

Title

Assessing Implementation Feasibility of Clinical Decision Support Tools to Increase Guideline-Recommended Use of Genetic Tests for Patients Recently Diagnosed with Metastatic Prostate Cancer

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Investigators

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TABLE OF CONTENTS

BACKGROUND AND RATIONALE	12
COMPLIANCE STATEMENT	12
INVESTIGATOR AGREEMENT	12
PILOT OBJECTIVES	13
PARTICIPANT SELECTION	13
PILOT OVERVIEW	13
PILOT EVALUATION AND ANALYSIS	16
PILOT IMPLEMENTATION TEAM TRAINING	17
ONGOING PILOT IMPLEMENTATION SUPPORT AND OVERSIGHT	17
POTENTIAL RISKS TO PARTICIPANTS	17
POTENTIAL BENEFITS TO PARTICIPANTS	18
COSTS TO PARTICIPANTS	18
PAYMENTS TO PARTICIPANTS	18
PROTOCOL ADHERENCE, GCP COMPLIANCE, AND ADDITIONAL INVESTIGATOR RESPONSIBILITIES	18
AUDIT/INSPECTION	18
FINANCIAL DISCLOSURE	18
INFORMED CONSENT	18
INSTITUTIONAL REVIEW BOARD OR INDEPENDENT ETHICS COMMITTEE	19
PRIVACY & CONFIDENTIALITY	19
REFERENCES	19

ABBREVIATIONS

- AE: Adverse Event
- ASTRO: American Society for Therapeutic Radiology and Oncology
- AUA: American Urological Association
- DOA: Delegation of Authority
- EHR: Electronic Health Record
- GCP: Good Clinical Practice
- HIPAA: Health Insurance Portability And Accountability Act
- IC: Informed Consent
- ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- IEC: Independent Ethics Committee
- IRB: Institutional Review Board
- IS: Information System
- IT: Information Technology
- KDL: Key Decision Leader
- mCRPC: Metastatic Castration-Resistant Prostate Cancer
- NCCN: National Comprehensive Cancer Network
- PHI: Protected Health Information
- SUO: Society of Urologic Oncology
- TKG: The Kinetix Group

1. BACKGROUND AND RATIONALE

Major guidelines, including the National Comprehensive Cancer Network (NCCN), American Urological Association (AUA)/American Society for Therapeutic Radiology and Oncology (ASTRO)/Society of Urologic Oncology (SUO), and Philadelphia Prostate Cancer Publication 2019,¹⁻³ recommend ordering genetic testing after patients receive a confirmed metastatic prostate cancer diagnosis. Data shows that 89% of metastatic castration-resistant prostate cancer (mCRPC) tumors contain a potentially actionable mutation, with about 9% of these occurring in the germline, demonstrating the importance of ordering a tumor genetic test.¹ Multigene testing, a type of genetic testing also known as broad panel testing, is recommended by guidelines to ensure all relevant genes are evaluated in the tumor test.¹ The broad panel test selected should include BRCA1/2 and other HRR genes of interest.¹ Additional biomarkers may be included in the broad panel test, depending on provider and patient preferences, payer coverage, and availability of testing panels.

Despite genetic testing being guideline-recommended and yielding actionable information to inform clinical decision making, testing rates for patients with metastatic prostate cancer remain suboptimal. Various barriers and clinical practice gaps exist across the complex care delivery pathways for genetic testing, which have hindered guideline concordance and optimal care. These barriers include a lack of provider understanding of applicable patient populations and testing options, complicated test ordering processes, and limited resources to support clinical decision making. Decision support tools and a guidelines-based care pathway have been developed to address these barriers by focusing on opportunities to inform clinicians and care team members on strategies to improve the identification of patients with metastatic prostate cancer who would benefit from genetic testing, and to optimize electronic care processes.

This pilot aims to assess the implementation feasibility and impact of two tools, a Data Pull Guide and an Electronic Health Record (EHR) Clinical Decision Support Tool, to: (1) aid in the identification of candidates for broad panel genetic testing, and (2) increase broad panel genetic testing rates for patients recently diagnosed with metastatic prostate cancer in the community practice and health system settings.

2. COMPLIANCE STATEMENT

This pilot will be conducted in full accordance with all applicable Institutional Research Policies and Procedures and all applicable federal and state laws and regulations, including 45 CFR 46 and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. It is the Investigator's responsibility to perform the pilot in accordance with the protocol and all applicable rules and regulations. Any instance of non-compliance will be documented and reported in accordance with Institutional Review Board (IRB) Policies and Procedures and federal requirements.

3. INVESTIGATOR AGREEMENT

I, the Investigator, acknowledge that I have read and understood this pilot implementation protocol. I agree to conduct and supervise the pilot according to all applicable regulations for protecting the rights, safety, and welfare of the subjects under my care. I will comply with the pilot requirements as presented in the protocol and agree to start the pilot only after IRB approval is obtained or this activity is deemed exempt. I will maintain accurate, complete, and current records relating to my participation in the pilot, consistent with good scientific and ethical practices.

Name: _____

Institution: _____

Signature: _____

4. PILOT OBJECTIVES

The primary objective of this pilot is as follows:

- Assess the implementation feasibility of tools (a Data Pull Guide and an EHR Clinical Decision Support Tool) to aid in the identification of candidates for broad panel genetic testing.

The secondary objective of this pilot is as follows:

- Assess the impact of the tools on increasing broad panel genetic testing rates for patients recently diagnosed with metastatic prostate cancer in the community practice and health system settings.

5. PARTICIPANT SELECTION

a. NUMBER OF PARTICIPANTS

Participating pilot sites will be responsible for recruiting 4-6 participants **each**. Participants will be comprised of practice administrators, operational managers, and/or healthcare professionals employed by or affiliated with the pilot site(s). Participants will include individuals (e.g., HCPs) responsible for either: 1) implementation of the tools, or 2) utilization of the tools.

b. INCLUSION CRITERIA

The following **inclusion** criteria apply to participants:

1. Oversight of service lines providing care to patients with metastatic prostate cancer (e.g. Administrators or HCPs such as Oncology Service Line Leaders, Directors of Urology), OR
2. Oversight of information technology (IT)/information systems (IS) resources or EHR-embedded processes specific to populations with metastatic prostate cancer.

c. EXCLUSION CRITERIA

The following **exclusion** criteria apply to participants:

1. Not employed by or affiliated with the pilot institution, OR
2. Do not consent to participate (if formal consent required per IRB determination), OR
3. Do not agree to participate in the pilot implementation and monitoring plan within the agreed upon timeframe.

6. PILOT OVERVIEW

a. TIMING

The pilot is anticipated to run for a period of 3 months, beginning in May 2024 and ending in July 2024.

b. PILOT DESIGN AND PROCEDURES

Investigators, with the support of their research teams, will be responsible for implementing the pilot according to the protocol framework outlined below. Whereas individual implementation of the tools by multiple pilot sites may vary due to uniqueness in each site's EHR infrastructure, resources, and operational and clinical processes, it is expected that the tools and the monitoring plan will remain consistent across the sites.

Pilot Framework

A visualization of pilot implementation steps and milestones is indicated in Figure 1 (below). Additional detail is provided within the text.

Figure 1: Pilot Implementation Schema

Pre-Pilot Implementation	Pilot Implementation			Post-Pilot Implementation		
MONTH 0	MONTH 1	MONTH 2	MONTH 3	MONTH 4	MONTH 5	MONTH 6
• Participant recruitment & screening • Investigator-led, pre-pilot alignment meeting • Administration of pre-implementation qualitative survey • Pre-implementation quantitative assessment • Baseline reporting	• Tool implementation • Monthly quantitative (EHR data) assessment • Ongoing pilot support	• Monthly quantitative (EHR data) assessment • Ongoing pilot support	• Monthly quantitative (EHR data) assessment • Ongoing pilot support • Post-implementation quantitative assessment (end of Month 3)	• Post-pilot qualitative and quantitative data analysis	• Post-pilot meeting to review results & key findings • Development of pilot results manuscript	• Submission of pilot results manuscript to peer-reviewed journal

- **Pre-Pilot Implementation**

- With support from The Kinetix Group (TKG), each Investigator will be responsible for identifying and recruiting 4-6 pilot participants, for a total of 8-12 participants across the two sites. Participants will be informed of the pilot design, their obligations if they wish to participate, and the intended output of the initiative. Participants will be screened for adherence with inclusion/exclusion criteria and will be consented if deemed necessary by the governing IRB.
- Upon recruitment of the pilot participants, Investigators will lead a 90- to 120-minute alignment meeting (live or virtual) to:
 - Educate participants on the pilot rationale and objectives
 - Orient participants to the tools (Data Pull Guide and EHR Clinical Decision Support Tool)
 - Gain alignment on the target patient population for which the tools apply
 - Identify the optimal placement of the tools within clinical and operational workflows

- Discuss implementation considerations (e.g. resources, roles/responsibilities, IT/IS integration)
 - Develop a plan for tool implementation leveraging the EHR
 - Align on a timeline and strategy for implementation
 - At the conclusion of the meeting, the Investigators will field a qualitative survey to participants (see “Data for Collection”) on perceived tool implementation feasibility across key indicators.
- **Pilot Implementation**
 - The pilot implementation approach will be mutually agreed upon by the pilot site(s), TKG, and Janssen Scientific Affairs with input from the Investigators, and will include education, on-going engagement, and support.
 - Investigators will collaborate with participants and other stakeholders as needed to implement the tools leveraging the EHR.
 - On-going support will be provided by Investigators and TKG as needed, including individual site visits (as required).
- **Performance Monitoring and Reporting**
 - The performance of this pilot will be evaluated utilizing a two-pronged, mixed methods approach, including collection of quantitative data (sourced from the EHR) and qualitative data (sourced from surveys administered to participants).
 - Both quantitative and qualitative data will be concurrently collected across a 3-month period, with initial metric reporting occurring at Month 0 (baseline/pre-implementation).
 - Quantitative data will be reported to TKG by the sites at the end of each month via secure electronic transmission. *(Important Note: All quantitative data must be reported as de-identified, aggregate, population-level data. No protected health information (PHI) is permitted.)*
 - Qualitative data will be captured by electronic survey, which will be administered by TKG to pilot participants at Month 0 and Month 3.
 - Survey questions may be tailored to participant role types as appropriate (e.g. Director, Implementer, End User)
 - Upon conclusion of the pilot study period, data will be analyzed according to the parameters described in the “Data Analysis” section below.
 - Upon completion of the pilot data analysis, a meeting will be conducted with the Investigators at each site, TKG, and Janssen Scientific Affairs to review the results and key findings.
- **Publication Development**
 - A manuscript will be developed to report out on quantitative and qualitative pilot results supporting implementation feasibility and impact on broad panel genetic testing rates.
 - Key sections will include: Abstract, Introduction/Background, Methods, Results, Discussion, and Conclusion.
 - The manuscript will be co-developed by the Investigators, TKG, and

Janssen Scientific Affairs, and authorship and submission journal will be mutually agreed-upon by all parties involved.

- Note: Investigators will need to sign co-authorship agreements prior to being included as authors within the manuscript.
- The manuscript will be submitted to a peer-reviewed journal for review within 3 months of pilot completion.

Note: The pilot is not intended to influence treatment decisions and will not include the testing of any medical devices or therapeutics. Patients associated with the pilot sites will continue to receive standard-of-care treatment.

7. PILOT EVALUATION AND ANALYSIS

a. ENDPOINTS

The primary endpoint to assess **feasibility** will include:

- Implementation feasibility index score greater than established threshold.

The secondary endpoint to assess **impact** will include:

- Change in rate of broad panel genetic testing for patients newly diagnosed with metastatic prostate cancer pre- vs post-implementation.

b. DATA FOR COLLECTION

Both quantitative and qualitative data will be collected during the pilot implementation period. Quantitative data will be collected on a monthly basis, beginning at Month 0 (baseline/pre-implementation) and ending at Month 3. Qualitative data will be collected at Month 0 (baseline/pre-implementation) and Month 3.

Feasibility data collected from the sites will include:

- Qualitative implementation feasibility variables captured via survey including:
 - Work effort (e.g., personnel time and resources) required to implement the tool reported by participants (Likert scale)
 - EHR compatibility reported by participants (Likert scale)
 - Time to deployment reported by participants (Likert scale)
 - Acceptability reported by participants (Likert scale)
 - Applicability of the tools to clinical workflows (open-ended)
 - Opportunities for tool optimization (open-ended)

Impact data collected from the sites may include:

- Quantitative impact data reportable from the EHR or practice management system including:
 - Number of records included in the analysis
 - Population demographics (race/ethnicity, age bands, sex assigned at birth)
 - Primary diagnosis (e.g., International Classification of Diseases, 10th Revision (ICD-10) code)

- Presence of metastatic prostate cancer diagnosis (e.g., date of diagnosis documented in medical chart, mention within problem list)
- Number of broad panel tests ordered within the past 30-days
- Rate of referral to genetic counselor
 - Genetic counseling referral by provider type and specialty
- Completion of genetic counseling
 - Genetic counseling role or entity
- Completion of genetic testing

c. MAINTAINING PILOT RECORDS

The Investigator or a delegated team member will be responsible for ensuring data are submitted within the indicated data capture time frames.

d. DATA STORAGE

At the end of the pilot, all data will be handled in accordance with the data use/pilot agreements established between TKG and the participating sites.

e. DATA ANALYSIS

Descriptive statistics will be generated for all quantitative data, and chi-square analysis will be conducted for baseline and follow-up data. Qualitative data containing any participant identifiers will be redacted prior to analysis. Qualitative data will be reported verbatim (with the exception of any participant identifiers) back to Investigators and Janssen Scientific Affairs within 2 weeks of survey collection. Qualitative output will be synthesized into key themes as inputs for the manuscript.

8. PILOT IMPLEMENTATION TEAM TRAINING

As appropriate, Investigators will identify additional team members to support pilot implementation. Team members will be selected based on pre-determined criteria such as experience, competency, and subject matter expertise. TKG will provide training to support the implementation and execution of the pilot at kick-off and on an ongoing basis as requested by the pilot site staff (e.g., in the event a new hire joins the team). Pilot sites are responsible for maintaining their own delegation of authority (DOA) documentation.

9. ONGOING PILOT IMPLEMENTATION SUPPORT AND OVERSIGHT

Investigators will be responsible for ensuring that the pilot is conducted in compliance with the protocol and all applicable rules and regulations. TKG will develop practice implementation resources to support the appropriate execution of the pilot.

10. POTENTIAL RISKS TO PARTICIPANTS

Time: Implementation of the tools and data collection may add additional time to participants' workload. Efforts will be made to minimize burden and reduce time required to support implementation.

11. POTENTIAL BENEFITS TO PARTICIPANTS

Participants may benefit from this pilot by contributing to the evidence base

supporting appropriate and timely use of broad panel genetic testing, which could uncover family risks, identify additional treatment options, and align care with evidence-based guidelines.

12. COSTS TO PARTICIPANTS

Participants will not incur any expenses through their participation.

13. PAYMENTS TO PARTICIPANTS

Participants will not receive any payment for their participation.

14. PROTOCOL ADHERENCE, GCP COMPLIANCE, AND ADDITIONAL INVESTIGATOR RESPONSIBILITIES

The Investigators will perform the pilot in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guideline E6 (R2) and the applicable regulatory requirements.

The Investigators will maintain a list of appropriately qualified persons to whom the Investigators have delegated significant pilot-related tasks. *Curriculum vitae* for these individuals as well as the Investigator will be on file and may be requested at any time during the pilot implementation.

If an Investigator suspends or terminates the pilot, the investigator will promptly inform TKG and provide them with a detailed written explanation. *If required*, upon pilot completion, the Investigators will provide the IRB/ Independent Ethics Committee (IEC), with final reports and summaries as required by regulations.

If required, it is the Investigator's responsibility to communicate with their local IRB/IEC to ensure accurate and timely information is provided at all phases during the pilot implementation.

15. AUDIT/INSPECTION

If required, to ensure compliance with relevant regulations, data generated by this pilot initiative will be available for inspection upon request by representatives of the IRB/IEC for each pilot site.

16. FINANCIAL DISCLOSURE

The Investigators will disclose any financial arrangement whereby the value of the compensation for conducting the pilot could be influenced by the outcome of the pilot.

17. INFORMED CONSENT

If required, participants will be required to complete an IRB-approved informed consent form prior to enrollment in the pilot. However, the pilot is not intended to inform treatment decisions.

18. INSTITUTIONAL REVIEW BOARD OR INDEPENDENT ETHICS COMMITTEE

If required, the Investigators will submit this protocol and relevant supporting

information to the IRB/IEC for review and will not initiate the pilot implementation prior to approval. Prior to implementing changes in the pilot design, the IRB/IEC will approve any revised documents and amendments to the implementation protocol. On the approval letter, the pilot (title, protocol number, and version), the documents reviewed (protocol, advertisements, and amendments, if applicable), and the date of review and actions taken should be clearly stated. The pilot implementation will not begin until the Investigator has received this written approval, along with copies of all revisions and approved documents.

The Investigators will keep the IRB/IEC apprised of the progress of the pilot implementation and of any changes made to the protocol at least once a year. The Investigators will also keep the local IRB/IEC informed of any serious and significant adverse events (AEs) that were reported during this pilot, as indicated in the pilot agreement.

19. PRIVACY AND CONFIDENTIALITY

This pilot will be conducted in compliance with all applicable rules and regulations, including the HIPAA from 1996.

20. REFERENCES

1. National Comprehensive Cancer Network. 2024. Prostate Cancer (Version 3.2024). https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
2. Giri, VN et al. Implementation of germline testing for prostate cancer: Philadelphia Prostate Cancer Consensus Conference 2019. *J Clin Oncol*. 38(24):2798–2811. <https://doi.org/10.1200/JCO.20.00046>.
3. Eastham JA, Auffenberg GB, Barocas DA, et al. Clinically localized prostate cancer: AUA/ASTRO guideline part I: introduction, risk assessment, staging and risk-based management. *J Urol*. 2022. <https://www.auanet.org/guidelines-and-quality/guidelines/clinically-localized-prostate-cancer-aua/astro-guideline-2022>.
4. Next-generation sequencing testing in oncology. *J Oncol Navig Surviv*. 2019. <https://www.jons-online.com/special-issues-and-supplements?view=article&artid=2318:next-generation-sequencing-testing-in-oncology>

BROAD PANEL GENETIC TESTING IN PROSTATE CANCER

Data Pull Guide



Background

Major committee/consensus guidelines, including the National Comprehensive Cancer Network (NCCN), American Urological Association (AUA)/American Society for Radiation Oncology (ASTRO)/Society of Urologic Oncology (SUO), and Philadelphia Prostate Cancer Publication 2019 recommend ordering tumor testing as soon as possible after patients receive a confirmed metastatic prostate cancer diagnosis. Multigene testing, also known as broad panel testing, is recommended by guidelines to ensure all relevant genes are evaluated in the tumor test.¹ The broad panel test selected should include *BRCA1/2* and other HRR genes of interest.¹ Additional biomarkers may be included in the broad panel test, depending on provider and patient preferences, payer coverage, and availability of testing panels.¹⁻⁴

Next-generation sequencing (NGS) is one type of broad panel genetic testing that can rapidly and accurately sequence a broad range of mutations, offering information on the genes of interest as well as a wider range of mutations that may be present. NGS may be considered for tumor testing in patients with metastatic prostate cancer.

Tumor molecular and biomarker analysis may be used for treatment decision making, including understanding eligibility for biomarker-directed treatments, genetic counseling, and eligibility for clinical trials.¹ However, rates of genetic testing remain low despite these opportunities to impact care.

About This Resource

This resource intends to support service line leaders, practice administrators, program coordinators, clinical auditors, and quality improvement specialists with actionable guidance to engage their information technology (IT) and information systems (IS) teams to generate an electronic health record (EHR) report to:

-  **Identify** patients recently diagnosed with metastatic prostate cancer who are eligible for but have not received a broad panel test that includes *BRCA1/2* biomarkers
-  **Link** these eligible patients with appropriate care
-  **Monitor** broad panel testing rates across time

Key Terms and Definitions

Tumor testing:

Genetic testing of a DNA sample from a tumor to identify acquired mutations (somatic) for treatment decision making¹

Germline testing:

Genetic testing of a DNA sample of a non-tumor cell to identify inherited mutations for treatment decision making and to inform family risk¹

Getting Started

Successful implementation of new initiatives requires strong cross-functional support and collaboration. Engaging service line leaders, IS/IT managers, practice administrators, program coordinators, clinical auditors, and quality improvement specialists early in the EHR reporting process can help to mitigate roadblocks and promote constructive dialogue around feasibility and impact. Convening the right stakeholders to assess practice readiness is a foundational step in this process.

Review and complete the below Practice Readiness Self-Assessment with your team to gauge your practice's readiness to effectively generate an EHR report and use the findings to proactively prepare for a successful implementation. A "No" or "Unknown" response may indicate that additional pre-work would be beneficial.

Practice Readiness Self-Assessment

Readiness Imperative	Yes	No	Unknown
A clinical and a technology champion for the initiative have been identified.			
There is engagement from leadership and other key stakeholders.			
Resources are available to implement any changes.			
The data sources for the inputs needed to generate the EHR report have been identified.			
There is a plan to capture data pertaining to care or testing occurring outside of the practice.			
Structured fields are available in the EHR to capture staging information.			
Relevant data is documented discretely and uniformly .			
Providers consistently use the appropriate codes .			

Step-by-Step Guide to Create an EHR Report to Identify and Monitor Patients Eligible for Broad Panel Testing

Follow the steps below to generate an actionable report.* Use the [Supplemental Worksheet \(Excel\)](#) to:

- Record data input values
- Facilitate data pull guide completion
- Calculate measures
- Monitor calculated measures over time and develop an action plan to improve and measure performance

STEP 1

Identify the patients with a confirmed metastatic prostate cancer diagnosis within a defined period of time.

1A

Determine what discrete EHR fields are currently available and utilized to capture a diagnosis of metastatic prostate cancer.



NOTE: If discrete EHR fields are available but not being used, discuss opportunities to ensure consistency in documentation with your team. Considerations for developing and/or capturing discrete fields within the EHR can be found in the Broad Panel Testing Clinical Decision Support Tool.

1B

Determine the best method to identify patients with metastatic prostate cancer. See the Supplemental Worksheet for further information on eligibility criteria. Relevant sources with discrete fields within the EHR include:

- International Classification of Diseases, Tenth Revision (ICD-10) Codes ([see Appendix A](#))
- American Joint Committee on Cancer (AJCC) Staging ([see Appendix B](#))
- Problem List and/or Disease Registry
- EHR Billing Module



EXAMPLE: Charge for prostate cancer medications and corresponding diagnostic U code

1C

Identify the patients who satisfy ≥ 1 of criteria listed in Step 1B within a defined period of time. This will generate the following:

- A list of all patients who have been diagnosed with metastatic prostate cancer within a defined period of time
- The number of patients who have been diagnosed with metastatic prostate cancer within a defined period of time. **This number can be used as the denominator when calculating measures in following sections.**

*The accuracy of this report is dependent upon precise coding of patients and thorough data collection by a practice.

Step-by-Step Guide to Create an EHR Report to Identify and Monitor Patients Eligible for Broad Panel Testing

STEP 2

Identify patients with a confirmed diagnosis of metastatic prostate cancer for whom a broad panel test has already been ordered.*

2A

Start with the list of patients with a confirmed diagnosis of metastatic prostate cancer within a defined period of time (Step 1).

2B

Determine the best method to capture patients with broad panel test orders within a defined period of time. Considerations for relevant sources with discrete fields within the EHR include:

- Current Procedural Terminology (CPT) codes ([see Appendix C](#))
- Local Observation Identifiers Names and Codes (LOINC) codes
- Send out orders for off-site testing within patient notes

2C

Identify the patients who satisfy: Step 2A criteria + ≥ 1 Step 2B. This will generate the following:

- A list of all patients who have been diagnosed with metastatic prostate cancer and received broad panel testing after the confirmed metastatic diagnosis



ACTION OPPORTUNITY: Consider building an EHR alert that prompts broad panel testing navigation and results follow-up for patients on this list

- The number of patients who have been diagnosed with metastatic prostate cancer and received a broad panel test with *BRCA1/2* biomarkers testing within a defined period of time. **This number can be used as the numerator when calculating the rate of broad panel testing.**

*Evaluate if tumor re-testing is warranted. Additional genetic mutations with clinical relevance may arise over time, and tumor re-testing may capture mutations that were not present at the time of the initial broad panel test in a small number of patients. These results may inform changes in treatment.

Step-by-Step Guide to Create an EHR Report to Identify and Monitor Patients Eligible for Broad Panel Testing

STEP 3

Identify patients with a confirmed diagnosis of metastatic prostate cancer for whom a broad panel test has **NOT** been ordered.

Identify patients who: meet Step 2A criteria + do not meet Step 2B criteria. This will generate the following:

- A list of all metastatic prostate cancer patients who need to be assessed for broad panel testing orders



ACTION OPPORTUNITY: Consider building an EHR alert that prompts evaluation of orders for broad panel testing for patients on this list

- The number of patients who have been diagnosed with metastatic prostate cancer and have not received a broad panel test within a defined period of time. **This number can be used as the numerator when calculating the rate of patients who should have broad panel testing ordered.**

Step-by-Step Guide to Create an EHR Report to Identify and Monitor Patients Eligible for Broad Panel Testing

If your practice **utilizes** a care pathway, leverage Steps 4 and 5 to calculate the rate of patient enrollment and evaluate care pathway adherence. Steps 4 and 5 can be implemented concurrently to Step 3. Combine the numbers in Step 4D and Step 5 to identify the eligible patient population for broad panel testing (also see Step 1C).

STEP 4 - Optional

Identify patients with a confirmed diagnosis of metastatic prostate cancer who are enrolled in a care pathway.

4A

Start with the list of patients with a confirmed diagnosis of metastatic prostate cancer (Step 1).

4B

Identify all practice pathways that may be applicable to patients with metastatic prostate cancer.



ACTION OPPORTUNITY: Convene a multidisciplinary group within the practice to evaluate and confirm all applicable pathways

4C

Determine the best method to capture patients who are currently/actively enrolled in a metastatic prostate cancer pathway within the EHR. Approaches for identifying these patients include:

- CPT codes (see [Appendix C](#))
- Keystroke (Y/N) within the applicable metastatic prostate cancer pathways (see Step 4B) within the last 30 days

4D

Identify patients who satisfy: Step 4A criteria + ≥ 1 Step 4C criteria. This will generate the following:

- A list of patients who have been diagnosed with metastatic prostate cancer and are currently enrolled in a relevant care pathway
- The number of patients who have been diagnosed with metastatic prostate cancer and are enrolled in a relevant care pathway. **This number can be used as the numerator when calculating the rate of patients who are currently enrolled in a relevant care pathway.**

Step-by-Step Guide to Create an EHR Report to Identify and Monitor Patients Eligible for Broad Panel Testing

STEP 5 - Optional

Identify patients with metastatic prostate cancer who are not enrolled in a care pathway.

Identify the patients who: satisfy Step 4A criteria + do not satisfy Step 4C criteria. This will generate the following:

- A list of patients who have been diagnosed with metastatic prostate cancer and are not enrolled in a practice-adopted care pathway



ACTION OPPORTUNITY: Consider building an EHR alert that prompts evaluation of the patient for a practice-adopted care pathway

- The number of patients who have been diagnosed with metastatic prostate cancer and are not enrolled in a relevant care pathway. **This number can be used as the numerator when calculating the rate of patients with metastatic prostate cancer who are not currently following a practice-adopted pathway.**

Evaluate Results and Monitor Additional Discrete Measures

STEP 6

Based on the results of Steps 1-5, consider monitoring additional measures to identify specific areas for improvement.

Select additional measures to monitor improvement by using discrete fields available within the EHR. Fields may be selected to monitor patient identification, broad panel testing use, provider compliance, and clinical decision making. Multiple measures may be simultaneously monitored. Results can be leveraged to inform quality improvement initiatives relating to improving broad panel testing rates and adherence for patients with metastatic prostate cancer.



NOTE: This list is not exhaustive; additional measures may be needed.

Area for Improvement

Measures

Referral Timing	- Metastatic diagnosis time stamp - First visit post-metastatic diagnosis time stamp - Referral order placement to medical oncologist time stamp (if applicable) - First medical oncologist visit time stamp (if applicable)
Test Ordering	- First visit post-metastatic diagnosis time stamp - First medical oncologist visit time stamp (if applicable) - Broad panel testing order time stamp - Order for germline testing time stamp - Order for tumor testing time stamp
Pre- and Post-Test Counseling	- Who completed pre-test and post-test counseling (medical oncologist, urologist, genetic counselor, external testing lab, other) - Date of pre-test and post-test counseling
Test Receiving	- Broad panel testing order time stamp - Order for germline testing time stamp - Order for tumor testing time stamp - Receipt of broad panel test results time stamp - Completion of germline testing - Completion of tumor testing - Date of first treatment post-test
Utilization of Test Results	- Broad panel testing order time stamp - Completion of germline testing - Completion of tumor testing - Broad panel test results - Date of first treatment post-test - Recommended treatment - Actual treatment
Equitable Access to Standard of Care	- Recommended treatment - Actual treatment - Health equity measures: race, ethnicity, age, ZIP Code, income, insurance (for testing and for treatment), transportation

Key Takeaways

Creating an EHR Report to Identify and Monitor Patients Eligible for Broad Panel Testing or Care Pathway Adherence



This resource demonstrates how to identify and to calculate:

Broad Panel Testing Rates:	STEP 2C	Number of patients who have been diagnosed with metastatic prostate cancer and received broad panel testing within a defined period of time	EXAMPLES
	STEP 1C	Number of patients who have been diagnosed with metastatic prostate cancer within a defined period of time	60 patients receive broad panel testing out of 100 eligible patients* = 60%
Broad Panel Testing Gaps:	STEP 3	Number of patients who have been diagnosed with metastatic prostate cancer and have not received broad panel testing within a defined period of time	40 patients did not receive broad panel testing out of 100 eligible patients* = 40%
	STEP 1C	Number of patients who have been diagnosed with metastatic prostate cancer within a defined period of time	
Care Pathway Adherence (optional):	STEP 4D	Number of patients who have been diagnosed with metastatic prostate cancer who are enrolled in a relevant care pathway	80 patients are enrolled in a care pathway out of 100 eligible patients* = 80%
	STEP 1C	Number of patients who have been diagnosed with metastatic prostate cancer within a defined period of time	
Care Pathway Gaps (optional):	STEP 5	Number of patients who have been diagnosed with metastatic prostate cancer who are not enrolled in a relevant care pathway	20 patients are not enrolled in a care pathway out of 100 eligible patients* = 20%
	STEP 1C	Number of patients who have been diagnosed with metastatic prostate cancer within a defined period of time	



This information can be used to:

- Identify, flag, and reach out to patients not receiving guideline-based or care pathway concurrent care
- Inform quality improvement performance monitoring for patients who have been diagnosed with metastatic prostate cancer and ensure appropriate use of broad panel testing

*Numbers are theoretical and not based on any existing practice data.

Appendices

APPENDIX A: ICD-10 CODES⁵⁻⁸

Code	Description
A. Primary Prostate Cancer Diagnosis Code	
C61	Malignant neoplasm of prostate
B. Codes for Secondary Sites of Metastases	
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.20	Secondary malignant neoplasm of skin
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites
C79.90	Secondary malignant neoplasm of unspecified site
Additional Codes That May Be Utilized During Delivery of Care	
R97.20	Elevated prostate-specific antigen (PSA)
R97.21	Rising PSA after prostate cancer treatment
Z19.1	Hormone-sensitive malignancy status
Z19.2	Hormone-resistant malignancy status (castration-resistant)

Appendices

APPENDIX B: AJCC STAGING OF ADVANCED PROSTATE CANCER RELEVANT TO GENETIC TESTING^{2,9}

AJCC Staging Description

Somatic tumor testing is recommended for the following:

M1	Distant metastases of prostate cancer
M1a	Nonregional lymph node(s)
M1b	Bone(s)
M1c	Other site(s) with or without bone disease*

Somatic tumor testing can be considered for the following:

N1	Metastases in regional node(s)
----	--------------------------------

APPENDIX C: CPT CODES FOR GENETIC TESTING PANELS^{8,10}

Code [†]	Code Description	Test Panel Size
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, <i>ALK</i> , <i>BRAF</i> , <i>CDKN2A</i> , <i>EGFR</i> , <i>ERBB2</i> , <i>KIT</i> , <i>KRAS</i> , <i>MET</i> , <i>NRAS</i> , <i>PDGFRA</i> , <i>PDGFRB</i> , <i>PGR</i> , <i>PIK3CA</i> , <i>PTEN</i> , <i>RET</i>), interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis	Small panel (5 – 50 genes)
81479 [‡]	Unlisted molecular pathology procedure	Comprehensive Genomic Profiling (CGP)

*When more than 1 site of metastasis is present, the most advanced category is used. M1c is the most advanced.

[†]Confirm codes align with most recent guidance prior to use. List is not exhaustive.

[‡]81479 must be accompanied by a test identifier DEX Z-Code™.

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2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 5, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.
3. Giri VN, Knudsen KE, Kelly WK, et al. Implementation of germline testing for prostate cancer: Philadelphia Prostate Cancer Consensus Conference 2019. *J Clin Oncol.* 2020;38(24):2798-2811.
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BROAD PANEL TESTING IN PROSTATE CANCER

Electronic Health Record (EHR) Clinical
Decision Support Tool



Background

Major committee/consensus guidelines, including the National Comprehensive Cancer Network (NCCN), American Urological Association (AUA)/American Society for Radiation Oncology (ASTRO)/Society of Urologic Oncology (SUO), and Philadelphia Prostate Cancer Publication 2019 recommend ordering tumor testing as soon as possible after patients receive a confirmed metastatic prostate cancer diagnosis.¹⁻⁴ Multigene testing, also known as broad panel testing, is recommended by guidelines to ensure all relevant genes are evaluated in the tumor test.¹ The broad panel test selected should include BRCA1/2 and other HRR genes of interest.¹ Additional biomarkers may be included in the broad panel test, depending on provider and patient preferences, payer coverage, and availability of testing panels.

Next-generation sequencing (NGS) is one type of broad panel genetic testing that can rapidly and accurately sequence a broad range of mutations, offering information on the genes of interest as well as a wider range of mutations that may be present. NGS may be considered for tumor testing in patients with metastatic prostate cancer.

Tumor molecular and biomarker analysis may be used for treatment decision making, including understanding eligibility for biomarker-directed treatments, genetic counseling, and eligibility for clinical trials.¹ However, rates of genetic testing remain low despite these opportunities to impact care.

About This Resource

This electronic health record (EHR) clinical decision support (CDS) tool is intended to provide urology and oncology service line leaders with the knowledge and tools to engage their information technology (IT) and information systems (IS) teams and create discrete fields to:

- ✓ **Identify** patients eligible for a broad panel test that includes *BRCA1/2* biomarkers
- ✓ **Provide** prompt alerts to complete the steps required for broad panel testing

Key Terms and Definitions

Tumor testing:

Genetic testing of a DNA sample from a tumor to identify acquired mutations (somatic) for treatment decision making¹

Germline testing:

Genetic testing of a DNA sample of a non-tumor cell to identify inherited mutations for treatment decision making and to inform family risk¹

Getting Started

Successful implementation of new clinical workflows requires strong cross-functional support and collaboration. Multi-disciplinary teams can work together to identify the most consistent data source(s) for appropriate patient identification and collaboratively design relevant decision support prompts in the EHR. Follow the steps outlined below to leverage your EHR to optimize patient identification, use of decision support prompts, and implementation support for broad panel genetic testing.

Step-by-Step Guide to Leverage the EHR to Systematically Identify and Link Patients Eligible for Broad Panel Testing to Care

Identify appropriate candidates for broad panel testing using criteria within discrete fields in the EHR. Patient identification criteria requires a confirmed metastatic prostate cancer diagnosis. (Reference **Appendices** for related International Classification of Diseases, 10th Revision [ICD-10] and American Joint Committee on Cancer [AJCC] Staging.)

STEP 1

Determine the optimal method to capture criteria for patient identification based on data completeness, recency, and relative administrative burden to obtain.

Ensure criteria are consistent with current clinical guidelines, practice policies, and protocols. It may be necessary to utilize various sources of data to capture patient identification effectively. Considerations for developing and/or capturing discrete fields within the EHR include:

- Order sets
- Problem lists
- SmartPhrases / dot phrases / smart text
- Diagnosis field
- Primary visit reason
- ICD-10 codes (See [Appendix A](#))
- AJCC Staging (See [Appendix B](#))



Tip for OncoEMR users:

OncoEMR can embed AJCC staging content, which can be leveraged for patient identification.⁵

Step-by-Step Guide to Leverage the EHR to Systematically Identify and Link Patients Eligible for Broad Panel Testing to Care

STEP 2

Evaluate whether exclusion criteria apply through standard documentation (e.g., via a discrete field in EHR) or during the patient visit (e.g., via exclusion criteria form before ordering).

Exclusion criteria should be consistent with guidance from practice medical staff and may include the following:

- Prior history of germline or tumor broad panel testing (tumor broad panel retesting may be warranted depending on the time since the previous test)
- Patient consent to testing and/or treatment
- Active do not resuscitate (DNR) order, advanced directive, or planned hospice
- Presence of any other additional diagnoses impacting the care plan

STEP 3

Based on discrete field capture value, consider referral to the appropriate clinical care team



EXAMPLES: medical oncologist, genetic counselor, academic center, etc (if required)

The referral process should be consistent with any existing pathways, protocols, or policies for the management of broad panel testing specific to a practice.



Tip for Epic users:

- SmartPhrases, also known as “dot phrases” can be used to generate decision support prompts and instructions by typing a period after a key phrase. A SmartPhrase can be created using the “SmartPhrase Manager” or by highlighting existing text within a note and right-clicking to convert to a SmartPhrase.⁶

Step-by-Step Guide to Leverage the EHR to Systematically Identify and Link Patients Eligible for NGS Testing to Care

STEP 4

There are a number of approaches to the design and implementation of decision support prompts. Clinical decision support builds should align with a practice's existing EHR workflows and protocols and appreciate any unique best practices for development. Consider leveraging the following decision support prompt alerts to ensure completion of the steps required for broad panel testing*:

Action	Mechanism	Timing†	Recipient
Confirm if genetic testing was performed previously - If yes, evaluate test results for relevant mutations that may impact treatment decisions and consider if tumor re-testing is needed - If no previous genetic testing performed, proceed with tumor testing	EHR interface	Within 48 hours of diagnosis (post-counseling, questionnaire and consent)	Provider
Select method to complete pre-test counseling	Provider Genetic counselor External lab completing testing External counseling vendor	Within 48 hours of diagnosis	Patient
Send pre-test questionnaire Collect patient information relevant for testing and share educational information ahead of counseling visit. Send prompt daily until completed.	Patient portal	Within 48 hours of diagnosis	Patient
Consent patient to conduct broad panel testing	Electronic or paper informed consent form	Within 48 hours of diagnosis	Patient
Collect blood, saliva, and/or tissue sample (if needed)	Provider or care team member (eg, registered nurse) Internal or external lab personnel (eg, phlebotomist, licensed laboratory technician)	Within 48 hours of diagnosis (post-counseling, questionnaire and consent)	In-house or external laboratory
Order tumor broad panel testing including BRCA1/2 Designate sample for test - Add description and year sample was collected - Include accession number if available	EHR interface or fax	Within 48 hours of diagnosis (post-counseling, questionnaire and consent)	In-house or external laboratory
Inform provider of tumor test results	EHR interface or fax	Within 24 hours of receipt of results from laboratory	Provider
Inform patient of tumor test results	Patient portal and genetic counseling	At provider discretion	Patient

*Example prompts were developed through consultation with clinical experts and do not represent an exhaustive list. Additional prompts may be developed or existing prompts may be refined depending on individual practice needs and access to resources.

†Timelines are recommendations and dependent on patient preference.

Implementation Support

For further considerations in establishing workflows to guide the test selection and ordering process, consider the 5 “Rights” of Clinical Decision Making when designing EHR prompts. The 5 “Rights” can help create EHR prompts that will deliver useful information to the correct user at the appropriate time in the workflow.



For further details on how to utilize the 5 “rights,” as well as other operationalization tips, review the accompanying Implementation Roadmap resource.



Tip for Athena users:

To increase functionality, add new API solutions to support clinical decision making. Decision support prompts for providers may include⁷:

- A list of orderable labs
- Available patient information handouts
- A list of procedure codes available for a given patient encounter

Appendices

APPENDIX A: ICD-10 CODES⁸⁻¹¹

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C79.90	Secondary malignant neoplasm of unspecified site
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R97.21	Rising PSA after prostate cancer treatment
Z19.1	Hormone-sensitive malignancy status
Z19.2	Hormone-resistant malignancy status (castration-resistant)

Appendices

APPENDIX B: AJCC STAGING OF ADVANCED PROSTATE CANCER RELEVANT TO GENETIC TESTING^{2,12}

AJCC Staging Description

Somatic tumor testing is recommended for the following:	
M1	Distant metastases of prostate cancer
M1a	Nonregional lymph node(s)
M1b	Bone(s)
M1c	Other site(s) with or without bone disease*
Somatic tumor testing can be considered for the following:	
N1	Metastases in regional node(s)

*When more than 1 site of metastasis is present, the most advanced category is used. M1c is the most advanced.

References

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2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2024. ©National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 15, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.
3. Giri VN, Knudsen KE, Kelly WK, et al. Implementation of germline testing for prostate cancer: Philadelphia Prostate Cancer Consensus Conference 2019. *J Clin Oncol.* 2020;38(24):2798-2811.
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OPTIMIZING CARE FOR METASTATIC PROSTATE CANCER THROUGH BROAD PANEL TESTING

An Implementation Roadmap

About This Resource

This evidence-based implementation roadmap was developed with administrative and clinical leaders* with applied experience in prostate cancer, genetic testing, and clinical decision support. This document is a guide that may support practices to:

- **Align** genetic testing care at their practice with guidelines
- **Identify** gaps in their process for broad panel testing
- **Use** clinical decision support to facilitate appropriate patient identification
- **Leverage** electronic health records (EHRs) to improve the efficiency, consistency, and timeliness of broad panel testing

The goal of this guide is to provide an actionable approach to broad panel testing with:



- Supporting tools and resources
- Tips for tailoring the recommendations to the needs and available resources that are unique to each practice

What's Inside

- ▶ The Burden of Metastatic Prostate Cancer & Need for Genetic Testing
- ▶ Guidelines & Known Barriers to Broad Panel Testing
- ▶ Overview of the Broad Panel Testing Care Pathway Toolkit
- ▶ Implementing the Broad Panel Testing Care Pathway - Tools
 - STEP 1: Prepare
 - Evaluating Your Resources & Identifying Your Team
 - STEP 2: Implement
 - **WHO:** Patient Identification
 - **WHAT:** Test Selection
 - **HOW:** Action Upon Testing Results
 - STEP 3: Sustain & Optimize
 - Evaluating Results & Adapting the Broad Panel Testing Care Pathway
- ▶ Key Takeaways

*A multidisciplinary group comprised of nine oncology, urology, clinical operations, technology, and laboratory experts guided the development and informed the content of this resource, including:

- A medical oncology leader at a large independent oncology practice in the Midwest
- A nationally recognized urologist at a urology practice in the Southeast
- A chief information officer at a large health system on the East Coast
- A vice president at a leading genetic testing company
- A medical oncologist at a prominent academic medical center in the Northwest

Despite Its Potential to Optimize Care, Rates of Genetic Testing Remain Low

The Burden of Prostate Cancer

5%

Rates of advanced-stage prostate cancer have increased 5% per year since 2014¹

5% to 10%

of all prostate cancer is hereditary²

"An estimated **89%** of metastatic, castration-resistant prostate cancer (mCRPC) tumors contain a potentially actionable mutation, with only about **9%** of these occurring in the germline⁴"

—NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2024

The Need to Increase Genetic Testing



Genetic testing is a critical component of guidelines-based, evidence-based care for metastatic prostate cancer.



Tumor molecular and biomarker analysis can be used for treatment decision making, such as⁴:

- Genetic counseling
- Use of biomarker-directed treatments
- Eligibility for clinical trials

Addressing gaps in genetic testing is critical to providing high-quality patient care



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Guidelines Recommend the Use of Genetic Testing for All Patients With Metastatic Prostate Cancer



Guidelines Recommend Genetic Testing

Major guidelines, including NCCN, AUA/ASTRO/SUO, and Philadelphia Prostate Cancer Publication 2019,¹⁻⁴ recommend ordering tumor testing **as soon as possible after patients receive a confirmed metastatic prostate cancer diagnosis.***

Multigene testing, also known as broad panel testing, is recommended by guidelines to ensure all relevant genes are evaluated in the tumor test.¹ The broad panel test selected should include *BRCA1/2* and other HRR genes of interest.¹ Additional biomarkers may be included in the broad panel test, depending on provider and patient preferences, payer coverage, and availability of testing panels.¹⁻⁴ **Broad panel genetic testing can analyze the following types of mutations¹:**

Tumor testing:

Genetic testing of a DNA sample from a tumor to identify **acquired mutations (somatic)** for treatment decision making¹

Germline testing:

Genetic testing of a DNA sample of a non-tumor cell to identify **inherited mutations** for treatment decision making and to inform family risk¹

Broad panel tests for metastatic prostate cancer should include HRR genes to ensure applicability in clinical decision-making

*Germline testing may be ordered prior to a confirmed diagnosis of metastatic prostate cancer. Additional information on guidelines is available in Appendix B.

AUA, American Urological Association; ASTRO, American Society for Therapeutic Radiology and Oncology; SUO, Society of Urologic Oncology.

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2024.

© National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 11, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. 2. Giri VN, Knudsen KE, Kelly WK, et al. Implementation of germline testing for prostate cancer: Philadelphia Prostate Cancer Consensus Conference 2019. *J Clin Oncol.* 2020;38(24):2798-2811. 3. Eastham JA, Aufferberg GB, Barocas DA, et al. Clinically localized prostate cancer: AUA/ASTRO guideline part I: introduction, risk assessment, staging and risk-based management. *J Urol.* 2022;208(1):10-18. 4. Giri V. Genetic education and practice considerations of non-genetic providers. *Can J Urol.* 2019;26(Suppl 2):S44-S45.

Barriers to Optimizing Broad Panel Testing

Known Barriers and Gaps to Broad Panel Testing

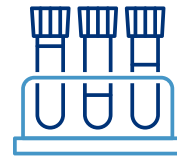
Common barriers that occur **BEFORE** and **AFTER** broad panel testing include:

PRE-Test

- Provider understanding of whom to test for mutations in key genes, such as HRR genes, relevant to metastatic prostate cancer¹
- Selection of test based on the treatment of interest and corresponding companion diagnostic¹
- Ability to educate patients on informed consent and discuss cancer inheritance, genetic test options, benefits/limitations of genetic testing, and GINA law¹
- Complex and variable insurance reimbursement that leads to limited coverage and awareness of benefits^{2,3}

POST-Test

- Inconsistent delivery of results from different labs that are not compatible with EHR systems¹
- Complex test results that require expert clinical consultation for accurate interpretation²
- Lack of provider knowledge to discuss inherited genetic results and provide recommendations based on test results and family history³



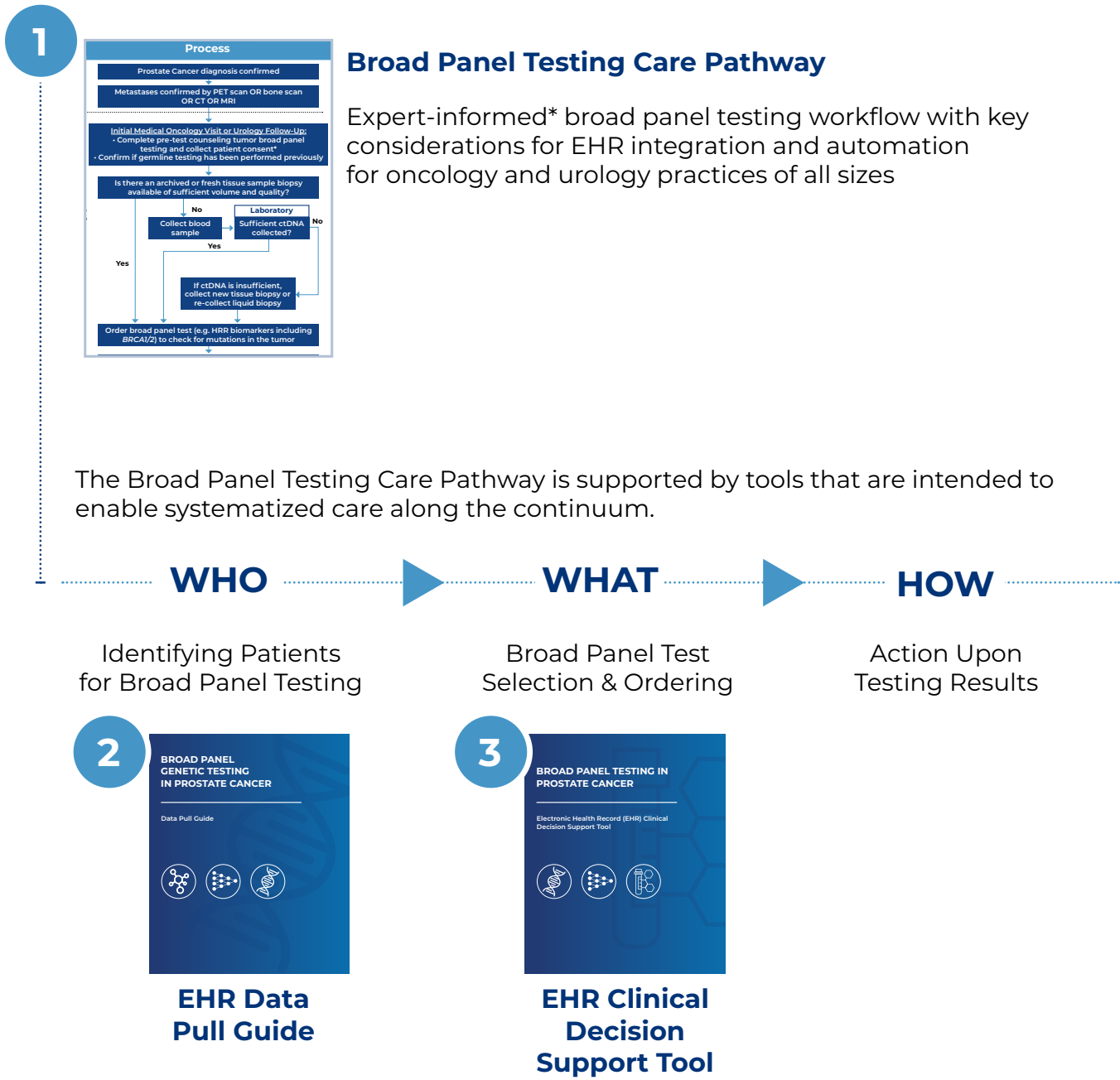
This roadmap will help practices implement guideline-directed care

GINA, Genetic Information Nondiscrimination Act.

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Broad Panel Testing Support Tools Offer Step-by-Step Guidance for Practices

Broad Panel Testing Support Tools Consist of:



*A multidisciplinary group comprised of nine oncology, urology, clinical operations, technology, and laboratory experts guided the development and informed the content of this resource, including:

- A medical oncology leader at a large independent oncology practice in the Midwest
- A nationally recognized urologist at a urology practice in the Southeast
- A chief information officer at a large health system on the East Coast
- A vice president at a leading genetic testing company
- A medical oncologist at a prominent academic medical center in the Northwest

To Apply the Broad Panel Testing Care Pathway, Practices Should Consider 3 Key Steps:

STEP 1

PREPARE

Ready the practice for pathway implementation by aligning the team and identifying key resources

STEP 2

IMPLEMENT

Take **action** to improve broad panel genetic testing rates for patients with metastatic prostate cancer by implementing the Care Pathway and supporting tools

STEP 3

SUSTAIN & OPTIMIZE

Ensure continuous improvement by **refining** broad panel testing workflows and incorporating care team feedback and/or guideline changes

Engaging Key Stakeholders in a Broad Panel Testing Implementation Team Can Help Ensure Success

A structured planning phase is important when developing or revising a practice's broad panel testing process.

A multidisciplinary approach to the planning phase can:



- Help ensure the broad panel testing workflow will serve to augment, not conflict with, existing patient care services
- Develop synergy among various organizational departments (eg, quality director, HIT, PI team) to maximize efficiency in the prostate cancer patient care journey
- Increase efficiencies by leveraging best practices in other oncology service lines

Consider including the following key stakeholders in planning sessions:



- Urologist
- Medical Oncologist
- Genetic Counselor
- Patient Financial Representative
- Care Navigator
- Lab Representative
- EHR/Informatics Representative
- PA/UM Coordinator
- Pathologist



Practice Tip

A multidisciplinary planning approach for broad panel testing will help develop synergy among departments by considering the impact on each individual stakeholder group.

An Effective Communication Strategy Is Critical to Engaging Practice Stakeholders in Broad Panel Testing Care Pathway Adoption

Communication should be strategically planned to ensure appropriate messaging is delivered to key stakeholders in an effective and efficient manner. Consider the impact a new broad panel testing workflow will have on others:

Internal communication

Healthcare Team

"How will this help my patient and impact my daily work?"

Administration

"How will this testing be reimbursed and how does it support our organizational goals?"

External communication

External Broad Panel Test Provider (If applicable)

"What services can be provided to support me and my patients?"

Patients & Caregivers

"Why am I having this testing and whom do I call with questions?"



Successful communication includes:

- **Proactive Engagement** – Communicate prior to the implementation of the new broad panel testing workflow
- **Reinforcement** – Repeatedly communicate using a variety of mediums (email, staff meetings, internal communication flyers, etc)
- **Care Team Education** – Make sure care team members understand why broad panel testing is important and how it will impact their existing workflows
- **Monitoring & Improvement** – Solicit frequent feedback and make appropriate adjustments to workflows accordingly
- **Best Practices/Record of Success** – Share what is working well and what can be improved

Pre-Work Can Help Ensure Teams Understand Pathway Implementation Goals and Can Identify Critical Success Factors and Unmet Needs

Successful implementation of care pathways is complex and warrants thoughtful planning by a multidisciplinary team to understand the practice's barriers and facilitators.¹ **Each practice is unique** and will need to tailor the Broad Panel Testing Care Pathway to its specific needs. It is important to consider the administrative support required to ensure a smooth implementation process.

The questions below can be utilized to help identify practice needs:

Key Program Considerations

1. What organizational goals will be supported and enhanced by the Broad Panel Testing Care Pathway (eg, adherence to pathways, improved patient outcomes)?

2. How will broad panel testing be reimbursed and who will provide financial counseling for patients if they do not have coverage?

3. Will the broad panel testing be conducted within the organization, or will testing be conducted by external service providers?

4. Are genetic counselors available (either internally or externally via collaborations) to perform pre- and post-test patient counseling? If not, do clinicians have sufficient resources to conduct counseling?

5. What patient navigation resources are available and/or needed to support the broad panel testing workflow?

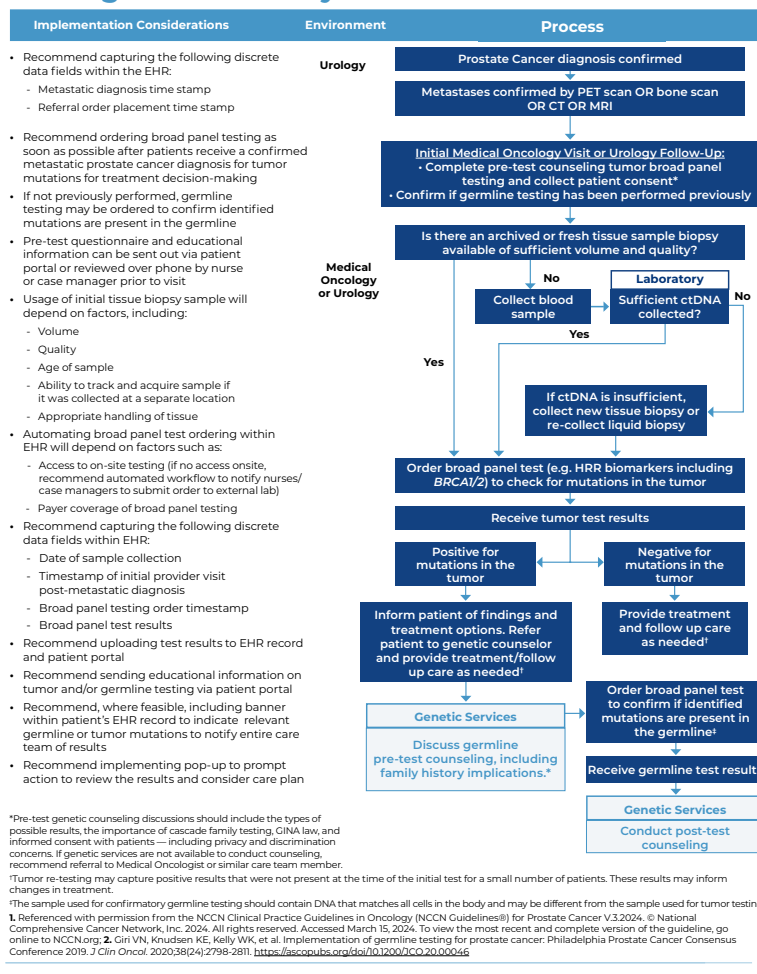
1. Rotter T, Baatenburg de Jong R, Lacko SE, Ronellenfitch U, Kinsman L. Clinical pathways as a quality strategy. In: Busse R, Klazinga N, Panteli D, eds. *Improving Healthcare Quality in Europe: Characteristics, Effectiveness and Implementation of Different Strategies*. European Observatory on Health Systems and Policies; 2019; 53.

Implementation of the Broad Panel Testing Care Pathway Begins With an Orientation to the Model

The **pathway*** illustrates a guidelines-based, consensus-built model for optimizing the use of broad panel testing:

1

Metastatic Prostate Cancer Broad Panel Testing Care Pathway^{1,2}



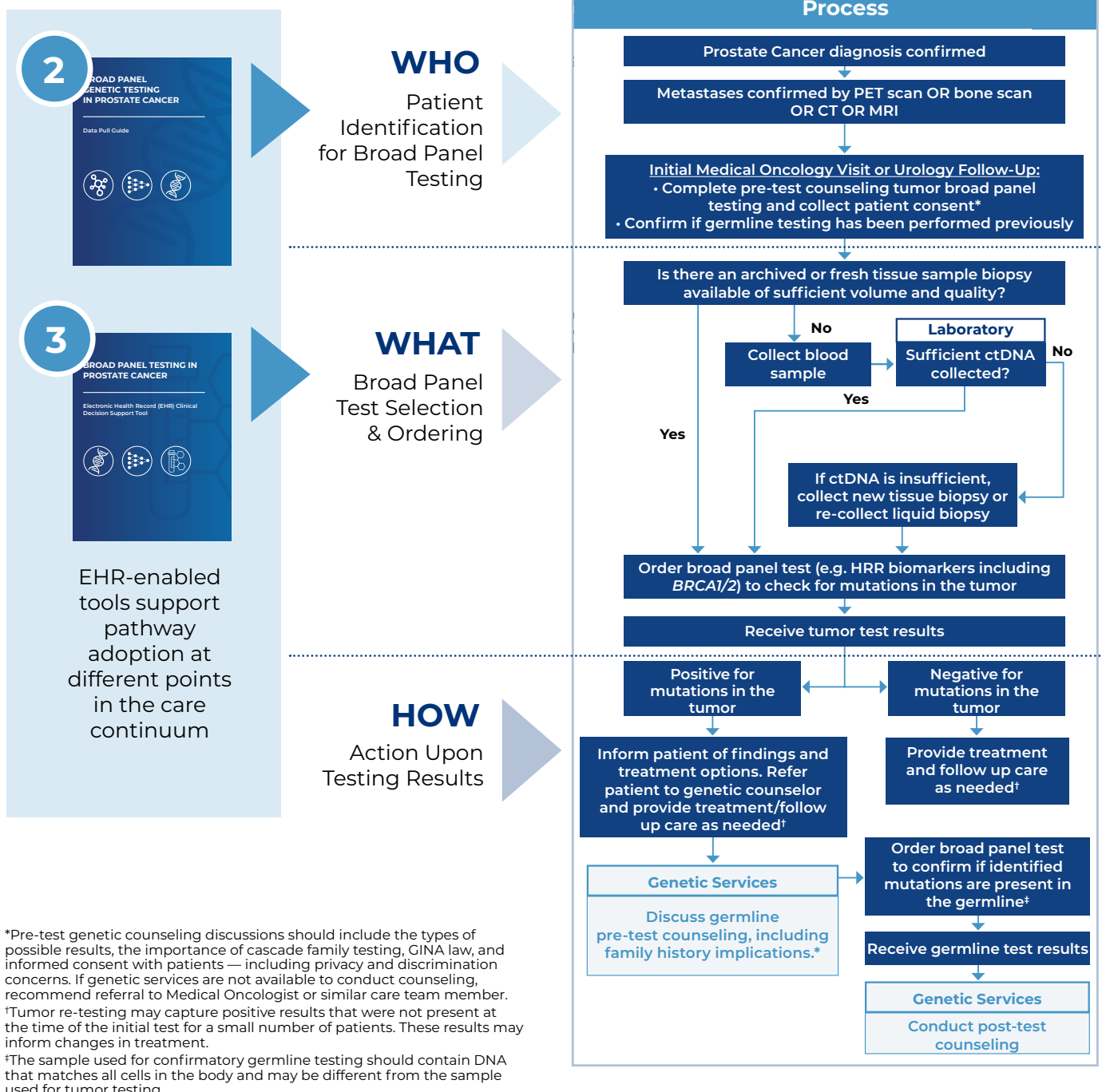
Leverage the Broad Panel Testing Care Pathway to:

- Identify potential gaps in current broad panel testing
- Identify considerations for operationalizing clinical practice guidelines for germline and broad panel tumor testing
- Provide decision support for clinicians at the point of care to promote adherence to evidence-based guidelines

*A full version of the care pathway is available in Appendix A.

The Broad Panel Testing Care Pathway Consists of 3 Essential Components:

- Identifying **WHO** to test
- Determining **WHAT** test is appropriate
- Informing **HOW** to action upon testing results



*Pre-test genetic counseling discussions should include the types of possible results, the importance of cascade family testing, GINA law, and informed consent with patients — including privacy and discrimination concerns. If genetic services are not available to conduct counseling, recommend referral to Medical Oncologist or similar care team member.
†Tumor re-testing may capture positive results that were not present at the time of the initial test for a small number of patients. These results may inform changes in treatment.
‡The sample used for confirmatory germline testing should contain DNA that matches all cells in the body and may be different from the sample used for tumor testing.

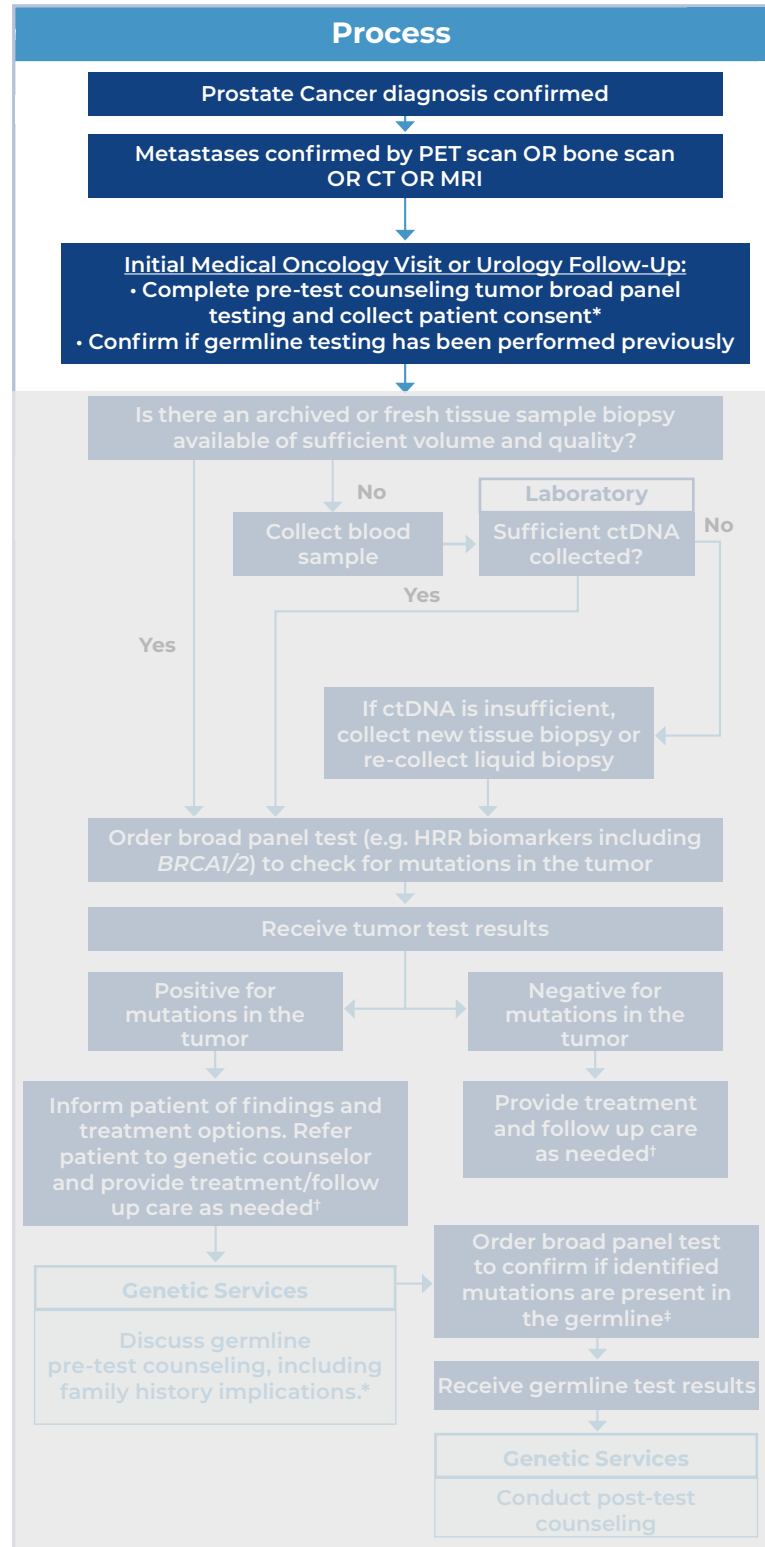
1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 15, 2024. To view the most recent and complete version of the guideline, go online to [NCCN.org](https://www.nccn.org); 2. Giri VN, Knudsen KE, Kelly WK, et al. Implementation of germline testing for prostate cancer: Philadelphia Prostate Cancer Consensus Conference 2019. *J Clin Oncol*. 2020;38(24):2798-2811. <https://ascopubs.org/doi/10.1200/JCO.20.00046>

Identifying WHO to Test

Patient identification is the foundation for the implementation of guideline-based care. In the Broad Panel Testing Care Pathway, patient identification begins with confirmation of a metastatic prostate cancer diagnosis. Opportunities to automate patient identification are discussed in this section. See [Appendix A](#) for the complete Broad Panel Testing Care Pathway.

WHO

Patient Identification
for NGS Testing



*Pre-test genetic counseling discussions should include the types of possible results, the importance of cascade family testing, GINA law, and informed consent with patients — including privacy and discrimination concerns. If genetic services are not available to conduct counseling, recommend referral to Medical Oncologist or similar care team member.

†Tumor re-testing may capture positive results that were not present at the time of the initial test for a small number of patients. These results may inform changes in treatment.

‡The sample used for confirmatory germline testing should contain DNA that matches all cells in the body and may be different from the sample used for tumor testing.

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Identifying Appropriate Patients for Testing Is a Foundational Step in the Pathway

Practices do not always have ways to quickly and proactively identify when a patient may be eligible for broad panel testing.

To leverage opportunities for patient identification using the EHR, practices should consider:



- The importance of clinical documentation excellence
 - Cleanliness and discreteness of data
 - Timeliness of coding
 - Accuracy of coding
 - Presence of secondary codes to specify metastatic diagnosis
- The use of EHR reporting and clinical decision support capabilities
 - Alerts
 - Order sets
 - Patient registries



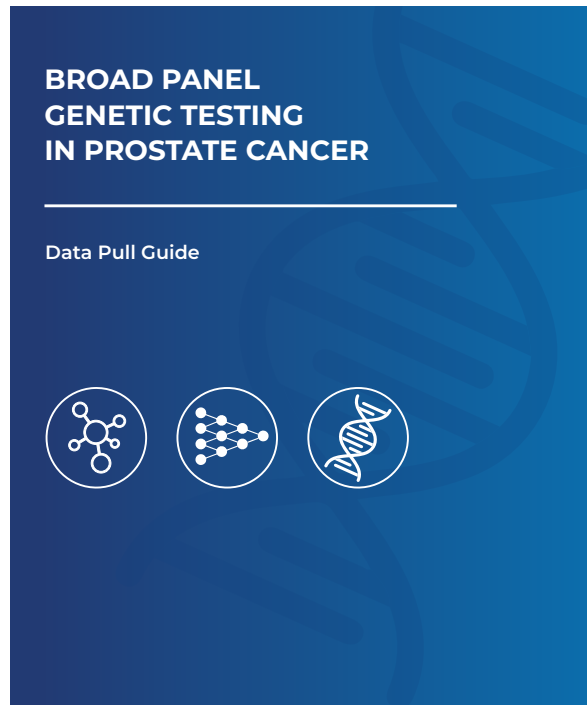
Practice Tips

Patients may be identified in different ways depending on a practice's infrastructure:

- Ideally, EHR-driven alerts prompt care teams to review patients who are eligible for broad panel testing
- Alternatively, a practice can pull routine lists of patients for staff to review for eligibility

The EHR Data Pull Guide Can Help Identify Which Patients May Be Eligible for Broad Panel Testing

The EHR Data Pull Guide enables practices to **extract standardized data** to evaluate the current rate of broad panel testing used to identify eligible patients within their organization.



Leverage the EHR Data Pull Guide to:

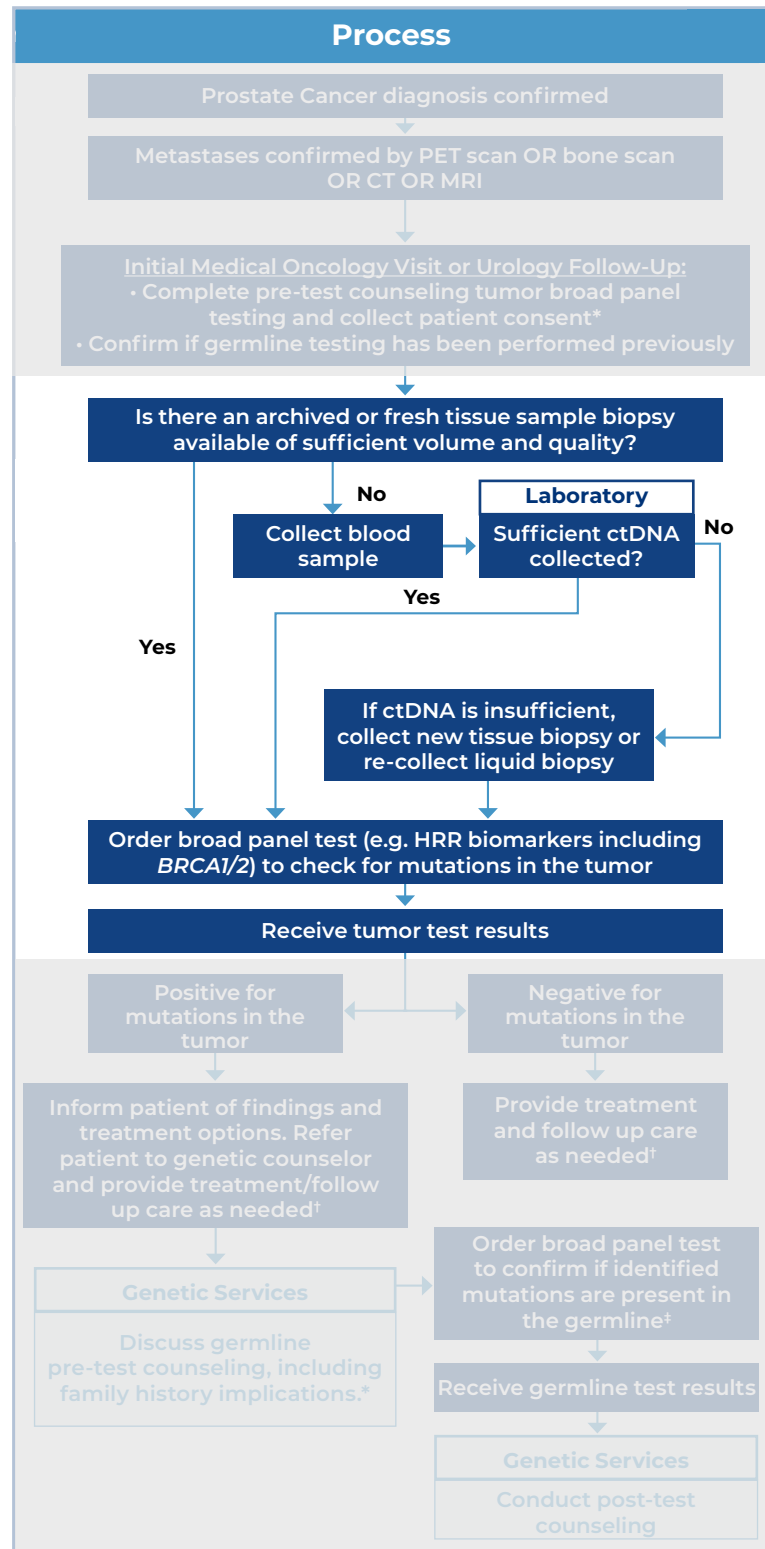
- Establish a baseline for a practice's current rate of broad panel testing
- Identify patients with a new or current metastatic prostate cancer diagnosis who may qualify for broad panel testing
- Understand practice-level trends in broad panel testing and identify opportunities for optimization

Determining WHAT Test Is Appropriate

There are many available testing panels that can be used for broad panel testing. Considerations for selecting the appropriate testing panel are discussed on the next pages, along with suggestions for simplifying the test ordering process. See [Appendix A](#) for the complete Broad Panel Testing Care Pathway.

WHAT

Broad Panel Test Selection & Ordering



*Pre-test genetic counseling discussions should include the types of possible results, the importance of cascade family testing, GINA law, and informed consent with patients — including privacy and discrimination concerns. If genetic services are not available to conduct counseling, recommend referral to Medical Oncologist or similar care team member.

†Tumor re-testing may capture positive results that were not present at the time of the initial test for a small number of patients. These results may inform changes in treatment.

‡The sample used for confirmatory germline testing should contain DNA that matches all cells in the body and may be different from the sample used for tumor testing.

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Once Patients Have Been Identified for Broad Panel Testing, Workflows Can Be Optimized to Streamline Test Selection

Understanding which broad panel tests are appropriate and how to order them with seamless, efficient accuracy is imperative for optimal patient outcomes.

Practices can leverage their EHRs to support the test selection process:

- Identify the type of testing panel (tumor (somatic) OR germline OR both)¹
- Ensure the genes of interest are included in the panel (eg, *BRCA1/BRCA2*, HRR, MSI status)¹
- Match the source of the DNA sample (blood or solid tumor) with the appropriate type of panel^{2,3}
- For commercial tests, confirm FDA Companion Diagnostic (CDx) status if needed¹

Practice Tips



Depending on a practice's EHR capabilities:

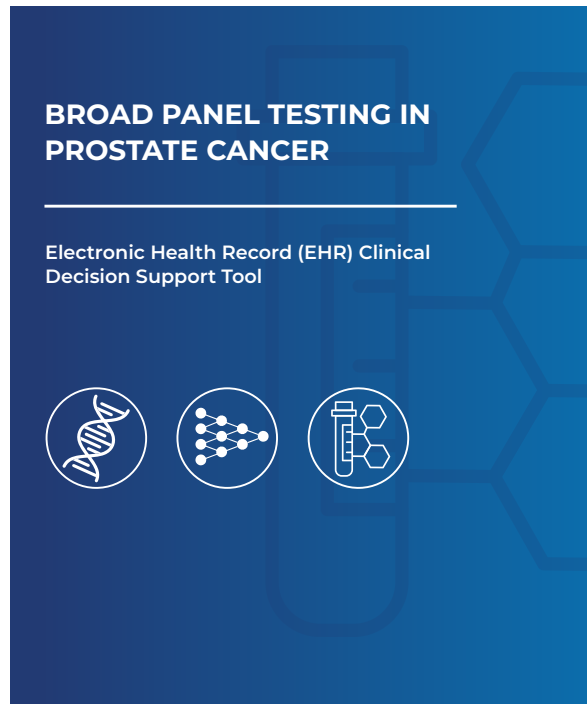
- Automated clinical decision support tools may be deployed to provide step-by-step prompts for ordering and follow-up
- Alternative workflows can identify the orders needed, but staff support will be required to ensure broad panel testing is ordered

*A tumor testing panel refers to acquired mutations. It does not refer to the type of sample being utilized.

1. Hicks JK, Howard R, Reisman P, et al. Integrating somatic and germline next-generation sequencing into routine clinical oncology practice. *JCO Precis Oncol.* 2021;5:884-895. **2.** Hollasch M. In-house next-generation sequencing improves turnaround time in NSCLC. *OncLive.* Accessed June 8, 2023. <https://www.onclive.com/view/in-house-next-generation-sequencing-improves-turnaround-time-in-nsclc> **3.** Zeng J, Johnson A, Shufean MA, et al. Operationalization of next-generation sequencing and decision support for precision oncology. *JCO Clinical Cancer Inform.* 2019;(3):1-12. doi: <https://doi.org/10.1200/cci.19.00089>

The EHR Decision Support Tool Helps Practices Streamline the Broad Panel Testing Clinical Cascade

The EHR Clinical Decision Support Tool helps providers and care teams **identify** patients and **automate** the broad panel test selection and ordering process once a patient has been deemed eligible.



Leverage the EHR Clinical Decision Support Tool to:

- **Create discrete fields within the EHR to help identify eligible prostate cancer patients who have not received broad panel testing**
- **Trigger automatic alerts when a patient needs to be evaluated for broad panel testing**
- **Establish workflows to guide the test selection and ordering process**

Practices Can Apply the 5 “Rights” of Clinical Decision Support to Optimize Broad Panel Testing Workflows

These tenets ensure meaningful and actionable information gets to the appropriate team member in a timely and congruent fashion:

The 5 “Rights”	Description	Implementation Considerations
Right Information	Confirm information is evidence-based, derived from broad panel testing guidelines, and based on nationally recognized codes and/or performance measures.	Alerts should contain the minimum amount of information Consider linking to NCCN guidelines and codes Update routinely with current guidelines
Right Person	Ensure the information to optimize broad panel testing gets to the right person(s) who can take action (eg, care team members, patients).	Use a RACI chart to identify who needs to have and who will benefit from broad panel testing information
Right Intervention Format	Consider the format that best solves the problem at hand, including broad panel testing order sets, actions/prompts, and alerts.	Inventory existing clinical decision support tools Determine if tools can be developed internally or will be outsourced
Right Channel	Select the most appropriate channel to deliver broad panel testing-related clinical decision support (including EHR, digital apps, or paper)	Evaluate the channels that are most centric to the needs of the end user
Right Time in Workflow	Clinical decision support for broad panel testing should appear at the appropriate time in the workflow to minimize disruptions and rework.	Document all clinical workflows Ensure broad panel testing is ordered within 48 hours of diagnosis Ensure broad panel test results are reviewed within 24 hours

Campbell RJ. The five “rights” of clinical decision support. *Journal of AHIMA*. 2013;84(10):42-47. <https://library.ahima.org/doc?oid=300027>

Informing HOW to Action Upon Testing Results

Once broad panel testing results have been received, care teams can determine appropriate patient care based upon the results. Opportunities to leverage the EHR to systematize care are reviewed in this section. See [Appendix A](#) for the complete Broad Panel Testing Care Pathway.

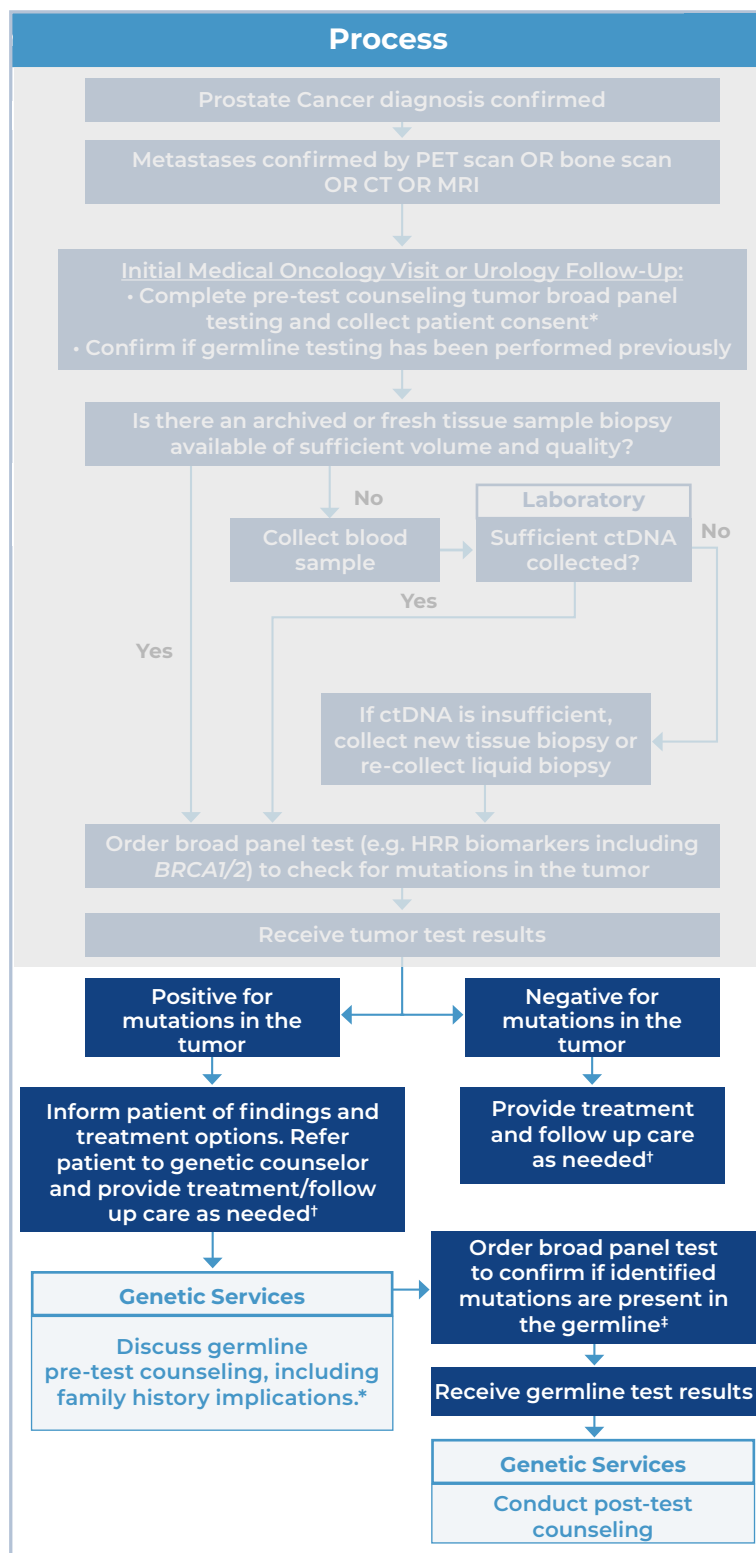
HOW Action Upon Testing Results

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[†]Tumor re-testing may capture positive results that were not present at the time of the initial test for a small number of patients. These results may inform changes in treatment.

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Hardwiring Care Navigation Processes Can Support Care Continuity and Inform Next Steps in the Metastatic Prostate Cancer Patient's Journey

The grid below can help practices construct a collaborative and consistent approach to broad panel testing care navigation focused on four key process points.

	Tool(s) Used (eg, phone, EHR alert, electronic order, portal message)	Person Responsible for Initiating and Completing (eg, ordering provider, genetic counselor)	Timing (eg, within 48 hours of diagnosis)	Source of Information to be Transmitted (eg, problem list)
Education on Broad Panel Testing				
Financial Counseling				
Genetic Counseling on Test Results				
Education on Care Plan				



Practice Tips

Consider leveraging the EHR to:

- Notify the ordering provider of testing results when they are received from the testing lab within 24 business hours
- Implement a pop-up to prompt review of test results
- Include a banner within patient's EHR record to indicate relevant germline or somatic mutations for care team visibility

Additional Implementation Considerations for Community Practices and Health Systems

As practice resources and capabilities vary, so do the barriers and opportunities related to the integration of genetic counseling, specimen access, and interpretation of results for broad panel testing.

Community Specialty Practices 	Health Systems 
• May seek genetic counseling* services through external lab vendors or partners • May need to track location of initial biopsy tests • May need additional support for broad panel test results interpretation	• May provide on-site genetic counseling and financial support for broad panel testing • Biopsy storage may be provided on-site • May have internal support for broad panel test results interpretation
Considerations to systematize care: • Leverage the Broad Panel Testing Care Pathway and tools to support implementation • Share genetic testing questionnaires and education via the patient portal or by phone prior to the visit • Consider utilizing a third-party testing vendor that offers genetic counseling services and results analysis	Considerations to systematize care: • Optimize the use of automatic EHR alerts for providers • Reinforce pathway adherence through regular reporting of metrics pertaining to genetic counseling

*Further information on genetic counseling is available in Appendix C.

Ongoing Refinement of Broad Panel Testing Care Pathway Implementation Can Ensure Continuous Care Improvement

Engaging the practice team in routine re-evaluation of the broad panel testing workflow will help it evolve with the practice needs and address changes to broad panel testing guidelines. Consider a simple example framework to facilitate improvement dialogue:

Optimization (What are we piloting?)	Measures (How will we measure the impact?)	What Worked Well?	What Needs to Change?	Adopt, Adapt, or Abandon?
Send pre-test questionnaire to patient via patient portal.	- Number of completed questionnaires - Time the questionnaire is completed - Time the broad panel test is completed	Pre-test questionnaire was automatically sent to patient when a metastatic prostate cancer diagnosis was added to the problem list.	- Trigger questionnaire timeliness of completion - Process needs further development to support trigger	Adapt: - Automate patient outreach within 24-48 hours of original - Send reminder text message to patient daily until questionnaire is completed

Defining success is an important step to connect pathway utilization to performance-based measures such as health equity and timeliness to care.

Key metrics to consider include:

- Rate of broad panel testing
- Time to test from diagnosis
- Provider experience or satisfaction
- Patient engagement or activation



Practice Tips

- The EHR Data Pull Guide can be used to track and monitor broad panel testing
- Facilitate visibility of trending data and quantify early successes to cultivate team engagement
- To accommodate quickly evolving guidelines, consider using Order Sets and Problem Lists to structure test ordering workflows, so they do not need to be rebuilt from scratch

Additional Considerations for Automating the Broad Panel Testing Care Pathway

Care for patients with metastatic prostate cancer can be improved through highly reliable, timely workflows embedded within the EHR for ease of use. Barriers and facilitators to automation should be considered throughout the planning and development processes to optimize results.

Facilitators to automation:

- ✓ Reinforcement and/or physician compensation mechanisms to support correct staging by providers
- ✓ Availability of HIT/IS resources
- ✓ Engagement of end users throughout development process of automation

Potential barriers to automation may include:

- X Incorrect staging
- X Processes rendered incorrect/obsolete by evolving guidelines
- X Lack of HIT/IS resources



Practice Tips

Consider leveraging best practice automations, such as:

- A banner within patient's EHR record to indicate relevant germline or somatic mutations to notify the care team of the results
- A pop-up to prompt review of a patient's test results and consider their care plan

Key Takeaways



Clinical guidelines support broad panel testing for all patients with metastatic prostate cancer



Addressing gaps in broad panel testing is critical for providing high-quality care for patients with metastatic prostate cancer



Following three clearly defined steps can help practices implement guideline-directed care for broad panel testing:

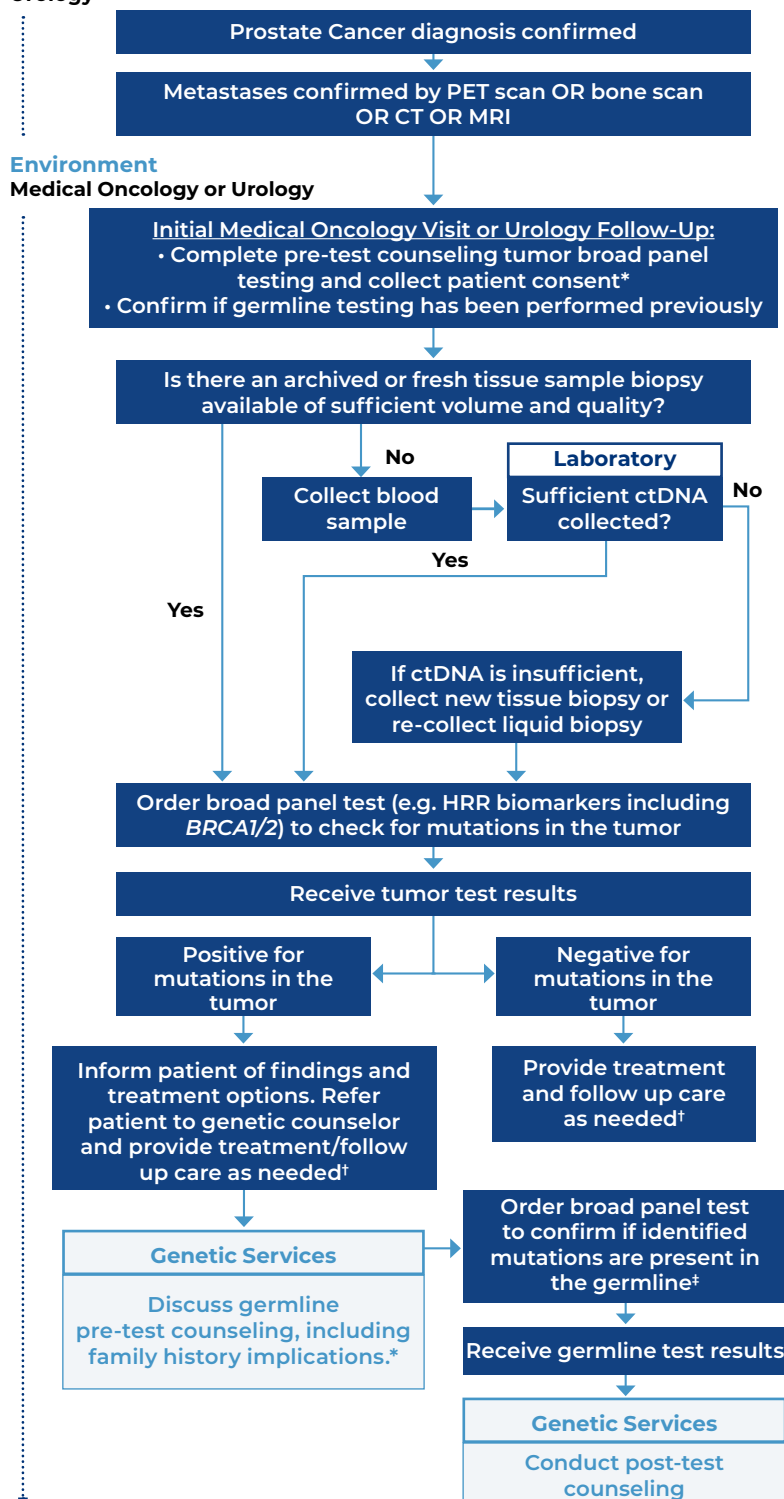
1. **PREPARE** your practice to focus on broad panel testing
2. Leverage your EHR to **IMPLEMENT** broad panel testing improvements by:
 - Identifying **WHO** to test
 - Determining **WHAT** test is appropriate
 - Informing **HOW** to action upon testing results
3. **SUSTAIN & OPTIMIZE** the broad panel testing workflow to reflect the latest guidelines and your practice's needs

Metastatic Prostate Cancer Broad Panel Testing Care Pathway^{1,2}

Environment Urology

Process

Environment Medical Oncology or Urology



Implementation Considerations

- Recommend capturing the following discrete data fields within the EHR:
 - Metastatic diagnosis time stamp
 - Referral order placement time stamp
- Recommend ordering broad panel testing as soon as possible after patients receive a confirmed metastatic prostate cancer diagnosis for tumor mutations for treatment decision-making
- If not previously performed, germline testing may be ordered to confirm identified mutations are present in the germline
- Pre-test questionnaire and educational information can be sent out via patient portal or reviewed over phone by nurse or case manager prior to visit
- Usage of initial tissue biopsy sample will depend on factors, including:
 - Volume
 - Quality
 - Age of sample
 - Ability to track and acquire sample if it was collected at a separate location
 - Appropriate handling of tissue
- Automating broad panel test ordering within EHR will depend on factors such as:
 - Access to on-site testing (if no access onsite, recommend automated workflow to notify nurses/case managers to submit order to external lab)
 - Payer coverage of broad panel testing
- Recommend capturing the following discrete data fields within EHR:
 - Date of sample collection
 - Timestamp of initial provider visit post-metastatic diagnosis
 - Broad panel testing order timestamp
 - Broad panel test results
- Recommend uploading test results to EHR record and patient portal
- Recommend sending educational information on tumor and/or germline testing via patient portal
- Recommend, where feasible, including banner within patient's EHR record to indicate relevant germline or tumor mutations to notify entire care team of results
- Recommend implementing pop-up to prompt action to review the results and consider care plan

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Guidelines for Broad Panel Testing

SOURCE	NCCN INTERMEDIATE/LOW/VERY LOW RISK LOCALIZED PROSTATE CANCER	NCCN VERY HIGH AND HIGH-RISK LOCALIZED PROSTATE CANCER	REGIONAL (N1)/ METASTATIC PROSTATE CANCER
GERMLINE			
NCCN Prostate Cancer Guidelines, Version 3.2024	Recommend if a family history of: - Ashkenazi Jewish ancestry - High-risk germline mutations (eg, <i>BRCA</i> 1/2, Lynch mutation) - PCa in brother/father/multiple family members diagnosed with PCa (not GG1) at <60 years of age or who died from PCa ≥3 cancers on same side of family, especially diagnoses ≤50 years of age: bile duct, breast, colorectal, endometrial, gastric, kidney, melanoma, ovarian pancreatic, prostate (not GG1), small bowel, or urothelial cancer Consider for: » Intraductal/criform histology	Recommended	Recommended
Philadelphia Prostate Cancer Consensus Meeting Publication 2019	- Consider for T3a or higher - Consider for intraductal/ductal pathology - Consider for Gleason 4 (Gleason 8 sum) or above - Consider for Ashkenazi Jewish ancestry - Consider for family history of ≥2 cancers in HBOC/Lynch spectrum in any relative on the same side of the family (especially if diagnosed at age <50 years) - Recommend for family history of 1 brother/father/≥2 male relatives with 1 of the following: » PCa at age <60 years » Died of PCa » Metastatic PCa		Recommended
AUA/ASTRO/SUO 2022	Recommend if: - First-degree relative or multiple second-degree relatives diagnosed with Grade Group 2 or higher prostate cancer, particularly at early age (<60 years), particularly if metastatic or lethal - Strong personal or family history of related cancers (eg, breast, colorectal, ovarian, pancreatic, upper tract urothelial carcinoma) - Known family history of familial cancer risk mutation (eg <i>BRCA1</i>, <i>BRCA2</i>, <i>ATM</i>, Lynch syndrome–associated genes) - Ashkenazi Jewish ancestry - Adverse tumor characteristics		Recommended
SOMATIC			
NCCN Prostate Cancer Guidelines, Version 3.2024	Consider Decipher, Oncotype DX Prostate, and Prolaris tumor-based molecular assays for patients with low- and intermediate-risk prostate cancer and life expectancy ≥10 years	Consider Decipher, Oncotype DX Prostate, and Prolaris tumor-based molecular assays for patients with high-risk prostate cancer and life expectancy ≥10 years	Consider in patients with regional (N1) prostate cancer and is recommended for those with metastatic disease
Philadelphia Prostate Cancer Consensus Meeting Publication 2019	N/A	N/A	Recommended
AUA/ASTRO/SUO 2023	N/A	N/A	Recommended

ASTRO, American Society for Therapeutic Radiology and Oncology; AUA, American Urological Association; GG1m grade group 1; HBOC, hereditary breast and ovarian cancer; N/A, not applicable; NCCN, National Comprehensive Cancer Network; PCa, prostate cancer; SUO, Society of Urologic Oncology.

1. Next-generation sequencing testing in oncology. Journal of Oncology Navigation and Survivorship (JONS). Accessed July 7, 2023. <https://www.jons-online.com/special-issues-and-supplements?view=article&artid=2318:next-generation-sequencing-testing-in-oncology> **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 15, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Giri VN, Knudsen KE, Kelly WK, et al. Implementation of germline testing for prostate cancer: Philadelphia Prostate Cancer Consensus Conference 2019. *J Clin Oncol*. 2020;38(24):2798-2811.

Genetic Counseling Support

Key Areas of Knowledge for Providers Conducting Genetic Counseling^{1,2:}

	Germline or Tumor Testing	Germline Testing-Specific	Tumor Testing-Specific
Patient Counseling	Consideration of men's psychosocial needs to determine suitability of genetic testing Discussion of genetic test options, benefits/limitations of genetic testing, types of results, and Genetic Information Nondiscrimination Act (GINA) law	Discussion of genetic results and recommendations based on test results and family history	Understanding variant reclassification and follow-up with patients Discussion of genetic results and recommendations based on test results
Test Ordering	Selection of lab for quality and genetic test offered that covers mutations of interest	Identification of men meeting criteria for genetic evaluation based on personal and family history Knowledge of cancer inheritance, genetic testing considerations	Knowledge of mutations in key genes relevant to precision therapy, precision management
Results Interpretation	Implications of test results	Facilitating cascade testing or further genetic evaluation for families	Available precision therapies and key corresponding genes

Recommended Topics for Pre- and Post-Testing Counseling Discussions with Patients^{3:}

Pre-Test	Post-Test
- Purpose of testing - Types of possible results (ie, pathogenic/likely pathogenic; benign/likely benign; VUS; no variants identified) - The possibility of identifying hereditary cancer syndrome and/or other cancer risks - Potential cost of testing - Importance of cascade family testing - GINA law - Informed consent with patients — including privacy and discrimination concerns	- Positive results for relevant mutations - Variants of unknown significance (VUS) results that could be reclassified as pathogenic/likely pathogenic in the future - Treatment implications for somatic results - Familial risk for direct relatives at risk from a genetically transferable condition (recommend genetic counselor)

← Cost and Data Privacy →

1. Giri, V. (2019, Oct). Genetic education and practice considerations of non-genetic providers. The Canadian Journal of Urology:International Supplement. https://www.canjurol.com/html/free-articles/Cdn_JU26-ISS2_23_DrGiri.pdf. 2. Bahnsen CJ. Next-generation sequencing: Examining an often oversimplified & misunderstood technology - Part III. Insights. <https://news.mayocliniclabs.com/2021/01/18/next-generation-sequencing-examining-an-often-oversimplified-misunderstood-technology-part-iii/>. 3. Sokolova A, Cheng H. Germline testing in prostate cancer: when and who to test. *Oncology*. 2021;35(10):645-653.