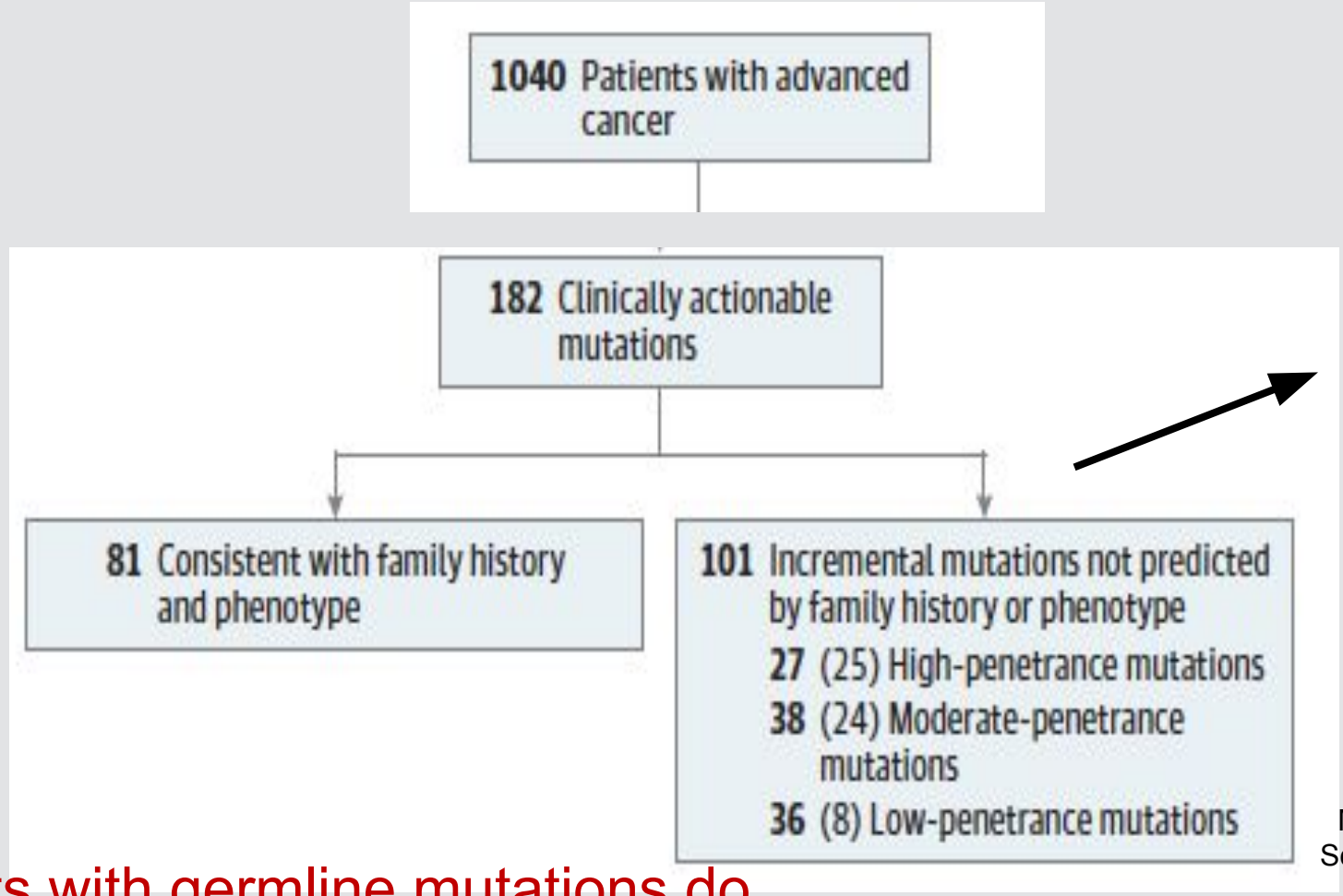
BRCA testing criteria met → See Follow-up (BRCA-2)

If *BRCA* testing criteria not met, consider testing for other hereditary syndromes → If criteria for other hereditary syndromes not met, then cancer screening as per NCCN Screening Guidelines

[a]For further details regarding the nuances of genetic counseling and testing, see BR/ . OV-A.

[g]Metastatic prostate cancer is biopsy proven and/or with radiographic evidence and includes distant metastasis and

14% of patients with advanced cancer have a hereditary cancer gene mutation



17% led to discussion of targeted therapy

Mandelker et al. JAMA. 2017; 318(9): 825-835
Schrader et al. JAMA Oncol. 2016;2(1):104-111

44% of patients with germline mutations do NOT meet clinical testing guidelines

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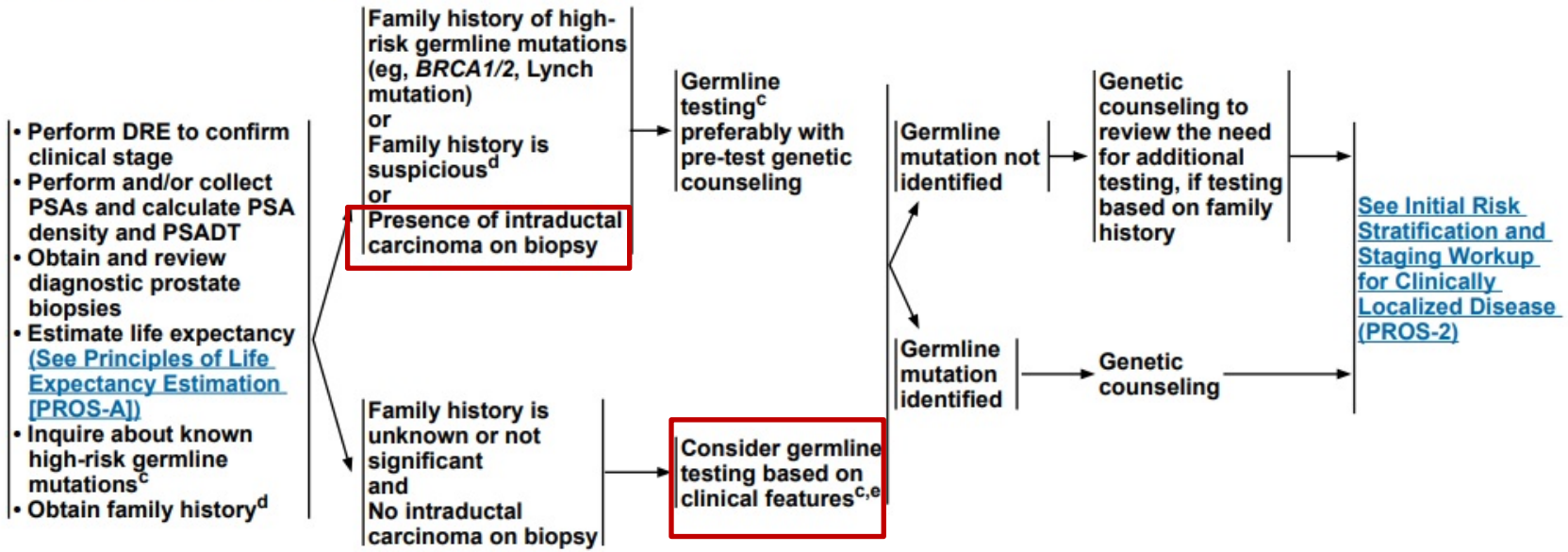
INITIAL PROSTATE CANCER DIAGNOSIS[a,b]



[a] See NCCN Guidelines for Older Adult Oncology for tools to aid optimal assessment and management of older adults.

[b] See NCCN Guidelines for Prostate Cancer Early Detection.

[c] Family history for known germline variants and genetic testing for germline variants should include *MLH1, MSH2, MSH6, and PMS2* (for Lynch syndrome) and homologous recombination genes *BRCA1, BRCA2, ATM, PALB2,* and *CHEK2*. Consider cancer predisposition next-generation sequencing (NGS) panel testing, which includes *BRCA2, BRCA1, ATM, CHEK2, PALB2, MLH1, MSH2, MSH6,* and *PMS2*. Additional genes may be appropriate depending on clinical context. For example, *HOXB13* is a prostate cancer risk gene that does not have clear therapeutic implications in advanced disease, but testing may be valuable for family counseling.

[d] Family history criteria and consideration to prompt genetic testing:
- A strong family history of prostate cancer consists of: brother or father or multiple family members who were diagnosed with prostate cancer (but not clinically localized Grade Group 1) at less than 60 years of age or who died from prostate cancer
- Ashkenazi Jewish ancestry
- ≥3 cancers on same side of family, especially diagnoses ≤50 years of age: bile duct, breast, colorectal, endometrial, gastric, kidney, melanoma, ovarian, pancreatic, prostate (but not clinically localized Grade Group 1), small bowel, or urothelial cancer

[e] Genetic testing in the absence of family history or clinical features (eg, high- or very-high-risk prostate cancer, intraductal histology) may be of low yield. The patient should be counseled to inform providers of any update to family history.

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INITIAL RISK STRATIFICATION AND STAGING WORKUP FOR CLINICALLY LOCALIZED DISEASE

Risk group	Clinical/pathologic features			Imaging[h,i]	Germline testing	Molecular and biomarker analysis of tumor[l]	Initial therapy
Very low[f]	• T1c AND • Grade Group 1 AND • PSA <10 ng/mL AND • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core[g] AND • PSA density <0.15 ng/mL/g			Not indicated	Recommended if family history positive or intraductal histology See PROS-1	Not indicated	See PROS-4
Low[f]	• T1-T2a AND • Grade Group 1 AND • PSA <10 ng/mL			Not indicated	Recommended if family history positive or intraductal histology See PROS-1	Consider if life expectancy ≥10y[m]	See PROS-5
Intermediate[f]	Has no high- or very-high-risk features and has one or more intermediate risk factors (IRF): • T2b-T2c • Grade Group 2 or 3 • PSA 10–20 ng/mL	Favorable intermediate	• 1 IRF and • Grade Group 1 or 2 and • <50% biopsy cores positive[g]	• Bone imaging[j]: not recommended for staging • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement • If regional or distant metastases are found, see PROS-9	Recommended if family history positive or intraductal histology See PROS-1	Consider if life expectancy ≥10y[m]	See PROS-6
		Unfavorable intermediate	• 2 or 3 IRFs and/or • Grade Group 3 and/or • ≥50% biopsy cores positive[g]	• Bone imaging[j]: recommended if T2 and PSA >10 ng/mL • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement • If regional or distant metastases are found, see PROS-9	Recommended if family history positive or intraductal histology See PROS-1	Not routinely recommended	See PROS-7
High	• T3a OR • Grade Group 4 or Grade Group 5 OR • PSA >20 ng/mL			• Bone imaging[j]: recommended • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement • If regional or distant metastases are found, see PROS-9	Recommended[c,k]	Not routinely recommended	See PROS-8
Very high	• T3b-T4 OR • Primary Gleason pattern 5 OR • >4 cores with Grade Group 4 or 5			• Bone imaging[j]: recommended • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement • If regional or distant metastases are found, see PROS-9	Recommended[c,k]	Not routinely recommended	See PROS-8

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GENETIC AND MOLECULAR BIOMARKER ANALYSIS FOR ADVANCED PROSTATE CANCER

Risk group	Clinical/pathologic features	Germline testing	Molecular and biomarker analysis of tumor[l]	Initial therapy
Regional	Any T, N1, M0	Recommended[c,k]	Consider tumor testing for homologous recombination gene mutations and for microsatellite instability (MSI) or mismatch repair deficiency (dMMR)[dd,ee]	See PROS-10
Metastatic[ff]	Any T, Any N, M1	Recommended[c,k]	Consider tumor testing for homologous recombination gene mutations and for MSI or dMMR [dd,ee]	See PROS-14

[c] Family history for known germline variants and genetic testing for germline variants should include *MLH1, MSH2, MSH6, and PMS2* (for Lynch syndrome) and homologous recombination genes *BRCA1, BRCA2, ATM, PALB2,* and *CHEK2.* Consider cancer predisposition NGS panel testing, which includes *BRCA2, BRCA1, ATM, CHEK2, PALB2, MLH1, MSH2, MSH6,* and *PMS2.* Additional genes may be appropriate depending on clinical context. For example, *HOXB13* is a prostate cancer risk gene that does not have clear therapeutic implications in advanced disease, but testing may be valuable for family counseling.

[k] The prevalence of inherited (germline) DNA repair gene mutations in men with metastatic prostate cancer, unselected for family history (n = 692), was found to be 11.8% (*BRCA2* 5.3%, *ATM* 1.6%, *CHEK2* 1.9%, *BRCA1* 0.9%, *RAD51D* 0.4%, and *PALB2* 0.4%, and 6% in the localized high-risk population in the TCGA cohort (Cancer Genome Atlas Research Network. The molecular taxonomy of primary prostate cancer. Cell 2015;163:1011-25; Pritchard CC, Mateo J, Walsh MF, et al. Inherited DNA-repair gene mutations in men with metastatic prostate cancer. N Engl J Med 2016;375:443-453). Germline genetic testing is recommended for all men with high-risk, very-high-risk, regional, or metastatic prostate cancer. Genetic counseling resources and support is critical and pre-test counseling is preferred when feasible. Post-test genetic counseling is recommended if a mutation is identified.

[l] Patients should be informed that somatic tumor sequencing has the potential to uncover germline findings. However, virtually no somatic NGS tests are designed or validated for germline assessment. Therefore, overinterpretation of germline findings should be avoided. If a germline mutation is suspected, the patient should be recommended for genetic counseling and follow-up dedicated germline testing.

[dd] DNA analysis for MSI and IHC for MMR are different assays measuring the same biological effect. If MSI is used, testing using an NGS assay validated for prostate cancer is preferred. If MSI-H or dMMR is found, refer to genetic counseling to assess for the possibility of Lynch syndrome. MSI-H or dMMR indicate eligibility for pembrolizumab in later lines of treatment for castration-resistant prostate cancer (CRPC) (see PROS-17 and PROS-18). Hempelmann JA, Lockwood CM, Konnick EQ, et al. Microsatellite instability in prostate cancer by PCR or NGS. J Immunother Cancer 2018;6:29.

[ee] Consider evaluating tumor for alterations in homologous recombination DNA repair such as: *BRCA1, BRCA2, ATM, PALB2, FANCA, RAD51D,* and *CHEK2.* At present, this information may be used for genetic counseling, early use of platinum chemotherapy, and/or eligibility for clinical trials (eg, PARP inhibitors). Clinical trials may include additional candidate DNA repair genes under investigation as molecular biomarkers. If mutations in *BRCA2, BRCA1, ATM, CHEK2,* or *PALB2* are found and/or there is a strong family history of cancer, refer to genetic counseling to assess for the possibility of hereditary breast and ovarian cancer (HBOC).

[ff] ADT alone (see PROS-F) or observation is recommended for asymptomatic patients with metastatic disease and life expectancy ≤5 years.

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Personalized Medicine

Surveillance or Prevention

Risk for other cancers (e.g. pancreatic, colon, stomach)

Treatment Options

Treatment may change if the cancer is hereditary in nature

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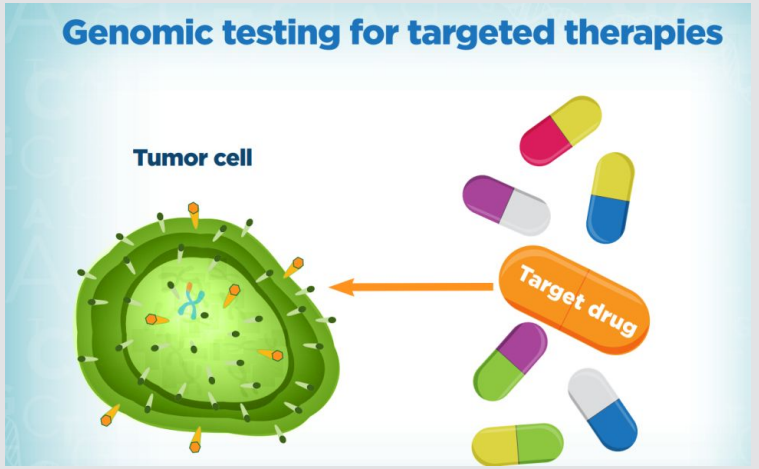
Genomic Testing for Targeted Therapies

- Some DNA mutations that lead to cancer also make the cancer cells susceptible to the effects of certain drugs
- These drugs are called targeted therapies, because they target the genetic changes in the cancer cells as a way of fighting the cancer
- Genomic molecular testing of the cancer tissue (also called tumor profiling) can sometimes reveal targeted therapies that are the most likely to kill the cancer cells



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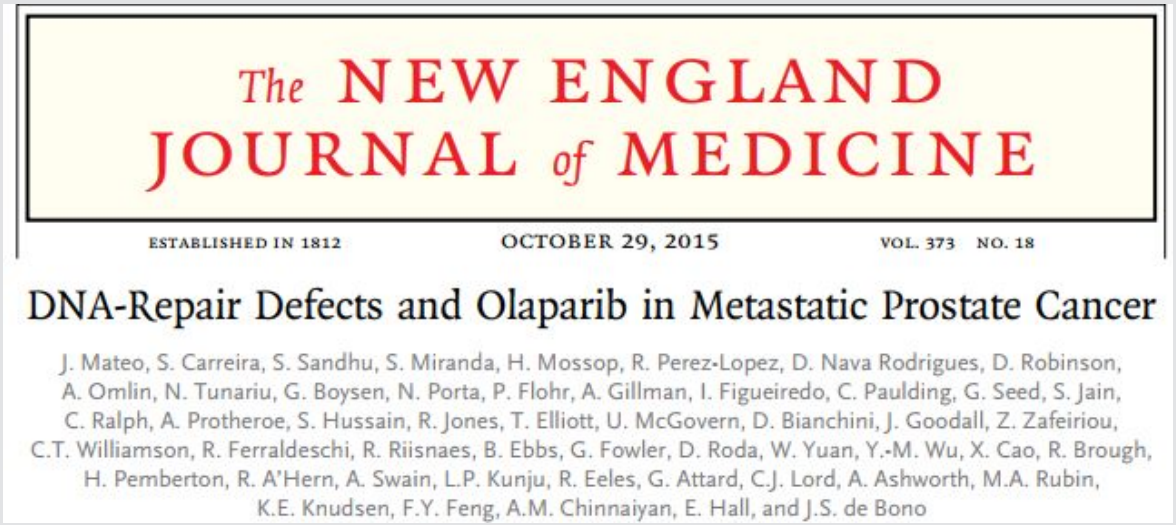

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DNA-Repair Defects and Olaparib in Metastatic Prostate Cancer

J. Mateo, S. Carreira, S. Sandhu, S. Miranda, H. Mossop, R. Perez-Lopez, D. Nava Rodrigues, D. Robinson, A. Omlin, N. Tunariu, G. Boysen, N. Porta, P. Flohr, A. Gillman, I. Figueiredo, C. Paulding, G. Seed, S. Jain, C. Ralph, A. Protheroe, S. Hussain, R. Jones, T. Elliott, U. McGovern, D. Bianchini, J. Goodall, Z. Zafeiriou, C.T. Williamson, R. Ferraldeschi, R. Riisnaes, B. Ebbs, G. Fowler, D. Roda, W. Yuan, Y.-M. Wu, X. Cao, R. Brough, H. Pemberton, R. A'Hern, A. Swain, L.P. Kunju, R. Eeles, G. Attard, C.J. Lord, A. Ashworth, M.A. Rubin, K.E. Knudsen, F.Y. Feng, A.M. Chinnaiyan, E. Hall, and J.S. de Bono

PARP inhibitors are effective in treating a variety of *BRCA*-related cancers, including metastatic, castration-resistant prostate cancer

REPORT

Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade

Dung T. Le[1,2,3], Jennifer N. Durham[1,2,3,*], Kellie N. Smith[1,3,*], Hao Wang[3,*], Bjarne R. Bartlett[2,4,*], Laveet K. Aulakh[2,4], Steve ...
+ See all authors and affiliations

Science 28 Jul 2017:
Vol. 357, Issue 6349, pp. 409-413
DOI: 10.1126/science.aan6733

"These data support the hypothesis that the large proportion of mutant neoantigens in mismatch repair–deficient cancers make them sensitive to immune checkpoint blockade, regardless of the cancers' tissue of origin."

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To Test or Not to Test

- Information for Family Members
- Increased and earlier surveillance
- Preventative or Risk Reducing Surgeries
- Risk-Reducing Medications

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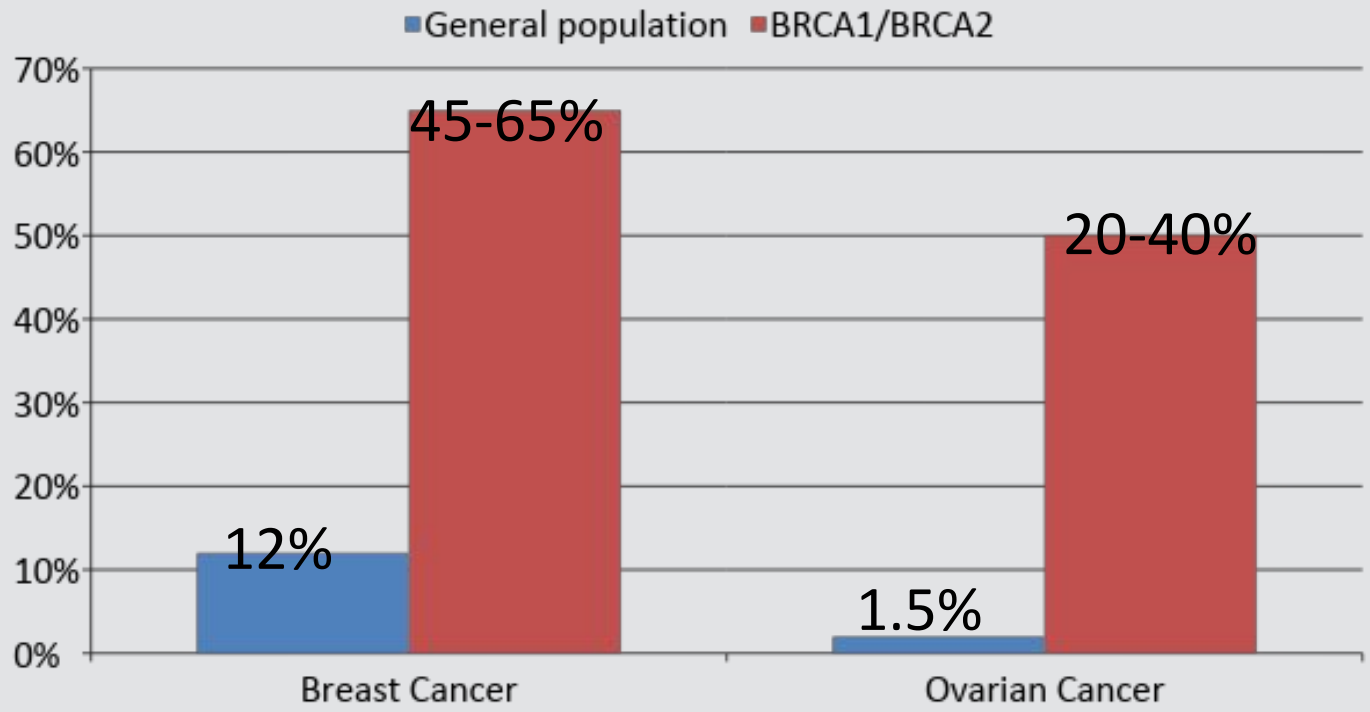
Risk for Family Members

Breast/Ovarian Cancer Risk: Lifetime



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To Test or Not to Test: Potential Risks

- You may be anxious or worried about yourself or your family members based on your results.
  - Your family members may become upset by learning about a genetic risk.
- You may feel frustrated or confused by the lack of specific information about the meaning of your results.
  - You may feel frustrated or confused by the lack of standardized medical recommendations based on your results.
- It is not known whether these results would impact your ability to get life insurance, disability insurance or long-term care insurance.

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Financial Considerations

Insurance Billing

- Most insurance plans cover the cost of testing *if* the patient meets criteria
- Some insurance companies have Genetic Testing Exclusions
- Flexibility to send to any lab you choose
- Total cost of test is at list price, but insurance often covers the test
- Lab will call before they run the test if your out of pocket expenses are *expected* to exceed a certain amount***
- Labs will work with patients to reduce their out of pocket expenses

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Financial Considerations

- Interest-free payment plans
- Discount for self-pay
- Financial hardship programs
- Foundations that can help with costs of genetic testing
  - Cancer Resource Foundation
  - Patient Advocate Foundation
  - Bright Pink
  - Susan G. Komen
  - FORCE

Financial Considerations

- **Affordable Care Act (ACA)**
  - Insurance companies required to pay for genetic counseling and ***BRCA*** testing for **women** who meet certain criteria
    - *Does not* include men or any other genes
- **Genetic Information Nondiscrimination Act (GINA)**
  - Prevents health insurance from discriminating based on predictive genetic testing results
    - D*oes not* apply to affected individuals, life/disability/long-term care insurance, military/federal/small group insurance
    - Certain states do have additional protections in place

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Genetic Testing Options

Testing Option	Definition
Single Gene(s)	•Test 1-2 genes for mutations. Tests for a single hereditary cancer syndrome
Gene Panel	•Test multiple genes at the same time for mutations. Tests for multiple, different hereditary cancer syndromes
No Testing	• You may decline genetic testing or defer your decision until a later date. Also, your provider may decide that genetic testing may not be appropriate.

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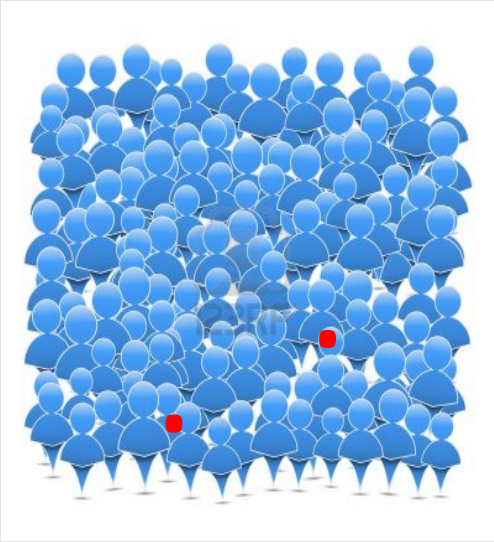
Types of Cancer Genes

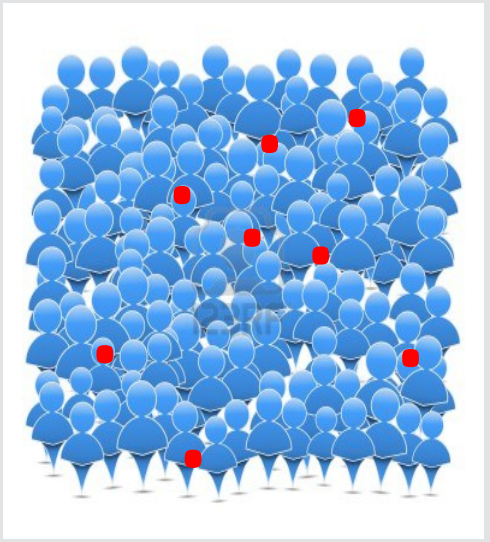
Mutations in **high risk genes** are relatively uncommon.



BRCA1
BRCA2
TP53

CDH1
PALB2

Mutations in **moderate risk genes** may be more common.



ATM
CHEK2

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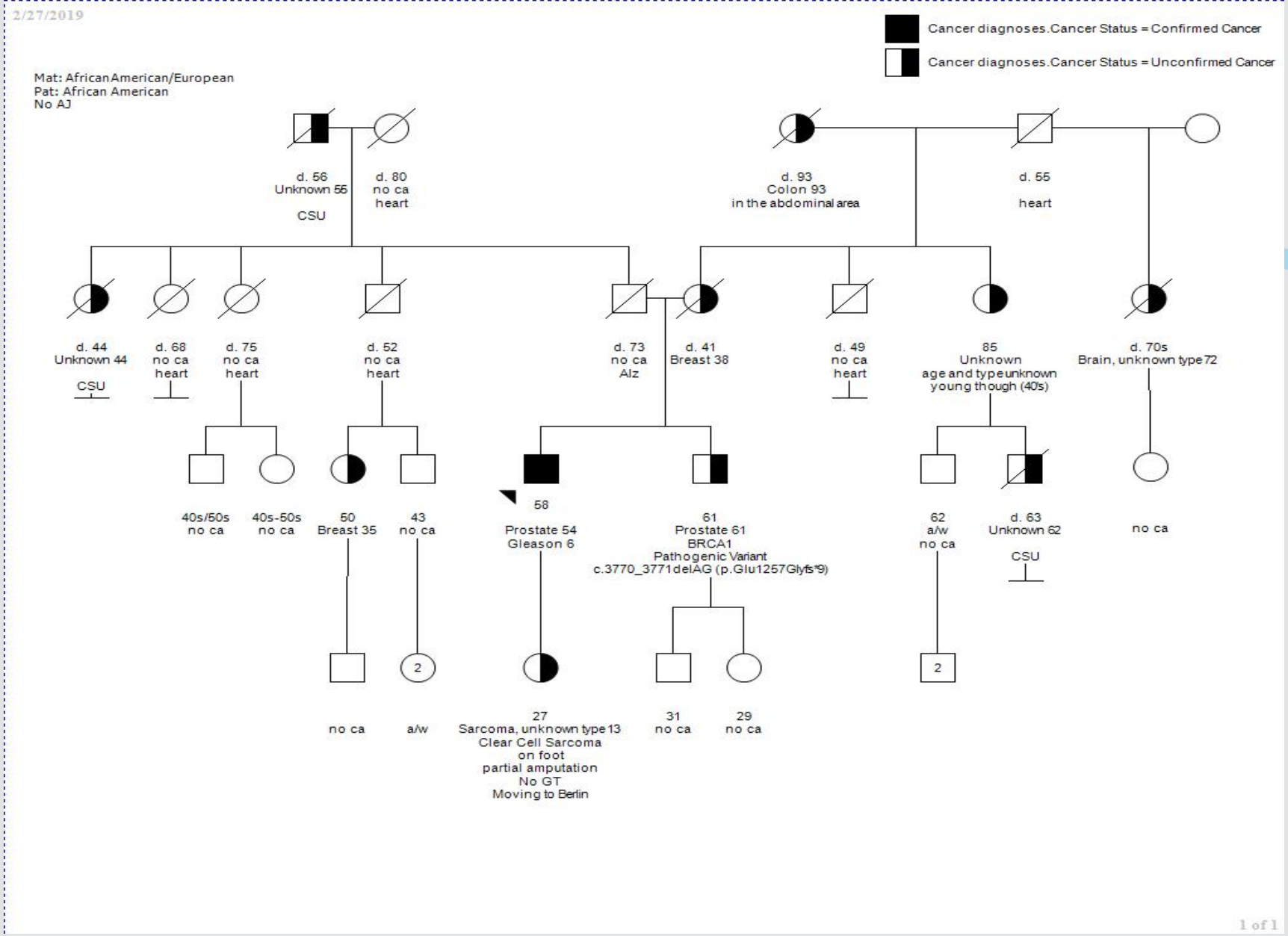
Possible Genetic Test Results

- Positive for a mutation in a breast cancer gene:
  - May be associated with a high risk
  - May be associated with a moderate risk
  - May be associated with an undetermined risk
- No mutation detected
- Variant of uncertain significance
  - A genetic change is found
  - This genetic change may or may not increase the risk for cancer
  - This result is not positive or negative
  - More information is needed before this information can help guide care

Case Example 1

- Mr. X was referred to genetics due to his personal history of Prostate cancer. He had a Gleason score of 6.

2ND ANNUAL NYC PROSTATE CANCER SUMMIT



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Case Presentation #2

- Mr. Y was referred to our UCHAP Clinic at UChicago due to his recent diagnosis of prostate cancer, Gleason 9.
- He was accompanied by his maternal uncle, Mr S.

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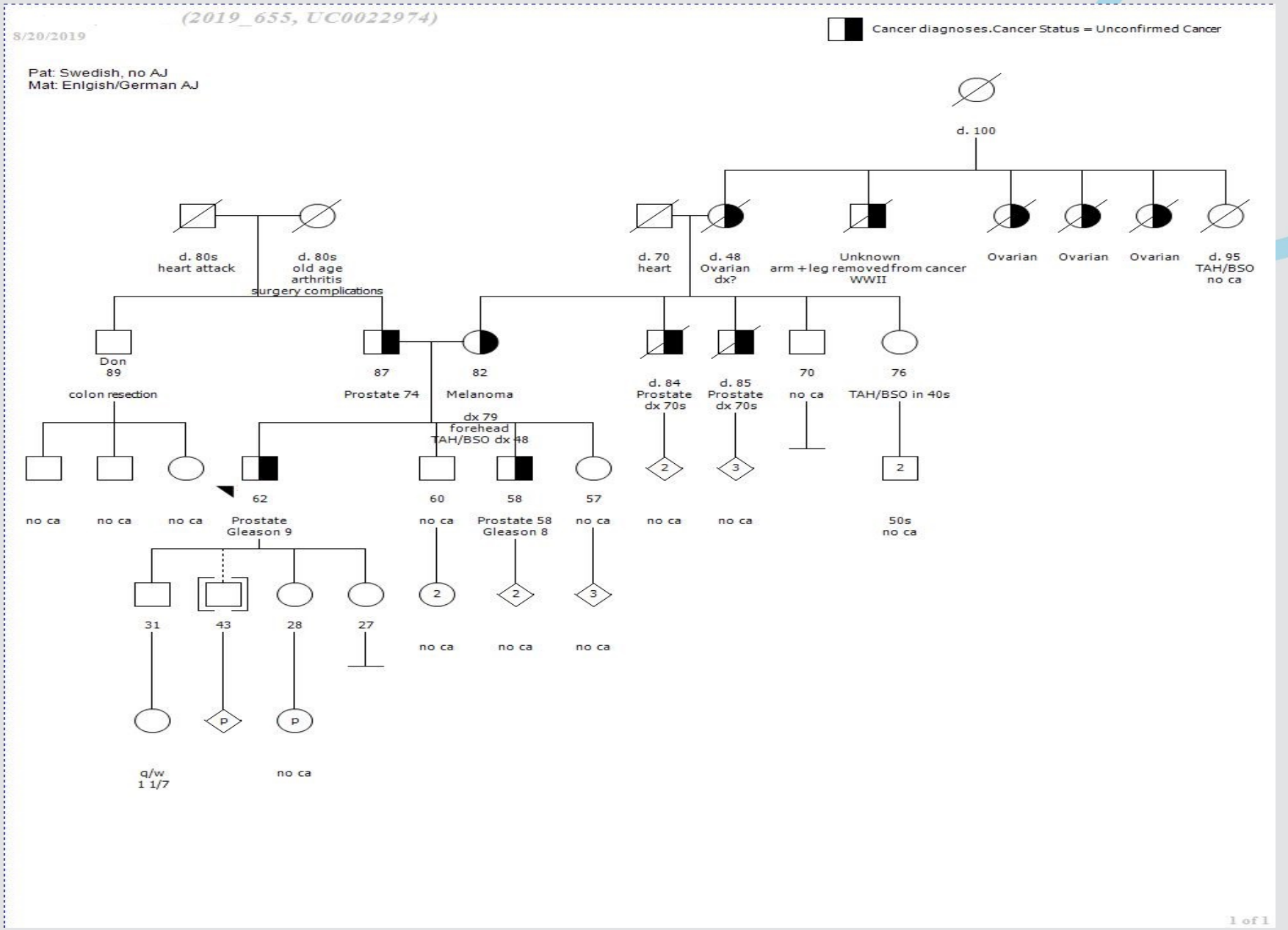

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