INSTITUTE FOR PROSTATE CANCER RESEARCH

Report to the Community 2023

Who we are

The Institute for Prostate Cancer Research is a collaborative effort between University of Washington Medicine and Fred Hutchinson Cancer Center.

Our expert team of scientists and clinicians work to fulfill our three-part mission:

- Understanding prostate cancer to improve diagnosis and treatment.
- Providing effective, individualized therapy for patients.
- Extending and enhancing the quality of a patient's life upon diagnosis.

To achieve this mission, we are committed to:

- Studying potential preventive agents and strategies.
- Developing new biomarkers for early diagnosis and therapy selection.
- Improving surgical, radiation and ablative techniques.
- Exploring the biology of prostate cancer metastasis and resistance to treatment.
- Understanding hereditary and acquired gene defects to develop better detection and therapy strategies.
- Advancing targeted imaging technologies and integrating them with novel therapies.
- Conducting innovative clinical trials to bring new discoveries to the bedside.

Message from the Director

Our 2023 Report to the Community provides you with a window into some of our most exciting and impactful ongoing research. In the following pages, we'll give you insight into various aspects of our program, introduce you to our newest research directions, and profile several recently recruited investigators. The stories outline some of the novel avenues of discovery we are pursuing as we endeavor to produce landscape-changing advances in the most common of all adult cancers.

Although the primary goal of IPCR involves engaging in foundational and revolutionary prostate cancer research, we are also fully committed to raising awareness in our community, educating patients and families, and providing the highest quality care to patients. The spirit of collegiality and team-science is palpable in our motivated and determined body of IPCR investigators, bringing together two world-class institutions: Fred Hutchinson Cancer Center and UW Medicine. I am constantly inspired by our collective efforts in tackling difficult problems in cancer research and care of patients.

We are committed to curing prostate cancer at all stages. To achieve this, we are launching an ambitious multiyear initiative to accelerate advances in screening, diagnostics and treatment of prostate cancer. We are delighted that Jon Fine, former CEO of United Way, will lead the IPCR Fundraising Council and partner with the Fred Hutch philanthropy team to inspire donors to fuel this effort (see pages 16-18).

I want to take this opportunity to thank the IPCR team and our community of generous supporters. Together, we are united in the words on the front cover of this report: to *imagine* novel approaches of investigation, to *innovate* and develop emerging frontiers of science, and to *transform* the landscape of prostate cancer care to make cure a reality. We certainly could not reach these new heights of research excellence without your support and generosity.

Thank you for your interest in our mission. If you would like more information, we are happy to arrange a tour of our facilities and an informational session. Feel free to reach out to me directly at any time (dlin@uw.edu).

Warm regards,

Daniel W. Lin, MD
Director, Institute for Prostate Cancer Research
Pritt Family Endowed Chair of Prostate Cancer Research
Chief of Urologic Oncology and Professor, Department of Urology, University of Washington

Message from the Scientific Director

We witness breakthroughs toward improving human health through biomedical research on a daily basis. From preventing lethal infections to correcting genetic diseases to enhancing outcomes after a cancer diagnosis, the pace of discovery is remarkable. The foundation for these advances continues to center on basic research.

Yet prostate cancer remains a common and potentially devastating disease. And while we can now cure most men diagnosed with localized disease, we cure very few whose cancer has spread. But as the pace of research accelerates, I believe we will soon have the potential to radically improve the effectiveness of treatments, leading to cures.

IPCR supports work across a spectrum of scientific areas designed to understand how the prostate develops, what factors contribute to its cancer risk, how hormones influence prostate cancer growth, and how the immune system recognizes targets. A key aspect of our work continues to focus on *translating new knowledge into clinical action* to improve the lives of patients with prostate cancer, ultimately driving prevention and cure.

My role as scientific director provides a unique vantage point to preview the progress made by the outstanding group of 45 physicians and researchers who make up IPCR. Notably, their work on prostate cancer research is extended through a network spanning more than 15 departments and divisions across the UW and Fred Hutch, incorporating novel ideas from other fields such as engineering, computer science, mathematics, chemistry and immunology. IPCR investigators are also connected to international efforts that foster collaboration and knowledge-exchange to rapidly test and apply precision-oncology strategies for prostate cancer prevention, detection and treatment.

We thank you for your interest in our work. We are inspired by the researchers you will read about in this Report to the Community, and we hope you will partner with us in our goal to eliminate prostate cancer, enabling men to live longer and better lives.

With gratitude,

Peter S. Nelson, MD
Research Director, Institute for Prostate Cancer Research
Director, Sloan Precision Oncology Institute
Professor, Division of Human Biology Division, Fred Hutchinson Cancer Center

TURNING ON THE PSMA switch

Metastatic prostate cancer, in which the cancer has spread to other parts of the body, is a difficult-to-treat disease and there is an urgent need for novel therapies that employ distinct mechanisms of action.

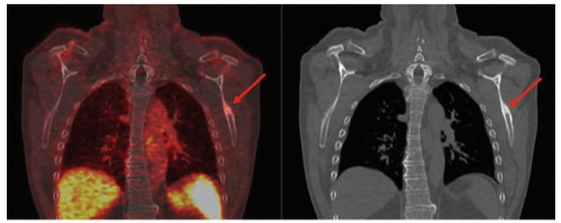
At the Institute for Prostate Cancer Research, a team of scientists led by Michael Haffner, MD, PhD, is working to develop new treatments that target PSMA, or prostate-specific membrane antigen. Although PSMA-directed therapies hold the promise to greatly improve prostate cancer treatment, there are limitations. In about 70% of patients, PSMA is expressed at low levels or shows significant variations when highly expressed.

"The way PSMA is expressed in prostate cancer cells can differ among patients and even across different metastatic sites within the same patient," said Haffner. "That means some individuals may respond well to PSMA-targeted therapies and others will not. We are looking at developing strategies that will enhance PSMA expression, which will improve treatment outcomes for more men."

Determining a cell's fate

All cells in the human body have the same DNA sequence but a cell in the heart looks and functions very differently than a cell in the prostate. These differences are dictated by an additional layer of information that is encoded by modifying the DNA molecule without changing the DNA sequence, called epigenetic marks (literally, "on top of the genome").

Epigenetic marks define the function and behavior of all cells, essentially determining a cell's fate, but cancers can find unique ways to highjack and change them. One of the most widely studied epigenetic marks is DNA methylation. Haffner and his team have discovered that a gain of DNA methylation in the gene encoding for PSMA can be found in up to 40% of prostate cancer metastases. It's as if this epigenetic switch turns off PSMA expression.



Can we turn PSMA expression back on? Haffner thinks so. "We've found that histone deacetylase inhibitors, a group of drugs that can change the epigenome, can induce PSMA expression," he said.

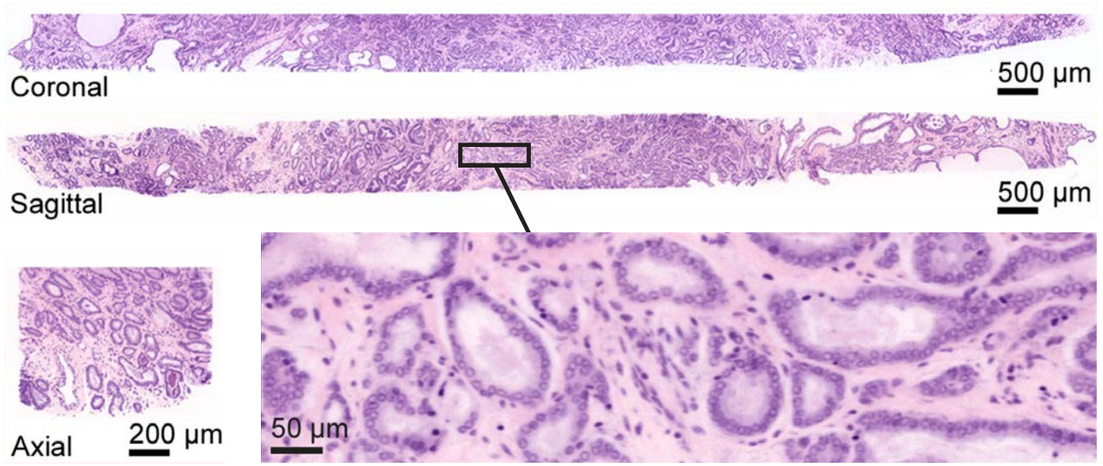
Next year, Haffner and his colleague Michael Schweizer, MD, plan to launch a first clinical trial to test if epigenetic therapies can enhance the benefits of PSMA-directed treatments. During the trial, funded by the Lopker Family Foundation, the team will administer vorinostat, a drug that induces PSMA expression. Eligible patients will receive a second drug called 177 Lu-PSMA-617 (Pluvicto), a recently approved treatment for men with advanced metastatic prostate cancer that specifically targets PSMA-expressing cells. The researchers will then study whether the combination therapy can assist patients with low levels of PSMA and extend survival time.

"We hope these treatments will shed light on how PSMA is expressed," said Haffner. "Understanding these patterns can help us identify unique vulnerabilities that may allow us to treat this disease even more effectively."

> "We hope these treatments will shed light on how PSMA is expressed. Understanding these patterns can help us identify unique vulnerabilities that allow us to treat this disease even more effectively."

LEFT: MICHAEL HAFFNER, MD, PHD
UPPER RIGHT: PSMA SCAN

Developing a REVOLUTIONARY approach to pathology



Some prostate cancers are slow-growing and can be easily monitored over time, but others are more aggressive and need immediate treatment.

To determine how aggressive a cancer is, pathologists use a microscope to look for abnormalities visible in paper-thin slices of biopsy tissue. The process, while precise, can take days to complete which is frustrating for patients and families. More importantly, since the biopsies use only thin slices, critical elements in the biopsy tissue may not be part of the sample.

Recently a cross-disciplinary team at the University of Washington developed a 3-dimensional (3-D) pathology microscope which can provide more accurate analysis while also potentially reducing wait times. Called an open-top light-sheet (OTLS) microscope, the groundbreaking new technology is the work of four researchers: Dr. Larry True, surgical pathologist and a founding member of the Institute for Prostate Cancer Research; Dr. Nicholas Reder, clinical instructor, Laboratory Medicine and Pathology; Dr. Jonathan Liu, professor, Mechanical Engineering; and Dr. Adam Glaser, senior scientist, Allen Institute for Neural Dynamics.

UPPER LEFT: LARRY TRUE, MD
UPPER RIGHT: BIOPSY TISSUE

How it works

Traditional pathology uses a 2-D method: Biopsy tissue is sectioned, embedded into wax and cut into paper-thin sections. The sections, about 4 microns thick, are mounted onto traditional glass slides for analysis. (In comparison, a strand of human hair is about 100 microns thick.)

To view a biopsy in the OTLS microscope, the tissue is placed in a solution containing fluorescent molecules, then rendered transparent using a non-toxic chemical. A thin sheet of laser light rapidly scans the tissue to stimulate the fluorescent molecules. The light is collected in a high-resolution camera as digital data.

Software stitches the images together to produce 2-micron thick virtual images. A stack of 2-micron thick images from a 1-millimeter biopsy provides 500 virtual sections—several hundred more sections than are provided by traditional 2-D microscopy. This means the pathologist can view at least 200 times as much image data.

The specimen is placed on top of a glass plate where a camera attached to the microscope transmits digital data to a computer to reconstruct a 3-D image. By viewing multiple digital images, pathologists can completely analyze the biopsy and the structure of the cancer as well as how each cell relates to surrounding cells. The open-top design—envision an office scanner—can accommodate a wide range of tissue-specimen sizes and shapes.

"The 3-D technology provides a way to look deeper into the tissue," said True. "Since we image intact tissue, a diagnosis can be made more quickly and with more precision. Deeper levels of tissue and larger sample sizes are immense aids to a more accurate diagnosis, especially in borderline cases."

The idea to digitize the pathology came about when Reder, at the time a research fellow in pathology, noted that the 3-D structure could not be seen in conventional tissue slices. He wondered if technology developed by colleagues Liu and Glaser could be used to expedite and improve the process used to diagnose and grade prostate cancer.

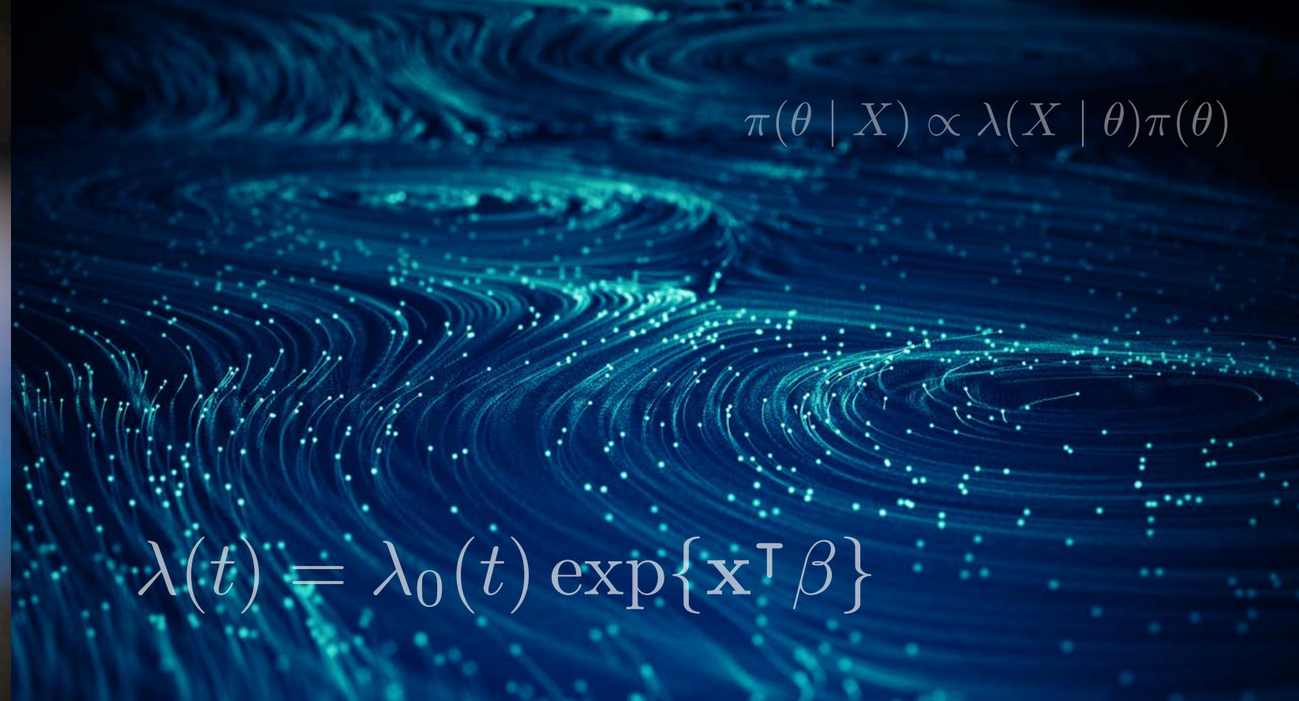
Along with True, the team came up with the idea of using light-sheet microscopy to more thoroughly analyze and diagnose prostate biopsies. Their invention—the first open-top light-sheet pathology microscope—led to the founding of Alpenglow Biosciences in 2019 with Reder as its CEO. The OTLS technology has been patented and is currently being tested.

Benefits of 3-D microscopy

Light-sheet microscopy is not only more informative than 2-D microscopy since tissue can be completely analyzed, but it can also potentially be faster since it minimizes the time it takes to prepare a tissue specimen. Digitizing also makes it easier to share data among health care professionals. "The downside might be that it's more expensive," said True.

In a pilot study by True and his colleagues, five pathologists in the United States, Canada and the United Kingdom analyzed 160 biopsies, using the new 3-D technology. "We found that 15% of the samples had more malignant histologic patterns than if we looked at them with standard 2-D screening," said True. "The 3-D technology also allowed us to find more cancer because we were viewing thicker tissue samples in all their complexity."

True believes that the collegial environment on the UW campus played a major role in the development of the 3-D microscope. "Our team included mechanical engineers, optical scientists and pathologists," he said. "Having access to this broad interdisciplinary network allowed us to percolate ideas and helped facilitate the end result."



BIOSTATISTICIAN WITH A MISSION

New technologies and tools for cancer diagnostics are being developed at breakneck speeds, but the research evaluating their outcomes and results has not kept pace. That's where public health researcher Dr. Ruth Etzioni comes in.

Referring to herself as a biostatistician with a mission, Etzioni is passionate about ensuring that the dizzying array of precision cancer diagnostics being released is properly, quickly and objectively evaluated for use in the real world. The data-driven evidence in turn drives clinical and policy decisions.

During the three decades she has worked at Fred Hutchinson Cancer Center, where she holds the Rosalie and Harold Rea Brown Endowed Chair, Etzioni has focused much of her work on prostate and breast cancer. She has helped refine the use of PSA (prostate-specific antigen) tests for prostate cancer screening, identified what constitutes over-diagnosis and over-treatment of prostate cancer, calculated costs and benefits of preventive screening, and tracked patterns and outcomes of cancer care. Along the way, she's been attuned to identifying and eliminating health disparities.

Her impact is enormous, and among her many honors is the prestigious Outstanding Investigator Award, presented to her by the National Cancer Institute in 2022. The award provides about $7.4 million over seven years to support her team's investigations into the accuracy of new cancer diagnostics, including nuclear imaging modalities and multi-cancer early detection tests, commonly referred to as liquid biopsies.

Making informed decisions

"If you want to have precision oncology, you've got to have diagnostics," said Etzioni. "But the rapid pace at which new technologies are entering the marketplace makes rigorous evaluation via controlled studies unfeasible for all but a few."

Some tests developed in laboratory settings can be marketed before they have final approval from the Food and Drug Administration, noted Etzioni, making it impossible to know the long-term benefits—or harms. "We don't know if these new tools are making patients' lives better or not," she said, "because the technologies have not been evaluated using controlled studies. Ultimately, my work is about people making informed decisions, whether they are a patient or a health care provider."

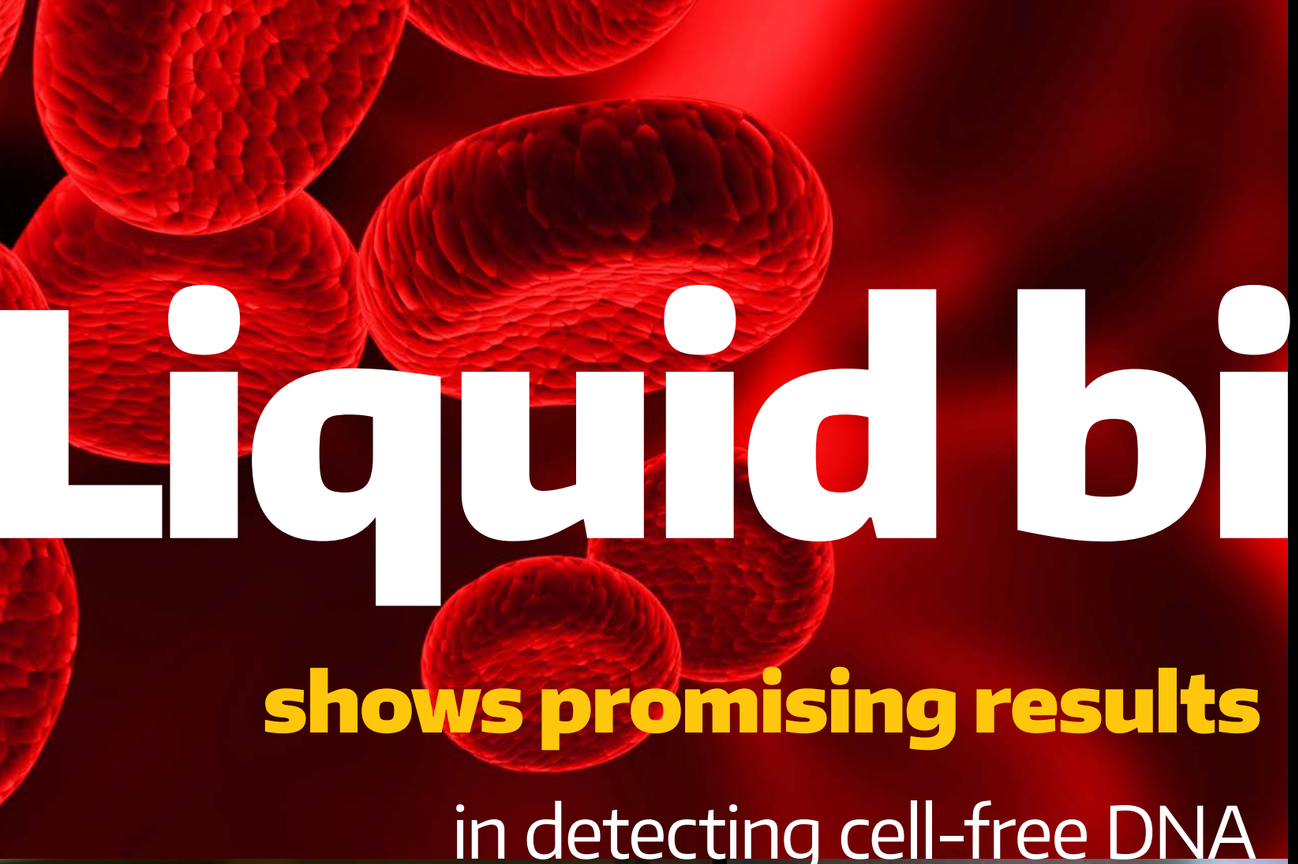
Ensuring equitable access

To ensure that emerging technologies are used equitably, Etzioni also examines dissemination patterns and test availability by race, ethnicity, geographic region and insurance status. "Creating access to a large body of clinical data from which we can ascertain who is getting access to these technologies and their clinical outcomes is a priority," she said. "We want to understand the impact not only on the disease but also on public health costs and health disparities."

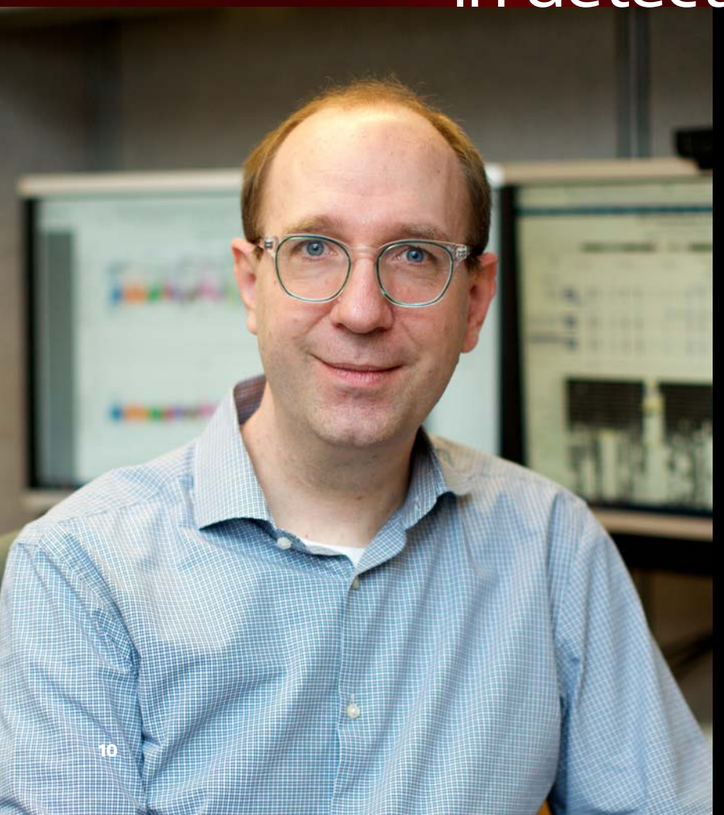
> "Together, we can move the field forward, not only by growing new technologies but also be learning how we can best use them to improve cancer outcomes."

Eventually Etzioni wants to create a go-to resource where researchers, patients, providers and the general public can better understand how to navigate diagnostic test options.

Etzioni is grateful to the support she has received over the years through collaborations with her colleagues at Fred Hutch—whether in radiology, nuclear medicine, pathology or lab testing. "Together, we can move the field forward," she said, "not only by growing new technologies but also by learning how we can best use them to improve cancer outcomes."



Liquid biopsy shows promising results in detecting cell-free DNA



Prostate cancer can change over time, evolving into one of several subtypes that are progressively resistant to treatment. Being able to classify the tumor subtype is important, but the current process, which relies on a tissue biopsy, can be costly, invasive and sometimes difficult to obtain. And repeated biopsies are not feasible, especially for advanced cancers.

An attractive solution is a "liquid biopsy," which can reveal the same information about a patient's cancer as a tissue sample. This noninvasive alternative uses blood as a diagnostic tool to detect and characterize cell-free DNA, also known as circulating tumor DNA. This is DNA that has been released from dead or dying tumor cells into the bloodstream. Although it still uses needles, a liquid biopsy is a simple blood draw so it carries less risk. Because it's less invasive, patients find it less stressful.

The idea of a liquid biopsy is not new but quickly becoming an attractive solution to address these challenges. This diagnostic tool has been used to detect genomic changes in both oncogenes and tumor suppressors, such as BRCA2. But the information that can be obtained from these blood tests is currently limited.

Enter Gavin Ha, PhD, a computational biologist and cancer geneticist, whose laboratory is working to develop novel computational approaches to study cell-free DNA. In a recently published landmark study, Ha and Peter Nelson, MD, along with a team of IPCR researchers, showed that it's possible to identify prostate cancer subtypes by analyzing tumor DNA circulating in a patient's blood.

"This research brings us closer to being able to glean more information from a simple blood draw."

With funding from the Lopker Family Foundation, Ha and his team are developing algorithms that will allow scientists to comb through the genetic analysis of the drawn blood to reveal whether DNA from cancer cells was released somewhere in the body. Along with colleague Colin Pritchard, MD, PhD, co-director of the UW Genetics and Solid Tumors Laboratory, the researchers will extend their work towards expanding the utility of current clinical blood tests.

Developing a simple, reliable blood test to accurately classify tumor subtypes will provide a more accurate diagnosis and allow physicians to better target cell-surface markers, predict response rates and monitor for treatment resistance.

Needle in a haystack

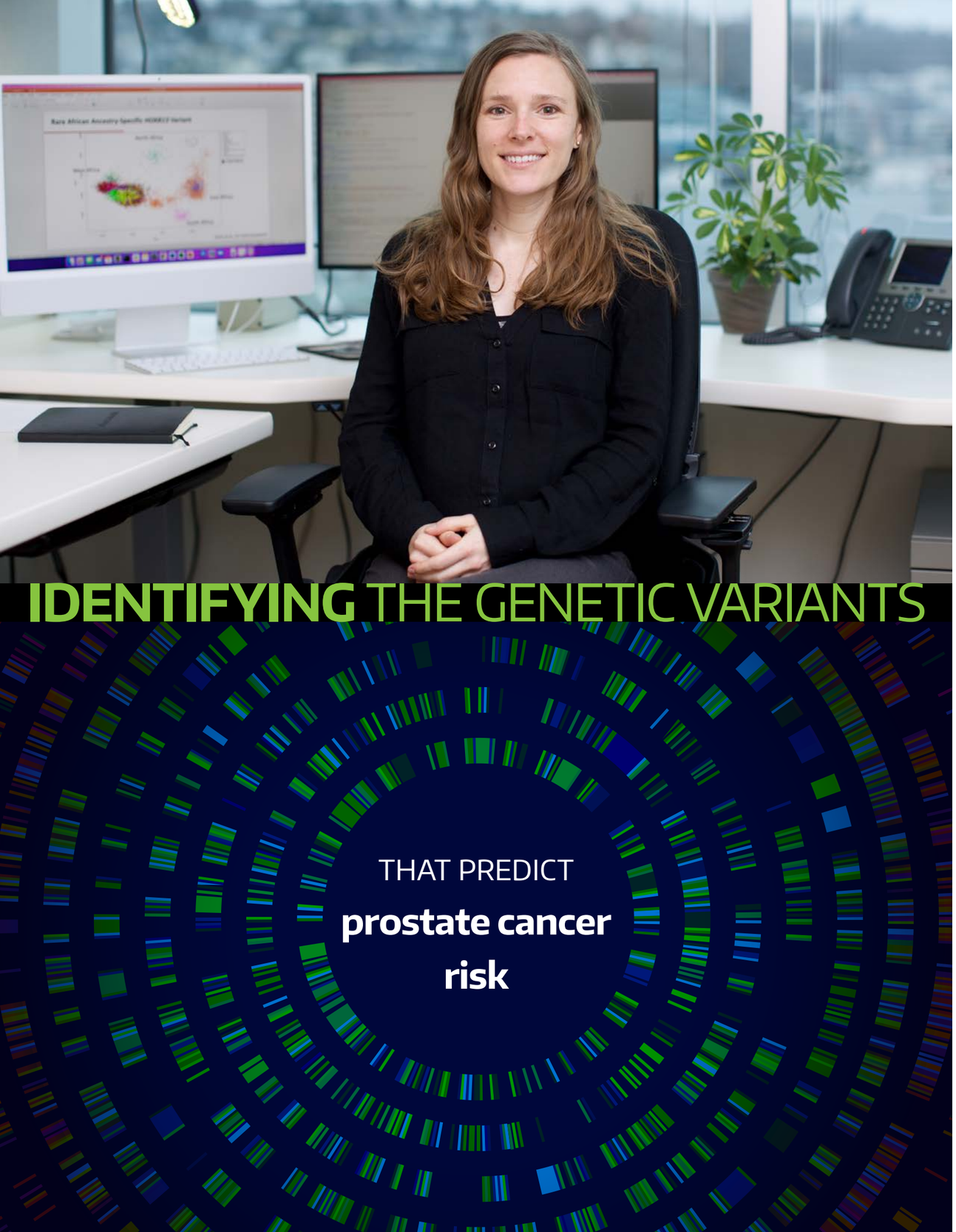
Although liquid biopsies are designed to be simple for the patient, the science behind them is anything but. Most of the DNA from a cancer cell looks identical to that of a normal healthy cell, so scientists must know the hallmark changes that distinguish normal DNA from tumor DNA.

The other challenge is having the ability to sift through enormous amounts of DNA molecules from normal cells, mostly white blood cells, to find the rare few molecules of cell-free DNA. It's the proverbial needle in a haystack.

"There's a real urgency to translate these methods to the clinic," said Ha. "This research brings us closer to being able to glean more information about a patient's cancer from a simple blood draw, allowing physicians to better inform treatment."

Ha's goal is to develop the software and collect study samples by summer 2024, and, working together with Pritchard, be ready with a clinical test the following year.

FAR LEFT: COLIN PRITCHARD, MD, PHD
NEAR LEFT: GAVIN HA, PHD



Prostate cancer is the second leading cause of cancer death among American men, with men of African descent having the highest incidence and mortality rates. While the causes of this health disparity are unknown, prostate cancer can run in families, making it likely that genetic and possibly environmental factors are at play.

Investigating the genetic risk of prostate cancer, particularly among diverse populations, is a research specialty of Burcu Darst, PhD, a genetic epidemiologist who joined Fred Hutch in 2021.

Currently, Darst leads a team of researchers working to identify rare genetic variants that can impact the risk for prostate cancer. It seems straightforward enough but identifying rare variants is particularly challenging since researchers need to assemble a huge study sample in order to detect them.

Common variants, on the other hand, have much smaller risk contributions individually but when viewed in aggregate, they too can be strongly predictive of prostate cancer risk. By combining these multiples of variants, researchers can determine an individual's polygenic risk score. "A polygenic risk score is strongly predictive of prostate cancer risk, much more so than polygenic risk scores for other diseases," said Darst. "The tool also works well across diverse populations."

Creating a polygenic risk score is as easy as taking a blood test or providing a saliva sample. From the blood or saliva, researchers can genotype or use DNA sequencing to determine whether patients inherited these risk-increasing genetic variants. "Currently our polygenic risk score has 451 variants, so we need to genotype those 451 variants," explained Darst. "We would also include some ancestry markers to determine an individual's genetic ancestry because the risk score can vary, depending on a person's ancestry."

When used with other screening measures, such as PSA testing, polygenic risk scores can help scientists develop a much more accurate risk assessment. Improving how scientists identify prostate cancer risk can lead to improved screening guidelines, which can save lives.

There is one drawback. The polygenic risk score has a limited ability to accurately distinguish between aggressive and non-aggressive forms of the disease. This raises concerns about using the scores in clinical settings for fear of over-diagnosing a non-aggressive cancer that may never threaten a patient, even if never diagnosed.

That's another area of research that Darst and her team are tackling. "We've recently been able to improve the polygenic risk score by having a larger sample size and including larger numbers of men from diverse populations," she said. "The data should help us better distinguish aggressive from non-aggressive forms of the disease, which is very promising news. We're also finding that men with higher polygenic risk scores are often diagnosed at a younger age."

Darst, who earned a PhD in epidemiology from the University of Wisconsin in 2018, has published several ground-breaking studies in prostate cancer genetics and polygenic risk scores. She has been honored by many national organizations for her work, and has received the Prostate Cancer Foundation's Young Investigator Award, NextGen Star Award from the American Association for Cancer Research, and K99/R00 Award from the National Cancer Institute, among others.

Taking it to the next level

Darst chose to establish her lab at the Fred Hutchinson Cancer Center because of its national reputation, innovative researchers, diverse research agenda and major prostate cancer program that includes the IPCR. "The IPCR covers so many different aspects of prostate cancer research," said Darst, "and there are so many people around to help you take it to the next level, whether it's clinical implementation or just getting a better understanding of the biological function of a particular genetic variant."

Darst's research on rare genetic variants is particularly helpful in identifying men at risk of aggressive disease. Considering rare variants along with polygenic risk will likely further distinguishing aggressive from non-aggressive disease.

Recently she teamed up with another IPCR researcher, Heather Cheng, MD, PhD, on a new study to enroll men recently diagnosed with prostate cancer through the Washington State Cancer Registry.

"We're going to focus on men regardless of diagnosis, aggressive or non-aggressive, but limit it to those who report as being non-white, which should help us better understand health disparities," said Darst. "We'll follow them longitudinally to see how their prostate cancer changes over time and try to get a better understanding of whether polygenic risk as well as other genetic factors, such as rare variants, can help us identify men who are more likely to progress to an aggressive form of the disease."

Using sound waves to treat localized PROSTATE CANCER

Removing prostate cancer without the side effects of surgery or radiation has been a long-term goal of George Schade, MD, a national leader in research to improve prostate cancer treatment.

Currently Schade and his colleagues at the University of Washington/Fred Hutchinson Cancer Center are working on a new treatment called prostate focal therapy in which a small portion of the prostate, including the cancer, is destroyed (ablated) using energy sources.

"Traditional treatments such as surgery and radiation therapy have been successful in wiping out prostate cancer," said Schade, "but both can affect nearby structures, which can lead to negative effects on urinary, bowel and sexual quality of life."

The most commonly used method for prostate cancer focal therapy is high-intensity focused ultrasound (HIFU). This approach uses approximately one-second pulses of ultrasound energy focused to a point about the size of a grain of rice. Within the focus, rapid heating occurs which causes cell death.

Other current options for focal therapy also rely on temperature changes, including freezing (cryotherapy) or heating (laser ablation). While all these options, including thermal HIFU, have shown promise as a prostate cancer treatment with fewer reports of side effects compared with surgery and radiation, there are limitations. In fact, 15% to 40% of men are found to have residual prostate cancer six to 12 months after treatment. Additionally, some men have experienced changes to their urinary and sexual health.

To address these shortcomings and improve existing focal therapy technologies, Schade and his team at the UW Applied Physics Lab are working on a specific type of HIFU called Boiling Histotripsy (BH), an experimental technique with the potential to revolutionize treatment for localized prostate cancer. (The word histotripsy comes from the Greek "histo" meaning "soft tissue" and "tripsy" which refers to breaking down.)

Like thermal HIFU, histotripsy uses focused ultrasound, or sound waves, delivered from outside the body to kill targeted tissues or cancer. However, BH uses shorter, higher-intensity bursts or pulses of ultrasound that cause vapor microbubbles to form, mechanically destroying cells in the targeted tissue without heating it. Using this minimally invasive approach, pre-clinical studies have shown this innovative technology can safely destroy prostate cancer tissue with pinpoint precision.

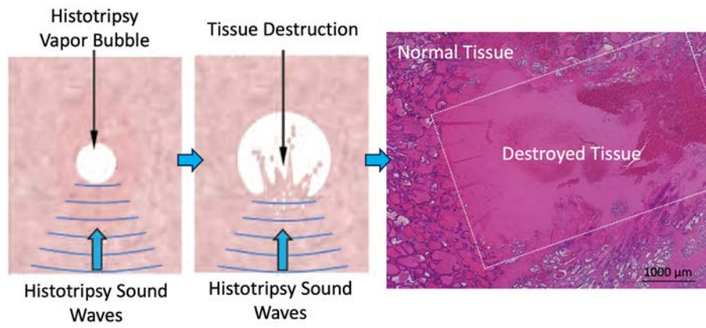
Improving cancer outcomes

Unlike other technologies, histotripsy also offers surgeons the ability to monitor treatment in real-time. "The procedure produces bright bubbles that are visible on ultrasound, so we know the exact area we're treating," said Schade. "The mechanical destruction of tissue produces a darker image that gives us real-time feedback on the success of the treatment, and the treatment margins—where tissue is injured but not destroyed—are considerably less than with other therapies."

As a result of the precision and ability to monitor imaging, BH should lead to improved prostate cancer outcomes while reducing side effects. By making prostate cancer treatment less invasive, more effective and with fewer side effects, BH may also reduce the costs of prostate cancer care.

In addition, several studies have found that HIFU and similar treatments activate host anti-tumor effects that may improve cancer outcomes long term. Histotripsy may be even more advantageous for inducing systemic anti-tumor immunity because it does not use heat. This might turn on a patient's own immune system to fight the cancer, further improving cancer outcomes.

While tests are ongoing, Schade and his team are finding that Boiling Histotripsy may have broad application for other medical procedures, as well. "In pre-clinical testing, BH has been shown to be effective for benign prostatic hyperplasia, a non-cancerous prostate enlargement," said Schade. "It also appears to be a potential treatment option for kidney stones and other cancers such as liver, kidney and pancreas. The future potential of successful treatments using histotripsy has yet to be fully uncovered."



This schematic of boiling histotripsy treatment and tissue effects shows how focused sound waves are delivered into tissue, producing vapor bubbles. Interactions between the vapor bubbles and sound waves produce mechanical tissue destruction without heating, allowing the treated tissue to be destroyed with precision.

Building on today's success to inspire tomorrow's breakthroughs

A conversation about IPCR's forthcoming fundraising initiative to help men live longer and live better

Our hopes for the future of precision oncology at Fred Hutchinson Cancer Center have been informed, in many ways, by the successes of the Institute for Prostate Cancer Research (IPCR). For more than two decades, researchers involved in this highly collaborative effort between Fred Hutch and UW Medicine have worked to understand prostate cancer's inherited nature. They've identified proteins expressed by its cells that can be used to detect its presence and as a target for treatments. And they've improved our ability to identify which patients need more aggressive treatment than others.

Now, they're preparing to redefine precision oncology for the next generation: This fall, the IPCR will launch a $100 million fundraising initiative to advance research that will better determine which individuals to screen and when to screen them, further develop methods for treating patients based on the unique characteristics of their cancer, and refine how much treatment patients need to minimize side effects and improve their quality of life.

It's an ambitious effort to accelerate research — and it needs to be. Prostate cancer continues to be the most prevalent and second deadliest cancer among men. We spoke to three of the people who will help drive the initiative to learn more about its goals and our community's role in ensuring its success.

Daniel W. Lin, MD
Director, Institute for Prostate Cancer Research

What does the phrase "precision oncology" mean to you?

It means the right treatment for the right patient at the right time. That's the easy way to think about it. In other words, personalized and specific treatment that is tailored to a variety of patient characteristics. That might be something about their genetics or the molecular makeup of their tumor.

But it also applies to people who haven't been diagnosed: How to screen and who to screen, based on their genetic makeup or other characteristics.

What potential advances in precision treatment for prostate cancer can you see just over the horizon?

We're currently working on methods of manipulating tumor characteristics to make them more susceptible to treatments. So, for example, a few of our researchers are trying to encourage prostate cancer cells to produce more of a certain protein that can be used as a treatment target.

And I think it's very attainable in the near future to develop a blood-based test for tracking changes in a patient's tumor over time, which would be invaluable for helping us be more responsive in adjusting treatment.

What do we need to do to make those advances?

Every discovery starts with an idea, then preclinical work to determine if the idea can move forward. And then you have to conduct a small version of your trial to gather the data you need to move on to a much larger trial. And you need people to gather and analyze the large amounts of data from all those endeavors.

All of that costs money, which is why our donors are so, so important. They make it possible for us to turn an idea into a discovery that can help patients.

Why is now the right time for IPCR to undertake a fundraising initiative of this size?

Generally speaking, we've made enormous leaps in our ability to interrogate the human genome, the tumor genome and the interaction between the two. That's what is driving precision oncology. And we're ideally situated to continue making discoveries in that space, thanks to Fred Hutch's new Stuart and Molly Sloan Precision Oncology Institute.

More specifically to IPCR, we have amassed an unbelievable team of driven investigators with big ideas for targeting more precisely everything from screening to treatment. I've been researching prostate cancer for more than 20 years, and I've never been more inspired by a group of people or more excited about the future than I am right now.

$100 million

Jon Fine
Chair, IPCR Volunteer Fundraising Council

Your involvement in and commitment to this community goes back decades, including 19 years as the CEO of United Way. Why have you chosen to take on a leadership role in IPCR'S fundraising initiative?

I've always believed in being engaged in the community, giving back, and helping where I can. Aside from believing that Fred Hutch has tremendously impressive people and programs that produce world-class research, I also have a very personal reason for being involved. A year and a half ago, I was diagnosed with prostate cancer. I've received wonderful care from the team at Fred Hutch and UW Medicine, and I believe so strongly in their commitment to world-class research and their vision for the future of prostate cancer care that when they asked me to help lead this effort, I agreed without hesitation.

What will your role be?

I will take a leadership role in recruiting other council members who value Fred Hutch in the same way I do and want to see it succeed. I'm looking to recruit other advisers who can help give us some ideas about where to fundraise and who to fundraise with.

You and your wife have already made a significant gift to this effort. Why?

First, the patient care, the research, the world-class thinking that goes on at Fred Hutch merit that kind of support. Second, I'm going to be going out and asking people to join me in giving. There's something special about being asked to give by someone who's not only not being paid to do it, but who also truly believes in what they're asking you to support.

Kelly O'Brien
Vice President and Chief Philanthropy Officer, Fred Hutch

Fred Hutch is in the early days of launching a comprehensive campaign. How does this funding initiative to support IPCR fit into it?

Creating an imperative in our community to support Fred Hutch at this scale is new for us. IPCR has engaged the donor community for nearly two decades, thanks in large part to the efforts of its founding director, Dr. Paul Lange. So it's only natural that we would leverage that strong foundation of engagement and trust as we launch our campaign. And what we accomplish will be a model, as we work with faculty and community members to develop focused fundraising efforts within the campaign for breast cancer, gastrointestinal cancers, multiple myeloma and lymphoma, Merkel cell carcinoma and others.

In a more practical sense, the majority of the men we love and admire will face prostate cancer at some point in their life. My father passed away from pancreatic cancer, but if he'd lived long enough, prostate cancer probably would have been in his future. We can't not make it a part of our larger campaign.

Fred Hutch received two truly transformational gifts in 2022. How would you respond to the donor who says, "What difference could my gift make?"

I would say that none of us knows which dollar is going to be the one to create the next breakthrough that offers today's patient a new treatment option.

I would also say that we are among the best institutions in the country at securing competitive grants, but our scientists first need to gather data or develop proof-of-concept to compete for those grants. Every dollar helps provide them additional flexibility to pursue those innovative ideas.

How will you inspire donors to give?

Part of that will involve working with donors to understand the impact that they want to make through their giving and creating an experience that is meaningful to them.

And our clinician partners will be vital to that effort. In many ways, they're on the frontline of our fundraising efforts, engaging with patients and their families every day. Supporting them as they cultivate those relationships and develop a culture of philanthropy within their clinics will ensure the success of both this IPCR initiative and the larger mission of Fred Hutch.

Every discovery starts with an idea, then preclinical work to determine if the idea can move forward. And then you have to conduct a small version of your trial to gather the data you need to move on to a much larger trial. And you need people to gather and analyze the large amounts of data from all those endeavors.

All of that costs money, which is why our donors are so, so important. They make it possible for us to turn an idea into a discovery that can help patients.

COMBATING
prostate cancer among
Black men

The statistics are alarming: Black men are not only more likely to get prostate cancer during their lifetimes, but are twice as likely to die from it than men of other races or ethnicities. This disparity is the largest racial inequity of any cancer in the U. S. And despite improvements in both diagnosis and treatment, the gap has persisted for more than five decades.

A new community-based, patient-centered toolkit called COMBAT-PC is being developed to increase awareness, education and support for the early detection of prostate cancer among Black men, particularly men aged 40-45. Under the direction of Dr. Yaw Nyame, a urologic oncologist, researcher and educator at the University of Washington, the program is supported by the Institute for Prostate Cancer Research and the National Cancer Institute.

COMBAT-PC builds on the findings of Nyame and Ruth Etzioni, PhD, a biostatistician at Fred Hutch. In their research, the scientists demonstrated that an intensified screening strategy, such as annual PSA (prostate-specific antigen) testing of Black men, could reduce the number of prostate cancer deaths among this population. This was especially true when testing began with younger men. Translating these findings to real-world application, though, has been challenging. That's where COMBAT-PC comes in.

Developing an equity-based toolkit

To get a better idea of the existing knowledge, attitudes, experiences and practices around the early detection of prostate cancer, the COMBAT-PC research team interviewed Black men who live in the Puget Sound region. Their findings revealed a number of critical equity-related barriers. For example, many men did not fully understand the benefits of early screening and others were reluctant to discuss prostate cancer screening or share decision-making with their primary care providers.

The team is now working to develop learning tools that reflect these concerns. To ensure the toolkit is accessible, culturally relevant and community-based, stakeholders representing diverse points of view are acting as sounding boards. Advisory group members include Black men both with and without a history of prostate cancer, patient and community advocates, urologists, researchers and health communications specialists.

Among the discussion topics are toolkit contents, format and distribution vehicle. "A toolkit is only as good as its dissemination," said Jenney Lee, UW School of Medicine senior research scientist, "so determining how patients and doctors communicate is an important part of our research. We want to give patients access to more information that is helpful and has value. On the clinical side, we know that doctors are busy people and we don't want to layer in one more thing for them to do. We hope this tool will be useful to doctors and support conversations with their patients."

Community collaborations are key

The COMBAT-PC team believes that community partners are central to creating the right message and delivering it via the appropriate vehicle. Advising the research team is a community-based organization called BACPAC, which stands for Black and African-descent Collaborative for Prostate Cancer Action, started by Nyame in 2020.

Just three years later, BACPAC's network includes more than 30 community partners, such as ZERO and Communities of Color Coalition. "A patient- and community-centered approach that addresses racial inequities in prostate cancer ensures we can pinpoint the priorities that matter most to Black men, that our approach is culturally appropriate and relevant, and that our research and interventions are effective," said Nyame.

The COMBAT-PC equity-based toolkit will be piloted in Washington state next year. Depending on results, researchers are prepared to scale up the project for a national roll-out in the future.

BAC
PAC

ABOVE: YAW NYAME, MD, MS, MBA (FAR LEFT), WITH MEMBERS OF BACPAC

Turning “doctor speak” into plain English

Patients who understand their prostate cancer prognosis and treatment options tend to become more involved in the decision-making process about their care, which can lead to better health outcomes. But it’s hard for patients to know what options are best—or even what questions to ask—if foundational health documents, such as pathology reports, are full of unfamiliar words and complex medical terms.

Dr. John Gore, a surgeon and researcher with a specialty in urologic oncology, has been interested in patient-centered communications for several years. During a systematic review of pathology reports, he found that communications were prepared with the physician—not the patient—in mind. “These reports use medical terminology and complex vocabulary that are beyond the health literacy of the average patient,” said Gore. “If patients can’t understand a pathology report, how can they choose between their treatment options?”

Today’s patients have unprecedented access to their medical records, making it even more important that documents such as pathology reports can be read and comprehended by a general audience. Greater knowledge not only leads to better patient-physician communication, but has also been linked to improved emotional health, improved decision-making and better comprehension of the overall cancer-management plan. It can also impact health disparities for vulnerable and marginalized populations.

Gore employed various methods to collect data and engage stakeholders, including patient focus groups to help him elicit themes and design recommendations for patient-centered pathology reports. Two common requirements emerged: The language should be framed in a way that informs and engages patients, and the clinical documentation format should be leveraged to enhance readability and information flow.

The Pathology Translator

With support from the Institute for Prostate Cancer Research, Gore is now working on developing a product that will automate a patient-centered pathology report, in essence, turning “doctor-speak” into plain English. Called the Pathology Translator, the software will be able to read a standard pathology report, recognize words or concepts common to diagnostic pathology, translate these concepts into language that is more accessible, and then issue a personalized patient-centered pathology report.

“Nothing is lost in the process,” said Gore. “The physician version of the pathology report remains untouched. Patients can choose to read the patient-centered version, the physician version or both. It’s their personal choice.”

In his pilot studies to see if patient-centered pathology reports are beneficial to patients, Gore found that clinicians would often use the patient-centered reports, and not the standard reports, when discussing the new cancer diagnosis with their patients.

Gore believes there is great potential for the Pathology Translator. “The Pathology Translator is designed to be used at clinical sites regardless of their electronic health-record infrastructure,” said Gore. “Its design will also enable it to translate pathology reports for other common cancer types, such as breast or bladder cancer.”

Jessica Hawley:

Improving treatment and care through science

Jessica Hawley, MD, MS, focuses on advancing new immunotherapeutics for patients with prostate cancer. It's not only a professional calling for Hawley but a personal one as well: Her father and both grandfathers were diagnosed or died from the disease. After college, Hawley served in the Peace Corps for two years, earned a medical degree from the University of Wisconsin and then a master's degree in biostatistics from Columbia. In 2020, she was honored with the Young Investigator Award from the Prostate Cancer Foundation. The following year, she joined IPCR, drawn by its outstanding reputation and depth of expertise in the field.

Tell us about some of your current research projects.

I have several projects going on. One is a clinical trial I designed focused on TNF-alpha, a pro-inflammatory protein. My earlier work showed that perturbations in the immune system can affect the androgen receptor (AR) in prostate cancer, and that high levels of TNF-alpha are associated with poor outcomes across the prostate cancer spectrum. Our preclinical and translational studies showed that if we block TNF-alpha, we can re-engage the drugs that block AR and extend the duration of response. We expect to have this trial start in 2024.

I'm also the clinical lead on a study advancing the work of CAR T cell therapy initiated by Dr. John Lee, an IPCR colleague. John's lab has engineered a novel CAR T cell therapy that targets the protein STEAP1, produced in most prostate cancers. This has shown excellent promise in laboratory models. We'll be following up with a Phase 1 clinical trial with a home-grown CAR T cell John developed, using it alone or in combination with enzalutamide.

What about your work with the Microbiome Research Initiative?

Dave Fredricks, a Fred Hutch investigator, and I put together a proposal where we'll collect stool samples from patients before and after hormonal therapy. Earlier studies had shown how important the microbiome is. For example, bacteria in the stool might be metabolizing some of the drugs we're giving to treat prostate cancer, rendering them ineffective. Another study showed the microbiome is responsible for making testosterone. So if we are suppressing testosterone with drugs, is the microbiome making its own and feeding cell growth? Our first step is to collect stool and blood samples before and after treatment in patients and confirm if these previous findings hold up.

Professional collaboration seems to be central to your work.

My goal is to be very interactive across the University and Fred Hutch. I don't have dedicated lab space, so all of the biospecimens I'm collecting will be studied in conjunction with IPCR colleagues. I'll be processing some patient biospecimens at facilities at Fred Hutch, and also working with Dr. Gavin Ha, a computational scientist, and his team on the computational side. I'll also work closely with the prostate cancer SPORE biostatistics core that Dr. Ruth Etzioni leads. Many heads might give us the answer that's needed.

How formative were your years in the Peace Corps?

I was an international relations major in college and considered becoming an interpreter for the United Nations. But after graduation I decided I first wanted to make an impact in the world. I joined the Peace Corps as a public health volunteer and was stationed on a tiny coral atoll country in the Pacific Ocean called the Republic of Kiribati. I lived in a hut on the clinic compound and worked with nurses to teach villagers basic health concepts. I also met my husband in the Peace Corps.

How did you find your way to prostate cancer research?

The Peace Corps was a transformative experience and redirected my focus to a medical profession. After additional post-baccalaureate coursework, I trained in internal medicine, working for three years as a general internist, including overseas in Nepal, before returning to medical oncology fellowship training.

At Columbia University, I met my future research mentor, a prominent prostate cancer immunologist. He had a great lab and a good team. I knew I wanted to work with him and learn everything I could.

A unique multi-stage trial focusing on gene-specific therapy

Just as there is great diversity among individuals, there is also great diversity among cancer cells and the genetic mutations that create the cancer. That's the foundation for an innovative study called the Genomic Umbrella Neoadjuvant Study, which uses genetic testing to determine which pre-surgery treatments best target a patient's specific gene mutation.

Led by Dr. Martin Gleave, MD, director, Vancouver (B.C.) Prostate Centre, in collaboration with Dr. Michael Schweizer, MD, a prostate cancer researcher at Fred Hutch, the trial is supported by funds from the Institute for Prostate Cancer Research.

Participants in the study all have high-risk localized prostate cancer and are scheduled to have their prostates surgically removed. Before surgery, though, each man receives a customized drug regimen for 16 weeks based on his individual gene mutation, with the aim of shrinking the tumor or altering the way the cancer cells grow.

The trial offers an efficient approach for deploying precision oncology to men with prostate cancer. For the first eight weeks, patients receive the same drug treatment (LHRHa and Apalutamide) while researchers perform genomic sequencing of the tumors. Once the sequencing is complete and for the next eight weeks, each man is assigned to one of four groups based on his lab results. Group 1 includes men whose tumors have no targetable aberrations and are likely to respond well to androgen deprivation therapy, or ADT.

Group 2, on the other hand, is for individuals whose tumor-genetic profile indicates the tumor would have a poor response to ADT. This group gets androgen receptor pathway inhibitor therapy, with or without chemotherapy. Group 3 includes the 6% to 8% of patients whose tumors have DNA-damage response alterations, for example, BRCA genes which are associated with responses to targeted therapies, while Group 4 comprises about 5% of patients who have hypermutated genes that predict for response to immunotherapy.

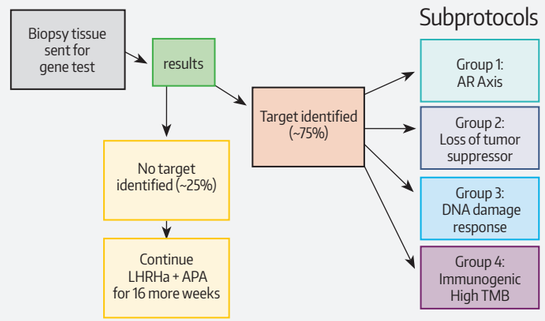
Targeting genomic alterations

After surgery, follow-up testing evaluates how well the gene-specific "neoadjuvant" therapy—a term that refers to the supplemental treatment received before surgery—improved patient outcomes.

By using genomics to understand the diversity of localized prostate cancer and how different subgroups may have variable responses to different treatment regimens, researchers hope to show that treatment can lead to a complete-response rate of at least 20%. (A complete-response rate means that the cancer has disappeared.)

"Neoadjuvant therapies have been slow to reach many cancer patients," said Schweizer. "The challenge was both the time and the cost required for getting a genomic signature. To try to capture 10% of the population in one trial is inefficient and costly. The novel trial design allows us to capture more subtypes, bundle them into one trial, and then do the testing."

Patients in both Canada and the U.S. are participating in the trial, providing researchers with more cases to study and compare. The resulting data will help scientists identify more targeted therapeutic options based on gene mutations, leading to better outcomes for high-risk prostate cancer patients.



GENOMIC UMBRELLA CUSTOMIZED DRUG REGIMEN

All patients receive LHRHa and Apalutamid for eight weeks, followed by customized approach, shown above

LEFT: MICHAEL SCHWEIZER, MD

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Prestigious Prostate Cancer SPORE grant renewed

In 2001, researchers from the Institute for Prostate Cancer Research were awarded a prestigious Specialized Program of Research Excellence (SPORE) grant, one of the most sought-after funding mechanisms available from the National Institutes of Health. Since receiving the award more than two decades ago, we have continued to pursue cutting-edge science, allowing us to reapply and receive funding every five years. Recently, we learned we were awarded $12 million to support new projects for the next five years.

The Pacific Northwest Prostate Cancer SPORE is one of only seven SPORE grants nationwide that focus on prostate cancer. The program was initially started to speed the flow of promising knowledge from the laboratory to the clinic, where it will benefit patients the most. The grant enhances our ongoing efforts to develop pioneering treatments and therapies for prostate cancer as well as better understand the biological basis of prostate cancer clinical behavior.

We've assembled an international team of talented clinical and fundamental research scientists dedicated to translational (bench-to-bedside) research in prostate cancer from the University of Washington, Fred Hutch, University of British Columbia, and Oregon Health and Sciences University. Importantly, we also have the full support of patient advocates who provide critical input from a patient perspective.

We would not have received our first SPORE grant, much less the continuous renewals, without the commitment of our donors. Their generosity gives us the flexibility to launch novel and groundbreaking ideas in the earliest stages before these projects could be considered for this type of federal funding.

Our current SPORE grant supports four primary projects:

1. *Molecular Predictors of Prostate Cancer Progression and Mortality:* Evaluates a panel of new biomarkers that can be assayed through noninvasive tests, assessing their influence on prostate cancer outcomes and delving into risk assessments in ethnic and racial groups disproportionately affected by prostate cancer.

2. *Understanding and Targeting Prostate Cancer Lineage Plasticity:* Uses deep-molecular profiling to characterize subtypes of prostate cancer resistant to typical hormone-directed therapies, then treats patients before surgery in a unique clinical trial to confirm on-target treatment efficacy and assess resistance factors.

3. *Modulating Androgen Receptor Signaling to Enhance Efficacy of CAR T Cell Therapy for Advanced Prostate Cancer:* Uses a highly original immune-system approach involving chimeric antigen receptor (CAR) T cells engineered to recognize a tumor protein called STEAP1. This approach holds high promise since STEAP1 is found on virtually all prostate cancer cells, unlike previous immunotherapy targets.

4. *Clinical Development of Therapeutic Strategies Targeting DNA Repair:* Harnesses an underused aspect of prostate cancer biology in which over-stimulation with testosterone can cause DNA damage and interfere with subsequent DNA repair, making prostate cancer cells susceptible to more conventional therapies.

We are very grateful to our community for its philanthropic support. Our work would not be possible without you.

THANK YOU!

Collaboration that drives impact

If you take away just one thing from reading this report, I hope it's that the Institute for Prostate Cancer Research is built on the belief that when working to eliminate cancer, two is better than one.

That starts, of course, with the collaboration between Fred Hutchinson Cancer Center and UW Medicine that drives this nationally renowned research program's work. In the last 20 years alone, brilliant researchers from those two organizations have worked collectively and continually to develop more effective treatments for patients with prostate cancer and provide them a higher quality of life. In fact, many of the advances made by IPCR scientists, from genomic profiling of patients' tumors to understanding the molecular mechanisms behind their development and progression, have laid the foundation for much broader precision oncology efforts at Fred Hutch.

It's no coincidence that Dr. Pete Nelson has been chosen to lead some of that work at our new Stuart and Molly Sloan Institute for Precision Oncology, which has the potential to benefit countless patients living with any number of different cancers, like breast, colon and multiple myeloma, among others. And that's on top of the tremendous impact IPCR already makes by routinely supplying invaluable tumor samples and biospecimens for prostate cancer research at other institutions around the world.

Progress like this takes more than the combined efforts of two prestigious organizations, though. At its core, lifechanging science is a collaboration between research and care, each fueling the other in a continuous cycle of discovery: Breakthroughs in the lab reach patients much faster, and their response to new treatments informs further exploration. Each patient-centered, patient-fueled project described in these pages is proof of that model's power to accelerate advances.

Above all, though, IPCR's success in helping men with prostate cancer live longer and live better—not to mention its support for their caregivers—is a testament to the program's longstanding, committed partnership with this community. When Dr. Paul Lange and his colleagues launched IPCR more than two decades ago, they recognized that they would need the support of donors who understood the stakes and shared their vision for bringing the community and researchers closer. Along the way, they built a culture of philanthropy that Dr. Dan Lin continues to nourish today.

As IPCR embarks on an ambitious fundraising initiative that will fuel research to drastically improve prostate cancer screening, treatment and prevention, continued support from the community will be crucial to the effort. Because we will always accomplish more together.

Thomas J. Lynch Jr., MD
President and Director
Raisbeck Endowed Chair
Fred Hutchinson Cancer Center

To learn more about the Institute for Prostate Cancer Research or to make a gift, please contact:
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Fred Hutch is an independent, nonprofit organization that also serves as the cancer program for UW Medicine. Our relationship allows for enhanced care coordination between a top-ranked cancer center and a leading integrated health system and accelerates the latest scientific breakthroughs in cancer and other life-threatening diseases.

Fred Hutch is proud to raise funds that fuel the adult oncology program on behalf of both Fred Hutch and UW Medicine.

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THIS REPORT WAS PRODUCED BY UW CREATIVE COMMUNICATIONS FOR THE INSTITUTE FOR PROSTATE CANCER RESEARCH ©2023
PROJECT COORDINATION: AGNES GAWNE • WRITING/EDITING: CIPALLA COMMUNICATIONS INC.
PHOTOGRAPHY: FISCHER WALLACE OF SWAE PHOTOGRAPHY (UNLESS OTHERWISE INDICATED)
DESIGN: JOHN LINSE & JULI RUSSELL, UW CREATIVE COMMUNICATIONS