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ISSUES

This publication is a benefit of membership Association of Community Cancer Centers

Vol. 38 | No. 2 | 2023

## The Hospital of the Future



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### The Hospital of the Future

Industry leaders share perspectives on the near- and long-term transformation of hospitals and health systems. Group consensus was gained around trends like more care will be delivered outside the four walls of the hospital or clinic, most care will be provided in ambulatory settings, and innovative solutions for patient care monitoring, patient engagement, and health promotion will be driven by greater integration of technology.

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### FROM THE EDITOR Bringing Health Equity to the Forefront

#### BY MARK LIU, MHA



s editorin-chief of *Oncology Issues*, I had the privilege of attending the January ACCC Board Retreat to think through the association's strategic plan over the next few years,

including the identification of key priority areas. It is an honor to be part of an organization that is full of innovative healthcare leaders, who are passionate about making a lasting impact in oncology, and it was wonderful to be back together in-person for this retreat. We started off the weekend with a landscape assessment on every part of the association and discussed strategies around advocacy and educational programming. Reflecting on the core values and mission of ACCC, we brainstormed what an ideal future state of oncology could be through small group discussions, pulling ideas together as a full group. We then worked toward identifying an extensive list of potential milestones and goals to keep us on track and accountable over the next few years.

While this was just the start of a year-long strategic planning effort, I am excited for the direction ACCC leadership is envisioning and to be able to share more as the plan is finalized. The topics of diversity, equity, and inclusion, as well as access to care, were a key focus in all our discussions, and I appreciate how committed ACCC is to addressing health disparities in cancer care delivery, clinical trials, and access. In the last few years, it has been impossible to ignore the disparate outcomes of the COVID-19 pandemic, the critical need to address social determinants of health, and how the murder of George Floyd sparked a global movement against racism and intolerance. These tragic events have brought to light the urgency to address systemic racism in our society.

As a diverse healthcare leader, this work is incredibly important to me personally and

professionally. I identify with the LGBTQ+ and Asian communities, and I am also a first-generation American. My own experience gives me greater appreciation for the diversity in the world. Yet, understanding that this is only one perspective, I am working to discover what unintentional biases I may have in how I approach my own work. There is much to learn about other origins of inequalities, ways in which we can address these inequalities, and how to improve the health status of our society. I often think about how diverse—and often underserved—communities navigate an already complicated healthcare system, without yet layering on the serious illness of cancer.

Coming out of the ACCC strategic planning retreat, one goal is to have a future issue of *Oncology Issues* solely dedicated to the important work happening across the country on ways healthcare organizations are approaching diversity, equity, and inclusion, as well as access to care. This hard work needs to happen at the individual and organizational level. If you would like to be involved, email the managing editor of the journal at <u>mmarino@accc-cancer.org</u>. Be a voice for the underserved communities in your area and share how your organization is addressing healthcare disparities and improving equity and access for all.

#### ACCC PRESIDENT'S MESSAGE .....

## Technology and the Ideal Future State of Oncology

BY DAVID R. PENBERTHY, MD, MBA



n February 15, 2023, I hosted my final Tech Talk: "The Impact of Big Data and Artificial Intelligence on Oncology." More than 40 ACCC members attended this live event

to listen and participate in an interactive discussion with our four distinguished panelists: Blythe Adamson, PhD, MPH, principal scientist, Flatiron Health; Rick Baehner, MD, chief medical officer, Precision Oncology, Exact Sciences; John Frownfelter, MD, FACP, lead, Data Driven Healthcare, NTTData; and Sarah McGough, PhD, senior data scientist, Genentech.

Dr. Baehner kicked off our discussion with the role big data plays in cancer diagnostics. As a practicing pathologist, he addressed the need to validate cancer diagnostic assays, like next-generation sequencing, to ensure their usability and efficacy in clinical practice. With the creation of the Oncotype DX Breast Recurrence Score<sup>®</sup>, Dr. Baehner's team completed several clinical validation trials over a 10-year period. Since, this assay has been used for more than 1.5 million people to inform treatment decisions.

Dr. Frownfelter was up next, with new and timely technologies that have enormous potential to positively disrupt the way we deliver healthcare today-from remote patient management (more than patient monitoring) to the digital human and OpenAI's Chat GPT. According to Dr. Frownfelter, the digital human is innovating interactions between humans and technology. "If you combine this [the digital human] and...Chat GPT and generative Al...then you've got an avatar that's interacting in a very human-like way with the data built into it [the avatar] to inform how it responds," Dr. Frownfelter enthused, adding that "the case for health literacy is pretty strong." This technology can help reduce medication errors, hospitalizations, and,

ultimately, mortality because people may be in a better position to receive optimal care when they present to the ED or hospital.

I then passed the baton to Dr. McGough to explain why investment in data and advanced analytics can transform drug development. In using health databases, companies like Genentech are given the big picture of the real-world patient-their clinical history and tumor genomic profile—which informs the development of targeted therapies. "We no longer have to study cancer in silos because these databases contain dozens of different cancer types and tens of thousands of patients," she said. Machine learning helps identify the most important predictors of survival across various cancer types and patient populations. "We can train machine learning models to predict survival using thousands of clinical and genomic variables that we can obtain from patient health records," Dr. McGough said. This technology can risk stratify patient populations and help inform treatment decisions in the clinic.

Wrapping up the day's discussion, Dr. Adamson shared a picture of her team. "Together we are building these large language models that are able to read things in a similar way," she said. Affirming that technology will never fully replace providers, Dr. Adamson shared that technology's role will be to assist providers in quickly identifying the important biomarker a patient may have to inform treatment decisions. To to do so, the ideal future state will require teams of engineers, healthcare professionals, researchers, and more, working together to innovate and fully implement these technologies in the clinic.

If you missed this forward-thinking conversation, listen to the on-demand recording of this Tech Talk at <u>accc-cancer.org/</u> <u>techtalks</u>.

As my 2022-2023 presidency ends, I am proud of the many real-world examples ACCC has shared of its member programs and practices leveraging technology to transform cancer care delivery and the patient experience. I look forward to continuing this journey with you. The future is bright!

#### Coming in Your 2023 ONCOLOGY ISSUES

- Digital Reasoning:
   An Innovative Lung Nodule
   Program
- Simulate and Educate:
   A Nurse-Led Pilot to Enhance
   Patient Education and
   Experience
- Genetic Navigation:
   Improving Patient Outcomes and Identification for Hereditary Cancers
- Chemotherapy Care Companion:
   A Remote Patient Monitoring
   Program
- Expediting Cancer Treatment
   Through a Rapid Access
   APP-Led Diagnostic Clinic
- Deploying Technology Across an Interdisciplinary Team to Improve Oral Oncolytic Compliance
- Interprofessional Collaboration with EHR to Optimize Oncology Navigation Efficiency and Value
- Supportive Oncology in Lung
   Cancer: Program Development
   for Patients and Care Partners
- Comprehensive Cancer Risk Management Clinic for Families with Hereditary Cancer Syndromes
- Coordinating RECIST 1.1: A Community Hospital Perspective
- Therapeutic Art: Transforming Self-Awareness for Those Impacted with Cancer

## \*more online @ accc-cancer.org

#### **ICYMI!** The Impact of Big Data 0 **VIDEO** and Artificial Intelligence on Oncology

A panel of subject matter experts engage in an informal discussion on a wide range of topics, including innovations like the digital human and Chat GPT; multi-cancer early detection and how AI is helping expand this technology; deep learning models for EHR data; and machine learning and how it is impacting the various stages of drug development, particularly in precision medicine. Watch today at accc-cancer.org/ techtalks.

#### How to Make the Pharmacy Your WEBINAR | Prior Authorization Ally

Learn how your pharmacy team can help support obtaining prior authorizations, navigating biosimilar changes, and addressing medical necessity. Learn more at accc-cancer.org/ prior-authorization-ally.



#### **Combatting Healthcare Workforce Issues with Proven Leadership Skills**

Lean in on leadership actions that are validated to support organizational success, including clear, frequent communication; employee development; and support of employees' wellbeing. Read more at accc-cancer.org/proven-leadership-skills.

**Milestone Episode of CANCER BUZZ PODCAST** To celebrate its 100th episode, CANCER BUZZ talks to ACCC Board Member and Treasurer Dr. Nadine Barrett about her journey with the Association. Plus, Dr. Barrett shares how ACCC is helping improve diversity, equity, and inclusion efforts in our cancer programs and practices nationwide and in patient care. accc-cancer.org/episode100.

#### Measurable Residual Disease Testing: PUBLICATION Integration Pathway

Two cancer programs pilot a roadmap through activities like identifying stakeholders involved in measurable residual disease testing; reviewing current testing methods and infrastructure; identifying associated testing costs and patient financial responsibilities; creating algorithms and processes; and identifying opportunities to improve education, communication, and coordination between providers and departments. Read online at accc-cancer.org/mrd-testing-pathway.



### A Snapshot of Health **Insurance Knowledge**

In this Harris Poll survey of more than 1,000 employed American adults:

72% wish someone could tell them the best health insurance option, while 44%

feel uncomfortable asking their HR representative questions about health insurance enrollment, and **47%** call their friends or family members for help when enrolling in health insurance.

- 62% do not change their health insurance selections year over year because it's too stressful, and nearly half (49%) feel pressure to select the most expensive health insurance option to ensure they have necessary coverage.
- **78%** say that having health insurance that meets their specific needs is important to them when looking for a new job, and 64% would be willing to sacrifice some pay for better health insurance. In addition, 63% say that their company's health insurance offerings impact how much they want to keep working there.

Source: Just Works. 2022 Health Insurance Knowledge Snapshot. justworks.com/lp/ benefits-knowledge-snapshot.

#### Latest Cancer Stats-Good News, Bad News

- Overall cancer mortality continues to decline, with a **33%** drop since 1991
- Women aged 20 to 24-the first group of women to receive the HPV vaccine-experienced a 65% from reduction in cervical cancer rates from 2012 to 2019.
- Data reveal an increase in diagnosis of advanced prostate cancer among men, with the highest incidence and mortality in Black men.
- Since 2011, the diagnosis of advanced-stage prostate cancer has increased by 4% to 5% annually.
- The incidence of prostate cancer in Black men is **70%** higher than in White men; prostate cancer mortality rates in Black men are approximately 2 to 4 times higher than those in every other racial and ethnic group.

Source. American Cancer Society. Cancer Facts & Figures, 2023. acsjournals.onlinelibrary.wiley. com/doi/full/10.3322/caac.21763

# facts

### Report Highlights Healthcare Challenges Facing the LGBTQI+ Community

- Transgender individuals face unique obstacles to accessing healthcare, including **1** in **3** who had to teach their doctor about transgender individuals to receive appropriate care.
- Around **3** in **10** LGBTQ+ Americans faced difficulties last year accessing necessary medical care due to cost issues, including more than half of transgender Americans.
- **15%** of LGBTQ+ Americans report postponing or avoiding medical treatment due to discrimination, including nearly 3 in 10 transgender individuals.

Source. Center for American Progress. The State of the LGBTQ Community in 2020. americanprogress.org/article/state-lgbtq-community-2020.



#### Higher Out-of-Pocket Patient Bills Hitting Hospitals Hard

According to data gathered by the Crowe Revenue Cycle Analytics software, hospital collection rates drop significantly when the patient portion reaches a balance of **\$7,500**. Other insights gleaned from this data:

- Total patient statements with balances of more than \$7,500 have more than tripled in the last three years, from 5.2% in 2018 to 17.7% in 2021.
- 2021 was the first time self-pay-after-insurance accounts were the leading source of bad debt, accounting for 57.6% of patient bad debt, compared to 11.1% in 2018.
- The percentage of patients with health insurance who paid their out-of-pocket bill dropped from 76% in 2020 to 54.8% in 2021.
- In 2021, the self-pay-after-insurance collection rate for claims between \$5,000 and \$7,500 was 32% and 17% for claims between \$7,501 to \$10,000.
- Patient statements with balances greater than \$14,000 nearly quadrupled from 4.4% in 2018 to 16.8% in 2021.

Source. Crowe Revenue Cycle Analytics. Hospital Collection Rates for Self-Pay Patient Accounts. crowe.com/-/media/crowe/llp/widen-media-files-folder/h/hospital-collection-rates-for-self-paypatient-accounts-report-chc2305-001a.pdf.



## Physician Burnout & Depression on the Rise

- Last year, 53% of physicians reported burnout—an 11% jump from 2018, when 42% of physicians said they were burned out.
- In Medscape's 2018 report, **15%** of physicians reported they had depression, compared to **23%** in 2022.
- Emergency medicine specialists had the highest rate of burnout at 65%, compared to oncology at 52%.
- The top 3 factors of physician burnout were the same pre- and post-COVID-19; in the 2022 report, 61% cited too many bureaucratic tasks, 38% cited lack of respect from co-workers, and 37% cited too many work hours.

Source. The Medscape Physician Burnout & Depression Report 2023. <u>medscape.com</u>.

# issues

## States Poised to Continue Banning Co-Pay Accumulators in 2023

BY MATT DEVINO, MPH



he last several years have seen a marked increase in state and federal policy seeking to address the cost and affordability of prescription drugs. One area of particular interest to state legislatures in 2021, 2022, and again in 2023 are co-pay accumulators.

A co-pay accumulator—or co-pay accumulator adjustment program—is a strategy used by health plans and pharmacy benefit managers (PBMs) that prevents manufacturer-based co-pay assistance programs and cards from counting toward two patient costs: their deductible and maximum out-of-pocket amount. Although pharmaceutical manufacturers attempt to create programs to subsidize out-of-pocket prescription drug costs for patients, health plans reduce the value of these programs by exhausting such funds, while also requiring patients to pay their full deductible and coinsurance (up to their out-of-pocket maximum) in order to obtain their medication(s).

Co-pay accumulator adjustment programs, in effect, extend the amount of time it takes for a patient to reach their deductible and/or out-of-pocket maximum, thereby reducing the plan sponsor's coverage until such cost-sharing is met. The only party that benefits from the co-pay accumulator model is the health plan, as they can collect both the manufacturerprovided co-pay assistance and the patients' full deductible or out-of-pocket limit. Patients, on the other hand, who manufacturers intend to provide benefit to from their co-pay assistance programs, instead see no savings at the pharmacy counter.

## What are States Doing About Co-Pay Accumulators?

Following two significant policy changes at the federal level, state governments are empowered to start challenging stateregulated health plans and banning co-pay accumulator adjustment programs. The first of these changes was a Centers for Medicare & Medicaid Services (CMS) final rule, issued in May 2020, that expressly allowed the use of co-pay accumulator programs. The 2021 Notice of Benefit and Payment Parameters final rule established that health plans and PBMs need not count toward a patient's annual deductible or cost-sharing limit "for specific prescription brand drugs that have an available and medically appropriate generic equivalent" to the extent consistent with applicable state laws.1

Later in December 2020, the United States Supreme Court ruled in Rutledge v. Pharmaceutical Care Management Association (PCMA) that the Employee Retirement Income Security Act (ERISA) did not preempt Arkansas state law regulating PBMs and prohibiting the use of co-pay accumulator adjustment programs.<sup>2</sup> This decision had an immediate impact on states' ability to regulate health plan benefits and PBMs specifically, therefore, increasing the amount of power states have to impact drug costs.

As a result of this activity in 2020, many states have endeavored to pass legislation banning co-pay accumulators in stateregulated health plans and PBMs, ensuring that manufacturer-based co-pay assistance is counted toward patients' cost-sharing limits. As of January 2023, 16 states and Puerto Rico have passed legislation banning state-regulated payer and PBM use of co-pay accumulator adjustment programs, including Arizona, Arkansas, Connecticut, Delaware, Georgia, Illinois, Kentucky, Louisiana, Maine, New York, North Carolina, Oklahoma, Tennessee, Virginia, Washington, and West Virginia.

According to Avalere, at least 13 percent of Americans enrolled in the U.S. commercial insurance market will belong to a health plan that must count co-pay assistance toward patient cost sharing by 2024.<sup>3</sup> Similar legislation banning co-pay accumulator programs has been introduced in a large number of other states, including Florida, Massachusetts, Michigan, Mississippi, New Mexico, Ohio, Oregon, Pennsylvania, Utah, Texas, Wisconsin, and D.C., and efforts to pass these laws will likely continue in 2023.

#### What is the Federal Government Doing About Co-Pay Accumulators?

The federal government has been slower in rolling back its 2020 decision to permit the use of co-pay accumulators. However, over the course of 2022, as drug pricing and the regulation of PBMs gained national attention, several policy proposals were announced by federal agencies and members of Congress.

In February 2022, the Federal Trade Commission (FTC) announced a request for information, soliciting public comments on PBM business practices that affect drug affordability and access, including contract terms, rebates, fees, pricing policies, steering methods, conflicts of interest, and consolidation.<sup>4</sup> In response to more than 24,000 public comments received, the FTC voted unanimously in June to launch an inquiry into the PBM industry and send compulsory orders to six of the largest PBMs in the country: CVS Caremark, Express Scripts, OptumRx, Humana, Prime Therapeutics, and MedImpact Healthcare Systems.<sup>5</sup>

At the same time, Senators Chuck Grassley (R-IA) and Maria Cantwell (D-WA) introduced legislation in May 2022 to empower the FTC to increase drug pricing transparency and hold PBMs accountable for unfair and deceptive practices that drive up the costs of prescription drugs at the expense of consumers.<sup>6</sup> While this legislation was favorably advanced by the Senate Committee on Commerce with a full Senate vote, it ultimately did not pass in the 2022 legislative session.

An additional piece of legislation was introduced in November 2021 by U.S. Representatives Rodney Davis (R-IL) and Donald McEachin (D-VA) to explicitly regulate the use of co-pay accumulators at the national level. The Help Ensure Lower Patient (HELP) Copays Act would require health plans to apply certain payments made by, or on behalf of, a plan enrollee toward a plan's cost-sharing requirements, thereby nullifying the impact of co-pay accumulator adjustment programs.<sup>7</sup> While this bill gained bipartisan support and endorsement by many provider and patient advocacy organizations, including ACCC, it also did not pass during the 2022 legislative session.

Sadly, bill sponsor Rep. McEachin passed away in late November 2022, following his own courageous battle with cancer. However, his former colleagues have taken up this issue, as a new co-pay accumulator bill has now been introduced in the 118th Congress. The new bill, which is again a bipartisan effort called the: <u>Help Ensure</u> <u>Lower Patient (HELP) Copays Act</u> (H.R. 830), was introduced by Representatives Earl L. "Buddy" Carter (R-GA), Nanette Barragán (D-CA), Mariannette Miller-Meeks (R-IA), and Diana DeGette (D-CO).\* Matt Devino, MPH, is the former director of Cancer Care Delivery and Health Policy at ACCC.

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# compliance

## Update Your Processes for Reporting Single-Dose Container Waste for 2023

TERI BEDARD, RT(R)(T), CPC

Since Jan. 1, 2017, the Centers for Medicare & Medicaid Services (CMS) has used a modifier on claims forms across all Medicare jurisdictions to reimburse providers for Medicare Part B drug and biological waste from single-use containers. The agency codified the requirement for all providers to report single-dose container waste with **modifier** JW (drug amount discarded/not administered to any patient) for those paid under Medicare Part B, along with documentation of the waste in the medical record.'

## What is Meant by Single-Use Container?

It is important for providers to understand that the definition of a single-use container (vial or package) varies based on the context, but the two definitions below are relatable to each other.

- The Centers for Disease Control & Prevention (CDC) defines single-use vials as: "A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/ procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative."<sup>2</sup>
- CMS defines a refundable single-dose container as applying to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a singledose container or single-use package based on FDA-approved labeling or

product information. This definition also includes drugs described in FDA-approved labeling as a 'kit' that is intended for a single dose or single use.<sup>3</sup>

#### A Change in Policy

While CMS has been paying for the discarded amount from a single-dose container, the Infrastructure Investment and Jobs Act changed this policy.<sup>4</sup> Even though providers do their best to ensure drugs are administered correctly per package inserts, State law, and regulatory guidelines, there are still instances when the remaining portion of a single-dose container must be discarded.

For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Issues arise when the single- dose container is sized based on an average BSA that is inaccurate because it is years old. The body mass index (BMI) number of the United States population has continued to increase. According to the National Health and Nutrition Examination Survey 2021, adult obesity increased from 30.5 percent to 41.9 percent from 1999 through 2017.5 If established singledose containers have not accounted for this increase in the national obesity rate, providers may need to administer the necessary dose from one full container and a portion of another container.

Other single-dose containers are sized more than the average BSA. If a manufacturer were to have a single-dose container that exceeded the directed dosing—or average patient size—it could result in the provider wasting a considerable amount of the drug as required by packaging or regulation, because the sizing does not correlate to the desired population.

According to CMS, 2020 claims data show payments of nearly \$720 million for discarded drug amounts billed with **modifier JW**, under Part B, for single-dose vials or single-dose packages. These payment amounts track with the yearly totals in 2017 to 2019, which ranged from approximately \$700 million to \$750 million each year. Based on these data, CMS questioned if it is the agency's responsibility to make payment for discarded drugs if manufacturer packaging is helping to create these issues.

Section 90004 of the Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.<sup>4</sup> The refund amount is the amount of the discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. CMS clarified that refundable single-dose vials or single-dose packages do not include radiopharmaceuticals, imaging agents, certain drugs requiring filtration, and specifically identified new drugs. With this policy shift, while providers will continue to be paid for the discarded amount as identified on the claim with **modifier JW**, the monies will be paid by manufacturers to CMS who will then pass on payments to providers.

This shift of payment responsibility for discarded drugs from CMS to drug manufacturers has the potential to change the size of available single-dose containers. If manufacturers are now responsible for paying for discarded drugs, the expectation is that manufacturers will change single-dose containers to more closely reflect appropriate sizing, if they do not already.

It is important that providers appropriately report for waste of single-dose containers with the appropriate modifier. When providers do not report **modifier JW** on the claim form line with the Healthcare Common Procedure Coding System (HCPCS) codes and amount of waste, appropriate payment may not be received (or calculated) and container sizes may not be adjusted.

#### **Billing Scenarios**

CMS does specify that the billing for drug waste must coincide with the smallest vial size available. Specifically, it is not appropriate to bill for a larger amount of waste due to the stocking or availability of larger vial sizes when smaller options are available. MLN Matters<sup>®</sup> SE1316, issued Aug. 1, 2013, states, "The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient."<sup>6</sup>

An example of proper reporting of **modifier JW** would be the following: Code **J9035** represents Avastin<sup>®</sup> (bevacizumab),<sup>1</sup> unit per 10 mg. If a patient is given 980 mg from two 400 mg and two 100 mg single use vials (total 1,000 mg), and the remainder of the last vial is discarded (20 mg), the provider should report the following:

- J9035 x 98 units (administered 980 mg)
- J9035-JW x 2 units (wasted 20 mg)

Modifier JW is only applied to the amount of drug or biological discarded. Modifier JW would not be reported when the actual dose of the drug or biological administered is less than the billing unit. CMS also states modifier JW should not be used "if the billing unit is equal to or greater than the total actual dose and the amount discarded."

For example, in medical oncology, it is common for 25 mg of Benadryl<sup>®</sup> (diphenhydramine), which is supplied in a 50 mg single dose vial, to be administered prior to chemotherapy. In this scenario, 25 mg is not used and will be wasted; however, as one unit of Benadryl equals 50 mg, no waste would be reported. Since one unit of the code is equal to the total amount administered plus the amount discarded, the provider will bill one unit of code J1200 and the **modifier JW** will not be applied.

In the 2023 Medicare Physician Fee Schedule final rule, CMS indicated that hospital outpatient departments are required to report **modifier JW**, or any successor modifier, to identify discarded drug amounts from single-dose containers described by HCPCS codes assigned status indicator (SI) "K" (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals) or SI "G" (pass-through drugs and biologicals) under the Hospital Outpatient Prospective Payment System (HOPPS).<sup>1</sup> Regardless of whether the drug is assigned pass-through status, **modifier JW** is reported when there is any discarded amount from the single-dose container.

**Modifier JW** would not be used for drugs that are not separately payable, such as packaged drugs administered in outpatient hospitals or ambulatory surgical centers, federally qualified health centers, or rural health clinics. In addition, CMS has excluded from refund any amount of drug units where payment is packaged into a comprehensive ambulatory payment classification (C-APC) service in an outpatient hospital.

#### **Creating a New Modifier**

Concerns about missed reporting when there is drug waste with single-dose containers coupled with the lack of data since **modifier JW** began led CMS to create a new modifier: **modifier JZ**. Providers will use this modifier to attest that there was no discarded amount from the single-dose container paid under Part B. CMS believes that this change will ensure that providers apply a modifier—regardless of whether or not there was drug waste. Use of **modifier JZ** will begin July 1, 2023, to allow providers time to update software and implement processes to ensure appropriate use of the new modifier. Starting in July and for the remainder of 2023, providers should use the following modifiers for singledose containers not excluded from drug waste reporting:

- JW: Drug amount discarded/not administered to any patient
- **JZ:** Zero drug amount discarded/not administered to any patient.

It is important that all providers are aware of these new guidelines regarding reporting of drug waste from single-dose containers. Historically, if a provider did not report **modifier JW** when there was waste from a single-dose container, they were still paid the full amount of the container. Whether it was split or a single-line item on the claim, the total was the same and the amount paid did not vary. Beginning Oct. 1, 2023, Medicare will deny all claims for single-dose containers that do not include **modifier JW** or **modifier JZ**.

CMS has also created a requirement for Medicare Administrative Contractors (MACs) to institute periodic audits of Part B claims to ensure billing and documentation are correct and billed appropriately.

#### **Proactive Steps for Providers**

Providers should identify the single-dose containers that are currently part of their treatment regimens and formularies and then audit their documentation and billing to identify any potential compliance issues and areas for improvement. Additionally, education for the staff responsible for coding and billing provider documentation should be conducted to ensure that these staff understand when modifiers are required and when they are excluded.

Drug payment programs and drug pricing have been a focus of CMS and Congress for many years. CMS is likely to adjust singledose drug waste reporting and payment as these changes are fully implemented and manufacturers begin issuing required refunds. Providers need to understand the key to success and appropriate payment for drugs begins in their court with:

- Appropriate selection of single-dose containers for treatment and management of patients
- 2. Accurate documentation

#### Table 1. CMS Guidelines on Use of Modifiers for Reporting Single-Dose Container Waste in 2023

	PHYSICIAN OFFICE BASED-SETTINGS	OUTPATIENT HOSPITAL- BASED DEPARTMENTS SETTINGS	
MODIFIER JW			
Report for single-dose container waste	January 1, 2023	January 1, 2023	
Report for waste on single-dose containers with HCPCS codes assigned non-pass-through and pass-through status indicators (SI) "K" or "G"	N/A	January 1, 2023	
Drugs supplied via multi-use containers	Excluded	Excluded	
Report for single-dose container wast Radiopharmaceuticals, imaging agents, and drugs requiring filtration during the drug preparation process	Excluded	Excluded	
New drugs after 11/15/21 and paid less than 18 months	Excluded	Excluded	
Packaged drugs in hospital setting	N/A	Excluded	
Single-dose containers packaged into comprehensive ambulatory payment classifications (C-APCs), includes SI "K" drugs when administered in conjunction with C-APC	N/A Excluded		
MODIFIER JZ			
Report attesting no discarded amount from single-dose container paid under Medicare Part B and would have required modifier JW if there was waste	July 1, 2023	July 1, 2023	
Drugs supplied via multi-use containers	Excluded	Excluded	
Radiopharmaceuticals, imaging agents, drugs requiring filtration during the drug preparation process	Excluded	Excluded	
New drugs after 11/15/21 and paid less than 18 months	Excluded	Excluded	
MODIFIER JW AND JZ			
Claims denied if modifier JW or JZ is missing from single-dose container claims	October 1, 2023	October 1, 2023	
Periodic audits by MACs of Part B claims ensure modifiers JW, JZ, discarded drug amounts billed correctly	Included	Included	

3. Accurate billing of the HCPCS code for the included single-dose containers.

To assist providers in these efforts, Table 1, above, provides a summary of the CMS guidelines surrounding use of modifiers for reporting single-dose container waste in 2023.

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 Medicaid programs; CY 2023 payment policies
 under the physician fee schedule and other
 changes to part B payment and coverage policies;
 Medicare Shared Savings Program requirements;

implementing requirements for manufacturers of certain single-dose container or single-use package drugs to provide refunds with respect to discarded amounts; and COVID-19 interim final rules. Published November 18, 2022. Accessed February 22, 2023. https://www.federalregister. gov/documents/2022/11/18/2022-23873/ medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-scheduleand-other

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# tools



#### **Approved Drugs**

- On December 16, the U.S. Food and Drug Administration (FDA) approved Adstiladrin<sup>®</sup> (nadofaragene firadenovec-vncg) (Ferring Pharmaceuticals, ferring.com) for adult patients with high-risk, Bacillus Calmette-Guérin unresponsive, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors.
- On January 19, the FDA approved Brukinsa<sup>®</sup> (zanubrutinib) (BeiGene, beigene.com) for the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma.
- On December 16, the FDA approved the targeted imaging agent Cytalux<sup>®</sup> (pafolacianine) (On Target Laboratories, <u>ontargetlabs.com</u>) for use in lung cancer surgery.
- On January 27, the FDA granted accelerated approval to Jaypirca<sup>®</sup> (pirtobrutinib) (Eli Lilly and Company, lilly.com) for the treatment of relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor.
- On January 26, the FDA approved Keytruda<sup>®</sup> (pembrolizumab) (Merck, merck.com) for adjuvant treatment following resection and platinum-based chemotherapy for Stages IB (T2a ≥4 cm), II, or IIIA non-small cell lung cancer (NSCLC).

- On December 12, the FDA granted accelerated approval to Krazati<sup>®</sup> (adagrasib) (Mirati Therapeutics, mirati.com) for the treatment of adult patients with KRAS-G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy.
- On December 22, the FDA granted accelerated approval to Lunsumio<sup>™</sup> (mosunetuzumab-axgb) (Genentech, gene.com) for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.
- On January 27, the FDA approved
   Orserdu™ (elacestrant) (Stemline Therapeutics, stemline.com) for the treatment of postmenopausal women or adult men with ER-positive, HER2negative, ESR1-mutated advanced or metastatic breast cancer, with disease progression following at least one line of endocrine therapy.
- On December 19, Eagle Pharmaceuticals (eagleus.com) announced that the FDA approved an additional indication for Pemfexy<sup>®</sup> (pemetrexed injection) in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic, non-squamous,

metastatic, non-squamous, NSCLS with no EGFR or ALK genomic tumor aberrations.

- On December 1, the FDA approved **Rezlidhia® (olutasidenib)** (Rigel Pharmaceuticals, rigel.com) for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible IDH1 mutation, as detected by an FDA-approved test.
- On December 9, the FDA approved
   Tecentriq<sup>®</sup> (atezolizumab) (Genentech, gene.com) for the treatment of adult and pediatric patients (2 years of age and older) with unresectable or metastatic alveolar soft part sarcoma.
- On February 3, the FDA approved Trodelvy® (sacituzumab govitecan-hziy) (Gilead Sciences, gilead.com) for the treatment of patients with unresectable, locally advanced or metastatic, HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer, who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.
- On January 19, the FDA granted accelerated approval to Tukysa® (tucatinib) (Seagen, seagen.com) in combination with trastuzumab for the treatment of RAS wild-type, HER2-positive, unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecanbased chemotherapy.

 On December 14, the FDA approved the updated labeling for Xeloda<sup>®</sup> (capecitabine) tablets (Genentech, gene.com).

#### **Drugs In the News**

- Mirati Therapeutics (mirati.com) announced that the FDA granted breakthrough therapy designation to adagrasib in combination with cetuximab for the treatment of patients with KRASG12C-mutated, advanced colorectal cancer, whose cancer has progressed following prior treatment with chemotherapy and an anti-VEGF therapy.
- Blueprint Medicines (<u>blueprintmedicines</u>, <u>com</u>) announced that the FDA accepted the supplemental new drug application for **Ayvakit® (avapritinib)** for the treatment of adults with indolent systemic mastocytosis.
- Bicycle Therapeutics (bicycletherapeutics.com) announced that the FDA granted fast track designation to BT8009 to treat adult patients with previously treated locally advanced or metastatic urothelial cancer.
- Checkpoint Therapeutics (<u>checkpointtx.</u> <u>com</u>) announced the submission of a biologics license application (BLA) to the FDA for the approval of **cosibelimab** as a treatment for patients with metastatic cutaneous or locally advanced squamous cell carcinoma, who are not candidates for curative surgery or radiation.
- Genentech (gene.com) announced that the FDA accepted and granted priority review to the BLA for glofitamab to treat people with relapsed or refractory large B-Cell lymphoma.
- Seagen (seagen.com), Astellas Pharma (<u>https://www.astellas.com/us/</u>), and Merck (merck.com) announced that the FDA accepted for priority review the

supplemental BLAs for **Padcev®** (enfortumab vedotin-ejfv) and Keytruda for the use of these two agents in combination for the treatment of patients with locally advanced or metastatic urothelial cancer, who are not eligible to receive cisplatin-containing chemotherapy.

- Fennec Pharmaceuticals (fennecpharma. com) announced that the FDA granted orphan drug exclusivity to Pedmark<sup>®</sup> (sodium thiosulfate) to reduce the risk of ototoxicity, or hearing loss, associated with cisplatin use in pediatric patients one month of age and older with localized, non-metastatic solid tumors.
- Mesoblast Limited (mesoblast.com) announced that it resubmitted to the FDA a BLA for remestemcel-L for the treatment of children with steroidrefractory, acute graft-versus-host disease.
- Syndax Pharmaceuticals (<u>syndax.com</u>) announced that the FDA granted breakthrough therapy designation to **revumenib** for the treatment of adult and pediatric patients with relapsed or refractory acute leukemia harboring a KMT2A rearrangement.
- Janssen (janssen.com) announced the submission of a BLA to the FDA for talquetamab for the treatment of patients with relapsed or refractory multiple myeloma.
- Syros Pharmaceuticals (syros.com) announced that the FDA granted fast track designation to tamibarotene (formerly SY-1425) for the treatment of higher-risk myelodysplastic syndrome.

#### **Devices and Assays in the News**

 Geneoscopy (<u>geneoscopy.com</u>) announced that it submitted a premarket approval application to the FDA for its non-invasive, stool-based, at-home screening test to detect colorectal cancer and advanced adenomas in average-risk individuals.

- Agilent Technologies (<u>agilent.com</u>) announced that the FDA approved Agilent Resolution ctDx FIRST as a companion diagnostic to identify patients with advanced NSCLC with KRAS G12C mutations who may benefit from treatment with Krazati™ (adagrasib).
- Foundation Medicine (foundationmedicine.com) announced that the FDA approved the FoundationOne®Liquid **CDx** as a companion diagnostic to identify patients with ROS1-positive NSCLC or patients with NTRK fusion-positive solid tumors, who do not have a tissue sample available and may be appropriate for treatment with Rozlytrek<sup>®</sup> (entrectinib) (Genentech, <u>gene.com</u>). This device was also approved by the FDA as companion diagnostic to identify patients with NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitutions and are appropriate for treatment with a group of current and future EGFR tyrosine kinase inhibitors (TKI) approved by the FDA for this indication.
- Guardant Health (guardanthealth.com) announced that the FDA approved the Guardant360<sup>®</sup> CDx liquid biopsy test as a companion diagnostic to identify individuals with advanced or metastatic breast cancer with ESR1 mutations who may benefit from treatment with Orserdu.
- Burning Rock (<u>us.brbiotech.com</u>) announced that the FDA granted breakthrough device designation to its **OverC™ Multi-Cancer Detection Blood Test.**
- Datar Cancer Genetics (<u>datarpgx.com</u>) announced that the FDA granted breakthrough device designation to **TriNetra™-Glio**, a blood test to help in the diagnosis of brain tumors.

# spotlight

## **CoxHealth, Hulston Cancer Center** Springfield, Missouri

oxHealth, Hulston Cancer Center was the first approved community hospital comprehensive cancer program in Springfield, Mo.—providing multidisciplinary care to more than one million patients across 22 counties. The cancer center and its satellite location offer radiation and medical oncology services to patients in its communities, in addition to infusion services. CoxHealth, Hulston Cancer Center is accredited by the American College of Surgeons and the American College of Radiology.

In describing the vision for the oncology service line, Abe Abdalla, MD, medical director for Oncology Services at CoxHealth, said, "Our vision is to provide comprehensive, compassionate, convenient, and state-of-the-art cancer care to our patients." Missouri is commonly referred to as the "show me state," and in true Missouri fashion, CoxHealth, Hulston Cancer Center does not simply talk about that vision, it shows this to each patient who presents to the cancer center.

While an expansive catchment area can pose a significant logistical challenge for most cancer programs in the United States, Hulston Cancer Center staff must overcome a greater hurdle: smoking. At \$0.17 per pack of 20 cigarettes, Missouri has the lowest cigarette tax in the U.S.—an amount much lower than the national average of \$2.14.<sup>12</sup> "There is sufficient data that establishes a direct correlation between tobacco tax and tobacco usage," said Ben Morris, assistant director at the Branson Cancer Center, the sole satellite location for Hulston Cancer Center. Due to the prevalence of smoking in Missouri, the cancer center provides care to a high number of patients with lung cancer. To ensure that these patients receive comprehensive, equitable, and quality care, Hulston Cancer Center leadership ensured a lung cancer navigation program was one of the first incorporated into its service line. This navigation program has since expanded, exemplifying a commitment to delivering state-of-the-art cancer care to patients, including construction of a new infusion center at Hulston Cancer Center.

#### **Delivering Patient-Centered Care**

"A year ago, we moved into our new infusion center to accommodate a growing patient population," said Michelle Jackson, nurse manager of outpatient oncology at CoxHealth, Hulston Cancer Center. "We took input from staff and patients. The patients wanted more bathrooms, more natural light, and their own television. They did not want to feel like they were in a hospital." While the new infusion center at Hulston Cancer Center was in the design process, 15 patients had the chance to look at the architectural designs and provide feedback before construction began. According to staff, each patient was committed to helping CoxHealth make a better infusion center that met patient and the staff needs.

Situated on the second floor of Hulston Cancer Center, the infusion center houses 35 infusion bays, each equipped with recliners, a curtain for patient privacy, and a chair for a caregiver. Five private rooms are available, two of which are negative air flow rooms for immunocompromised



patients. The infusion center is staffed by 9 to 10 chemotherapy-credentialed registered nurses each day. In addition, three certified nurse assistants help with patient care.

"Our full-service pharmacy is centrally located on the second floor, so we have direct access to the three dedicated mixing pharmacists," Jackson explained. These pharmacists can also complete rounds, making connections with patients during treatment and helping with any concerns they may have.

Additionally, the infusion center now includes a hope and healing garden—a space of which Jeff Robinson, assistant director of radiation at CoxHealth, Hulston Cancer Center is proud. "If anybody is going to use it more so, it would be infusion patients, who are required to be there for hours at a time," he said.

Robinson describes the infusion center as completely oriented to patients and staff. "Everybody needs to be in a good space," he said. "It has helped the morale of staff and brightened the patient's perspective."

#### **A Robust Service Line**

Robinson also considers the adaptive radiation therapy services the cancer center offers as a major accomplishment. Radiation therapy staff include two radiation oncologists, eight radiation therapists, four physicists, three dosimetrists, four oncology certified registered nurses, and several welcoming support staff. Also offered is SRS, SBRT, IMRT, IGRT, Prostate Seed and breast and gynecological HDR brachytherapy services.





The Gynecological Oncology Clinic is located on the seventh floor of Hulston Cancer Center and houses the practice of three gynecologic oncologists and one nurse practitioner. CoxHealth hematology and medical oncology, also located at the Hulston Cancer Center, is home to three medical oncologists, a nurse practitioner, a physician assistant, four nurses, seven certified medical assistants, one medical lab technician, and six medical secretaries. Providers are full-time and employed by CoxHealth, Hulston Cancer Center—as are the two physicians located at the Branson Cancer Center.

Located 35 miles south of Springfield is the Branson Cancer Center, which opened in 2008. Here, patients can access medical and radiation oncology services, as well as oncology and non-oncology infusion services close to home. This cancer center is staffed by a radiation oncology physician, a medical oncology physician, three radiation therapists, a dosimetrist, a physicist, and several registered nurses, as well as office support staff. Branson Cancer Center includes 10 chairs in its infusion center and 1 private room for patients. A dedicated pharmacy is embedded in the infusion center and is staffed by nine registered nurses. The primary difference between both CoxHealth cancer centers are the subspecialties, such as neurosurgery, surgical oncology, and colorectal surgery, which patients can access only in Springfield.

## Patient Advocacy, Navigation, and Support Services

The advocacy program at CoxHealth,

Hulston Cancer Center owes its origin to an endowment received in 2002. "At that time, this [patient advocacy] was all kind of new, and we had some donors that were interested in making our cancer program cutting edge," said Autumn Bragg, oncology manager at CoxHealth. Hulston Cancer Center. "We were able to staff two full-time patient advocates solely through that fund." Since then, the advocacy program has grown to include five patient advocates, all of whom are social workers. Four are located at Hulston Cancer Center and one at Branson Cancer Center. "Our patient advocates focus on the logistical barriers to treatment that patients may encounter," Bragg said. They can assist patients with issues related to transportation, lodging, and treatment-related costs.

The cancer center also employs five nurse navigators—four of whom service Hulston Cancer Center. Three of these nurse navigators are dedicated to a specific disease—gynecologic; gastrointestinal; and lung, head, and neck cancers—with the final nurse navigator serving a general role to assist all other patients. The single nurse navigator at Branson Cancer Center serves a general role, dedicated to any patients seen at this location.

Hulston Cancer Center employs a parttime dietitian who receives patients through physician referrals. "The dietitian does a lot in tube feeding education—making sure that patients, who have feeding tubes, understand how to feed themselves," Bragg explained. In addition, patients can access genetic counseling services, pastoral care, and pet therapy. "The latter is hugely popular," Bragg said. "Our patients and staff love it."

#### **Clinical Research**

While many rural cancer programs struggle to offer clinical trial opportunities to patients, CoxHealth, Hulston Cancer Center has made this a priority in delivering high-quality, comprehensive cancer care. Its center for research allows patients to enroll in pharmaceutical trials for gynecologic, medical, and radiation oncology studies. This center is part of the CoxHealth healthcare system and consists of a director and four oncology-dedicated staff. Another research arm of CoxHealth is the Cancer Research for the Ozarks. This National Cancer Institute (NCI) Community Oncology Research Program is rooted in the spirit of collaboration with other health systems in southwest Missouri. It works to bring cancer clinical trials to patients who present to the cancer center by adopting evidence-based practices that contribute to improving patient outcomes and addressing health disparities.

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# The Hospital of the Future



uring a recent virtual briefing on the Hospital of the Future hosted by Modern Healthcare, industry leaders shared perspectives on the near- and long-term transformation of hospitals and health systems. "Hospital of the future is really a metaphor for healthcare of the future," said featured speaker Richard Zane, MD, chief innovation officer UCHealth, Colorado Health. Across the board, these stakeholders agreed that tomorrow's hospitals will be "smarter," more "connected," and will better leverage technology to expand access to care, improve operational and clinical efficiency, support sustainability, and advance health equity.

Among the speakers, there was consensus that in coming years more care will be delivered outside the four walls of the hospital or clinic, most care will be provided in ambulatory settings, and innovative solutions for patient care monitoring, patient engagement, and health promotion will be driven by greater integration of technology. "We actually used to say that the hospital was the center of the healthcare universe," said opening keynote speaker Robert Garrett, CEO, Hackensack Meridian Health. "Today, one could say it's the cell phone."

Garrett's remarks centered around four major strategies that will be vital to health systems in the future:

- Expanding access and innovating care
- Advancing health equity
- Building a workforce for the future
- Reinventing medical education to align with future healthcare needs

"The only way for future healthcare to survive and grow is that we must partner with machines."

RICHARD ZANE, MD, CHIEF INNOVATION OFFICER, UCHEALTH, COLORADO HEALTH

Hackensack Meridian Health, headquartered in New Jersey, is a large, integrated health network with 18 hospitals, 500 patient care locations, 7,000 affiliated physicians, and 36,000 team members. Hackensack Meridian Health is already deploying advanced technology to address challenges in each of four strategic areas cited by Garrett.

#### **Expanding Access**

"COVID-19, the pandemic, made it clear we need a robust digital healthcare system that extends from the doctor's office right to peoples' home," Garrett said. "One of the major trends for the future is creating...a 'virtual' front door between patients and the health system." Hackensack Meridian Health launched its Patient Access Center system in 2021, and has since seen a 15 percent increase in appointments, Garrett said. The health system's digital front door helps consumers find a provider, service, specialty, COVID-19 test, and more, with most incoming calls handled within 20 to 30 seconds.

In the months and years ahead, Garrett believes that the role of telehealth will expand and that reimbursement will become a standard for both Medicare and private payers. At present, about 15 percent of all visits across Hackensack Meridian Health's medical groups are done through telehealth, Garrett said. However, more than 60 percent of the health system's behavioral health visits are now conducted via telehealth. As demand for these services rises, telehealth is enabling more consumers to access behavioral health services, and telehealth solutions are also helping to mitigate the shortage of behavioral health providers. In another innovative step, Hackensack Meridian Health has opened a behavioral health urgent care center, offering individuals experiencing a mental health crisis streamlined access to care, an alternative to a general hospital emergency department.

As one of the early recipients of a Centers for Medicare & Medicaid Services (CMS) Hospital at Home waiver during the pandemic, Hackensack Meridian Health is continuing its investment in this model. Garrett believes the model is "here to stay" and will be "critical to meet the needs of an aging population." At two health system sites, Hackensack Meridian Health is launching a Hospital at Home pilot for eligible patients with congestive heart failure, COPD (chronic obstructive pulmonary disease), pneumonia, and/or cellulitis. Expectations are that this care model will eventually expand across the health system, Garrett said.

"When I look ahead to the next 5 years, 10, 20, even 50 years, imagine what our health system could look like," he said. "Artificial intelligence will continue to help us bridge the gap to a smarter healthcare system. The role of genomics will transform care delivery profoundly and help us make quantum leaps toward prevention. Remote care delivery will also continue to define the future of healthcare and provide even more connectivity and maybe address the equity issue—[imagine] a day when your ZIP code will not be an indicator of the quality of your health."

#### **Staffing Challenges**

Across the country, hospitals and health systems continue to face workforce shortages. "We're all looking for ways to retain, recruit, really re-tool our staff for the future," Garrett said. With the aging U.S. population and the demand for healthcare services on the rise, no one-size-fits-all solution is likely to solve the staffing dilemma. Hackensack Meridian Health is deploying a multipronged approach that includes:

- Enhancing salaries and benefits by about \$600 million since the start of pandemic.
- Launching a network-wide employee assistance program that provides one-on-one support.
- Establishing, with the community's help, a Circle of Compassion program that assists team members and families experiencing hardships during the pandemic.
- Creating partnerships with nursing schools and allied health schools to build the pipeline.

- Piloting a virtual nursing program that will use advanced technology to allow some nursing tasks to be handled remotely such as patient observation, care coordination, and aspects of the discharge process.
- Innovating to address workforce shortages.

Some healthcare institutions are re-tooling the hospital work environment by integrating automated solutions and investing in remote monitoring and patient-wearable technology, leveraging advances in these areas to improve care, provide real-time data, and reduce inefficiencies in the existing care environment.

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The COVID-19 pandemic increased awareness of the need for and readiness to adopt wider integration of technology in healthcare.

In a discussion on "Leveraging Automation and Patient-Worn Technology to Enhance Patient Care," Angelo Venditti, DNP, RN, executive vice president for Patient Care, and chief nursing executive, Temple University Health System, and Michael Becker, RN, PhD, vice president and chief nursing executive, Masimo, talked about the role of patient-wearables and remote monitoring in the inpatient hospital setting and the potential for patient-worn technology to advance health. Masimo is a global medical technology company that develops and produces leading monitoring technologies, including measurements, sensors, and patient monitors.

Both agreed that the COVID-19 pandemic increased awareness of the need for and readiness to adopt wider integration of technology in healthcare. "We think about innovation differently today than we did pre-pandemic," said Venditti. "We think about the opportunity for technology differently than we did pre-pandemic...It's a real inflexion point [in healthcare]." Becker agreed, "[We are] managing technology like we've never managed it before because it became an essential part of the team."

As an example, Venditti cited the nursing shortage, which he said has been a problem in U.S. hospitals since the 1930s. Hiring more staff will not solve the issue, in his opinion. "Wearable technology, patches to gain information, is really where we need to go. Why? Because it creates a diverse care environment where we can do so much more without shifting the patient from unit to unit or nurse to nurse. We can have that information at our fingertips, and I think that creates a better practice environment for the nurse, whereby we get better outcomes. I think nursing is ready for this as a profession," he said.

Temple University Health System is already using a wide range of technology with complex patients and is partnering with Masimo to roll out wearable-patch technology in some of the system's intensive care units (ICUs). The technology will support better patient turning and reduce hospital-acquired pressure injuries, Venditti said. He and Becker agreed on the importance of vendors and healthcare clients "innovating together." Becker attributes the success the current ICU project at Temple to the health system frontline staff's comfort level in providing feedback to the vendor. "We each need the other to get the technology to the next level," he said.

While Venditti believes healthcare organizations are ready for increased application of technology to care delivery, he cautions that "cost will play a huge role. Can we get technology that hospitals can consume at an affordable pace? Can vendors and suppliers think about how they supply hospitals differently and really partner with organizations in acquiring technology and working through innovation so that we see an adoption uptick? I think that partnership piece is really important," he said.

Wearables and patch-technology offer opportunities for improving individual health and patient-centered care. "[With] wearable technology and bio-patches...we will have more information visiting our physician—whether that is in person or virtual—than we've ever had. Imagine what that means to wellness, the cost of care, the amount of time it takes to provide care. If you could walk into [the] physician's office with 60 days of vital sign data, and they [the physicians] know what your blood pressure is, and how your weight fluctuates, etc., etc.—imagine the impact we could make," Venditti said.

What will the hospital of the future look like? "[We], as a healthcare community, [will] no longer [be] spending \$1 billion on a building but rather putting \$250 million or \$500 million into technology," Venditti said. "Because while the workflow, and the flow, and the storage, and the office space of the building might be inadequate, I think we're not too far off from hospitals looking much smaller than they do today because of technology. I think we have to ramp up our investment in technology. I also think that just like we measure patient experience, just like we measure quality outcomes, I think there should be standards, and organizations should be recognized for their innovation and adoption of technology."

#### Intelligence at the Point of Care

Briefing keynoter Richard Zane, MD, chief innovation officer UCHealth, Colorado Health, began his presentation by zeroing in on the essence of healthcare: people, processes, and tools. Taking a wider view, he then shared a look at the U.S. healthcare delivery system through the lens of the current era. "[A time where] everything is connected to something else...[an] age of data science...a fundamental age of disruption." Technology and its rapid evolution—is a driver of disruption to everyday life, from information and knowledge dissemination, to communication, to entertainment, commerce, and education. U.S. healthcare, which at present is not accessible for many, lacks efficiency, and is insupportably expensive—needs to be disrupted as well, he said. In the midst of this age of disruption, we are also experiencing a cognition revolution, where what we are connected to helps us make decisions, he said. (Think about your smart phone, Siri, GPS, apps, crowdsourcing, and more.) Data science—and its influence on cognition—are powering this revolution, he said. The exponential increase in information today means that "providers are actually encountering seven times the amount of variables and data than a human brain can actually adjudicate at the same time," Dr. Zane said. "The only way for future healthcare to survive and grow is that we must partner with machines."

Artificial intelligence (AI) will help shape the healthcare environment of the future, assessing where humans and human intelligence are needed and where tasks are appropriate for machine intelligence, he forecast. As our partnership with machines in healthcare advances, bricks-and-mortar hospitals will largely provide intensive care and ED (emergency department) services. In the future, most healthcare services will not require hospitals. Instead, the hospital of the future will have a smaller footprint, as increased adaption of technology-enabled solutions leads to a healthcare environment where care delivery is more streamlined, efficient, and affordable, he said.

For the future, "we need to have smart healthcare and smart hospitals. Intelligence at the point of care," Zane said. With greater integration of technology, including ongoing advances in AI, he envisions a future where healthcare is delivered "in bricks-and-mortar facilities, along with virtual, synchronous, and asynchronous communication." Much more than a "virtual" visit, a technology-enabled delivery system will provide care to patients across the entire health continuum, allowing earlier intervention that will prevent not just hospitalizations but suffering.

Amanda Patton, MA, is a freelance healthcare writer. She worked as a senior writer and editor for the Association of Community Cancer Centers for more than 15 years.

Find a current list (as of 1/31/2023) of the 260 hospitals and 114 health systems in 37 states that have approval for Acute Hospital Care at Home at:

https://qualitynet.cms.gov/acute-hospital-careat-home/resources. Addressing Social Determinants of Health through a Medical-Legal Partnership



hen chemotherapy, multiple surgeries, and a number of fractures in her body left a patient at Virginia Commonwealth University (VCU) Health System, VCU Massey Cancer Center, unable to maintain her job in the education field, she found herself in a precarious position. The patient was eventually terminated from her job, losing her income and all her retirement benefits. Her nurse referred her to VCU Health's medical-legal partnership. A pro bono attorney negotiated with her employer, appealed the denial of benefits, and succeeded in restoring the patient's retirement income of approximately \$600 a month, plus one year's worth of back pay. (The value of the legal services donated by the attorney was approximately \$15,000.) With improved economic stability, the patient can now focus on her health.

Since the creation of VCU Health's medical-legal partnership in 2018, there have been many stories like the one above. An attorney can be a powerful part of a patient's healthcare team, especially for those and their families who cannot otherwise access a lawyer. While the United States Constitution guarantees representation by a lawyer at public expense in cases where a person is facing time in prison or jail, there is no such right to counsel when an individual's basic human needs—shelter, sustenance, safety, and health—are at risk. An individual's health, home, and autonomy can be threatened by an eviction, loss of public benefits, and/or a child custody hearing, and they will be left to navigate an opaque and complicated legal system on their own.

Low-income Americans do not get any or enough legal help for 92 percent of their substantial civil legal problems, according to a 2022 report by the Legal Services Corporation.<sup>1</sup> Similar Virginia-based studies in 1991 and 2007 found that at least 80 percent of low-income Virginians received no help from an attorney with their legal needs.<sup>2</sup> Individuals who are represented by counsel are twice as likely to have a favorable outcome, compared to those who are unrepresented.<sup>3</sup> In Virginia, poverty and the concomitant inability to retain counsel creates a significant barrier to successful outcomes for unrepresented poor litigants.<sup>4</sup>

Poverty can have a direct and devastating impact on health. Medical-legal partnerships were created to address the health inequities resulting from an individual's poverty and lack of access to legal services. These partnerships provide free legal help to low-income patients and their families to address social determinants of health, such as safe and stable housing, access to food, employment, education, and access to healthcare. Studies show that most people of low socio-economic status have one or more legal needs that can potentially impede access to healthcare.<sup>5</sup>

#### A Snapshot of Healthcare in Richmond, Va.

In Richmond, health disparities along racial, gender, socioeconomic, and geographic lines shape opportunities and health outcomes. The Virginia Department of Health created a health opportunity index<sup>6</sup>, which ranks communities based on a combination of place-based indicators, including environmental quality, employment, educational attainment, food access, transportation, and healthcare. Eighty-two percent of residents in Richmond live in census tracts with low (22 percent) or very low (60 percent) levels of health opportunity, according to this aggregate measure.<sup>6</sup>

According to an analysis by the National Center for Health Statistics, life expectancy varies by more than 20 years across the city.<sup>7</sup> Compared to the general population in metropolitan Richmond, Black individuals living in the east end are at much higher risk for high blood pressure, heart disease, obesity, and diabetes.<sup>6</sup> These disparities are linked to social determinants of health, which are often treatable by legal intervention. For example, Richmond has the second-highest rate of evictions in the country, and evictions disproportionately impact residents of the same racially segregated, disinvested neighborhoods where health inequities also concentrate.<sup>6,8</sup>

Employing more than 800 physicians in 200 specialties, VCU Health operates the largest safety-net hospital—VCU Medical Center—in Virginia. VCU Medical Center is the only comprehensive level I trauma center in the state that is verified in adult, pediatric, and burn trauma care by the Virginia Department of Health. VCU Health includes one college and four health sciences schools, a National Cancer Institute-designated cancer center— VCU Massey Cancer Center—and the region's only full-service children's hospital—Children's Hospital of Richmond at VCU. Its mission is to advance health equity by preserving and restoring health to all people in Virginia. One innovative, collaborative strategy to combat local and regional health inequities is providing free, compassionate, and comprehensive legal aid through a medical-legal partnership.

VCU Health's medical-legal partnership was created in 2018 to serve two specific patient populations: those being treated at Massey Cancer Center and the children and families being treated at the Children's Hospital of Richmond. In less than five years, the medical-legal partnership expanded access to legal services to seven additional patient populations, as well as two community locations. The medical-legal partnership serves these patient populations through six community-based legal partners, including CancerLINC, Central Virginia Legal Aid Society, Legal Aid Justice Center, McGuireWoods, Dominion Energy, and the University of Richmond School of Law, as well as volunteer pro bono attorneys in the community.

#### **Development of the Medical-Legal Partnership**

A committee of VCU Health's leaders, including representatives from Massey Cancer Center, Children's Hospital of Richmond at VCU, Division of Community Health, Care Coordination, and General Counsel's office, used resources from the National Center for Medical-Legal Partnership (medical-legalpartnership.org) to create a strategic business plan for the program. This committee met regularly to advise on organizational structure, clinical workflow, data-sharing, funding, community partnerships, and priorities. Exploratory work and planning were funded in large part by the Medical College of Virginia Foundation—a non-profit foundation that seeks, secures, and stewards philanthropic resources for VCU Health.

Once leadership approved a business plan and additional non-profit foundation funding was obtained, the medical-legal

partnership was launched at two locations: Massey Cancer Center and Children's Hospital of Richmond at VCU, with attorneys from CancerLINC and Central Virginia Legal Aid Society working on-site. The medical-legal partnership executed memorandum of agreements (MOAs) with each legal partner, outlining the roles and responsibilities of each organization and partnership goals. Within one year of launching on-site services at these two locations, the medical-legal partnership was able to demonstrate a 400 percent return on investment, based solely on anecdotal evidence. With this evidence, VCU Health agreed to fund most of the medical-legal partnership's costs through its operating budget, creating a sustainable growth model.

Over the next several years, the medical-legal partnership expanded its footprint to provide free legal services to several additional patient populations, including complex care, those with HIV and sickle cell disease, and the emergency department. VCU Health's medical-legal partnership also provides free legal services at two community locations, serving low-income community members; individuals do not need to be patients with the health system to receive free services. Funding to support serving these additional patient populations and community locations comes from a variety of sources, including non-profit community foundations, the HRSA (Health Resources and Services Administration), and a sponsored Equal Justice Works Fellowship.

The medical-legal partnership's attorneys ensure access to justice on almost every civil legal issue that could affect the health

Table 1. Common Legal Services Offered by VCU Health's Medical-Legal Partnership

Evictions and poor housing conditions

Health coverage (i.e., Medicaid, Medicare)

Public benefits (i.e., SNAP, SSDI, SSI, cash benefits)

Estate planning (wills, powers of attorney, advance medical directives)

Income and employment

Personal and family safety

Immigration and legal status

Special education

Guardianships and conservatorships

SNAP = Supplemental Nutrition Assistance Program; SSDI = Social Security Disability Income; SSI = Social Security Income.

and quality of life of patients and their families (see Table 1, on page 22). For example, these attorneys increase access to basic needs, such as food, stable housing, and medication, by securing government benefits, fixing housing problems, and preventing evictions. They ensure patients' continued adherence to treatment and monetary reimbursement to the health system by providing employment advice and working to obtain and preserve insurance and public benefits. They also help families by advocating for children's rights in school, addressing family law and domestic violence issues, and handling immigration matters. Additionally, the attorneys bring patients and families peace of mind by drafting life-planning documents. Altogether, the medical-legal partnership provides patients and their families the resources and stability required to care for their health.

#### VCU Health's Medical-Legal Partnership

This medical-legal partnership partners primarily with CancerLINC—a central Virginia non-profit that connects low-income patients with cancer to pro bono legal services, financial counseling, and community resources. Patients with the greatest social needs often have the least access to the legal and financial services that are necessary to improve their health and well-being. This medical-legal partnership helps patients with cancer:

- Secure government benefits, such as Social Security Disability Income, Supplemental Security Income, Medicaid, and Supplemental Nutrition Assistance Program (SNAP) (formerly known as food stamps)
- Plan ahead by developing advanced care plans
- Prevent evictions and improve poor housing conditions
- Fight employment discrimination and wrongful termination
- Appeal insurance denials
- Handle immigration matters
- Address family law and domestic violence issues.

These services provide many benefits to patients and the health system, including improved patient and provider experiences, increased trust and community building, better use of staff time and resources, and an effective process to address the underlying social and legal issues that exacerbate health problems or interfere with recovery.

In addition to legal services, a unique aspect of VCU Health's medical-legal partnership is CancerLINC's provision of free, professional financial counseling services to address a key social determinant of health—economic stability—for low-income and vulnerable patients with cancer. These financial services are not routinely offered by most medical-legal partnerships, even though many patients with cancer and their families often are in financial crisis due to high treatment-related costs, and many legal problems begin with experiencing financial challenges.

The medical-legal partnership operates as a fully integrated program and service that is available to all patients with cancer. The CancerLINC attorney works on-site in a dedicated office two days per week, during which time the attorney meets with patients and providers, offers advice and counsel, and often completes and executes estate planning documents at patients' bedside. During the COVID-19 pandemic, CancerLINC was flexible and responsive to patients' needs, finding creative ways to provide their services, for example, arranging "drive-by" estate planning document executions so that patients did not need to leave the safety of their cars.

A unique aspect of VCU Health's medicallegal partnership is CancerLINC's provision of free, professional financial counseling services to address a key social determinant of health economic stability...

Training clinical staff is a key component of the medical-legal partnership and is important to build capacity and knowledge among the healthcare team regarding how legal issues affect patients' health and well-being. In addition to regular trainings on understanding the role of the medical-legal partnership and identifying patients' legal needs, substantive trainings are offered on topics like Medicaid eligibility for immigrant families, qualifying for Social Security Disability Insurance, housing, special education, and advance care planning.

The medical-legal partnership also provides indirect legal services through consultations with providers one-on-one as issues arise, which can result in successful medication and treatment approvals. For example, a pediatrician contacted the medical-legal partnership after a Medicaid managed care organization refused to cover a standard-of-care medication for a six-year-old, delaying care and worsening the child's condition after a few months of back-and-forth communication. Within hours of receiving an email from a medical-legal partnership attorney, a representative from the state ombudsman's office worked with the Department of Medical Assistance Services to get the medication covered and expedited through the patient's pharmacy. At the same time, a nurse raised a similar concern involving a different patient and was able to leverage the medical-legal partnership to benefit another child. These "curbside consults" demonstrate how legal advocacy can have a multiplicative effect.

#### **The Referral Process**

Clinicians, social workers, caseworkers, and community health workers identify patients with possible legal issues and refer them to VCU Health's medical-legal partnership through an online platform or directly to attorneys on-site. (All healthcare professionals have access to a web-based medical-legal partnership referral form.) Once the webform is submitted, a case is automatically created in JusticeServer—a Salesforce-based platform. Medical-legal partnership staff then complete the patient intake, confirming eligibility for pro bono services and ensuring the patient has consented to participate in the program. The medicallegal partnership recently gained access to DocuSign, which allows patients to sign necessary HIPAA and legal consent forms electronically, expediting the referral process. The patient's case is then sent through a secure, HIPAA-compliant portal to the appropriate legal partner. All referrals are triaged based on the legal issue, clinical location, and household income. Figure 1, below, illustrates this referral process.

A unique aspect of VCU Health's medical-legal partnership is the use of multiple legal partners to serve large and growing patient populations and referrals. Partnering with six different legal service organizations allows the medical-legal partnership to offer a broad scope of civil legal services, as each partner brings different expertise and experience. Often, patients present with multiple legal issues, which can be handled by one or more attorneys across the partnership.

These legal partners provide case status updates through the portal and in regular weekly and monthly reporting to the medicallegal partnership, as outlined in the MOAs between VCU Health and each legal partner. The medical-legal partnership also tracks the quantitative and qualitative benefits of each patient case using LSC (Legal Services Corporation) benefit codes, such as:

- Improved housing conditions
- Drafted end-of-life planning documents
- Delayed or prevented eviction
- Obtained guardianship and/or conservatorship
- Obtained, preserved, or increased public benefits
- Stopped and/or reduced debt collection.

VCU Health's medical-legal partnership also tracks financial benefits that are accrued to patients, such as successful Social Security Disability Insurance appeals, SNAP benefit appeals, and garnishment cases, which put money back in patients' pockets to pay for basic needs like housing, food, and medicine. In addition, the medical-legal partnership tracks financial benefits to the health system that result from legal intervention, including reimbursement, avoided costs, and reduced utilization of healthcare services.

When a case is closed, the referring clinical team member receives an email notice of the case closure, describing the service provided to the patient. Cases can be re-opened if legal issues resurface or if the same client encounters a new legal issue.

#### **Patient Benefits**

Embedding lawyers into the healthcare team greatly improves the patient experience. In the words of Sara Blose, an attorney with VCU Health's medical-legal partnership, "I work with clients to understand their goals and all of their options to work toward achieving them. By explaining why and how advocacy strategies work, what their legal rights are, and involving them in the process, clients gain confidence in their ability to advocate for themselves and their families. It's a skill that easily transfers to other areas of life, such as advocating for your child's health, in the school system, or at work."

Most patients who are served by the medical-legal partnership are already navigating a complex web of social and legal challenges. Part of the intangible value of these free, timely, and compassionate legal services for low-income patients is in how they reinforce a trusting patient-provider relationship. For lowincome, at-risk patients, this relationship can be fragile, and access

#### Figure 1. VCU Health's Medical-Legal Partnership Referral Process





#### Figure 2. Types of Legal Issues Faced by Patients at VCU Massey Cancer Center, Fiscal Year 2022

to affordable legal services is unlikely. A successful referral and responsive, effective legal intervention demonstrate that the healthcare team is invested in patients' holistic well-being. It also demonstrates that legal advocacy can be an effective way to show individuals that the legal system there is to protect—not penalize—vulnerable patients and communities.

For example, one client was referred to the medical-legal partnership after her wages were garnished because she had fallen behind on her car payments and was missing time at work to care for her son, who had recently been diagnosed with lymphoma. By filing a homestead deed, the attorney was able to recover the garnished wages, putting money back in the patient's pocket for life's basic necessities, including housing, food, medicine, and transportation.

In two cases, legal intervention to preserve patients' insurance produced better health outcomes and higher rates of reimbursement for the healthcare system.

In one case, a patient with cancer was forced into early retirement because of his diagnosis. However, he did not receive retirement income for several months and fell behind on his mortgage, car, and other payments. The medical-legal partnership helped him to file chapter 13 bankruptcy, which prevented the imminent foreclosure of the patient's home, returned his repossessed car, and restructured his debt so that he can afford his payments going forward. The healthcare system was also reimbursed hundreds of thousands of dollars through private insurance for this patient's care. Had he lost his car—his transportation to medical appointments—his home, his insurance, or his financial security, the payment balance would have looked very different and so might his health.

Another patient with cancer was denied supplemental insurance coverage through a private company. After a medical-legal partnership attorney advocated for the patient on her behalf, her insurance was reinstated; the hospital was reimbursed through private insurance for this patient's cancer care.

Medical-legal partnership attorneys also work with patients to guard against workplace discrimination, protecting their rights to paid leave and benefits, while preserving favorable reimbursement rates for the healthcare system. One patient with cancer engaged with the medical-legal partnership after her rights under the Family Medical Leave Act were violated. The attorney successfully advocated for the restoration of this patient's leave benefits, and she was able to return to the same position, receiving the same salary and benefits, as required by law. Consistent employment provides money for food and safe housing, which often reduces utilization of healthcare services. In this case, preserving the patient's job also allowed the patient to maintain her insurance.

At Massey Cancer Center, the most requested medicallegal partnership service is the preparation of life planning documents—basic wills, powers of attorney, and advance medical directives. These documents provide peace of mind to the patient and, in many cases, establish legal and financial security for surviving children, family members, and significant others. Medical-legal partnership attorneys are often asked and able to prepare and execute these documents at patients' bedside. Preparation of these documents also avoids the high levels of tension that often accompany a cancer diagnosis and treatment plan, as well as family disagreements about end-of-life care and decision making. Figure 2, above, illustrates the distribution of medicallegal services among this patient population.

A number of underserved groups receive assistance through the medical-legal partnership. Most clients are women (60.6 percent), and most are unmarried (69.7 percent). Nearly half (48.5 percent) are Black, and about two-thirds (67.7 percent) are over the age of fifty. Finally, many are living at or below the federal poverty line, reporting a median household income of \$1,300 per month. Figure 2, page 25, illustrates the distribution of medical-legal services among this patient population. Table 2, right, shows the patient demographics of Massey Cancer Center's medical-legal partnership in fiscal year 2022.

Legal intervention to preserve patients' insurance produced better health outcomes and higher rates of reimbursement for the healthcare system.

#### **Planning and Implementation**

The medical-legal partnership model is simple and replicable, with an abundance of information, templates, and resources available to cancer programs and practices, hospitals, and health systems through the National Center for Medical-Legal Partnership. This organization leads education, research, and technical assistance efforts to help every healthcare organization in the U.S. leverage legal services as a standard response to social needs. Founded in 2006, the National Center for Medical-Legal Partnership is based at the Milken Institute School of Public Health at the George Washington University in D.C.

On its website, the organization provides a comprehensive list of resources, including toolkits, sample memorandums of understanding, screening tools, and training opportunities for healthcare and legal service organizations interested in implementing or improving a medical-legal partnership. The website also hosts a wealth of peer-reviewed research, white papers, and legal and medical journal articles on a variety of medical-legal partnership topics, including addressing legal issues for specific patient populations, best practices, and demonstrating the value of medical-legal partnerships and return on investment.

Each medical-legal partnership is unique. Many are based at hospitals and health systems like VCU Health; others are based at cancer centers, children's hospitals, Veteran's Affairs Medical Centers, and HRSA-funded health centers that serve large populations comprised of low-income individuals. Medicallegal partnerships also vary in their scope of legal services, income guidelines, variety and type of legal partners, and funding mechanisms.

Medical-legal partnerships range from a simple patient referral from a physician, nurse, or social worker to a more complex referral from a local legal aid agency for a specific legal issue. At most medical-legal partnerships, a "lawyer in residence" works on-site in the healthcare setting, not only providing legal services to patients, but also participating in clinical meetings and providing training to clinicians and staff.

#### Table 2. Demographics of Massey Cancer Center Medical-Legal Partnership Participants, FY22

July 1, 2021, to June 30, 202	July	1,	2021,	to	June	30,	2022
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Variable	Percentage
Age (Years)	
18-29	2.0%
30-39	7.1%
40-49	23.2%
58-59	30.3%
60-64	21.2%
65+	16.2%
Gender	
Female	60.6%
Male	37.4%
Not Filled Out	2.0%
Race	
Black	48.5%
White	37.4%
Asian	2.0%
Other	7.1%
Not Filled Out	5.1%
Ethnicity	
Non-Hispanic/Latino	87.9%
Hispanic/Latino	8.1%
Not Filled Out	4.0%

Medical-legal partnerships establish formal processes to screen patients' health-related social and legal needs, share data between healthcare and legal partners, communicate about patient-clients, and jointly set service and evaluation priorities that reflect their shared mission. There is also a formal agreement between health and legal organizations.<sup>9</sup>

VCU Health's medical-legal partnership is hospital-based, leveraging hospital resources in partnership with legal service organizations to achieve a fully integrated program. The medicallegal partnership's director and program manager build relationships and trust among clinical staff, manage and oversee all case referrals, and serve as an internal resource for referring providers. Having known, accessible, and trusted colleagues within the healthcare system to advocate for patients, serve as the liaison for multiple legal partners, and coordinate education among providers and social workers improves both the patient and provider experience.

Many successful medical-legal partnerships are built on partnerships with local legal aid organizations. The goals and priorities of Legal Service Corporation-funded legal aid organizations align exceptionally well with those of medical-legal partnerships. The mission of the Legal Service Corporation is to promote equal access to justice in our nation and provide high quality civil legal assistance to low-income persons.<sup>10</sup> Hospitals, cancer programs and practices, and health centers interested in starting a medical-legal partnership should begin by reaching out to their local legal aid organization. The National Center for Medical-Legal Partnership offers a toolkit for creating a medical legal partnership,<sup>11</sup> as well as sample MOAs between healthcare and legal partners,<sup>12</sup> and a tool for developing workflows for screening and legal services.<sup>13</sup>

#### **Vision for the Future**

Over the last 10 years, the medical-legal partnership model has taken its rightful place as a critical innovation in healthcare and legal service delivery for underserved patient populations. In that time, the American Medical Association,<sup>14</sup> American Academy of Pediatrics,<sup>15</sup> and American Bar Association<sup>16</sup> have all released reports or resolutions, calling on their members to engage in medical-legal partnership activities.

Though there is increasing support for medical-legal partnerships to be fully integrated as part of the standard of care, making these collaborative services a normative part of today's healthcare system and broadly adopted requires more education and funding. To improve community health and create long-term sustainable change, we must build accountable and trusting relationships with the patients we serve. We must advocate for those patients who have no voice and no access to legal services.

The vision of VCU Health's medical-legal partnership is to create a safer, healthier, more equitable community through access to justice. As U.S. Supreme Court Justice Lewis F. Powell stated in August 1976, during his tenure as president of the American Bar Association, "Equal justice under law is not merely a caption on the facade of the Supreme Court building; it is perhaps the most inspiring ideal of our society. It is one of the ends for which our entire legal system exists. And, central to that system, is the precept that justice not be denied because of a person's race, religion or beliefs. It is fundamental that justice should be the same, in substance and availability, without regard to economic status."<sup>17</sup>

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## National Landscape

The medical-legal partnership model has been adopted by more than 450 healthcare institutions in 49 states.<sup>18</sup> These partnerships embed lawyers in healthcare settings to collaborate with the healthcare team to detect, address, and prevent health-harming conditions. Most medical-legal partnerships include direct legal services, consultation and training for medical providers, as well as systemic advocacy for policy changes at the institutional, local, or state level.<sup>19-22</sup> Integrating attorneys into the treatment team helps address underlying social causes of disease and also mitigates barriers to legal aid in underserved communities, such as a lack of awareness or trust of legal services.<sup>23</sup> Medical-legal partnerships work in a variety of formats, and often involve students as trainees to serve diverse populations, depending on the community context.<sup>21,24-26</sup> Studies show that when legal expertise and services are used to address social needs, people with chronic illnesses are healthier and admitted to the hospital less frequently, benefitting the patient and saving healthcare costs. Examples include:

- Improved housing conditions that led to improved health in patients with asthma<sup>27,28</sup>
- Youth with diabetes showed significant improvement in their glycemic control<sup>29</sup>
- Patients with sickle cell disease were healthier after receiving legal services<sup>30</sup>
- A reduction of healthcare spending on high-need, highcost patients<sup>31</sup>
- Families of healthy newborns in a randomized control trial increased their use of preventive healthcare.<sup>32</sup>

Additional studies show that when legal expertise and services are used to address social needs:

- People more commonly take their medications as prescribed.<sup>33,34</sup>
- People report less stress and experience improvements in their mental health.<sup>35-37</sup>
- People have more stable housing, and their utilities are less likely to be shut off.<sup>37-39</sup>
- People have access to greater financial resources.

One medical-legal partnership recovered \$300,000 in back benefits for families over a three-year period,<sup>28</sup> while another recovered more than \$500,000 in financial benefits for families over a seven-year period.<sup>40</sup>

• Clinical services are more frequently reimbursed by public and private payers; medical-legal partnerships have been shown to save patients healthcare costs and recover cash benefits.<sup>41,42</sup>

Finally, clinicians have a positive view of the services offered under a medical-legal partnership. When surveyed in 2016 about benefits to medical-legal partnerships, healthcare organizations shared that:<sup>43</sup>

- 86 percent of clinicians anecdotally reported improved health outcomes for patients
- 64 percent of clinicians anecdotally reported improved patient compliance with medical treatment
- 38 percent of clinicians anecdotally reported improved ability to perform "at the top of their license."

Of the VCU Health Medical-Legal Partnership, Sean McKenna, MD, shared these comments: "For those providers lucky enough to work in a [health] system with a medical-legal partnership, lawyers become one of our most powerful tools in advocating for the rights of our patients and their families. The partnership of physicians-who are able to work longitudinally with patients and develop strong bonds of trust-[and] lawyers, who understand the rights of those patients and how to protect those rights, is an incredible professional synergy. We, medical providers, can access the information needed to protect patients, but in the past we could do little with that information beyond letter-writing. Lawyers know exactly how to empower our families but would either never get a chance to help or would not get involved until the legal situation was already quite desperate. We have been practicing preventative medicine for as long as there have been doctors, but we only now are learning to practice preventative justice here in our clinics and hospitals. Having this sort of ally in our fight has been a truly transformative experience for us and our patients."

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## **Calm Minds** and Grateful Hearts

## The Value of **Medical-Legal Partnerships**



edical-legal partnerships are a service provision model based on the integration of legal services in healthcare organizations to address patients' legal needs (e.g., estate planning, powers of attorney, advanced directives and living wills, and insurance or employment issues) and improve their health outcomes.1 The first of such partnerships occurred in 1993 between Boston Medical Center and Greater Boston Legal Services. The cause: Boston Medical Center experienced an unorthodox influx of pediatric patients with asthma who, regardless of the medication prescribed, continually returned to the emergency department for care. Upon investigation, Boston Medical Center staff discovered that the children's living conditions were to blame because landlords ignored sanitary regulations and their apartment complexes were riddled with mold-causing the families to seek legal aid from Greater Boston Legal Services. Thus, giving way to the first medicallegal partnership.

Since that time, medical-legal partnerships have been implemented within 450 healthcare facilities across 49 states.<sup>2</sup> In 2006, the National Center for Medical-Legal Partnership was established, serving as an invaluable resource for individuals—lawyers or not—around the country looking to implement such a program. This growth is emblematic of an overdue recognition by healthcare organizations that social determinants of health are key players in patients' health outcomes. The World Health Organization estimates that social determinants of health account for 30 percent to 55 percent of all health outcomes.<sup>3</sup> Yet financial toxicity, a term that highlights the stress patients and their families



Kathryn Smolinski, MSW, JD

more than a decade of experience in the medical and legal fields, Smolinski is uniquely positioned to provide poignant insight for cancer programs and practices looking to provide similar services.

## **OI.** Can you provide some background about Karmanos Cancer Institute?

**SMOLINSKI.** It is the only National Cancer Institute (NCI)-designated cancer center in the Detroit metropolitan area. It is also one of only two NCI-designated cancer centers in the state. The cancer center sees about 12,000 new patients every year, and it is now part of McLaren Health Care, which is a community health system. This affiliation allows staff to provide cancer care in 16 locations throughout Michigan and Ohio. Prior to this acquisition, patients had to come into the city to receive care, but now there are multiple satellite locations where patients can

bear due to the high costs associated

with cancer care, is relatively new to

Kathryn Smolinski, MSW, JD, director

of the Legal Advocacy for People with

Cancer Clinic (LAPC) and associate

clinical professor at Wayne State University Law School. She is also at the

center of a medical-legal partner-

ship between the law school and

Karmanos Cancer Institute. With

Oncology Issues interviewed

the medical lexicon.4

receive care. Karmanos Cancer Institute offers radiation, medical, and surgical oncology services, as well various supportive care services.

Most of the institute's patient population comes from southeastern Michigan, with the majority of Wayne County using it as their primary source of cancer care. It is also a large research institute, partnering with Wayne State University.

#### OI. Can you share a little about yourself?

**SMOLINSKI.** I am both a licensed social worker and a licensed attorney. I obtained my Master of Social Work from the University of Michigan, and my law degree from Wayne State University. I have worked my entire career with individuals who have cancer, primarily with individuals who have a serious diagnosis or life-limiting illness. My journey began in home hospice, which caters to individuals with a life-limiting illness, who want as much support as possible to enable them to live as fully as possible until they die. I was primarily in the individual's home, supporting the patient and their family. That is where my career started, and I absolutely loved it.

It is an honor to be with people who are facing their own mortality, and I do anything I can so that their life and experience can feel a little lighter as they walk their journey. I am inspired by the resiliency these individuals display in the face of so much going on in their lives.

While I was doing that, I attended the Association of Oncology Social Work conference. Through this forum, I met fabulous oncology social workers throughout the country, and was recruited to work at Johns Hopkins Hospital where I spent about 10 years. I worked primarily with individuals who had life-limiting illnesses, helping them and their families deal with all the non-medical issues that come with healthcare—the coping, stress, and anxiety. In addition to the practical concerns like where someone is going to be discharged to, who they are going to live with, and their ability to work and earn an income, social workers touch on so many aspects of care that, ironically, I am doing in my current career field, which is why I think my background propelled me to be where I currently am.

Following my time at Johns Hopkins Hospital, I became the executive director for the Association of Oncology Social Work, a position I held for three years. After that, I decided to go to law school, primarily due to my work with individuals in end-of-life care and their families.

**OI.** What initially sent you down the path of hospice care? **SMOLINSKI.** When I was 13 years old, my brother—who was 16 years old at the time—was killed in an automobile accident, and it was a very sudden and unexpected death. I just remember the devasting impact his death had on my family. He was here and then he was gone. Perhaps, on some level, that set me on this path at a young age.

It is an honor to be with people who are facing their own mortality, and I do anything I can so that their life and experience can feel a little lighter as they walk their journey. I am inspired by the resiliency these individuals display in the face of so much going on in their lives. For my law students to see that, I think this provides them a unique opportunity.

Also, one of my instructors in my Master of Social Work program said I would do well working in a hospice program. So once I graduated, I started looking for job opportunities at a hospice program in my hometown. Luckily, one happened to be hiring, and I immediately fell in love with the work.

#### **OI.** What fueled your desire to pursue a legal degree?

**SMOLINSKI.** I saw the benefits and limitations of law in medicine. While law can help a patient and their family obtain a benefit or exercise a right, it can also be very obstructive. For example, when people need to have surrogate decision makers.

If a patient is incapacitated and, thus, unable to speak for themselves but has not legally designated a surrogate decision maker, most states and hospitals have laws or policies in place as to who can assume that responsibility. Sometimes the individual who could legally decide on that patient's behalf is not the person the patient would want to have this responsibility.

In my experience, this situation happened a lot with individuals in same-sex relationships. Years ago, the policies at most hospitals did not include a provision for a significant partner to have that responsibility. Thankfully, that is changing. It bothered me to see things like that happen; I did not think it was fair.

I watched people leave this earth without having the opportunity to think about who was going to get their possessions or oversee the care of their children. So many times, individuals with cancer are very much focused on their treatment and trying to stay alive for their families that no one pauses for a second to put some things in place if their journey does not turn out the way they want. I watched all that happen, and my interest was sparked. I was at a point in my life where I could be supported by my family to go back to school in my forties, so I attended Wayne State University Law School.

**OI.** How did you first come across medical-legal partnerships? **SMOLINSKI.** In the summer of 2010, during my third year of law school, my professor asked what I planned to do with my law degree. I was not sure at the time. I knew I wanted to go back and work with individuals who have cancer, but I had not figured out how to do that. My professor asked me if I had ever heard of medical-legal partnerships, and I had not at the time. He asked me to go and read about them, as he expressed Wayne State University's desire to implement one of its own. He believed my 20+ years in cancer care and newly minted law degree made me the right candidate to launch the medical-legal partnership, so he encouraged me to apply for a national Equal Justice Works fellowship.

## **OI.** How did you develop the medical-legal partnership between Karmanos Cancer Institute and Wayne State University Law School?

**SMOLINSKI.** The Equal Justice Works fellowship program is a post-graduate fellowship that allows law school graduates to design a two-year program that impacts the legal needs of a population that previously lacked those services. In this case, we were dealing with individuals who have cancer and do not have the income to pay for an attorney but who need legal services. So following the advice of my professor, I applied. Wayne State University became my home organization, and Karmanos Cancer Institute became our partner.

I asked their director of Social Work how the department handled patients who could not afford an attorney but needed one. I discovered that they kept a list of local legal aid organizations, and if a patient required legal services, they would hand them that list. Alas, the need was always greater than the supply. One of the local legal aid organizations had a hotline where they tried to give some clients as much education as possible, so the clients would be able to handle their affairs themselves. The organization simply could not take on everyone that needed their services.

In a bid to solve this problem, I suggested that we use law students, working under my license with the social work team, to help individuals who cannot afford an attorney, and our team would represent them. We would take on their legal issues.

Cities like Detroit have a large population of individuals with financial constraints. I applied for the fellowship in the fall of 2010, and I started one year later. I was one of 46 individuals across the country that were selected to receive this fellowship. Prior to the targeted launch date, we spent a few months designing the program. In January 2012, the Legal Advocacy for People with Cancer Clinic, which is the name our medical-legal partnership, took on its first client.

**OI.** How did you help the staff at Karmanos Cancer Institute understand what a medical-legal partnership is and what it does? **SMOLINSKI.** When we first started 10 years ago, I met with the outpatient nurses and their managers to explain the program and areas of law we cover. With this training, staff has a solid understanding of when a patient might require our services. We made brochures that were distributed throughout the hospital about who we were and what we did. This information was included in the packet that every new patient received, and that is one way patients could find out about our services. We also trained all Karmanos Cancer Institute social workers to be able to identify and listen for issues a patient may have that would require our services.

When the physician, nurse, or social worker says, "We know Kathy, and we know her team. I am going to send her your information, and they are going to give you a call," we then develop credibility and ensure that patients answer our phone call. Many patients are too intimidated to talk to anyone in the legal field, even if it is a law student. We can go over and see patients at the hospital, and they can come to the law office if they would like. We are embedded within the cancer care team, and that makes the patient feel more comfortable and confident in working with our program.

I occasionally ask a social worker to teach in one of my law seminars. This interdisciplinary partnership allows the social worker to learn about the legal aspect of care, while teaching our law students how to interact with social workers in a hospital. I also ask the social worker to teach about loss, death, and the impact these have on individuals.

We also go to the hospital either once or twice a week to educate the staff at Karmanos Cancer Institute. During what we call the "Ask the Attorney Hour," anyone can stop by and ask the law students any questions they may have. This practice has been very helpful due to the high turnover rate that healthcare organizations usually experience, as it allows us to essentially onboard new oncology staff to our programs and services.

Additionally, I occasionally ask a social worker to teach in one of my law seminars. This interdisciplinary partnership allows the social worker to learn about the legal aspect of care, while teaching our law students how to interact with social workers in a hospital. I also ask the social worker to teach about loss, death, and the impact these have on individuals. Individuals with cancer usually experience much loss—whether that is the loss of their job, health, hair, or friends. Law students start to pick up on that loss and are usually not sure how to deal with those feelings, so the social worker can help.

## **OI.** Can you describe the role of the law students in the medical-legal partnership?

**SMOLINSKI.** When individuals enroll in law school, they are expected to graduate with credits in experiential education. This requirement means that students must work on real cases with real clients. One way they can do that is through law school clinics, where the law school partners with an agency and receives referrals from that agency. Law students sign up for a clinic class, and that time is about half of their workload per semester. At Wayne State University, a clinic is limited to eight individuals because it is very

hands on. The students are graded on the work they do in solving the clients' legal issues that the clinic takes on.

Once enrolled in the Legal Advocacy for People with Cancer Clinic (our medical-legal partnership), students attend a seminar portion of the class, which I teach twice a week. During this class, students learn how to be a lawyer. They learn how to draft a will, a power of attorney, and other life-planning documents. I also teach interviewing, legal counseling, and research, I have a special class on compassion fatigue, burnout, and stress because lawyers, just like healthcare providers, experience those issues. So I want them, as students, to be aware of those concepts. Every student has a weekly supervision meeting with me where they discuss case strategy and resolutions.

Moving forward, this experience will teach students the value of taking care of themselves, allowing students to be the best version of themselves. Students then spend another 17 hours a week meeting, calling, and writing letters to clients, as well as updating client files. These students are the legal advocate on record. The medical-legal partnership work is primarily done by law students, overseen by an attorney on staff and myself. One of us is present at every document signing, and I oversee every piece of paper that leaves the clinic.

It is important to note that patients are told that they are going to be working with law students, who are being supervised by a licensed attorney. I think this is beneficial, as it can be less intimidating for patients to work directly with law students rather than licensed attorneys. Law students can also learn a lot from patients about resilience and how to tackle life's issues. The law students never stop talking about all that they learn from patients: confidence, resilience, stress management, perspective, and humor in the face of mortality. It is incredible what the students take from patients, and we do our best to remind patients of that unexpected benefit. Patients are always thrilled to learn this information.

## **OI.** Did you experience any challenges in implementing and executing the medical-legal partnership?

**SMOLINSKI.** Part of the challenge is deciding what areas of law a medical-legal partnership is going to cover. We practice five areas of law. Most medical-legal partnerships follow the IHELP acronym: insurance, housing, employee benefits, life planning, and public benefits. We do not practice immigration law, but many medical-legal partnerships do. So the "I" in the acronym may also represent immigration. In some cases, we help patients who may have a legal issue that is not within our purview find a local legal aid organization that can provide that needed service.

You want to practice enough areas of law to ensure that you are helpful to the healthcare organization, and that you have enough staff to ensure you are not being flooded with too many cases. Finding the right areas of law that satisfy these criteria and are easy for law students to pick up was a challenge.

The biggest challenge we experienced was probably the COVID-19 pandemic. At the onset of the pandemic, the hospital placed major restrictions on who could walk through their doors.

For a long time, it was only the patient, then it was only the patient and their caregiver. Law students were not able to go the hospital like they could in the past.

Our students managed to work around this issue by connecting and talking to patients by phone. Some patients welcomed us into their homes, and we would meet people on their porch or at a park. We wanted to keep every individual with cancer safe; every student in the clinic was required to be vaccinated and wear a mask when meeting with patients.

These types of partnerships have a lot of benefits...patients experience a decrease in stress...are also healthier...developing better habits related to attending their medical appointments and adhering to their treatment. They also have stable housing and income support, all because a lawyer was able to intervene.

**OI.** What members of the cancer care team were involved in the development of the medical-legal partnership?

**SMOLINSKI.** The chief nursing officer, who welcomed and supported the partnership, was a great asset. The volunteer coordinator was also involved, offering to process the law students as volunteers, so they would have IDs that allow them to access different clinic areas, as well as to park for free when they come to meet with patients. The director of Social Work Services and Case Management was integral to the design and implementation of the Legal Advocacy for People with Cancer Clinic, as all the referrals were processed by that department.

If any Karmanos Cancer Institute staff came across a patient who they thought was eligible for the Legal Advocacy for People with Cancer Clinic, they would refer the patient to the social work department, who would then screen the patient and send them to us. This process was wonderful because sometimes patients require only social work intervention, and other times they would require both social work and legal services. The Risk Management department was also crucial to the development of the medical-legal partnership, as was the in-house counsel and nursing staff.

## **OI.** What happens when a patient you are representing has some legal issue with the medical care they have received?

**SMOLINSKI.** All medical-legal partnerships establish a memorandum of understanding, which explains the roles and responsibilities of the legal and medical partners. In doing so, we make it very clear that we will never be part of any type of lawsuit against our medical partner—Karmanos Cancer Institute. If a patient ever brings up an issue, we will refer them to the state bar where they can then pursue a medical malpractice claim if they choose to do so. Further, the memorandum outlines the type of support Karmanos Cancer Institute will provide to the students, such as access to copiers, phones, meeting rooms, as well as outlining the services the Legal Advocacy for People with Cancer Clinic will provide to patients at Karmanos Cancer Institute.

## **OI.** What type of benefits do medical-legal partnerships have for patients with cancer?

**SMOLINSKI.** These types of partnerships have a lot of benefits. Outcome studies have shown that patients experience a decrease in stress after meeting an attorney and resolving their issues. Clients are also healthier, in addition to developing better habits related to attending their medical appointments and adhering to their treatment. They also have stable housing and income support, all because a lawyer was able to intervene.

I think what I do is an extension of my career as a social worker. Lawyers and social workers are social justice professionals; we are problem solvers. When I was a social worker, I could not really leave the hospital. I could meet with patients and their families and make phone calls, but my job ended at the door. In my new role, as a legal advocate in the medical-legal partnership, I can now work with federal and state agencies, walk into their hearing rooms and offices, explain laws and enforce regulations on behalf of clients, and affect the entire landscape.

Medical-legal partnerships also allow patients to experience benefits they may be unaware they qualify for. I had one patient who was asked to fill out an adult function report that would determine his eligibility for disability services. One of the questions was about his ability to do his own laundry. He said he did his laundry himself. But I then asked him to describe that process. The client proceeded to explain that he was too weak to carry his clothes together in a basket, so he would throw each piece of clothing down the stairs. Then he would walk down the stairs, pick up his clothes one at a time, and put them in the washer. Once the wash cycle is done, someone else in the house would have to move the wet laundry to the dryer because the clothes would be too heavy for him to lift on his own. When the clothes are finished drying, the patient then puts each piece of clothing in a basket and attaches a rope that he has tied around his waist to pull the basket up the stairs.

Had that client indicated that he could do his laundry himself, there is no way the Social Security Administration would understand his actual limitations. Instead, lawyers can interview individuals in depth to better understand what is going on in their lives and help them access benefits that they are not privy to.

Medical-legal partnerships are also a preventative model of legal services. We work to keep people out of a courthouse. We want to resolve something with the patient's landlord before they must go to court. If a patient is not able to pay rent for a certain month, we negotiate with the landlord, and many landlords, especially if the client has been a long-time tenant, are amenable.

## **OI.** What value does a medical-legal partnership bring to comprehensive cancer care?

**SMOLINSKI.** The value to any oncology setting is that you are going to have healthier, better adjusted, less stressed patients because these other areas of their lives have been attended to. The data support this statement, and you cannot care for people who cannot show up to their medical appointments or have such housing conditions where they cannot flush their lines or ports at home. You need patients to have a stable life to be able to handle the stress of cancer and its treatment, and that is one value the medical-legal partnership brings to cancer care. These types of partnerships also provide the support patients need to return for treatment and stick with it. In general, a medical-legal partnership helps cancer programs and practices provide better health outcomes for their patients.

## **OI.** What advice would you give another cancer program or practice that is looking into developing and implementing a medical-legal partnership?

**SMOLINSKI.** The first would be to understand the legal issues that your patients encounter. Then you should think about what legal practices cover those issues in your state and locality. Once you find one, be it a local legal aid organization or even one of the larger firms that has a very robust pro bono department, you need to gauge their interest in a medical-legal partnership. Models can range from a lawyer from one of these organizations coming into the cancer program two to three times a year to help patients with issues they may have to a fully integrated medical-legal partnership like ours. (Editor's note: Read how Virginia Commonwealth University Health System, VCU Massey Cancer Center won a 2022 ACCC Innovator Award for its medical-legal partnership on pages 20–30.)

Additionally, speak with the cancer program or practice administration and determine how the partnership would be funded. Work with the National Center for Medical-Legal Partnerships because it is built to support medical-legal partnerships around the country. These services are such an essential component of comprehensive cancer care. I wish they were in every oncology setting.

#### Chidi Ike is associate editor, Oncology Issues, Rockville, Md.

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## Reimagining Healthcare for Incidental Lung Nodules

ung cancer, the third most common cancer in the United States, represents 12.3 percent of all new cancer cases and is the leading cause of cancer-related deaths, accounting for 21.4 percent of all U.S. cancer-related deaths annually.<sup>1</sup> Early detection is of paramount importance, as it represents the single most effective tool to improving lung cancer survival.<sup>2</sup>

Early-stage lung cancer can be detected either as incidental lung nodules identified on imaging studies or via annual low-dose computed tomography (LDCT) screening. In 2021, the U.S. Preventative Services Task Force (USPSTF) revised criteria for LDCT screening, extending the upper age limit to 80 years old and lowering the pack-year threshold to 20 years. Current smokers or those who quit within the last 15 years, who are between 50 years and 80 years old and who have amassed at least a 20-pack year smoking history, are eligible for LDCT screening.<sup>2,3</sup> Despite the USPSTF casting a wider net for lung cancer screening and its clear life-saving results, LDCT screening remains underutilized. Moreover, some believe that the expanded inclusion criteria may not capture all individuals at risk.<sup>4</sup> Incidental lung nodule programs complement LDCT screening by expanding access and increasing early lung cancer detection.<sup>4-6</sup>

An estimated 1.6 million incidental lung nodules are identified annually on imaging studies in the U.S.<sup>7</sup> These incidental lung nodules present unique barriers to care coordination, particularly within a large healthcare system.<sup>8</sup> Because these lung nodules are often discovered in acute care settings, such as the emergency department or inpatient setting, the ordering provider is unlikely to follow up with findings or implement next steps in workup or An increasing number of cancer programs and practices have leveraged health information technology to develop incidental lung nodule programs to track nodules and retrospectively communicate findings to PCPs, so they can direct subsequent care.<sup>13, 14</sup>

management.<sup>8.9</sup> Instead, those responsibilities typically fall to the primary care provider (PCP).<sup>7,8</sup> Communication of incidental findings may be inadequate during transitions of care, resulting in failure to provide timely follow-up and leading to poor patient outcomes. <sup>8,9</sup>

#### The Role of Health Information Technology

Health information technology involves processing, storing, and exchanging of health information in an electronic environment.<sup>10</sup> Utilization of health information technology within the healthcare industry improves medical care, lowers healthcare costs, increases administrative efficiencies, decreases paperwork, reduces errors, and improves patient satisfaction.<sup>11,12</sup> An increasing number of cancer programs and practices have leveraged health information

technology to develop incidental lung nodule programs to track nodules and retrospectively communicate findings to PCPs, so they can direct subsequent care.<sup>13,14</sup>

Despite advances in health information technology, challenges exist in the management of incidental lung nodules. PCPs may not be immediately clear on guideline-driven recommendations for next steps. Moreover, discovery of the lung nodule may elicit concern, confusion, and anxiety for patients who may be awaiting guidance from their PCP.<sup>13-15</sup> Patients without a PCP can have immediate access to personal healthcare information but no one to manage their care. Hence, a strong need emerges for a comprehensive, innovative approach for incidental lung nodule findings that supports both patients and providers.<sup>13,16</sup>

Recognizing the need for better care coordination and prompted by the experience of a patient partner, in 2017, WellSpan Health embarked on a multispecialty effort to reimagine how incidental nodules are managed through the lens of the Quadruple Aim...

#### WellSpan Health's Challenges & Solutions

A nationally recognized, large, and integrated healthcare system located in south central Pennsylvania and northern Maryland, WellSpan Health is comprised of seven hospitals and hundreds of care locations spread across nine counties. This non-profit organization has a mission to improve health through exceptional care for all, lifelong wellness, and healthy communities. Throughout the healthcare system, more than 5,000 new incidental lung nodules are identified annually, with 3 percent to 3.5 percent representing malignancies.

Recognizing the need for better care coordination and prompted by the experience of a patient partner, in 2017, WellSpan Health embarked on a multispecialty effort to reimagine how incidental nodules are managed through the lens of the Quadruple Aim: improving the patient and provider experience, lowering per capita cost of care, and optimizing the health of populations.<sup>17</sup> In a two-day value stream project facilitated by a performance specialist and oncology service line, multiple WellSpan Health team members from primary care, diagnostic, and treatment specialties joined a patient partner to map the journey of a patient with lung cancer from incidental finding to treatment. The resulting map revealed a complex maze of events and communications that patients and families had to navigate on their own. Our patient partner learned that he had a high-risk lung nodule on a chest computed tomography (CT) via the MyWellSpan patient portal. From the moment he saw his findings, the patient partner described his journey as one filled with anxiety, questions, waiting, and self-navigation of a complex landscape with no map. After hearing from this patient, the WellSpan Health team recognized that the map was more than a measure of time; it embodied the patient experience and patient-provider communications throughout the care continuum.

Four improvement goals were established through the value stream mapping:

- Improve patient outcomes with timely and appropriate care
- Improve the patient experience by reducing anxiety
- Lower the cost of care by avoiding inappropriate testing
- Improve the provider experience by providing access to a pathway for well-coordinated care.

To meet these goals, WellSpan Health opened WellSpan Diagnostic Support Specialists (a remote virtual practice) in 2019.

#### **Designing a New Care Delivery Model**

WellSpan Health hired two certified, registered nurse practitioners (CRNPs) to develop and implement a consistent, well-coordinated lung nodule care experience that supports patients, their families, and their PCPs, while also bridging gaps in care. Working to their full scope of practice, these CRNPs identified the most important roles that impact patients' journey from incidental finding to final diagnosis and treatment, including radiology, thoracic surgery, pulmonology, and medical informatics. These groups then spent three months identifying current state workflows and detailing specific responsibilities of each provider specialty to understand how they fit into the larger patient experience. Re-aligning workflows was foundational to the formation of WellSpan Health's Diagnostic Support Specialists, enabling CRNPs to effectively provide follow-up care to patients with new incidental lung nodules confirmed on a CT chest scan. CRNPs use evidence-based guidelines and malignancy risk assessment tools to create an individualized treatment plan. Patients may or may not require follow-up based on their CT chest finding(s). Those needing follow-up are put into a low-risk or high-risk pathway.

Patients placed into the low-risk CT chest surveillance pathway are managed by Diagnostic Support Specialists for up to three years if 1) they are young, 2) they have a minimal smoking history, and 3) their lung nodules are smoothly marginated, smaller than 8 mm, and not in the upper lobe. If surveillance is required beyond the three-year mark, Diagnostic Support Specialists do a warm handoff to the PCP, transitioning lung nodule follow-up to primary care.

Criteria for the high-risk diagnostic pathway consist of 1) older patients with a heavy smoking history, 2) those with a family history of lung cancer, 3) those with exposure to carcinogens, and 4) those with irregular lung nodules and/or upper

#### Figure 1. Best Practice Advisory for Non-CT Chest Findings; Pending Order for Follow-Up

Recommended on: Sep 3 Read by: Radiology, Rad Finding: Lung nodule or Acuity: Incidental Impression: This is a te	liologist, MD (555- suspected lung	555-5555) nodule, not clearly benign		
Order	Do Not Order	CT chest without co	ntrast	
Acknowledge Reason				
Patient Refused Study	Study Ordered	Performed at another facility	Not attending	Recommendation not applicable

#### Figure 2. Best Practice Advisory for Nodules Confirmed on CT Chest Finding



lobe location, and greater than 8 mm. For these patients, Diagnostic Support Specialists' CRNPs place a referral to a specialist and order pre-testing as clinically indicated.

A registered nurse (RN) and two office support staff aid with courtesy notification to PCPs for lung nodules identified on non-CT chest studies, patient notification of lung nodules and treatment plans, nodule tracking, scheduling, and obtaining prior authorizations.

The Diagnostic Support Specialists team collaborates with the Diagnostic Physician Advisory Team, which includes specialists who represent interventional radiology, pulmonology, thoracic surgery, family practice, and medical oncology. Biannual meetings with the advisory team are used to review the Fleischner Society's guideline updates<sup>18</sup> and program performance, and identify opportunities for regional and systemwide improvements. The Diagnostic Physician Advisory Team is available for immediate collaboration and consultation upon CRNP request.

#### Technology to Optimize Lung Nodule Care

Leveraging technology to align workflows and implement a process to address identification, documentation, communication, and follow-up of incidental lung nodules was essential to the success of Diagnostic Support Specialists.<sup>19</sup> An in-depth review of our current electronic health record (EHR) identified the tools below, which helped align workflows, optimize lung nodule identification, conduct tracking and documentation, and improve communication with patients and PCPs so that care is provided in a timely manner.

#### Identification and Tracking

The tools radiologists use within the EHR are customized to automatically communicate incidental lung nodule follow-up recommendations. The method in which radiologists sign the study within the EHR is also modified to document acuity (incidental), identify the suspected lung nodule(s), and enter follow-up recommendations based on the Fleischner Society's guidelines. The DSS [Diagnostic Support Specialists] prefix was added to the recommendations for confirmed lung nodules on a CT chest scan to route patients' imaging results to the appropriate recommendation work list at Diagnostic Support Specialists.

#### Documentation and Communication Tools

Diagnostic Support Specialists developed and included these documentation and communication tools:

- "Smart tools" within the EHR to provide structured, consistent documentation. The creation of "DSS reason for encounters" signifies involvement of Diagnostic Support Specialists and is easily identified within the EHR.
- Customized documentation and telephone encounter note templates with embedded smart phrases and links to capture reason for encounter, follow-up plan, personal/family history, smoking history, past imaging, as well as patient and PCP

#### Figure 3. Best Practice Advisory Coordination: Incidental Lung Nodule Workflow

Recommendation is being reviewed by Diagnostic Support Specialists. Follow-up action to be determined and will be communicated to the ordering provider



notification. These templates provide guidance and scripting for staff during patient calls, which expedite efficient documentation in the EHR.

• A "DSS Smart Set" with note templates for documentation of initial and surveillance treatment plans that provide quick, consistent, and efficient care when initiating a treatment plan. Once the Smart Set is opened, the diagnosis, follow-up imaging, medications, and referrals are available for ordering with a simple click.

Best practice advisories to facilitate and communicate clear recommendations for next steps to the ordering provider, helping to avoid inappropriate testing. Radiologists electronically deploy these advisories when incidental lung nodules are found in an imaging study (Figures 1 and 2, on page 40).

- Letter templates in English and Spanish to communicate with patients and PCPs. The templates feature drop-down menus that include reminders for scheduling overdue CT chest scans, completion of surveillance, discharge from the program, and (if eligible) referrals to the LDCT program.
- A secure group chat, "WSH [WellSpan Health] Diagnostic Support Specialists," so that any provider within WellSpan Health can reach out to Diagnostic Support Specialists (through the EHR) with any questions or concerns.

#### Clinical Follow-up

Diagnostic Support Specialists created treatment follow-up algorithms based on the Fleischner Society's guidelines. Vetted annually by the Diagnostic Physician Advisory Team, these algorithms improve the provider experience by enabling access to a pathway for well-coordinated care.

#### **Metrics**

Diagnostic Support Specialists created a patient registry to capture demographic and clinical data, PCP affiliation, and malignancy

risk score. Three reports in the registry track and quantify patients and capture practice metrics for those under surveillance by Diagnostic Support Specialists and those referred to specialists for high-risk work up.

A diagnostic-risk Excel spreadsheet maps the patient's journey, capturing the time from initial CT scan sign date to referral to Diagnostic Support Specialists, pretesting and consult completion, and, lastly, final diagnosis. The spreadsheet helped establish baseline metrics and identify areas where resources are needed to optimize lung nodule care within the healthcare system.

#### Education and Implementation of Incidental Lung Nodule Workflow

Once Diagnostic Support Specialists established a workflow process, patient care delivery options were explored. Diagnostic Support Specialists deemed telehealth options viable as they are convenient for patients, while also allowing providers to establish a patient relationship and provide quality lung nodule care. In collaboration with WellSpan Health Marketing, Diagnostic Support Specialists developed a systemwide plan to educate key

#### Figure 4. Follow-up Recommendation Options Available for Radiologists



players and end users, who would receive help from this new lung nodule care delivery model. A computer-based module educated radiologists on how to tag a study to start follow-up through Diagnostic Support Specialists algorithm. Through a coordinated and deliberate rollout plan, Diagnostic Support Specialists introduced its workflow to primary care practices. PCP feedback was then used to refine the workflow (Figure 3, page 41), and the initiative went live in late 2019.

#### **Evidence-Based Care in Real Time**

This novel care delivery model uses technology to align the clinical workflow of the radiologist, CRNP, ordering provider, and PCP to communicate incidental lung nodule findings in real time and provide evidenced-based guidance on next steps in patient management.

#### Step 1. Image Study Completed

The lung nodule workflow begins when an individual obtains an imaging study at any WellSpan Health location.

#### Step 2. Radiologist identification and electronic notification to ordering provider and Diagnostic Support Specialists

The radiologist is critical to the initiation of this workflow. If a lung nodule is found incidentally, the radiologist will identify:

- 1. The acuity of the study as "incidental"
- 2. The finding as a "lung nodule or suspected lung nodule"
- 3. An appropriate "recommendation" for follow-up imaging study.

All three steps must be completed to initiate the Diagnostic Support Specialists workflow.

The radiologist signing the study immediately triggers an electronic best practices advisory notification—with clear recommendations based on clinical guidelines—that is sent to the ordering provider, and the patient is categorized into one of two work lists at Diagnostic Support Specialists.

#### Step 3. Lung Nodules Routed to Diagnostic Support Specialists

The type of study and recommendation for follow-up determines which worklist the patient will populate. Lung nodules identified on non-CT chest studies are routed to pathway 1; lung nodules confirmed on a CT chest are routed to pathway 2. Recommendations with a "Diagnostic Support Specialists: recommendation" prefix route patients to the pathway 2 worklist for CRNP review (Figure 4, page 42).

#### Step 4. Pathway 1 Worklist

For non-CT chest findings, the radiologist marks the finding as incidental lung nodule, or suspected lung nodule, with a recommendation of a "CT chest w/o [without contrast] in 1 week" (Figure 5, below). An electronic best practice advisory notification and preliminary order for nodule confirmation on a CT chest is then sent to the ordering provider (Figure 1, page 40). Simultaneously, the identified patient is routed to the pathway 1 recommendation work list. Program assistants and nurses at Diagnostic Support Specialists monitor this worklist in the EHR to confirm that the ordering provider or PCP is notified. Because Diagnostic Support Specialists has limited EHR access to patients being

#### Figure 5. Radiologists Workflow to Initiate Pathway 1

lings & Recommend	lations
Lung nodule or Incidental	suspected lung nodule, not clearly benign - Completed after 48m 32s
Result acuity:	Critical         Significant: Delay MyWellSpan         Significant         Incidental         Non-Significant         None
Finding:	Lung nodule or suspected lung nodule, not clearly benign
	Patch in Physician Lung nodule or suspected lung nodule, not clearly benign
Finding comment:	
Recommendation:	CT Chest WO - 1 Wk
	XR Chest 1 VW - 1 Wk         XR Chest 2 VW - 1 Wk         CT Chest With - 1 Wk         CT Chest WO - 1 Wk
	Specify Additional Imaging

#### Figure 6. Radiologist Workflow to Initiate Pathway 2

rinding - inclue	ental 72h 00m remaining 🗙	
Result acuity:	Critical Significant Delay MyWellSpan Significant Incidental Non-Significant None	
Finding:	«Non-specific finding»	,o
	Lung nodule or suspected lung nodule, not clearly benign	
Finding comment:		
Recommendation:	DSS: CT Chest wo 12 Mo	,o
	Specify Additional Imaging	

treated by independent and/or out-of-network providers, a letter is sent to the PCP for follow-up on the same day the CT is routed to Diagnostic Support Specialists.

WellSpan Health's medical providers are given one week to use the best practice advisory for lung nodule follow-ups that are routed to them. If no action is taken within seven days, Diagnostic Support Specialists sends a courtesy reminder to WellSpan Health's medical group PCPs. If a patient has no PCP, Diagnostic Support Specialists' CRNP orders follow-up testing for lung nodule confirmation.

#### Step 5. Pathway 2 Work List

For confirmed nodules on CT chest scans, the radiologist marks the finding as incidental lung nodule or suspected lung nodule with the recommendation of "Diagnostic Support Specialist CT chest w/o [without contrast] in X months." The follow-up timeframe adheres to the Fleischner Society's guidelines (Figure 6, above). When the radiologist signs the image report, a best practice advisory is immediately sent to the ordering provider to inform them that a "Diagnostic Support Specialists' CRNP is reviewing the study and follow-up action will be communicated" (Figure 2, page 40).

Concurrently, the patient's CT chest results are sent to the Diagnostic Support Specialists pathway 2 worklist. The nature of the finding and a protocol-based approach determines if follow-up is needed and what action is taken by Diagnostic Support Specialists. The CRNP acts on any new incidental lung nodules found on CT chests scans for patients with WellSpan Health medical group providers. To ensure that no patients are lost to follow-up, the Diagnostic Support Specialists treatment plans are sent to the PCPs, so they can assist with coordination of care when necessary. Diagnostic Support Specialists' services are offered to WellSpan Health independent providers; treatment plans are initiated upon receipt of referral. For patients with out-of-network providers, Diagnostic Support Specialists sends a courtesy letter to the PCP, so they can provide the needed follow-up.

Diagnostic Support Specialists' services encompass all steps following discovery of an incidental nodule, from scheduling to obtaining prior authorizations and monitoring patients to ensure that CT surveillance and specialty referrals are completed.

#### Step 6. Patient Notification

All patients with new lung nodules confirmed via CT chest scans completed at a WellSpan Health facility—regardless of PCP affiliation—are called within two business days. Video visits are available upon request. If unable to notify patients via telephone, Diagnostic Support Specialists will use WellSpan Health's patient messaging or mail to relay this information.

If a patient needs to speak to someone right away, a radiologist inserts a statement in the image impression report with a contact number to call Diagnostic Support Specialists directly. As the 21st Century Cures Act requires immediate release of patient information,<sup>20</sup> the ability to contact Diagnostic Support Specialists directly offers access to a medical professional immediately when a patient with a lung nodule finding may be particularly anxious.

Regardless of where in WellSpan Health's service area the imaging study occurs, this novel approach allows patients to be monitored through transitions of care, minimizing loss to follow-up. If a patient has no PCP, Diagnostic Support Specialists will assume care and provide follow-up as clinically indicated. This approach facilitates the longitudinal surveillance of lung nodules. Subsequent surveillance results are sent directly to the CRNPs, ensuring the lung nodules are not lost to follow-up.

(Continued on page 46)



Figure 7. CT Sign Date to Positron Emission Tomography (PET) Scan

#### Figure 8. CT Sign Date to Diagnosis



#### **Challenges Faced**

Inadequate smoking history was a significant barrier to implementing an appropriate treatment plan across the continuum. Diagnostic Support Specialists developed and implemented standard documentation pertinent to obtaining an accurate pack-year history and ensured this information was updated at each patient encounter. Collection of this data was a clinical quality metric, and Diagnostic Support Specialists surpassed the goal, achieving a score of 98 percent completion.

This care delivery model identifies, implements, and expedites patient lung nodule care in real time and provides consistent follow-up along the continuum of care.

Accurate documentation of smoking history is foundational not only to the success of Diagnostic Support Specialists but to patients' care going forward. Once a patient completes lung nodule surveillance, Diagnostic Support Specialists sends a letter to the patient and their PCP. The patient is informed of their eligibility for future lung cancer screening, and a best practice advisory is set up to trigger ongoing lung cancer screening by the PCP. This simple intervention can significantly impact the identification of lung cancer in these high-risk patients.

Another challenge encountered is when outside radiologists' (or nighthawks) read WellSpan Health studies. Because these reads are not captured in the EHR, the incidental lung nodule workflow is not triggered. To overcome this challenge, the Diagnostics Support Specialists use artificial intelligence in the form of a Human-in-the-Loop machine learning framework to programmatically identify incidental findings in the narratives of reports signed by outside radiologists. This process was a gap measure until 2022, when the imaging service line implemented a tool within the EHR to capture these outside images.

#### **Outcomes and Next Steps**

More than 900 patients are currently under lung nodule surveillance by Diagnostic Support Specialists, with 235 patients under high-risk surveillance or diagnostic work-up. The implementation of Diagnostic Support Specialists' workflow has positively impacted the time from CT sign date to final diagnosis.

This care delivery model allowed Diagnostic Support Specialists to achieve a 20 percent reduction from baseline CT sign date to pretesting order completion prior to specialty consult (Figure 7, page 45). Forty patients have undergone a diagnostic procedure. Twenty-seven patients have been diagnosed with lung cancer; 50 percent of those were found at an early stage. The average time from CT sign date to diagnosis decreased by approximately 50 percent since the inception of Diagnostic Support Specialists practice (see Figure 8, page 45). Of the 27 patients with initial CT chest scans, 10 occurred in the hospital and 1 patient had no PCP. These vulnerable patients were at particular risk of being lost to follow-up if not for the workflows developed by Diagnostic Support Specialists.

The ability to diagnose patients at an early stage is greatly enhanced when LDCT and incidental lung nodule programs are used in tandem. Our next step is to formalize the transition of eligible Diagnostic Support Specialists patients into the WellSpan Health LDCT program.

#### **Final Thoughts**

This care delivery model identifies, implements, and expedites patient lung nodule care in real time and provides consistent follow-up along the continuum of care. Thus, patient outcomes are optimized by early intervention of undiagnosed lung cancer. This novel care delivery model for incidental lung nodule findings can serve as a springboard for other incidental findings and help detect other early carcinomas.

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Ithough the U.S. has realized tremendous progress in diagnosing and treating many types of cancer over the last 20 years, not all segments of society are benefiting equally from these advances. The AACR Cancer Disparities Progress Report 2022 highlights the challenges: "Despite these advances, racial and ethnic minorities and other medically underserved populations continue to experience more frequent and higher severity of multilevel barriers to quality cancer treatment including treatment delays, lack of access to guideline-concordant treatment, and higher rates of treatment-related financial toxicities. The same population groups may also experience overt discrimination and/or implicit bias during the delivery of care."<sup>2</sup>

The COVID-19 pandemic further exacerbated health inequities—as communities most affected by social determinants of health factors lived with a greater burden from the virus both in terms of disease and economic impact.<sup>3</sup>

In the 2022 American Society of Clinical Oncology Education Book, *Strategies to Advance Equity in Cancer Clinical Trials*, Guerra et al. write, "Underrepresented populations—including minority groups, elderly individuals, and rural populations—limit the generalizability of research and prevent clinicians and patients from determining whether new cancer drugs have the same efficacy and safety in these subsets of excluded populations. In addition, exclusion of these populations contributes to delayed enrollment and thus inefficiency of clinical trials."<sup>4</sup>

During the past several decades, research has identified common barriers to patient participation in clinical trials and, specifically challenges to enrollment for medically under-served patient populations. A recent systematic review and metaanalysis by Unger and colleagues posits that with the current complex, intertwined barriers inherent in the U.S. clinical trial enterprise, patients have little opportunity to consider clinical trials as a treatment option.<sup>5</sup> The analysis focused on the rate of participation among adult patients who were offered the opportunity to enroll in a cancer clinical trial. The findings revealed that patients—regardless of race or ethnicity—when asked, agree to participate in a cancer clinical trial more than half the time.<sup>5</sup> In conclusion, the authors write: "Indeed, this finding indicates that perhaps the best way to improve enrollment "The pursuit of health equity ought to be elevated as the fifth aim for health care improvement, purposefully including with all improvement and innovation efforts a focus on individuals and communities who need them most."

of minority patients to cancer trials is simply to ensure that minority patients are invited to participate. The recognition of this may inform efforts to alleviate potential bias in the provision of healthcare resources by race or ethnicity, including trial offers for eligible patients."<sup>5</sup>

Among the strategies to advance equity in cancer clinical trials suggested by Guerra and colleagues are the following:<sup>4</sup>

- 1. Establish a systemic process to screen all patients for trial eligibility. (Without a standardized process, the authors note, programs adopt ad hoc approaches to screening, which can create opportunity for implicit bias in the selection process.)
- 2. Invite all patients who match trial eligibility criteria to participate.

In 2020, the American Society of Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACCC) came together in a multi-year collaboration that built on these study findings, publishing a joint ASCO-ACCC Research Statement that outlined specific actions for individual stakeholders in the cancer clinical trial ecosystem to increase diversity in research participation. Among the published recommendations: "Recommendation 1: Clinical trials are an integral component of high-quality cancer care, and every person with cancer should have the opportunity to participate."<sup>6</sup>

On July 25, 2022, ASCO and ACCC released three resources to help cancer programs and practices increase racial and ethnic equity, diversity, and inclusion in cancer clinical trials:

- <u>The ASCO-ACCC Equity, Diversity, and Inclusion Research</u> <u>Site Self-Assessment</u> can be used to identify systemic areas that are known to affect enrollment of diverse patient populations into clinical studies and to gain site-specific recommendations to modify rules and procedures. Completion of the self-assessment helps to identify opportunities for performance and quality improvement across various levels of the organization. The assessment covers the clinical trial enrollment continuum through seven domains that include patient access to the site, screening patients for clinical trials, offering patients clinical trials, and participation and retention in trials.
- The Just ASK<sup>™</sup> Training Program addresses the recognized 2. barrier to clinical trial enrollment highlighted in the recent study by Unger and colleagues-i.e., not being asked to participate. The free, interactive training helps research and healthcare staff to better understand the universal nature of implicit (unconscious) and conscious bias, to underscore the imperative to increase diversity in accrual to clinical trials, and to raise awareness of opportunities for change at the individual level. Real-world examples connect underlying challenges with everyday clinical care. The training materials are adapted from a Duke University program pioneered by Nadine Barrett, PhD, Assistant Professor Family Medicine and Community Health at Duke University and Associate Director for Equity and Stakeholder Strategy, Duke Cancer Institute. The adaption process was spearheaded by a steering group composed of leading experts in diversity, equity, inclusion in cancer care. Learn more at https://www.accccancer.org/home/learn/community-oncology-research/ascoaccc-initiative.
- The <u>Just ASK<sup>™</sup></u><u>Training Facilitation Guide</u> complements the training with guidance for facilitators on how to keep the conversation around implicit biases going once the initial training is completed.

#### A Use Case Study

Dr. Marisa Weiss, director of breast radiation oncology and breast health outreach at Lankenau Medical Center, Wynnewood, Pa., is a champion for the Just ASK program. Dr. Weiss has been in clinical practice for more than 30 years. She is also founder and chief medical officer of <u>Breastcancer.org</u>, a global patient advocacy organization providing free expertise and support to individuals with breast cancer in English and Spanish. In both roles, Dr. Weiss is an advocate for equity in cancer care delivery and empowering informed patients to fully participate in their cancer care.

In her dual roles, Dr. Weiss is witness to the collateral damage the COVID-19 pandemic has brought to patient populations that were already medically under-served and she is concerned about the pandemic's persistent negative effect on cancer disparities. Lankenau Medical Center's service area includes West Philadelphia, where the median annual income is about \$35,000 and multi-layered social determinants of health impede health equity.

Through the lens of <u>Breastcancer.org</u>, Dr. Weiss has been immersed in the 24/7 devastation from the pandemic, with the exacerbation of pre-existing health disparities "resulting in delayed diagnoses, treatment disruptions, and dangerous social isolation." Among the medically underserved, "we are slipping and losing precious ground that took decades to obtain," she said. "We've seen the data. Breast cancer incidence [is] still rising in Black women and the death rate has risen at a greater level compared with White women." The American Cancer Society reports that although Black women have a 4 percent lower incidence rate of breast cancer compared to White women, they have a 40 percent higher mortality rate [than White women]. This death rate disparity has been unchanged for the past 10 years.<sup>7</sup>

"Half to three-quarters of people note financial hardship...financial toxicity ends up being another disease. Maybe your treatment is over, but this disease of financial toxicity with mounting unpaid bills and the threat of bankruptcy lingers on."

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Dr. Weiss is acutely aware of "the financial toxicity that compounds every one of the social determinants of health. Further, it constrains a person's ability to get timely quality care. Overall, in the literature, we know that half to three-quarters of people note financial hardship." She cited a recent <u>Breastcancer.org</u> survey where just over half of respondents reported financial hardship, and about 25 percent indicated that they were stretching out their medicines to make them last longer—a step that disrupts the efficacy of their treatment. "We know that financial toxicity ends up being another disease. Maybe your treatment is over, but this disease of financial toxicity with mounting unpaid bills and the threat of bankruptcy lingers on."

Pre-pandemic Dr. Weiss and colleagues at <u>Breastcancer.org</u> had collaborated with Dr. Nadine Barrett and Duke Cancer Institute on health equity research. Through the Lankenau Institute for Medical Research, Dr. Weiss began development of a use case study designed to engage medically under-represented patients to participate in clinical trials, addressing a major barrier to health equity in cancer care.<sup>8</sup> Although the use case study was planned prior to the Just ASK program launch, the study design incorporated recommendations for improving diversity, equity, and inclusion that align with those in the ACCC-ASCO research statement, Weiss said. This included:

- Identifying an urgent study topic highly relevant to the under-served patient population. In this instance, the clinical trial focused on chemotherapy-induced peripheral neuropathy, a common yet difficult-to-treat side effect from the most commonly used chemotherapies, i.e., taxanes and -platins. Chemotherapy-induced peripheral neuropathy is a doselimiting toxicity that disproportionately affects Black patients with cancer treated with neurotoxic chemotherapies and is associated with negative outcomes, Weiss said.
- Making study eligibility criteria as non-restrictive as possible. To appeal to a broad patient cohort, the study was open to people with breast cancer, ovarian cancer, uterine cancer, colorectal cancer, and pancreatic cancer receiving either a taxane or -platin chemotherapy. Except for potential study drug interactions with other medicines and conditions (like a recent heart attack), and preexisting neuropathy, most other co-morbidities were not exclusions.
- *Providing a culture of respect and inclusion.* Building trust with all potential participants was foundational to Lankenau Medical Center's study culture including always being respectful; full transparency; protecting patient privacy; providing as many study visits as necessary, as well as access to all members of the team; never rushing any conversation or process (like consent); and being accountable for timely follow-up on any question or request.
- Making sure that the diversity of the research team represented the diversity of study participants. The main clinical research coordinator was African American and the research assistants were Latina and Muslim.
- *Enabling convenient participation.* The trial design allowed a flexible schedule for study visits with an option for virtual visits when in-person visits were not feasible.
- Designing accessible study materials. Care was taken to design study materials that were "understandable, appealing, inviting, informative, and shareable," Weiss said.
- *Identifying and inviting all eligible patients.* "We knew we needed to make sure that all people who were able to participate in the clinical trial were asked to participate," Weiss said. As the team learned, this was not a one-step process. First, everyone on the study team was asked to invite anyone who could be eligible to participate in the trial. "But that turned out to be very unreliable," Weiss said. One problem was timing. The study was launched during the early days of the COVID-19 pandemic. Under these extraordinary circumstances, with everyone working at capacity and beyond, this was not a reliable recruitment strategy, Weiss said.

Next, the study team turned to technology, manually querying Epic to identify all patients who would potentially be eligible for the trial. Manual queries were necessary because the hospital does not have an automatic query system in Epic to effectively identify patients eligible for specific trials. This manual query process, conducted daily, ultimately yielded about half the patients enrolled on the trial, Weiss said.

- *Identifying and addressing patient barriers to clinical trial enrollment.* Once an eligible patient was invited to enroll in the trial, the study team worked with the Lankenau Medical Center social worker and support staff to identify and address social determinants of health barriers with an asset-based approach, Weiss said. This included common barriers such as transportation, food insecurity, housing instability, and medical insurance coverage.
- Collecting and reporting data on patient demographics. Although the study launched in 2020 during the early days of the pandemic, the study achieved 30 percent enrollment by Black individuals, and points to the power of "just asking" all eligible patients to consider clinical trial participation.

"The long-term goal would be systemwide Just ASK training so that everyone in the hospital who touches on the care of a cancer patient could benefit...along with an ongoing commitment to reduce and eliminate any institutional racism."

Despite this success, Weiss emphasized that the years-long COVID-19 pandemic has further exacerbated challenges to equity in clinical trial enrollment. "Under-represented patient populations' participation in cancer clinical trials-already less than 5 percent-saw further declines during the pandemic," she said. "We know the decline in clinical trial participation was multifactorial. Our research program, like many, was shut down for six months in 2020. When clinical and research teams are understaffed and overworked, there is much less time to identify eligible patients and invite them to participate in clinical trials. Then, too, there was an abrupt shift to focus more on the COVID-19 pandemic than on breast cancer clinical trials. Patients' ability to join a trial was further constrained by a greater burden of social determinants of health challenges (due to the pandemic), with associated highrisk of disease and comorbidities. It wasn't just that people couldn't address their breast cancer concerns; they couldn't address other underlying conditions such as diabetes, heart disease, and everything else."

#### **Aligned to Advance Health Equity**

Going forward, Lankenau Medical Center is taking innovative steps to advance equity in clinical trials and leading this effort within the Main Line Health system (of which Lankenau is part). The newly developed RESPECT (Reaching Equitable Standards for Patient Engagement in Clinical Trials) Initiative is one example. This program aims to help grow capacity skills in the community and build bridges between community-based organizations and the Lankenau Medical Center healthcare team that includes social workers, navigators, nurses, physicians, financial counselors, clinical research coordinators, and other staff, so that Lankenau can improve the quality and continuity of care for the patients it has the honor of serving, Weiss said.

The ASCO-ACCC Just ASK training program is a pillar of the RESPECT Initiative, Weiss said. "It is a beautifully developed and executed program to train our hospital staff with evidence-based information, cultural sensitivity, cogent case examples, and immediately implementable practical solutions." The long-term goal would be system-wide Just ASK training so that everyone in the hospital who touches on the care of a cancer patient—physician, nurse, navigator, social worker, clinical research coordinator, financial counselor, receptionist—could benefit and the health system could advance the goal of improving health equity along with an ongoing commitment to reduce and eliminate any institutional racism, she said.

At present, bringing together leadership across the health system to learn about and experience the Just ASK Training program is yielding key insights into internal foundational steps that must precede system-wide roll out to maximize opportunities for success. Dr. Weiss recommends the following:

- Identify champions in leadership and within each department for the Just ASK training program.
- Publicly acknowledge and reward the completion of Just ASK.
- Establish CME accreditation for any staff completing the Just ASK program
- Ensure that assessment of social determinants of health is done effectively and consistently across the health system.
- Address social determinants of health needs consistently and effectively across the system.
- Enable EHR system(s) to handle clinical trial eligibility queries so that once staff is trained in the Just ASK program, they can follow through as easily as possible.
- Have all clinical trials in a ready-to-access portfolio available at physicians' or clinical research coordinators' fingertips.
- Create a process to track completion of Just ASK training by staff.

Maintaining a focus on health equity across all sectors of hospitals and health systems requires alignment across leadership. Below is a sample of what leadership alignment on health equity at Lankenau Medical Center Main Line Health looks like.

Amanda Patton, MA, is a freelance healthcare writer. She worked as a senior writer and editor for the Association of Community Cancer Centers for more than 15 years.



Katie Galbraith, President and CEO, Lankenau Medical Center

**PRESIDENT AND CEO KATIE GALBRAITH** assumed her new role at Lankenau Medical Center in October 2022. Previously, she served as president of Duke Regional Hospital and during the past two years as co-incident commander for the COVID-19 response for the Duke Health System. Her tenure at Duke also included an 18-month stint as interim head of community health for the health system.

"Health equity is a critical part of our mission as hospitals, as health systems. We are all focused on improving the health of the communities we serve. We can't say we're improving the health of the communities we serve unless we are improving it for everyone, and part of that responsibility is to really partner and collaborate with our communities to learn what their needs are and to be responsive and to work together in partnership to eliminate health disparities."

"And one of those disparities, of course, has been in access to clinical trials and participation in clinical trials. This is where the Just ASK program is going to be so valuable and has been proven to be valuable already in other settings. Making sure we are doing everything we can to understand implicit bias, to understand and acknowledge the disparities that do exist, and then work together through that knowledge to close the gap and eliminate disparities."

"This is one of the most challenging times in healthcare that we're living through right now. I have had the concern-just broadly-that we could lose our focus on equity if we're not careful. We can't do that. We have to make sure that equity is front and center because it is core to who we are as healthcare organizations. It's core to our mission of caring for our communities and improving the health of the communities we serve. We can't do that if we don't do that through the lens of equity, making sure that we are caring for everyone and valuing every individual for who they are, understanding their unique needs, and then being able to serve those unique needs. Being able to work together to eliminate disparities and make sure that we are providing the very best care and getting the best outcomes for everyone that we are serving."



George Prendergast, PhD, President and CEO, Lankenau Institute for Medical Research

**DR. GEORGE PRENDERGAST** has served in his role at Lankenau Institute for Medical Research since 2004. This nonprofit, biomedical research institute is located on the campus of Lankenau Medical Center in Wynnewood, Pa. Dr. Prendergast affirms the institute's deep commitment to equity, diversity, and inclusion in clinical research, in accord with Lankenau Medical Center and Main Line Health. The use case study for which Dr. Weiss serves as principal investigator was conducted through Lankenau Institute for Medical Research and is just one example of innovation underway to address diversity in trial enrollment.

Dr. Prendergast describes the ASCO-ACCC Just ASK Training program as an accessible and foundational resource "to prompt clinical trial participation for those who might not otherwise have been approached."

Recently, the Lankenau Institute for Medical Research launched a new population health research center in collaboration with Thomas Jefferson University with oversight from an advisory committee composed of Jefferson and Lankenau Institute for Medical Research experts. A priority for the population research group, Prendergast said, is improving understanding of diversity in research with regard to patient populations within the Main Line Health's catchment area. This includes a focus on data collection on the demographics of patient populations being accrued to clinical trials to better understand how patient accrual demographics compare with those of the catchment area.



Deric C. Savior, MD, System Division Chief, Hematology-Oncology, *Main Line Health*; Co-Director of Main Line Health Cancer Care and Chief, Medical Oncology, *Lankenau Medical Center* 

MEDICAL ONCOLOGIST DERIC C. SAVIOR, MD, previously served as Head of Medical Oncology at Fox Chase Cancer Center at Temple University Hospital. Throughout his career, Dr. Savior has centered his practice on ensuring that all patients, particularly the sickest patients from the local medically underserved community, have access to and receive high quality cancer care.

Dr. Savior completed the Just ASK Training, which he describes as an "accessible and practical" step toward keeping health equity front of mind. He believes the Just ASK training is really important because "it will help us to acknowledge and combat the biases that we have that too often affect the delivery of equitable care and access to research in under-represented populations. It will help also raise awareness about the biases and beliefs that we as providers may harbor and how these beliefs may impact equitable care to all of our population. It helps us acknowledge the bias and gives us strategies to combat it."

"Just asking a patient to participate in a trial will not only potentially help them, but also help the people that come behind them. Something as simple as asking the patient—and that intervention alone kind of levels the playing field, and tells us how far we have to go in addressing our own biases, how we can ask one patient population and not the other—shines a light on the issues we have to address within ourselves as practitioners so that we can make sure all of our patients have equal access to these modalities and interventions."

Amidst the complex, competing priorities of our rapidly shifting healthcare landscape, Dr. Savior is wary of the potential for health equity to become a "check the box" exercise. "It's great to acknowledge these important issues and to discuss them. Thoughtful discussion and analysis are no longer sufficient. It is now the time for effort and action. You have to implement strategies to combat inequities. The Just ASK program does just that. It is one strategy in a multitude of things we need to do, but it's a good starting point.... So many lives hang in the balance. The way technology and innovations are advancing, we have to make sure everybody has equal access to quality care and clinical trials. Otherwise, certain vulnerable populations will be left further behind. It's really imperative that we get this right as soon as possible.



Marisa C. Weiss, MD, Director, Breast Radiation Oncology and Breast Health Outreach, *Lankenau Medical Center* and Founder and Chief Medical Officer, Breastcancer.org

"TREATMENT DECISIONS ARE OFTEN made between a doctor and a patient in the community setting or in the hospital environment," Weiss said. "To make shared decision-making more equitable, more of a level playing field, more effective, we need to address what is going on in a hospital between a doctor and a patient. I have a clinical practice that gives me the ability to work in a system, Main Line Health, that is a large community hospital system with a strong commitment to equity, diversity, and inclusion in research and to reducing health inequities—starting at the top of the system, there is fierce commitment."

"Health disparity is an urgent public health problem that threatens the lives of precious populations. Their lives are at stake, they are losing ground, requiring immediate action by community-based hospital systems."

"When we learned that Dr. Nadine Barrett's pivotal research at Duke would be scaled through a collaboration with ACCC and ASCO, we thought, 'this is perfect timing.' We can use this well-done, beautifully developed program to train our staff...so that everybody in the hospital who touches on the care of a cancer patient doctor, nurse, nurse navigator, clinical research coordinator, social worker, financial counselor, receptionist could all have the benefit of the Just ASK training to empower them to become more effective in their role and to achieve our strong commitment to health equity, including improved access to clinical trial participation by addressing social determinants of health with an assetbased approach."

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DEVELOPING A HEALTH LITERACY AND CLEAR COMMUNICATIONS E-COURSE

ASSESS & IMPROVE HEALTH LITERACY AT YOUR CANCER PROGRAM



# Introduction ?

uality patient care begins with clear and compassionate communication between providers and patients. In fact, communication is the cornerstone to achieving positive patient outcomes. Patients with cancer have unique communication needs, which vary and can change at different points during their care. Providers who take time to assess where a patient is coming from (e.g., language, literacy level, culture, etc.) and who encourage open communication, have better patient health outcomes.

Health literacy is generally defined as an individual's ability to find, understand, and use information or services to make decisions for their care or the care of others.<sup>1</sup> A survey of Association of Community Cancer Center (ACCC) members found that 45 percent of respondents identified limited health literacy on behalf of the patient as a barrier to effective shared decision-making.<sup>2</sup> Yet, of those surveyed, only 28 percent said they always or frequently assessed for health literacy.

Patients with poor health literacy have difficulty with written and oral communications that can limit their understanding of cancer symptoms and tests, which can negatively impact their stage at diagnosis.<sup>1</sup> Beyond diagnoses, low health literacy can also impact shared decision-making on treatment options, informed consent for routine procedures, and participation in clinical trials. Improving the capacity of patients to understand information related to their cancer diagnosis, treatment, and post-treatment follow-up is key to closing gaps that impede health equity.

### e-Course Development



In 2021, ACCC worked with a multidisciplinary advisory committee to develop an interactive electronic learning course (e-Course) titled, *Health Literacy and Clear Communications e-Course*. This dynamic online course provides cancer care team members with the tools needed to be clear and concise in communications with patients, build awareness and skills regarding health literacy, and improve health equity. Available on the ACCC Learning Management System, the self-paced e-Course provides:

- Actionable tips and strategies on clear communications with patients
- Evidence-based health literacy practices
- An explanation of the teach-back method
- Assessment of patient education materials.

The Health Literacy and Clear Communications e-Course identifies the following actionable strategies for learners:

- Use clear communication and body language
- Translate complex oncology concepts into plain language
- Calm patient fears and correct misconceptions
- Enhance cultural competency.

Funded and supported by *Lilly Oncology*, the *Health Literacy and Clear Communications e-Course* can be used by healthcare providers to immediately implement effective practices into their cancer programs. The e-Course includes the following key concepts.

#### Communication

Studies show patients with low health literacy levels struggle to understand medication regimens, disease progression, and management.<sup>3</sup> However, cancer care providers may not know or even be able to assess literacy. This can create a tendency to overestimate the patient's literacy level. Because it is critical for cancer care providers to communicate with patients based on their literacy level, effective communication skills are promoted throughout the *Health Literacy and Clear Communications e-Course*.

#### Non-Verbal Communication or Body Language

The Health Literacy and Clear Communications e-Course examines how non-verbal communication impacts patient comprehension of health information. Non-verbal communication includes body language, mannerisms, facial expressions, and actions.<sup>4</sup> Body language is a specific tactic highlighted within the e-Course. To provide clear communication, key factors to consider include:

- Body position: How and where the body is positioned, for example, folding arms, inclining the head, and where we are in relation to others
- Facial expression: Smiles, frowns, or raised eyebrows
- **Eye contact:** How and when we look at others. This can include staring, looking away, or looking over your shoulder
- **Touch:** How and where we touch ourselves, others, and objects, such as glasses, clothing, a computer, etc.
- Physical reactions: Blushing, rapid breathing, or sweating.

#### Teach-Back Method

This method is used to educate patients with necessary information and ensure they understand the information shared by their cancer care provider.<sup>5</sup> The teach-back method follows four key steps: 1) Explain, 2) Teach Back, 3) Assess, and 4) Repeat, as needed. Providers explain information in short, plain language statements called "chunks." Then, patients are asked to repeat back the information in their own words to check for comprehension. Cancer care providers will then assess whether patients understand the health information shared. If not, providers will repeat the process until they are comfortable that patients understand the health information being conveyed.

#### **Health Equity**

Health literacy and health equity are connected. In laymen's terms, health literacy makes health information clear and understandable, while health equity principles ensure inclusivity. Health equity refers to the ability of all people to achieve the highest level of health. Health literacy principles put into practice, help to advance health equity.<sup>6</sup> In healthcare settings, these concepts include:

- Testing materials with patients
- Providing language services to those with limited English proficiency

- Creating materials at a sixth-grade reading level
- Communicating in a way that does not blame patients for their circumstances.

Research has shown that incorporating health equity principles into health information promotes better adoption of healthy practices because it meets patients where they are at—culturally and linguistically.

#### **Cultural Competence**

Health literacy is impacted by cultural competence. Studies show that unaddressed cultural differences and contrasting concepts of health and illness can lead to poor patient health outcomes.<sup>7</sup> In addition, due to the aging and increasingly diverse patient population, these challenges are likely to increase. The *Health Literacy and Clear Communications e-Course* looks to train cancer care providers to identify and address health literacy and cultural competence to deliver patient-centered care that also reduces health disparities. Evidence shows training providers to address both issues can lead to less medication errors, improved patient adherence, and clear communication between patients and providers.

## Results and What Learners Are Saying



In 2022, ACCC analyzed pre- and post-survey assessments to evaluate the outcomes and effectiveness of the *Health Literacy and Clear Communications e-Course*. In the initial pilot, 87 learners registered for the course; 37 completed the post-assessment following e-Course completion. These learners shared that they felt proficient in:

- Providing clear communication with patients
- Using evidence-based applications of health literacy practices
- Explaining complex oncology concepts in plain language
- Applying the teach-back method
- Assessing patient materials.

A look at pre- and post-survey results showed an increase for all learning objectives:

- Clear communication with patients increased from 70
   percent to 94 percent
- Evidence-based application of health literacy practices rose from 43 percent to 83 percent
- Explanation of complex oncology concepts in plain language increased from 39 percent to 81 percent
- Use of the teach-back method rose from 41 percent to 89 percent.

In addition to these findings, 89 percent of learners reported that they were likely to recommend the e-Course to a colleague, and 75 percent reported they were likely to implement the e-Course within their cancer program or practice.

## Qualitative interviews with learners also shared positive data:

- <sup>66</sup> Reflecting on our own practice makes you think and consider elements that you may not have considered when reaching for a pamphlet...I really liked the cultural competency piece. At our cancer center, we must always use an interpreter if English is not the first language. And I don't feel that a lot of the education pieces have been modified to reflect cultural competency.<sup>21</sup>
  - Sandi Vonnes, DNP, GNP, AOCN Geriatric Oncology, Moffit Cancer Center
- Excellent review on all the components involved in teaching and communicating with patients...Would recommend this course. It is a very nice basic course, very understandable, [and I] would like every new nurse to take it.<sup>27</sup>
  - Vicki Vann, MS, APRN, OCN Nursing Professional Development, Patient Education Specialist, Moffitt Cancer Center

## Conclusions and Next Steps



Education programs like the *Health Literacy and Clear Communications e-Course* can help provider learners effectively communicate with patients. Cancer care providers can use evidence-based health literacy practices, such as the teach-back method and assessment of printed materials, to explain complex oncology concepts to patients. ACCC will examine future educational opportunities to conduct concurrent assessment of patient and caregiver perspectives and incorporate them into provider education and evaluation of health literacy training programs in clinical practice.

#### **Additional Resources**

- Gap Assessment Tool. By completing the assessment tool, cancer programs and practices can identify educational needs and pinpoint areas where targeted education could improve patient care. Available at accc-cancer.org/assess-your-program
- Ask Me 3 Tool and Video. Developed by health literacy experts at the Institute for Healthcare Improvement, this tool encourages patients to ask three simple questions each time they talk to a care team member: 1) What is my main problem?, 2) What do I need to do?, and 3) Why is it important for me to do this? Available at accc-cancer.org/ask-me-3-tool
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Association of Community Cancer Center

#### ASSOCIATION OF COMMUNITY CANCER CENTERS

## An Innovative Approach to Navigating Patients Through Cancer Diagnostics

## An Inside Look at Precision Medicine Stewardship at TriHealth Cancer and Blood Institute

s advancements in cancer diagnostics have propelled precision medicine forward, next generation sequencing (NGS) technology has become a popular way to perform multigene testing in patients with cancer.<sup>1</sup> Recently, the American Society of Clinical Oncology (ASCO) released a clinical opinion encouraging the use of multigene panel-based assays in patients with metastatic or advanced cancer if more than one biomarker-linked therapy is approved for the patient's disease;<sup>2</sup> however, implementation of such guideline-concordant testing continues to present challenges. Surveys and focus groups have reported impediments associated with ordering biomarker tests, tracking tissue samples, communicating results to clinicians, and other operational challenges. One solution that has been gaining popularity is the development of a new role in the multidisciplinary cancer care team-a precision medicine steward, who serves as the point person and navigator for biopsy samples and biomarker testing processes.

The Association of Community Cancer Centers (ACCC) explores how cancer programs are overcoming common barriers associated with cancer biomarker testing through its education initiative, *Precision Medicine Stewardship*. In this article, ACCC shares how TriHealth Cancer and Blood Institute has improved coordination of its biomarker testing program through the introduction of its own steward role in the form of a precision medicine test coordinator.

#### **TriHealth Cancer and Blood Institute**

TriHealth Cancer and Blood Institute provides multidisciplinary cancer care at over 125 locations throughout the greater Cincinnati area in Ohio. Featuring the largest personalized medicine program for adults in the region, TriHealth is leading the way in immunotherapy and in the development of customized treatment plans for its patients. Because TriHealth believes in providing patients with a full, multidisciplinary program of care, its precision oncology team includes medical oncologists, nurses, genetic counselors, clinical researchers, genetic specialty lab coordinators, pathologists, surgeons, pharmacists, and laboratory partners. Together, this team works to recommend genetic testing, review genetic lab results, ensure accurate diagnoses, identify the best treatment plans, deliver treatments at patient-centered infusion centers, and coordinate advanced care with seamless communication between physicians and medical teams. Beyond this, clinical experts and oncology scientists meet regularly for molecular tumor boards to review tumor profiling test results and make therapy or trial recommendations.

Recognizing the expanding role of biomarker testing in patients with cancer, TriHealth Cancer and Blood Institute formed their first precision oncology working group eight years ago and developed innovative ideas around streamlining the biomarker test ordering process; today, this has evolved into the precision medicine test coordinator role, whose primary purpose is to ensure optimal clinical workflows and to reduce delays in test ordering.

#### **Precision Medicine Test Coordinator**

As a member of the precision oncology team, the precision medicine test coordinator works closely with oncologists, nurses, pathologists, and genetic counselors. TriHealth Cancer and Blood Institute has digitized several steps in the biomarker test ordering process, which has created a more efficient workflow for the precision medicine test coordinator. Working with a single reference lab that offers comprehensive NGS testing, TriHealth built an electronic order that links directly to the partner lab in its Epic system and integrated the workflow using the Epic Genomics Module for the return of discrete biomarker results. While most biomarker tests are ordered through this reference lab, occasionally an order may be placed with a different lab, requiring manual entry into the lab portal. Regardless of the lab used, the consistency of using Epic to place test orders and utilizing the precision medicine test coordinator as the point of contact for clinical and lab teams has improved TriHealth's ability to return results quickly to ordering providers and their patients. Through the power of technology and the addition of this single role, TriHealth's turnaround time from order to results decreased from an average of 24 days to 12 days and the quantity not sufficient (QNS) rate of testing decreased by five percent (unpublished, internal data).

The precision medicine test coordinator role also includes the following responsibilities:

- Coordination with internal and external anatomic pathology departments to ensure that documentation and samples are sent to the reference lab as quickly as possible when pathology slides or cell blocks need to be obtained from an outside institution.
- Coordination of blood draws for QNS tissue samples to complete biomarker testing. Blood is usually drawn during medical oncology visits but can be collected through mobile phlebotomy services.
- Working with patients to complete patient financial assistance applications. On a weekly basis, the reference lab sends the precision medicine test coordinator a list of patients who have already applied for patient assistance. This helps the precision medicine test coordinator direct communication to patients who are eligible but have not yet applied.
- Entering test orders into the lab portal when an oncologist orders a test from a non-integrated reference lab. When the results become available, the precision medicine test coordinator retrieves the results, enters them into Epic, and notifies the ordering physician.

#### EHR Integration: Discrete Genomic Data

At TriHealth Cancer and Blood Institute, the use of Epic ordering (rather than through outside portals) and the Epic Genomics Module has streamlined several key components around biomarker test ordering and results. Test orders are entered directly into Epic and results appear in Epic's "Lab" section as discrete data elements. A PDF of the report is connected to the order as a reference and uploaded into the "Media." Currently, the Module directly interfaces with a single reference lab for tumor biomarkers and a second lab for germline genetic tests, however TriHealth is working to build Epic integrations with several other labs.

By using the Epic Genomics Indicators Module, TriHealth Cancer and Blood Institute can display test results alongside other lab tests (where providers are accustomed to looking), but also features separate sections for easy readability:

- 0 11	Clinical Snapshot More -	Variant Results Report
- C 🖁 👪 🖪 😨 Clinical Snapshot More -		Variant Results Report 🔎 🌽 👻
Z Pharmac	ogenomic Results	
No content to d	lisplay.	
Somatic	Genomic Results	Expand All Collapse A
Myoepithelia	I carcinoma (HCC)	
	TUMOR GENOMIC PROFILE	Results Report Collected: 6/7/2
(1) Presen	t - Pathogenic (4)	
Gene	Variant	VAF
BCOR	BCOR - Copy number loss	_
CDKN2A		-
CDKN2B	CDKN2B - Copy number loss	-
MTAP	MTAP - Copy number loss	_
Present -	Uncertain significance (6)	4
X Miscellar	eous Genomic Results	Expand All Collapse A
т	UMOR GENOMIC PROFILE	Results Report Collected: 5/22/2
Present - Un	certain significance (1)	٩
₫ Germline	Genomic Results	Expand All Collapse A
		Results Report Resulted: 10/14/2
() Present -	Pathogenic (1)	
Gene	Variant	Allelic State & Phase
CFTR	CFTR NM_000492 c.2052dupA p.Q685Tfs*4	Heterozygous
Present - Un	certain significance (1)	
Gene	Variant	Allelic State & Phase
BRCA2	BRCA2 NM_000059 c.4037_4043delCTGTTTGinsT p.T1346_C1348delinsl	Heterozygous

Figure 1. Example of Epic Genomics Indicators Module

Structured genomic data can be linked to automated genomic indicators and trigger alerts (e.g., best practice advisories) that provide clinical decision support for providers. Using the Epic SlicerDicer software (a data extraction, analysis, and reporting tool), the precision oncology team has also been able to study whether certain patient groups may be receiving suboptimal testing. While researchers have used SlicerDicer for a variety

#### Figure 2. Example of Epic Care Gap Logic

Topic	Due Date	Frequency	Date Completed
Current Care Gaps			
Pneumococcal 0-64 (1 - PCV)	Overdue - never done	Imm Details	
MRI Breast PALB2 Positive	Overdue - never done	1 year(s)	
Mammography PALB2 Positive	Overdue - never done	1 year(s)	
COVID-19 Vaccine (3 - Booster for Janssen series)	Overdue since 1/26/2022	Imm Details	12/1/2021 - COVI 5/29/2021 - COVI
PAP Screening	Overdue since 4/17/2022	3 year(s)	4/17/2019 - CYT
Upcoming			
DTap, Tdap, and Td (4 - Td or Tdap)	Next due on 1/18/2032	Imm Details	1/18/2022 - Tdap 5/19/2020 - Tdap 5/24/2016 - Tdap
Completed or No Longer Recommended			
Influenza Vaccine	Completed	Imm Details	10/26/2022 - Influ 10/19/2021 - Influ 9/23/2020 - Influe 11/11/2019 - Influ 11/11/2019 - Influ 12/1/2018 - Influe
Meningococcal conjugate valent 4 (MCV4)	Aged Out	Imm Details	

of clinical and epidemiological analysis<sup>3</sup> and to identify eligible patients for research studies,<sup>4</sup> at TriHealth, a designated research coordinator reviews cases that have been flagged by the NGS lab for clinical trial inclusion/exclusion criteria and cases are subsequently reviewed during monthly molecular tumor board meetings.

By integrating genomic test results into the electronic health record (EHR), clinicians can build rules so that the Epic Care Gap logic (a built-in care planning and coordination tool) automatically triggers specific follow-up items for patients who have specific indicators (e.g., schedule a follow-up meeting with the multidisciplinary clinic to discuss screening tests).

#### Precision Oncology Team

As biomarker testing has continued to expand and include more patients with advanced cancers, TriHealth Cancer Institute has added a second precision medicine test coordinator to its roster. Together, these coordinators share responsibilities and coordinate workflows to ensure that biomarker test orders are entered completely and any delays when obtaining pathology slides from outside institutions are minimized.

The precision oncology team has also established a vetting process for reviewing new labs and tests. The team regularly gathers internal data to identify opportunities for quality improvement in cancer biomarker testing. Using the analytics and reporting tools in Epic, the team has built automated data dashboards for genetic counselors and specific oncology areas such as lung cancer or breast cancer to visualize trends in biomarker testing.

Examples of key metrics tracked by the precision oncology team include the following:

- What proportion of patients with advanced cancers are receiving biomarker testing? How many patients had actionable results? Team members can see a breakdown of this information by different cancer types.
- When a new targeted therapy becomes available, which patients are potentially eligible for treatment? Using a few clicks, a report can be generated to identify these patients.



#### Patients that match to a clinical trial reported by physician Learner & Vitable Metaletises Metale - Jun 30, 2022 Physician 1 Patient Level Data Physician 2 Physician 2 Physician 3 9

Physician 4

#### Figures 3 and 4. Examples of Epic SlicerDicer Software

- What proportion of patients apply for financial assistance? How many receive assistance? Using these data, the precision medicine test coordinator can reach out to oncologists and nurses to inform them about which patients may still need to be offered an assistance application.
- Are there any groups of patients who are receiving suboptimal testing? Could this indicate a health disparity?

#### **Future Direction**

As oncologists continue to expand their use of NGS testing in patients with advanced cancer, the need for precision medicine test coordinators will continue to grow. The precision oncology team at TriHealth Cancer and Blood Institute also continues to seek ways to improve operational efficiencies and enable their oncologists to have the right information they need to make informed treatment decisions. As they work to integrate other labs through the Epic Genomics Module, Tri-Health Cancer and Blood Institute will be able to streamline the test ordering process across multiple areas of oncology and receive test results as discrete data elements for analytics and reporting. These refinements will affect both somatic and germline testing, so there may be more coordination needed between precision medicine test coordinators and genetic counselors to ensure the right tests are being ordered. As the cancer biomarker landscape evolves, more testing may be

needed as patients undergo liquid biopsy, sequential testing to identify resistance genes, or other tests to track treatment progress. Moreover, by having genomic data directly linked to clinical decision support tools, clinicians will be better equipped to recommend optimal treatments for patients.

For more examples and resources, visit the ACCC Precision Medicine Stewardship program <u>webpage</u> (accc-cancer.org/precision-medicine-stewardship).

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## ASSOCIATION OF COMMUNITY CANCER CENTERS

## Examining Patient-Centered Small Cell Lung Cancer Care: PATIENT AND PROVIDER PERSPECTIVES

#### **BACKGROUND INFORMATION**

o uncover barriers in obtaining optimal care for patients with small cell lung cancer (SCLC), the Association of Community Cancer Centers (ACCC) conducted patient and provider surveys. The purpose of the surveys was to garner real-world insights into the factors that lead to delayed diagnoses and treatment, and poor symptom management of patients with SCLC.

The provider survey was developed by the Association of Community Cancer Centers (ACCC) and sent via direct email to providers between March and April 2022. A survey was also developed for patients with SCLC to impart additional context to the provider survey. The patient survey was developed by CE Outcomes, LLC, and reviewed by ACCC. Managing physicians and online support groups distributed the survey to patients between May and July 2022. Both surveys were submitted and received internal review board (IRB) exemptions. A follow-up survey was also conducted to better understand physicians' prescriptive treatment approaches for their patients with extensive-stage SCLC (ES-SCLC).

#### **Provider and Patient Surveys**

Of the 100 provider responses, 32 percent were physicians, 26 percent were advanced practice providers (APPs) or pharmacists, 27 percent were nurses or nurse navigators, and 15 percent were psychosocial support providers (PSS). Physicians identified equally to working in a community cancer program (34%), versus a private practice (34%). Work environment was similarly distributed among other provider types (APPs/pharmacists and nurse/nurse navigators). In contrast, psychosocial support providers were most commonly found working within a private or physician practice at 47 percent. The physician follow-up survey had a 41 percent response rate (13/32).

Of the 51 patients who responded, the median age was 40. Fifty-three percent (53%) were male, and 59 percent had limited-stage SCLC (LS-SCLC). Racial and ethnic breakup was as follows: 69 percent were White, 10 percent were Black/ African American, and six percent (6%) were Asian/Asian American, Hispanic/Latinx, American Indian/Alaska Native, or Native Hawaiian/Pacific Islander. Forty-five percent (45%) of surveyed patients held private insurance, 33 percent were beneficiaries of Medicare, eight percent (8%) had Medicaid, and two percent (2%) were under- or uninsured.

#### **Diagnosis and Management of SCLC**

Delays in the diagnosis of SCLC have been variably estimated due to the use of different parameters across studies. In a systematic review, the median time from symptom onset to diagnosis was estimated to be 69 days for patients with any stage of SCLC, and the median time from symptom onset to the first visit with a specialist was 33.3 days among patients with any type of lung cancer.<sup>1</sup> A US-based study not included in the systematic review, found that there was a median time of 52 days between the first clinic visit to treatment for patients with NSCLC (69% of cohort) or SCLC (31% of cohort).<sup>2</sup>

In the ACCC patient survey, patients reported they saw a median of three doctors for their symptoms prior to receiving their SCLC diagnosis. Given the rapid doubling time of SCLC, clinical presentation can be consistent with pulmonary inflammatory or infectious conditions, leading to delays in appropriate management.<sup>3</sup> Providers reported that the top three contributors to a delay in SCLC diagnosis were biopsy confirmation or pathology results, patient access to care, and scheduling delays such as availability of office appointments (see Figure 1, page 4).

In a systematic review of lung cancer research, nine studies found an association between shorter wait times from diagnosis to treatment, and improved patient outcomes.<sup>1</sup> Additionally, a single-center study from the MD Anderson-Cooper Cancer Center in New Jersey found that SCLC stage at diagnosis was predictive of survival.<sup>4</sup> Although the data are somewhat mixed, taken together, early diagnosis is critical to improve outcomes for patients with SCLC.

Currently, molecular profiling by next-generation sequencing (NGS) is recommended for only those patients with ES-SCLC who have never smoked or lightly smoked tobacco.<sup>5</sup> Molecular profiling does not change the treatment approach, however, because targeted therapies that require the presence of gene mutation as identified by NGS are not yet approved for SCLC. Because of this, it is not surprising that 15 percent of APPs and 19 percent of physicians in the ACCC provider survey reported rarely/never ordering NGS for limited-stage SCLC patients.

The mean time from diagnosis of SCLC to treatment has been reported as 18 days.<sup>1</sup> In previously conducted research in SCLC care, factors associated with delayed time to treatment initiation included outpatient versus inpatient workup, number of diagnostic procedures, early- versus late-stage disease, and increasing age.<sup>6</sup> Physicians and APPs reported in the ACCC survey that the major causes of significant delays in treatment for limited- and extensive-stage disease were insurance approval, biopsy confirmation, and staging evaluation (see Figure 2, page 5). Clinic infusion availability was reported as a cause for delay in treatment more frequently for extensive-stage disease, particularly by physicians.

#### **Quality of Life**

Providers indicated that quality of life (QOL) was an important factor in treatment decisions (see Figure 3, page 5). Most providers indicated that the role of QOL in decision-making is dependent on disease staging, and whether the treatment is considered curative or palliative. Providers also noted that a shared decision-making approach was important with consideration of the patient's stated preferences and goals. Providers measured QOL primarily through discussions with their patient. In this instance, a good QOL is considered to be the ability to continue activities of daily living (ADLs) or desired activities, achieve goals, and interact with family and friends. In the patient survey, respondents indicated that their QOL could be improved with assistance in overcoming the following challenges during treatment: management of their pain or any other unwanted symptoms, addressing their psychological wellbeing, help with logistical aspects of SCLC care, such as financial barriers and living situations, and addressing spiritual or existential suffering.

#### **Disease Burden**

Frequently, patients present with symptoms suggestive of widespread metastatic disease, such as weight loss, bone pain, and neurologic compromise. Increasing symptom burden has a negative impact on patients' quality of life.<sup>5</sup> ACCC's patient survey found the most bothersome symptoms of SCLC were persistent cough (48%), loss of appetite (47%), chest pain or discomfort (45%), fatigue (43%), difficulty breathing or wheezing (36%), and hoarseness or difficulty speaking (30%) (see Figure 4, page 6).

#### TREATMENT PATTERNS AND REFERRALS

#### **Limited-Stage SCLC**

The provider survey used a case study to ask specific questions about treatment and management patterns for LS-SCLC. The case study patient had LS-SCLC with multiple involved nodes (see side bar). The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) specify concurrent RT and a platinum agent plus etoposide as a preferred first-line treatment option for a patient with medically inoperable LS-SCLC.<sup>7</sup> Consistent with this recommendation, most physicians (91%) and APPs (73%) would treat the case study patient with concurrent RT and chemotherapy (see Figure 5, page 7). The NCCN Guidelines® preferred recommendation for second- and subsequent-line treatment is clinical trial participation or a platinum-based doublet chemotherapy regimen. Rechallenging with the original or a similar platinum-based regimen should only be considered, however, if there has been a disease-free interval of three to six months.

#### **Case Study: LS-SCLC**

- JD: 69-year-old man with fatigue, weight loss, dry cough, shortness of breath
- 50-year history of tobacco use but quit 3 years ago
- Bronchoscopy showed right hilar mass with 4 right and 4 left lymph nodes involved
- PET-CT showed no distant disease
- Diagnosed with limited-stage SCLC

#### **Referral to a Clinical Trial for LS-SCLC**

Fifty-one percent (51%) of physicians and sixty-seven percent (67%) of APPs indicated they would either definitely or likely refer the case study patient for clinical trial participation (see Figure 6, page 7), depending on clinical trial availability. However, multiple barriers to clinical trial participation were identified by physicians, including lack of trial availability, lack of transportation or other logistical barriers, patient preference, narrow inclusion criteria, and need for more immediate treatment (see Figure 7, page 8). The primary reason for not referring to a clinical trial was that the provider would try the standard of care/first-line treatment first, or it was felt that a trial was not needed. In addition, not all providers had access to clinical trials in their practice.

#### **Extensive-Stage SCLC**

The NCCN Guidelines recommend preferred first-line treatment regimens for ES-SCLC include doublet chemotherapy with atezolizumab or durvalumab followed by atezolizumab or durvalumab maintenance, regardless of PD-L1 expression.<sup>7</sup> In the follow-up survey, respondents reported that most of their patients (80%) with newly diagnosed ES-SCLC receive a platinum doublet plus atezolizumab or durvalumab as first-line therapy. Autoimmune disorders, prior allergies, and cost concerns were all reasons given by respondents for the 18 percent of their patients who receive chemotherapy alone as first-line therapy. Physicians in this cohort shared that an average of four percent (4%) of their patients did not receive any first-line treatment for ES-SCLC due to factors such as poor performance status, multiple comorbidities, and patients' decision to choose palliative care. SCLC is highly sensitive to initial chemotherapy with good response rates, however most patients will relapse.8 As such, the survey also explored second and subsequent-line ES-SCLC treatment and management patterns. NCCN Guidelines preferred second-line regimens include platinum-based doublets or a clinical trial. Other recommended regimens include chemotherapy or immune checkpoint inhibitors. In the ACCC survey, 13 percent of physicians reported that less than or equal to 50 percent of their patients with ES-SCLC initiated second-line treatment at disease progression. Twenty percent (20%) of APPs reported that less than or equal to 50 percent of patients initiated second-line treatment at disease progression. In the follow-up survey, physicians reported that many factors are considered in whether they would recommend platinum-based rechallenge when choosing subsequent systemic therapy for patients with SCLC. These include degree and duration of first response, patient performance status and organ function, as well as number of comorbidities.

Data from the ACCC survey shows a potentially substantial portion of patients are not receiving second-line therapy (see Figure 8, page 8). Several barriers to second-line treatment initiation among patients with ES-SCLC were identified by physicians, with the most important being concerns about patient fitness, followed by concern about managing treatment-related adverse events, and the presence of multiple comorbidities. APPs reported a greater concern for comorbidities and managing treatment-related adverse events than physicians. They also reported concerns with lack of transportation, lack of a support system, and difficulty comprehending the diagnosis for patients. In a follow-up survey, physicians noted several key factors that would need to be present in new anti-cancer agents before they would consider recommending for second-line treatment to patients with ES-SCLC. Factors included fewer side effects, manageable cost, and high response rates with improved survival.

#### **Patient Role in Decision Making**

Overall, patients reported feeling that they make substantial contributions to final decisions regarding treatment selection. Twenty-seven percent (27%) of patients said that although their physician made the final decision, their opinion was considered, 27 percent said that they made the final decision but seriously considered the physician's opinion, 24 percent said the responsibility was shared, 14 percent indicated leaving all decisions to the physician, and eight percent reported that they made the decision.

#### Caregivers

Caregivers are frequently involved in treatment and care planning. Thirty-two percent (32%) of providers indicated that more than half of their patient cases involved a caregiver. Of the patients who involve a caregiver, while the majority of communication regarding treatment and care is conducted with the patient, 41 percent of physicians and 35 percent of APPs said they had this conversation with the caregiver more than 50 percent of the time (see Figure 9, page 9). This suggests that most caregivers provide an important supportive role to patients with SCLC. Inclusion of caregivers at patient visits should be strongly considered, and caregivers should be included in communication, education, and the decision-making process.

#### SUPPORT SERVICES AND TRUSTED RESOURCES

#### **Support and Ancillary Services**

The ACCC survey found that APPs, nurses, and psychosocial support providers were more likely to provide education and information to patients, including an explanation of the diagnosis, answering questions, providing educational handouts and trusted internet resources, and providing referrals to supportive care services. These data highlight the importance of APPs as part of the care team, as they are the primary team member who provides patients with education and information about their diagnosis and treatment.

An important aspect of supportive care is referral to palliative care. The American Society of Clinical Oncology (ASCO) recommends that all inpatients and outpatients with advanced cancer be referred to dedicated palliative care services, preferably with an interdisciplinary team, early in their disease course.9 This recommendation is based on data from randomized controlled trials that demonstrated palliative care services improve quality of life, reduce rates of depression and depressed mood, and in some cases, prolong overall survival. Specific to SCLC, a single-center, retrospective study found that patients who received early palliative care demonstrated improved overall survival (P=.01), and a numerically lower median number of hospitalizations compared with delayed palliative care.<sup>10</sup> A larger retrospective study of over 23,000 patients with lung cancer, including 18 percent with SCLC, found that palliative care improved survival when initiated between one month and one year after diagnosis (adjusted hazard ratio, 0.47; 95 % Confidence Interval, 0.45-0.49), but there was no improvement in survival if it was initiated after one year.11

Regarding the case study patient presented in the survey, 31 percent of physicians, 58 percent of APPs, and 70 percent of nurses indicated they would make a direct referral to palliative care. Physicians reported, they typically refer patients to palliative or supportive care at various stages during treatment, including, after failure of multiple lines of therapy, upon first recurrence or refractory disease, at diagnosis, or when symptoms become difficult to manage or are uncontrolled. APPs were more likely to refer their patients when symptoms became difficult to manage or after multiple lines of therapy (see Figure 10, page 9). These data highlight an opportunity to improve patient care, as palliative care is recommended to be initiated at earlier stages of the disease. Barriers that limit referral to palliative care were most commonly patient resistance, lack of understanding of the value or focus of palliative care, and the capacity of palliative care services.

#### **Trusted Resources**

An important part of oncology care is to support patients through their cancer journey, from diagnosis to survivorship. This includes education about their diagnosis and treatment. However, the ACCC survey found that, for the case study patient, 59 percent of physicians would provide an explanation of the patient's diagnosis and what it means for them, 47 percent would provide materials or handouts about their diagnosis, 50 percent would answer all of the patient's questions, and 22 percent would provide a list of trusted internet sources or patient advocacy organization for support (see Figure 11, page 10). APPs were more likely to provide this information to patients, but at least a quarter or more of APPs said that they would not. Patients reported this type of information is something they would like more of, including links to specific websites with accurate and updated information about SCLC (67%), paper pamphlets or handouts from their care team (63%), information about support groups, both social medical groups or local options (59%), information about smartphone and tablet applications (51%), and more information about

how national SCLC organizations or advocacy groups help patients (51%; see Figure 12, page 10). ACCC's upcoming Comprehensive Care Initiative aims to help address this gap.

#### **Patient Advocacy Groups**

- LUNGevity Foundation
- Cancer.Net
- GO2 Foundation for Lung Cancer
- American Cancer Society
- Cancer Support Community

#### CONCLUSION

The results from the provider and patient surveys identified several critical gaps in the management of SCLC, including barriers to access clinical trials, delayed referral to palliative and supportive care services. Additional areas of concern, as identified in other published studies and discussed by members of this project committee, include a need for earlier detection of SCLC when it is potentially curable, as well as the identification of new, more effective personalized therapies. NCCN recommends clinical trial participation as an important treatment option, particularly for second and subsequent-line therapy, yet a majority of providers reported a concern about the presence of barriers that prevent many patients from participating in trials. Moreover, although nearly all patients receive first-line treatment, many patients are not receiving second-line therapy and are not being referred to palliative or supportive care services during their SCLC journey, highlighting a critical gap in the overall management of SCLC. (continued on page 74)

#### **FIGURE 1.** Provider-Reported Reasons That Contribute to Delays in SCLC Diagnosis

	■ Physician (n = 32)	■ APP (n = 26)
Delay in biopsy confirmation or pathology results	59%	77%
Patient delays in accessing care	59%	62%
Scheduling delays (office appt. unavailable in a timely manner)	44%	54%
Referral patterns from PCP or pulmonologist	31%	42%
Limited access to specialists/ tumor board	25%	19%
Other	0%	0%

	FIGURE 2. Provider-Reported Causes of Significant Treatment Delays for SCLC		
	Limited-stage SCLC ■ Physician (n = 32) ■ APP (n = 26)	Extensive-stage SCLC ■ Physician (n = 32) ■ APP (n = 26)	
Insurance approval	56% 77%	56% 77%	
Biopsy confirmation	59% 62%	56% 54%	
Staging evaluation	63% 54%	59% 54%	
Clinic infusion time availability	19% 19%	33% 15%	
Patient social/compliance factors	26% 54%	37% 62%	
Other* *Patients often seek second opinions and this delays the start of treatment.	4% 0%	4% 0%	

#### FIGURE 3. Provider-Reported Role of QOL in Treatment Decisions



How often are each of th Multiple times per day Daily	e following potential symptoms of SCLC bothersome to you? Weekly Present, but bothers me less than once per week Not presen
Cough that won't go away	24% 24% 25% 16% 12%
Fatigue	18% 25% 31% 18% 8%
Loss of appetite	<b>18% 29% 25% 14% 14%</b>
Chest pain/discomfort	<b>16% 29% 27% 16% 12%</b>
Difficult breathing or wheezing	12% 24% 33% 27% <mark>4%</mark>
Hoarseness or difficulty speaking	12% 18% 25% 20% 25%
Weight loss	10% 22% 25% 18% 25%
Facial swelling	8% 14% 24% 27% 27%
Swollen neck veins	8% 20% 24% 24% 25%
Coughing up blood	6% <mark>14%27%25%27%</mark>

#### FIGURE 4. Patient-Reported Frequency of SCLC Symptoms

#### Other symptoms related to SCLC

Sleep issues/tired/weakness **8%** Back/spine pain/localized pain **6%** Trouble eating/weight loss **6%** Fever **3%** Blood issues/bleeding **3%** Inflammation/swelling **3%** 

#### FIGURE 5. Treatment Patterns of Limited-Stage SCLC With Involved Nodes

#### Physician (n = 32) APP (n = 26) Combination of 91% 73% chemotherapy/radiation Combination of 6% 19% surgery/chemotherapy/radiation 8% Chemotherapy 3% Surgery 0% 0% Radiation 0% 0% 0% Other 0%

#### What type of treatment would you recommend to JD?

#### FIGURE 6. Clinical Trial Referral Rates for LS-SCLC

#### How likely would you be to refer JD for clinical trial participation?

	■ Physician (n = 32) ■ APP (n = 26)	
l would definitely refer JD for clinical trial participation	13%	31%
l would liking refer JD for clinical trial participation	38%	35%
l would not likely refer JD for clinical trial participation	47%	35%
I definitely would not refer JD for clinical trial participation	3%	0%

#### FIGURE 7. Provider Beliefs of Barriers to Clinical Trial Participation by Patients

#### 67% 73% Lack of trial availability 44% 58% Patient preference 46% 37% Urgency of treatment initiation Performance status important 30% 46% for treatment decisions Lack of transportation/ 22% 34% other logistical barriers 19% 46% Inclusion criteria for trial is too strict Sufficient administrative support to 15% 31% enroll/identify patients 23% 15% **Financial constraints** 0% 0% Other

#### What barriers would you anticipate confronting in attempting to enroll JD in a clinical trial? $\square$ Physician (n = 32) $\square$ APP (n = 26)

#### FIGURE 8. Patterns of Second-Line Treatment Initiation for ES-SCLC

## What percentage of your patients with extensive-stage SCLC initiate treatment with second-line therapy at the time of disease progression?

Physician (n = 32) APP (n = 26)

l don't know	3%	15%
0% - 25%	0%	8%
26% - 50%	13%	12%
51% - 75%	38%	27%
76% - 100%	47%	38%



#### FIGURE 9. Provider Perception of the Role of Caregivers







#### FIGURE 11. Proportion of Providers Who Would Offer Education to the Case Study Patient

#### FIGURE 12. Patient-Requested Resources About SCLC

#### What educational material about SCLC would you like more of?

Links to website with updated SCLC information	67%
Pamplets/handouts from medical team	63%
Information about support groups, social media groups, local options	59%
Smartphone and tablet applications	51%
Information about how SCLC organizations help patients	51%
None of these	2%

#### (continued on page 74)

Key findings from the patient survey include that caregivers are frequently involved in treatment and care planning, which highlights the importance of including caregivers in discussions at patient visits, and ensuring they are also provided with education, information, and trusted resources. In addition, patients want more information about where to find accurate and updated information about SCLC on the Web, via paper pamphlets or handouts, and/or smartphone applications. Patients are also interested in learning more about patient advocacy and pertinent support groups across their care journey.

Specific recommendations from both the patient and provider surveys include a need to increase the referral rates to, and use of, palliative care and supportive services, reduce barriers to clinical trial access, educate providers on the tools and resources for assessing quality of life and patient appropriateness for second- and subsequent-line therapies, and involve the patient's and caregiver's perspectives on care planning and treatment goals. Healthcare providers and care teams should consider increasing the promotion of these resources to patients as early as possible at and/or after diagnosis. In addition, more print resources should be developed and disseminated to multidisciplinary care teams to share with patients.

#### LIMITATIONS

There were some limitations of the surveys. For the provider survey, the sample size was 100, but this was subdivided, thereby decreasing the sample size for specific types of providers. In addition, the follow-up physician survey was developed after the initial survey and included a small sample size. For the patient survey, the sample size was small at 51, and LS-SCLC was over-represented relative to the epidemiologic proportion of patients diagnosed with LS-versus ES-SCLC. Therefore, the data discussed herein may not be fully representative of the larger provider and patient populations.

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# views

## Acupuncture for Patients with Cancer at St. Elizabeth Cancer Center

RAJEEV KURAPATI, MD, MBA, AND NATALIE ADRIANO

hile anti-cancer treatments are being researched and improved daily, patients with cancer are still burdened by numerous treatmentrelated symptoms and side effects. Cancer is an incredibly mentally and physically taxing disease.<sup>1</sup> People are often faced with their own mortality, which creates stress, anxiety, and existential dread.<sup>1</sup> On top of the symptoms from the disease itself, anti-cancer treatments are often harsh with major side effects that commonly persist after the treatment is finished.<sup>2</sup> These side-effects can include immunosuppression, nausea, peripheral neuropathy, and many others.<sup>2</sup>

#### Acupuncture: Integral Component of Integrative Oncology

To improve quality of life and manage side effects associated with cancer and anticancer treatments, the practice of Integrative Oncology was developed.<sup>3</sup> Integrative oncology involves alleviating symptoms of cancer, managing side-effects from treatments, and addressing the mental health of patients.<sup>3</sup> Integrative oncology is meant to supplement traditional anti-cancer treatments to create a holistic approach.<sup>3</sup> One such treatment is acupuncture therapy, which is often used for management of physical and mental issues related to a cancer diagnosis and its treatment.<sup>4.5</sup>

Numerous research studies have suggested that acupuncture may be helpful for managing:

- Cancer-related pain<sup>6</sup>
- Chemotherapy-induced neutropenia<sup>7</sup>

- Post-chemotherapy induced fatigue<sup>8</sup>
- Radiation-induced xerostomia<sup>9</sup>
- Chemotherap-induced nausea and vomiting<sup>10</sup>
- Hot flashes<sup>11</sup>
- Psychological well-being<sup>12</sup>
- Post-operative pain<sup>13</sup>
- Anxiety and depression.<sup>13</sup>

Clinical research in acupuncture continues to provide answers for patients and oncologists about the safety and effectiveness of this integrative treatment to manage cancer- and treatment-related symptoms.

#### Acupuncture at St. Elizabeth Cancer Center

Through an internal referral system, patients with cancer, who would benefit from acupuncture, are identified and referred to our Integrative Oncology department. Patients are then scheduled for an initial consultation and treatment from our cancer program's acupuncturist, Shilpa Dias. One year after adding acupuncture to our cancer service line, we made the decision to obtain patient feedback. A cohort of 13 patients with cancer, who received acupuncture treatment from July 2021 through March 2022, were asked to share feedback about their experience in a questionnaire and in a focus group conducted in April 2022. Data from this feedback included:

• Before the acupuncture treatment, 2 out of 13 total patients reported feeling nervous about the treatment. During the acupuncture treatment, however, no



patients (0/13) reported any discomfort from the treatment.

- About half of patients (7/13) reported feelings of relaxation during the acupuncture therapy.
- Of the 13 patients, 12 reported feeling symptoms of pain or neuropathy from their cancer or anti-cancer treatment.
- After acupuncture, 5 out of 12 total patients reported analgesic effects or relief from neuropathy symptoms.
- Nearly all patients, (12/13), reported some beneficial effect from the acupuncture therapy either during or after their treatment, including the aforementioned effects, as well as improved sleep and improved appetite.

All patients (13/13) showed improvements in their most debilitating symptoms. Common improvements in symptoms included neuropathy, pain, stress, and anxiety. Individual patients reported improvements like better handwriting, better walking, and a decrease in headaches. Overall, most patients reported the acupuncture therapy as a positive experience that helped improve their physical or mental health and general well-being. These improvements enhance the quality of life for patients with cancer.

While the majority of patients reported the acupuncture treatment to be beneficial, there were two major concerns raised. The first concern was the timing of the acupuncture treatment. Patients reported wanting to start acupuncture treatment at the beginning of their chemotherapy or radiation therapy, as opposed to later in the course of their anti-cancer treatment. This idea was supported by our acupuncturist, Shilpa Dias. To help better manage symptoms, Dias recommended that acupuncture treatment start in the early phases of the symptoms, such as neuropathy, anxiety, insomnia, nausea, etc., rather than later. In other words, both patients and the provider believed that if acupuncture treatments were started sooner in the cancer treatment, they would be more effective.

The second major concern reported was the cost of the treatment; several patients (5/13) discontinued the acupuncture treatment, citing financial stress from the anti-cancer treatment as their reason. Nonfinancial reasons given for discontinuing the acupuncture treatment include travel, surgery, and resolution or improvement of symptoms.

Lack of coverage by insurance providers remains a major barrier to receiving acupuncture treatment. Currently, Medicare only covers acupuncture for lower back pain,<sup>14</sup> and commercial insurers often impose limits on the number of visits or on the total amount of coverage.<sup>15</sup> Patient advocacy groups are working for enhanced coverage for this safe and effective intervention for many patients with cancer. Meanwhile, healthcare systems, foundations, and donors can contribute to make a positive influence in providing low-cost services to people burdened by cancer.

In addition to the acupuncture services covered in this article, we offer several other Integrative Oncology modalities, including mindfulness meditation, yoga, Reiki, art and music therapy, and whole food nutritional education.

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