

RACIAL MINORITY PATIENTS UNDERREPRESENTED IN 80% OF HOSPITALS, U.S. NEWS "EQUITY MEASURES" FIND

The vast majority of hospitals in the United States—up to 80%—treat patient populations that are disproportionately white, U.S. News & World Report said, unveiling a new suite of health equity measures earlier this week.

BEN HARDER: U.S. NEWS
MAY USE HEALTH EQUITY
MEASURES TO RANK
HOSPITALS IN THE FUTURE

→ PAGE 12

SHOULD HOSPITALS, CANCER CENTERS BE RANKED ACCORDING TO THEIR HEALTH EQUITY SCORECARDS?

→ PAGE 19

HAIT AND LIBUTTI IN CONVERSATION; RUTGERS CANCER INSTITUTE FOUNDER AND ITS CURRENT DIRECTOR TALK HISTORY

→ PAGE 26

IN BRIEF

LAKSHMANAN KRISHNAMURTI NAMED CHIEF OF PEDIATRIC HEMATOLOGY, ONCOLOGY, AND BONE MARROW TRANSPLANT AT YALE

→ PAGE 32



The University of New Mexico Comprehensive Cancer Center is the Official Cancer Center of New Mexico and the only National Cancer Institute-designated Cancer Center in a 500-mile radius. Its 146 boardcertified oncology specialty physicians include cancer surgeons in every specialty (abdominal, thoracic, bone and soft tissue, neurosurgery, genitourinary, gynecology, and head and neck cancers), adult and pediatric hematologists/medical oncologists, gynecologic oncologists, and radiation oncologists. They, along with more than 600 other cancer healthcare professionals (nurses, pharmacists, nutritionists, navigators, psychologists and social workers), provide treatment to 65% of New Mexico's cancer patients from all across the state and partner with community health systems statewide to provide cancer care closer to home. They treated approximately 13,000 patients in more than 100,000 ambulatory clinic visits in addition to inpatient hospitalizations at UNM Hospital. A total of nearly 1300 patients participated in cancer clinical trials. 40% of whom participated in clinical trials testing new cancer treatments that include tests of novel cancer prevention strategies and cancer genome sequencing. The more than 100 cancer research scientists affiliated with the UNMCCC were awarded \$36.2 million in federal and private grants and contracts for cancer research projects. Since 2015, they have published nearly 1000 manuscripts, and promoting economic development, they filed 136 new patents and launched 10 new biotechnology start-up companies. Finally, the physicians, scientists and staff have provided education and training experiences to more than 500 high school, undergraduate, graduate, and postdoctoral fellowship students in cancer research and cancer health care delivery. Learn more at cancer.unm.edu.

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Editor & Publisher Paul Goldberg

Associate EditorMatthew Bin Han Ong

Reporter Alexandria Carolan

Director of Operations, Illustrator Katie Goldberg

Marketing & Account Manager Mona Mirmortazavi

DesignerJacqueline Ong

IT Manager David Koh

Editorial, Subscriptions and Customer Service

PO Box 9905 -Washington, DC 20016

T 202-362-1809F 202-379-1787W www.cancerletter.com

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In this issue

COVER STORY (HEALTH EQUITY)

4 Racial minority patients underrepresented in 80% of hospitals, U.S. News "equity measures" find

CONVERSATION WITH THE CANCER LETTER

12 Ben Harder: U.S. News may use health equity measures to rank hospitals in the future

HEALTH EQUITY

19 Should hospitals, cancer centers be ranked according to their health equity scorecards?

CANCER HISTORY PROJECT

26 Hait and Libutti in conversation; Rutgers Cancer Institute founder and its current director talk history

IN THE ARCHIVES

The National Cancer Act of 1974: Expanding "Comprehensive"

IN BRIEF

- 22 Lakshmanan Krishnamurti named chief of pediatric hematology, oncology, and bone marrow transplant at Yale
- 32 Stephanie Graff named director of breast oncology at Lifespan Cancer Institute
- 32 Jay T. Bishoff named regional director of urology at Northwell Health

- Ray Bailey, John Mills named to new leadership roles at Florida Cancer Specialists & Research Institute
- 33 Andre Nussenzweig receives 2021 Basser Global Prize
- 34 UCLA's Beth Karlan receives IGCS's lifetime achievement award
- 34 NJ appropriates \$10M for pediatric cancer research
- 34 Dana-Farber uses \$10M gift to establish the David Liposarcoma Research Initiative
- 35 AACR establishes Cancer Evolution Working Group
- 36 House approves language to protect 340B Program

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

- 37 ASTRO issues clinical guideline on radiation therapy for soft tissue sarcoma in adults
- Patients with advanced bladder cancer could benefit from immunotherapy regardless of gene mutation status

DRUGS & TARGETS

- 39 Keytruda receives FDA approval for high-risk early-stage TNBC
- 39 BMS withdraws Opdivo for liver cancer indication
- **40** FDA issues alert about increased risk of death associated with Pepaxto

HEALTH EQUITY

RACIAL MINORITY PATIENTS UNDERREPRESENTED IN 80% OF HOSPITALS, U.S. NEWS "EQUITY MEASURES" FIND

By Matthew Bin Han Ong



t roughly 4 out of 5 U.S. hospitals, racial and ethnic minorities are underrepresented among patients who access many common services ... at more than 1,400 hospitals," U.S News health analysts wrote in a July 27 editorial.

The finding stems from new health equity metrics—part of the largest expansion of decision-support services offered by U.S. News in over a decade—that now accompany the online descriptions and ratings of most healthcare institutions listed in the 2021-2022 Best Hospitals rankings.

Experts agree that these institution-specific equity scorecards should be used to inform the iconic U.S. News rankings of hospitals. The U.S. News assessment is unprecedented in visibility, scale, and character, said Ben Harder, managing editor and chief of health analysis at U.S. News.

The new measures weren't used in the rankings this year, but should that change, the existing rankings of cancer centers would likely change as well. Institutions where racial minorities are underrepresented may slide down in the pecking order.

The health equity data, which appears alongside overall and specialty care ratings, can be accessed by scrolling to the bottom of U.S. News profile pages for each evaluated hospital.

"I could not find any study that looked as broadly at elective care as we have," Harder said to *The Cancer Letter*. "This is also the first time, to my knowledge, that data like these have been reported for each individual hospital, not just the nation as a whole."

A conversation with Harder appears on page 12.

The U.S. News health equity suite largely relies on inpatient Medicare data

from 2015 through 2019 to evaluate more than 1,900 hospitals, primarily by comparing the racial demographics of patients to community benchmarks—in other words, the actual diversity within each hospital's service area.

Patients can now use the health equity measures to make informed decisions about their choice of hospital, Harder said.

"We want to understand which hospitals are providing the care that their population needs and achieving good outcomes for everyone in their community, and not just for those who may find it easier to access care or may be diagnosed earlier," Harder said. "We want to provide decision support—essentially data-driven information that patients can use to make more informed decisions."

Harder didn't say when the metrics would be used in the rankings.

"We look forward to having conversations with equity researchers, patient advocate groups, with healthcare organization leaders, about what we have measured and what remains to be measured, and how those measures might fit into our future rankings," he said.

Key findings from this year's U.S. News analysis, which focus on access, include:

- Only 29% of hospitals treated a proportion of Black patients that was comparable or higher than the proportion of Black residents in the hospitals' service areas.
- Only 18% and 5% of hospitals met that bar for Hispanic and Asian/Pacific Islander patients, respectively.
- Medicare-insured residents who are Black, compared to similarly insured residents of other races, have experienced more hospitalizations that might have been

- avoidable if they'd had access to better preventive health care.
- The racial gap in potentially preventable hospitalizations grew worse since 2011 in nearly a third of U.S. communities, despite incentives for hospitals in the 2010 Affordable Care Act to invest in improving the health of local populations.

In addition to gauging access, Harder and his team intend to expand the health equity suite to include measures on:

- Outcomes: Results of hospital care, which may include death, preventable hospital admissions or readmissions, and other consequences, and
- Social determinants of health: How hospitals, as institutions, contribute to and invest in reducing social inequities in the communities that they serve.

To comprehend the significance of disparities articulated in the U.S. News study and define the scorecards' impact on bragging rights at cancer centers, *The Cancer Letter* asked four leaders in oncology to evaluate the health equity measures:

- "More health systems are in need of a health equity report card like we use in quality and safety. I am looking forward to the day when these health equity report cards are widely used, by most if not all health systems," said Robert Winn, director of Virginia Commonwealth University Massey Cancer Center and president-elect of the Association of American Cancer Institutes.
- "Having just stepped away from leading cancer care at a major safety-net hospital, I would say

Percentage of hospitals' local elective-care Medicare patients who were Black

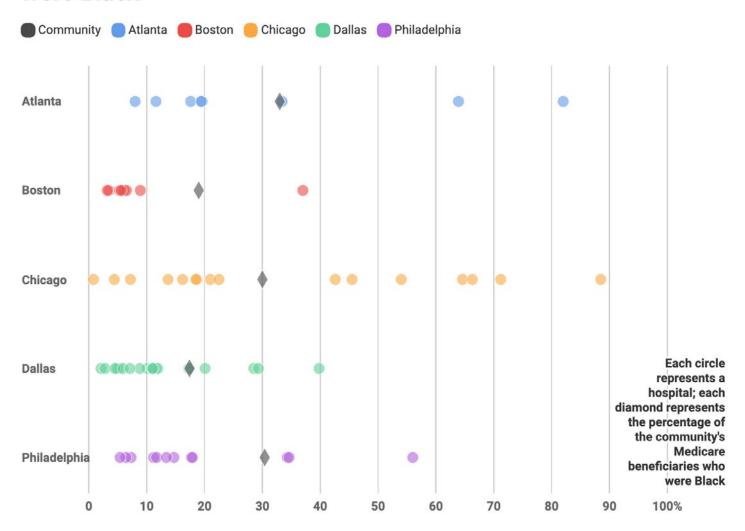


Chart: R. Corgel • Source: Centers for Medicare and Medicaid Services & U.S. Census Bureau, 2015 - 2019



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yes—health equity is, in my opinion, something that is reasonable to consider in the evaluation of hospitals," said Karen Knudsen, CEO of the American Cancer Society and former enterprise director of Sidney Kimmel Cancer Center at Jefferson.

 "The USNWR rankings are both highly visible, but also impactful in everything from marketing cancer care, to attracting faculty, to contracting with third-party payers. USNWR would likely increase the emphasis and corresponding resources that institutions would devote to these efforts and the inclusive outreach of their cancer care in their respective communities," said Ruben Mesa, executive director of Mays Cancer Center at UT Health San Antonio MD Anderson.

"I do believe that the fact that all patients assessed were insured

by Medicare, make the disparities and outcome differences seem even more profound. And yes, I am sure that when individuals insured by Medicaid, the Medicaid Waiver, private insurance, and uninsured patients are examined, the differentials and disparities in patients served and outcomes will be tremendous and concerning," said Cheryl Willman, director and CEO of University of New Mexico Comprehensive Cancer Center,

incoming executive director of Mayo Clinic Cancer Programs, and incoming director of Mayo Clinic Comprehensive Cancer Center.

Full responses from Winn, Knudsen, Mesa, and Willman appear on page 19.

Cancer centers focus on disparities

Many top-tier U.S. academic cancer centers have conducted in-depth analyses of their catchment areas, thanks to existing review processes for NCI designation.

"That does happen for all [71 of] the NCI designated cancer centers," Knudsen said to *The Cancer Letter*. "It's one of the things you report in the peer reviewed way to the NCI—here is the demographic and distribution of our catchment area. Here's who's coming in the door.

"And so, when there's the gap there, quite justifiably, we as cancer centers hold each other to the mat and say, why? What is the reason why there's this group in your area that's not coming in for cancer care? And if there is a gap, what are you doing about it? This is why I feel very comfortable saying that the cancer centers are making major efforts within the limitations of the resources that they have. But I don't think that they can close the gap alone."

Also, efforts are underway at a majority of North American cancer centers—AACI member institutions—to characterize catchment areas and identify major cancer disparities within their respective regions.

The two-step process was established through a 2020 AACI presidential initiative led by Knudsen before she joined ACS (*The Cancer Letter*, Oct. 16, 2020).

"The survey data from the cancer centers came back, and we had 100% com-

pliance with the AACI centers to give us their data. The manuscript is written, actually, to completion. It's really interesting," Knudsen said. "The second wave has already begun, which is saying to the cancer centers, please let us know about the major cancer disparities that you identify within your region.

"We put out a survey to all the centers that gave them a list and asked them to rank order-what are the things that are the highest priority in your area? And then we asked the cancer centers to tell us two things. One, tell us a win, something that was successful, an implementation, some sort of intervention in your catching area that was successful in reducing a cancer disparity, because we'd like to learn from each other about what's been possible. We also asked them to tell us one area of consternation, something that you've thrown resources at, that you've had an intervention.

"So, we're waiting for all those to come back. I can't wait to see what those data look like. I think they will be incredibly instructive and informative for us as a cancer community. And for the first time, I think will illustrate where major gaps lie and where cancer centers are truly struggling."

To address these challenges, several cancer center directors are banding together to cross-pollinate on equity initiatives.

"Dr. Robert Winn and I have been working to gather a group of similar minded NCI Designated Cancer Centers, to join the Mays Cancer Center in San Antonio and Massey Cancer Center at VCU, to develop a collaborative effort to advance Cancer Health Equity across our communities, our states, our country," Mesa said. "We look forward to sharing more with *The Cancer Letter* as these efforts mature."

A change in the rankings?

If the U.S. News health equity metrics are used to inform hospital rankings, how would the data affect the Best Hospitals <u>hierarchy</u> of cancer centers?

It's too early to tell, for several reasons:

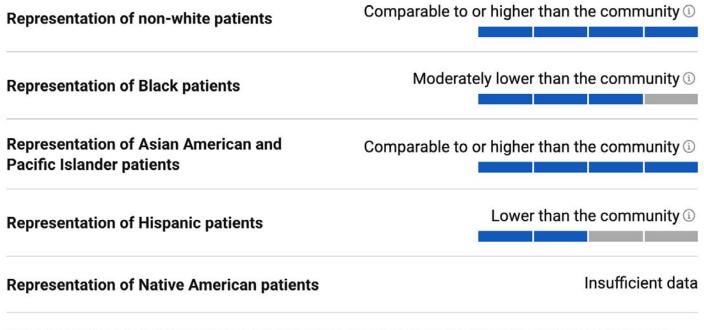
- In this inaugural iteration, the data appear to describe each hospital or health system en bloc, which may not be representative of patient demographics within individual specialties or departments, e.g. cancer centers in matrix institutions. Also, there is no breakdown of data by treatment modality e.g. cancer surgery.
- It's unclear whether data for freestanding cancer centers can be interpreted as representative of the institutions' performance on cancer health equity.
- The existing health equity measures, while useful, are primarily characterized according to inpatient Medicare data, which represent a sliver of patients who seek treatment at cancer centers. The largest share of cancer treatments occurs in outpatient settings, which aren't included in the U.S. News analysis.
- It's not publicly known how health equity would be weighted in the rankings framework.

U.S. News would need to collect and process comprehensive inpatient and outpatient data specific to the cancer patient population in order to weigh health equity in its ranking of cancer centers.

As it stands, the existing health equity measures developed by U.S. News are built on five data sources:

Community Residents Who Accessed Elective Care at this Hospital

How well the surrounding community is represented in the population treated by the hospital. Lower scores indicate that non-white populations may be underrepresented in the hospital's patient population.



Community access is calculated as the percentage of local patients by race or ethnicity treated at this hospital for elective inpatient procedures compared to their proportion within the community. The hospital's community is defined as its hospital service area (HSA), a group of surrounding zip codes whose residents receive a majority of care from hospitals in the area.

FIGURE 1: ELECTIVE CARE MEASURES FOR MEMORIAL SLOAN KETTERING CANCER CENTER

- Dartmouth Atlas Project—Primary Care Access Measures and Hospital Service Area Crosswalk,
- Medicare administrative claims—Inpatient Limited Data Set Standard Analytical Files (Inpatient LDS SAF),
- American Hospital Association annual survey,
- American Community Survey and County Population Estimates, and

 ZIP Code to County Crosswalk, available through the U.S. Department of Housing and Urban Development.

A detailed breakdown of the U.S. News methodology for the health equity measures is posted here.

While U.S. News's reliance on Medicare data could be characterized as a limitation of the health equity analysis, Harder argues that it eliminates some confounding variables.

"I think it's also a strength of our analysis in that by focusing on just the Medicare population, we take the effect of not having insurance out of the equation," Harder said. "So, you would expect, since everyone we're looking at has the same insurance plan, that we should not see disparities in access. Yet, we do."

Harder and his team assessed equity across eight measures:

 Five on elective care, which describe representation according to major racial and ethnic groups, and

Preventive Care for Black Residents in This Community

How effectively preventive care for Black residents in this hospital's service area reduces potentially avoidable hospitalizations. Lower scores indicate that preventive care may be inadequate for Black residents in this community. Preventive care may be provided in hospitals or other healthcare settings in the community. Scores are determined for the hospital service area as a whole, not individual hospitals, and all hospitals in a given hospital service area received the same score.

Preventive care within the community

Compares the rate of potentially preventable hospitalizations among Black residents in this hospital's service area to that of non-Black residents in the same community.



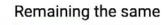
Preventive care compared to national average

Compares the rate of potentially preventable hospitalizations among Black residents in this hospital's service area to that of residents nationwide.



Trend over time in disparities

Compares the rate of potentially preventable hospitalizations for Black and non-Black residents in this hospital's service area over a 5-year period.



The data set forth at the Preventive Care for Black Residents in This Community portion and certain elements of the Community Residents Who Accessed Elective Care at This Hospital portion of this Health Equity section were obtained from the Dartmouth Atlas Data website, which was funded by the Robert Wood Johnson Foundation, The Dartmouth Clinical and Translational Science Institute, under award number UL1TR001086 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), and in part, by the National Institute of Aging, under award number U01 AG046830.

FIGURE 2: PREVENTIVE CARE MEASURES FOR UCSF MEDICAL CENTER

Three on preventive care, which assess the effectiveness of preventive care for Black residents (in a hospital's service area) in reducing potentially avoidable hospitalizations.

The assessments are characterized according to intervals, which correspond

to labels that indicate the degree to which representation of minorities are, for example, "comparable to" or "lower than" the community.

For illustration, see Figure 1, a screenshot of the elective care section for Memorial Sloan Kettering Cancer Center. Similar intervals are applied to the preventive care measures, which are assessed as e.g. "less equitable" or "equitable" for Black residents. Figure 2 is a screenshot of the preventive care portion of the health equity suite for UCSF Medical Center.

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More health systems are in need of a health equity report card like we use in quality and safety. I am looking forward to the day when these health equity report cards are widely used, by most if not all health systems.

99

- Robert Winn

Although these data may not necessarily be representative of cancer patient populations, the 2021-22 health equity assessments for hospitals ranked according to excellence in cancer care might be worth looking at.

The top 11 are: MD Anderson Cancer Center, Memorial Sloan Kettering Cancer Center, Mayo Clinic, Dana-Farber/Brigham and Women's Cancer Center, Cleveland Clinic, Johns Hopkins Hospital, Northwestern Memorial Hospital, UCLA Medical Center, Cedars-Sinai Medical Center, Hospitals of the University of Pennsylvania-Penn Presbyterian, and UCSF Medical Center.

Of these institutions, only Dana-Farber lacked an equity scorecard. Across the remaining 10:

- Black patients are consistently underrepresented.
- At hospitals with available or sufficient data on Hispanic patients, this population is underrepresented.
- At three hospitals—MD Anderson, MSK, and Johns Hopkins—Asian/ Pacific Islander patients are represented at levels "comparable to or higher than the community."
- Only MSK is rated "comparable to or higher than the community" for overall "representation of non-white patients."
- Only UCSF is rated "equitable for Black residents" on a measure that compares the rate of potentially preventable hospitalizations among Black residents in this hospital's service area to that of residents nationwide.

"I really think many of the barriers are beyond the cancer centers. Now, it doesn't absolve them of responsibility. They certainly have a role to play, and I'm not saying that there's no room for further improvement," ACS's Knudsen said. "But I don't know that there's any cancer center director that goes to bed at night and feels that they have the resources to do everything they need to do to bring in equitable service and equitable access to care.

"Reimbursement has quite a lot to do with it. So, if you just look dispassionately and objectively at the data, we understand very clearly that areas where there's been Medicaid expansion have then seen better cancer outcomes. There's a clear correlation there," Knudsen said. "That's beyond, for example, the level of the cancer center. Having access to coverage and basic cancer care is obviously critical for that to work and for the community to be represented within any given health system or hospital.

"The U.S. News & World Report data are a good basis for us to have this conversation. I applaud them for doing it. I think it's a good plan for us to move towards this and start the dialogue."

U.S. News intends for the just-published health equity data to compel healthcare executives to focus on disparities.

Said Harder:

"I think the time is now. The time has been now for a long time when it comes to disparities in health care."

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This story is part of a reporting fellowship on health care performance sponsored by the Association of Health Care Journalists and supported by The Commonwealth Fund.





Harder spoke with Matthew Ong, associate editor of The Cancer Letter.



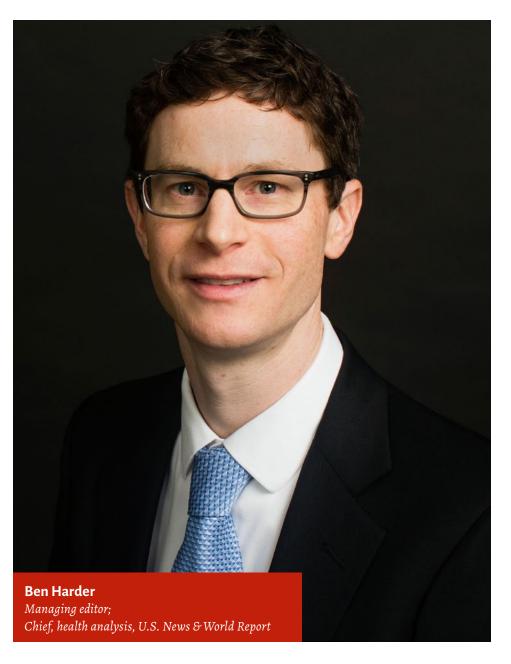


Ben Harder: U.S. News may use health equity measures to rank hospitals in the future



To be honest, the hospitals that excel in many different areas, advanced clinical care, are not the same ones that we see indexing high on representation of nonwhite groups.





When Ben Harder and his team of health analysts at U.S. News & World Report developed a suite of health equity measures for America's hospitals, they expected to find some level of disparity, but nothing prepared them for the shocking magnitude of inequity they uncovered.

"I think the scale of it, I would say, was a surprise to me," Harder, managing editor and chief of health analysis at U.S. News said to *The Cancer Letter*. "To see that four of five hospitals treated a patient population that was disproportionately white was a surprise."

The new health equity metrics were designed to assess representation of racial and ethnic minorities among patients who access common services at hospitals across the United States. As it turns out, at 80% of hospitals that were evaluated, racial and ethnic minorities are underrepresented among patients, relative to the demographics of the hospitals' service areas.

These measures are one way of navigating the labyrinthine nature of health disparities, Harder said. For instance, it's important to examine whether the quality of care offered to racial and ethnic minority patients is contributing to disparate patient outcomes.

"Differences in the quality of hospitals that tend to treat different racial and ethnic populations, that's potentially a big problem right there," he said. "There have been a number of studies that have looked at racial differences in where patients get treated—the literature and the evidence shows that people of lower income status and of racial and ethnic minority background tend to be treated at lower quality hospitals, however you define lower quality, whether you use the U.S. News rankings, or you use some proxy like volume or academic status.

"Unless two hospitals have equivalent outcomes, you have a disparity simply because there's a difference in hospital quality and they're not treating the same population."

If U.S. News decides to use health equity measures to inform the Best Hospitals rankings, these rankings may change, with many top-tier institutions sliding downward.

"To be honest, the hospitals that excel in many different areas, advanced clinical care, are not the same ones that we see indexing high on representation of nonwhite groups," Harder said.

"To what extent that's because of something the hospital is doing or not doing, we don't know. This is really just descriptive, but it does reflect differences in access to that care for that entire community."

Harder spoke with Matthew Ong, associate editor of The Cancer Letter.

Matthew Ong: This year's Best Hospitals rankings found that racial and ethnic minority patients are underrepresented at four out of five hospitals. That's 80% of hospitals. Has this been documented before?

Ben Harder: We found a number of studies that looked at specific procedures or specific areas of care that had similar findings. So, this is certainly consistent with what scientists have identified in the past.

But I could not find any study that looked as broadly at elective care as we have. We really included everything in our analysis, every type of procedure that is generally performed on an elective basis. And so, that included things like colon cancer surgery, lung cancer surgery, various heart procedures, knee replacement, hip replacement and so on.

This is also the first time, to my knowledge, that data like these have been reported for each individual hospital, not just the nation as a whole.

So, this is an analysis of health equity—or rather, inequity—on an unprecedented scale.

BH: I think that's fair, yes.

I see that these new health equity measures, although separate, would now be available alongside hospital rankings. What prompted you and your team to embark on these measurements?

BH: The issue of health equity is central to health care in the U.S.

A lot of preventable or manageable conditions become as serious as they do because of inequities in access to health care, in the social determinants that influence people's health and the outcomes that the medical community can achieve for different populations. And so, that is really the impetus for us looking at this.

We want to understand which hospitals are providing the care that their population needs and achieving good outcomes for everyone in their community, and not just for those who may find it easier to access care or may be diagnosed earlier.

Was it a surprise for you to find that this is a problem across 80% of U.S. health care? I ask this, because I can almost hear some people I know say, "Well, but we already knew disparities and underrepresentation are systemic issues. It's an evergreen societal problem," in that nasal Washingtonian know-it-all undertone.

BH: I think the scale of it, I would say, was a surprise to me. We weren't surprised that nonwhite patients were underrepresented among the important services, these are therapeutic services.

Given everything that we know about the access to care and the limits on access, the obstacles to access for many racial and ethnic minorities and for lower income patients, we unfortunately expected to see some disparity here.

But to see that four of five hospitals treated a patient population that was disproportionately white was a surprise.

Could you describe your methodologies for assessing health equity?

BH: We looked at eight different measures of health equity. And I want to just be candid, this is not a comprehensive look at health equity.

We are at the beginning stages of this initiative, which I anticipate extending many years into the future, but we focused on some measures that we felt would help us understand who is accessing care, hospital care, specifically, and for what.

And so, several of those measures look at elective care and assess if the hospital's elective-care population represents the residents in its community. That was one piece.

Several other measures looked at, essentially, preventable hospitalizations for conditions that are sensitive to the outpatient care, the ambulatory care that a person receives, including preventive care, disease management.

We wanted to understand things like diabetes and heart failure and COPD—how equitable is the manage-

ment of that disease, and the preventive steps that can stave off the need for hospitalization?

And unfortunately, for those measures, we found overwhelmingly that minority patients, specifically Black patients, were overrepresented. We focused those measures on looking at Black versus non-Black.

The Black residents were more frequently hospitalized for preventable causes, which we interpret as a sign they are not getting the same degree of access to preventive services and to disease management within the community.

It's not too complicated. So, the elective care measure, it's the same measure concept across five different populations. One is all nonwhite patients, and then we subdivided it into Black patients, Hispanic patients, Native American patients and Asian and Pacific Islander patients.

There's sort of that roll-up measure of all nonwhite patients, and that's what the four of five is—a reference to how patient population at each hospital of nonwhite patients compared to the proportion of residents in the community who are nonwhite, but the findings were broadly similar across each of those subgroups, with particular focus depending on the community.

There are some areas where there's a large Black population, but most of the hospitals did not see as many Black patients in elective care services as resided in the community.

The other three measures are related to this other concept called the ambulatory care sensitive conditions.

What we looked at was the rate at which patients were hospitalized for these conditions, patients who were Black

versus patients who were non-Black residents, because it's looking at a community-level rate where Black residents in the community are hospitalized at a similar rate to non-Black residents, or were they in fact hospitalized at a higher or a lower rate.

In about seven in 10 communities that we evaluated, Black patients were hospitalized at a higher rate, and in most of those communities, their rate was not only higher than non-Black patients locally, but also higher than the national average.

I noticed that cancer surgery is one of the services in which minorities are underrepresented. Do you have numbers specific to cancer surgery?

BH: Unfortunately, I don't at this time, although that's a good question and something we can try to look at in the future. We defined this panel of procedures as elective care procedures and pooled all patients across those procedures.

My teammates Tavia Binger and Ronan Corgel, who performed most of our equity analysis, have looked at, in the past, several different services that were more specific in building up to this work.

They were looking specifically at colon cancer disparities that have been identified by the research community as an issue, particularly related to the efficacy of screening rates in different populations.

They found, for example, that both Black and Hispanic Medicare patients were <u>less likely</u> than their white peers to undergo surgery after a diagnosis of colon cancer.

What are your sources of data for these health equity measures? Are they the same as the ranking data?

BH: Yes, for the most part they are the same, which is to say that we looked at Medicare data where we have tens of millions of records of individual encounters that patients have had with hospitals.

If Medicare paid the bill, we have a record of the visit and it's all anonymized. So, we don't know the names or anything else about the individuals. We just know which community they live in and what particular hospital they were treated at, but that's it.

Their privacy is secured, but from the perspective of what we need, we can identify which hospital they were treated at, where they're from broadly within that community. And so, that was the data that we used for most of this analysis.

For the measures, looking at ambulatory care and preventable hospitalizations, we actually used data that was generated also from Medicare data, but it was published by the Dartmouth Atlas, which is a long running academic project at Dartmouth.

And so, Tavia used data from that project that was publicly available to supplement the data that we had directly from Medicare.

At this point in time, you don't include Medicaid or private claims data; right?

BH: That's right. And some would say that that's a limitation of our analysis, because obviously insurance differ-

ences have a massive impact on access to care and what care people feel they can afford.

On the other hand, I think it's also a strength of our analysis in that by focusing on just the Medicare population, we take the effect of not having insurance out of the equation.

So, you would expect, since everyone we're looking at has the same insurance plan, that we should not see disparities in access. Yet, we do.

That is most striking. Did you find specific regions, states, or even hospital systems in which these disparities are most obvious or severe?

BH: We found differences, for sure, regionally, and we focused much of our analysis on both the hospital and looking at that hospital in the context of its community.

So, we weren't necessarily comparing disparities around the elective care, say, this community's in worse shape than that one. We defined "community" as the "hospital service area," which is actually a concept that was developed by researchers years ago.

Each hospital is assigned to a hospital service area. In suburban and rural parts of the country, it is often the case that there's only one hospital in each hospital service area.

And so, if a hospital is the only hospital in the service area and it's one of the four to five that has the disproportionately white elective care population, then that pretty much means that hospital service area, that everyone living in that community, we're seeing less access, less utilization of elective care by nonwhite patients.

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I think the scale of it, I would say, was a surprise to me. To see that four of five hospitals treated a patient population that was disproportionately white was a surprise.



And to what extent that's because of something the hospital is doing or not doing, we don't know. This is really just descriptive, but it does reflect differences in access to that care for that entire community.

In other communities, predominantly some more densely packed urban communities, there may be multiple hospitals in some cases, even a dozen hospitals or more in a community, in a hospital service area.

And in those parts of the country—particularly where we see large minority populations in both cities in the South and in cities that received either large immigrant populations at some point or were destinations of the Great Migration—what we see is that there are, in many cases, one or few hospitals that serve a population that is reflective of the demographic makeup of the community, or even treats a disproportionately large nonwhite population.

And there are many other hospitals in that community, in some cases, that treat a disproportionately white population. And so, what we see is that there appears to be hospitals that tend to treat nonwhite patients and hospitals that tend to treat white patients.

Even within the same community we'll see both types. That won't surprise anyone in health care.

Many cities have a safety net hospital where lots of uninsured patients go, where lots of Black and Hispanic patients go—and where lots of people who've historically been disadvantaged by society go, whether it's structural racism or linguistic barriers—those safety net hospitals, in general, we see are the ones that are indexing higher on our measures.

They are treating more minority patients, racial and ethnic minorities than reside in their community. Other hospitals, particularly those specialty hospitals that focus on surgical care, tend to treat more white populations.

The remaining 20% of hospitals with good representation of the demographics in their service areas—are these hospitals mostly located in urban centers, and are they mostly hospitals that provide care to a disproportionate share of minority residents? Who are they, and where are they?

BH: That's a great question. I would not say that there's a clear pattern there at this point.

We see some of those hospitals in rural areas or in areas where there's only a single hospital in the HSA and they have a population that is pretty representative of their community.

But we also see them especially in these urban areas: the safety net hospital, or one of a few hospitals where patients from racial ethnic minority groups tend to go. In some cases, most of the other hospitals that are near them are at the far end with a disproportionately white population.

No, I wouldn't say that there's a clear urban/rural distinction or based on population size. It really does vary.

You've talked about expanding your measurements of health equity in the future. What might those expansions entail?

BH: We think of these measures that we're publishing this week as measures of access, and they look at when, where and for what patients in different demographic groups are utilizing hospital care, but there are many other facets of health equity that we'd like to look at.

In addition to access, we'll look at outcomes as a second domain of health equity. Are patients who are Black or Hispanic, or economically disadvantaged achieving the same outcomes at a hospital as patients who are from the majority group? And then social determinants being the third domain.

Those three domains are not mutually exclusive—there's overlap and there are things that may be worth measuring that don't necessarily fit neatly into one of these. But each represents an important category of equity.

So, between access, outcomes, and social determinants—there are different terms for this concept, social factors or social drivers—what are the actions that hospitals are taking to meet the needs of the population, of everyone who they could serve, before those people need hospital care? And ideally that's what prevents illness rather than restoring it when they are sick enough to need hospitalization.

Indeed, you can look at so many variables—education, socioeconomic status, etc.

BH: Exactly, right. Food insecurity is one that frequently comes up when I'm talking with hospital leaders. Homelessness, housing insecurity, all of those things, and environmental threats, whether it's triggers for asthma, air pollution, and so on.

Will these health equity measures be factored into overall ranking metrics in the future?

BH: It's possible. That's not something we've decided on. We are looking forward to a healthy dialogue with many different stakeholders.

I mean, we're publishing these measures this week. This will be the first time that many people have seen them. We look forward to having conversations with equity researchers, patient advocate groups, with healthcare organization leaders, about what we have measured and what remains to be measured, and how those measures might fit into our future rankings.

So, I think that that future remains unwritten, but we look forward to having a far-ranging discussion about what the right way is to advance social health justice.

What do you hope your audience, and perhaps even policymakers, would do with your findings? What's the urgency here?

BH: I think the time is now. The time has been now for a long time when it comes to disparities in health care.

These measures may not be actionable in and of themselves, but we think they're part of the solution in the sense that both patients and the public and healthcare leaders need to understand these disparities if they're going to address them.

There may be certain things that we see in our data that don't necessarily require action, and maybe other things that require immediate remediation. So, it's not for me alone to say which of these observations require the highest level of urgency.

But I think one thing that concerns many people, because we're not the first ones to observe this or think of this, is the fact that when different hospitals treat different populations—if one hospital treats this disproportionately white population, and one treats this disproportionately Black or Hispanic population, or a low-income population—unless two hospitals have equivalent outcomes, you have a disparity simply because there's a difference in hospital quality and they're not treating the same population.

There have been a number of studies that have looked at racial differences in where patients get treated—the literature and the evidence shows that people of lower income status and of racial and ethnic minority background tend to be treated at lower quality hospitals, however you define lower quality, whether you use the U.S. News rankings, or you use some proxy like volume or academic status, or what have you.

Differences in the quality of hospitals that tend to treat different racial and ethnic populations, that's potentially a big problem right there. So, if we can't achieve equitable outcomes within each hospital, there's an issue, but also we need to be able to achieve equitable outcomes across the population.

We have a second-order challenge if different demographic groups are being treated at different hospitals. So, I think just highlighting that is a really important aspect of what we're doing, because to be honest, the hospitals that excel in many different areas, advanced clinical care, are not the same ones that we see indexing high on representation of nonwhite groups.

And that's very telling?

BH: It is, yes.

I do realize that there are other announcements in this year's rankings. Could you describe them briefly? What should we be paying attention to?

BH: I think that the broad theme is that, as it has been our mission for years, we want to provide decision support—essentially data-driven information that patients can use to make more informed decisions, that they and their doctors together can use to make more informed decisions and provide that to as broad a swath of patients as possible.

And from a clinical perspective, what that means is evaluating different services, so that a patient who has a heart failure can identify a hospital that can meet her needs, and a patient who has lung cancer and needs a resection can identify a hospital that can meet his needs.

We've expanded the portfolio of services that we evaluate hospitals in actually pretty substantially this year. And this is our largest single-year expansion since just around the time I joined U.S. News in 2007, that was the year we created the Best Children's Hospitals rankings.

This year, we've added ratings in seven different procedures and conditions that we previously didn't evaluate, and those are part of really some big ones. Pneumonia is one of them, which is more important in the middle of a respiratory pandemic than ever, but it's always been an important component of hospital care.

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These measures may not be actionable in and of themselves, but we think they're part of the solution in the sense that both patients and the public and healthcare leaders need to understand these disparities if they're going to address them.

Other new ratings this year include heart attack, stroke, kidney failure, in which there were also major racial and economic disparities. We evaluated hospitals in back surgery, spinal fusion. We've also evaluated hospitals in managing hip fracture cases, and in diabetes, a very important and highly prevalent disease.

Those are all new ratings that we've added this year. For some of those, we've evaluated 4,000 or more hospitals, pretty much every hospital in the country that provides care to patients with that condition or who need that procedure. And so, we've been able to add those facets to the total picture of hospital care that we provide.

All of those ratings are based entirely on objective data. So, we're looking at risk-adjusted outcomes, at things like staffing and the availability of specific therapies, patient experience and so on.

In addition, we revamped one of our specialty ranking methodologies—we evaluate hospitals in medical rehabilitation. That had been one of the very few specialties that we evaluated based entirely on a physician survey, because we didn't feel in the past that we had good objective measures to bring to bear on that particular specialty.

This year, we're deploying an objective methodology that still uses physician opinion as a component, but we've added 11 objective measures as well.

Our results didn't change that much, actually. I guess it goes to show that when hospitals excel on one measure of quality, even a subjective one like expert opinion, they often do excel in the objective measures as well.

But it's an important step, I think for us and for the community of patients who need rehabilitation in a hospital that we're able to now evaluate that in a rigorous, objective way.

It definitely sounds like you've outdone yourself in the middle of a pandemic.

BH: We've been busy. I got more done when I didn't have to commute!

Working from home is great. Did we miss anything?

BH: I think that that really covers the highlights. I think with the expansion of our services, the other major thing that we've really been focused on in addition to equity this past year, is our hope that that serves a broader population of patients, so there are more patients who can identify the services they need.

There are still services that we don't evaluate, including some areas of cancer care that I'd love to be able to address and shed light on in the future. There's still work ahead.

Thanks for taking the time to speak with me.

BH: Thank you.

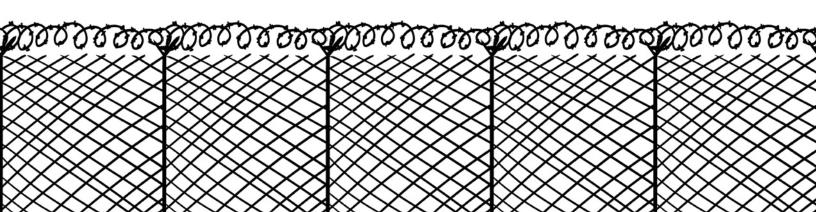
99

HEALTH EQUITY



Winn, Knudsen, Mesa, Willman discuss the health equity measures introduced by U.S. News & World Report

By Matthew Bin Han Ong





Robert A. Winn, MD

Director, VCU Massey Cancer Center;
Senior associate dean for cancer innovation,
VCU School of Medicine;
Professor, Division of Pulmonary Disease
and Critical Care Medicine,
Virginia Commonwealth University;
President-elect, Association of
American Cancer Institutes



Karen E. Knudsen, PhD, MBA

Chief executive officer,
American Cancer Society and ACS CAN;
Professor, Sidney Kimmel Cancer
Center at Jefferson Health,
Thomas Jefferson University;
Past president, Association of
American Cancer Institutes



Ruben A. Mesa, MD

Executive director, Mays Cancer Center at UT Health San Antonio MD Anderson; Mays Family Foundation Distinguished University Presidential Chair; Professor of medicine



Cheryl L. Willman, MD

Incoming executive director,
Mayo Clinic Cancer Programs;
Incoming director,
Mayo Clinic Comprehensive Cancer Center;
Director and CEO, UNM Cancer Center;
Distinguished professor,
UNM Departments of Pathology and Medicine

What are your takeaways from the inaugural health equity findings by U.S. News?

Robert Winn, VCU: This is an important issue finally getting the attention of more people, and it is a good first step. But we have more work to do and will get more nuanced over time gathering this important data.

More health systems are in need of a health equity report card like we use in quality and safety. I am looking forward to the day when these health equity report cards are widely used, by most if not all health systems.

Karen Knudsen, ACS: I applaud USNWR for delving into how well hospital systems are addressing health equity. This is a critical issue that leads to greater incidence, suffering, and death from cancer, and we need better ways to advance our nation's work in this area. It must be a priority, and from my perspective, it's long overdue.

Ruben Mesa, UTHSCSA: I am pleased they did this analysis to really help quantify what a gap can exist in cancer health equity at some of our finest cancer centers across the country. The NCI Cancer Centers Program has helped deepen institutional and NCI Cancer Center Commitment to Community Outreach and Engagement by including this as an area of review for Cancer Center Support Grants.

USNWR can make an impact towards expanding cancer health equity by quantifying the current gaps.

Cheryl Willman, UNM: I am not surprised by data demonstrating that racial/ethnic minorities are significantly underrepresented in four of five pre-eminent, primarily referral hospitals in the U.S., as these hospitals provide a lot of tertiary/quaternary care.

The access bar is often very high and the facility capacity to take "care of everyone" at these hospitals and health systems is not sufficient, even if they desire to provide care to everyone in their catchment area.

I do, however, think that one cannot conclude from these data alone that the "quality" of care delivery is significantly less at public safety net hospitals, based solely on the criteria used by USNWR to rank hospitals, some of which are highly subjective, some of which are based on mortality index, which is going to be higher when treating underserved and vulnerable patients who too often present at advanced stages of disease, and some of which is based on personal opinion.

The characteristics of patients treated by large academic public/private referral centers and public safety net hospitals are so dramatically different. Public safety net hospitals, like University of New Mexico Hospital where I have worked for many years, provide critical health care for diverse, underserved, rural, and racial/ethnic and sexual/gender minority patients who often have no other means of access to health care.

Patients who enter these sites often present with more advanced stages of disease, have significant comorbidities, and have had limited access to high quality primary care and means of disease prevention and screening.

For instance, at the UNM Comprehensive Cancer Center in New Mexico, over 50% of our patients are racial/ethnic minorities, over 50% are from deeply rural counties, and nearly 25% of patients who present with a cancer diagnosis have had no primary medical home and have not been under the care of a primary care physician.

Over 40% of New Mexico's population is insured under the Medicaid Waiver, a federal program which has been a

godsend to provide a means of health insurance to vulnerable patients who have had no insurance before; the New Mexico program has grown 66% since 2013.

It will be very important in future analyses and comparisons of "quality care delivery" to actually adjust or consider all of these different patient characteristics, beyond race and ethnicity.

Is the "four of five" finding striking to you? Also, are these results new to you, compared to what you've known from experience and from the literature?

Winn, VCU: Nothing was particularly striking to me. Most of these inequities have been present for many decades. What's new is that the study pointed them out, but generally these issues are not new. Health disparities have certainly been talked about in literature, but they have frequently been fragmented. There is a porosity of literature on these topics.

Knudsen, ACS: Without seeing the methodology and the data, this one is hard to comment on specifically. My initial reaction is that four of five seems very high, but I would withhold true opinion until I had the opportunity to learn more about the patient population vs. the population each of these hospitals serve.

What I do feel, however, is whether it's one out of five or four out of five, it's not good enough unless we are equitably meeting the needs across the populations we serve!

Mesa, UTHSCSA: Sadly, this number does not surprise me. Financially, centers have been incentivized to prioritize commercially insured patients that, of course, deprioritizes the care of Medicare, Medicaid patients and let alone

unfunded or self-funded patients. This is the double whammy of both financial barriers, combined with the impact of social determinants of health limiting access, time to receive care, compounded by barriers in health literacy overrepresented in populations of minority patients.

Willman, UNM: I found this result striking, but I know this sadly rings true: that "Medicare-insured residents who are Black, compared to similarly insured residents of other races, have experienced more hospitalizations that might have been avoidable if they'd had access to better preventive health care."

In my experience, this is undoubtedly true of Hispanics and of indigenous Native Americans or undocumented individuals, results which are not new to me given we have served these populations for many years.

I am also not surprised that "the racial gap in potentially preventable hospitalizations grew worse since 2011 in nearly a third of U.S. communities." There are several reasons for this in my opinion, unfortunately many of which are due to our nation's political environment and the constant attack and stripping away of provisions of the Affordable Care Act.

As I noted above, the Medicaid Waiver has provided a vital means of insurability for so many underserved and diverse individuals and communities. So, secondly, the failure of so many of our nation's governors and state legislatures to participate in the federal Medicaid Waiver program has had a tremendously detrimental effect on the health and wellbeing of the people and communities they serve.

Third, an issue that is often uncomfortable to discuss in the Cancer Centers' community, is the federal attack by the Trump administration on the congressionally-mandated 340B Drug Reimbursement Program, which had a

disproportionate impact on the nation's Cancer Centers and their ability to deliver care to the underserved.

As you know, in 2018, CMS reduced reimbursement by 30% of lifesaving cancer drugs to public safety net hospitals and cancer centers, effectively negating the benefit of the 340B drug purchasing program which allows hospitals, cancer centers, and health systems to purchase cancer drugs and other therapeutics at a discounts that range from 20-40%. Congress had expressly intended for the margin generated by the 340B Drug Purchasing program to be used for expansion of comprehensive medical services to the underserved.

At the UNM Comprehensive Cancer Center alone, we suffered an immediate \$12 million annual reduction in CMS revenues in January of 2018—a severe impact when we also provide over \$10 million annually in unreimbursed cancer care in our ambulatory clinics alone.

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Having just stepped away from leading cancer care at a major safety-net hospital, I would say yes—health equity is, in my opinion, something that is reasonable to consider in the evaluation of hospitals.

In contrast, cancer centers who are Prospective Payment System (PPS)-Exempt (including the cancer centers associated with the five health systems who were studied in this report), a program that is now closed to others, were exempted from this most recent CMS reimbursement reduction. This differential impact, and undue harm to cancer centers impacted by the CMS reimbursement reduction, only further exacerbate the difference in capability and resources to deliver cancer care to all.

The inequity in differential CMS payment and reimbursement models to many rural and frontier states and these differential CMS payment models need to be reconsidered.

Should health equity measures be weighed in the ranking of hospitals? If so, what are some important considerations that should be included?

Winn, VCU: Absolutely. We've recognized the gap in disparities is not shrinking. Not even close. Just as we implemented standards for quality and safety, we should monitor what health systems are not doing when it comes to health equity. It will put the metrics and framework in place for all health systems to improve health equity over the years.

Knudsen, ACS: Having just stepped away from leading cancer care at a major safety-net hospital, I would say yes—health equity is, in my opinion, something that is reasonable to consider in the evaluation of hospitals.

Notably, NCI does in fact ask the major centers to report on how well the center aligns outreach and research to the needs of the patient population. So, many of the key measures are fairly well known. A potential metric of success is how well the patients served re-

flect the composition of the catchment area, and the extent to which needs are met. A further extension, which the NCI Centers also very much consider, is how well clinical trial enrollment represents the catchment area served.

From my past experience, I honestly believe that the major centers are making every effort to strive toward access and equity, but there are major barriers that stand in the way of equitable access and care. Many of these barriers are beyond the means of the cancer centers to address.

For example, gaps in transportation, lack of housing near the care delivery sites, and lack of patient navigation are each major, well documented factors that contribute to reduced cancer care access and resultant disparities in outcome. Each of these are known factors that contribute to inequities in cancer care and outcomes; notably, ACS functions in all 50 states to overcome these barriers through direct patient support programs, and seek to further extend our reach to areas most in need.

As such, I applaud USNWR for making this a priority, because we all must make it a priority.

Mesa, UTHSCSA: I think this is a wonderful idea. The USNWR rankings are both highly visible, but also impactful in everything from marketing cancer care, to attracting faculty, to contracting with third-party payers.

The "cancer scorecard" each center receives has evolved over the years to include an expanded group of parameters to measure quality, from patient experience, nursing ratios and magnet status, to the quality of programs (FACT accreditation, NCI Designation, radiation therapy technologies).

It would be both appropriate and impactful to recognize the importance of caring for the entire regional communi-

99

ty (including corresponding percentages of underrepresented populations to match the community, and programs to expand cancer health equity) in assessing the "quality" a cancer center/hospital brings to a community for cancer care.

In so doing, USNWR would likely increase the emphasis and corresponding resources that institutions would devote to these efforts and the inclusive outreach of their cancer care in their respective communities.

Willman, UNM: Yes, but I think it will be very important to define the measures by which we define the "diversity" of populations served or in a catchment area to go far beyond urban/rural, race/ethnicity to include aspects of the social built environment, environmental exposures and behaviors, socioeconomic factors, access to health care, insurance status of populations, and the health care infrastructure of a region.

I also think we should consider splitting the analysis between the regional, adjacent communities that a hospital/health system serves from their broader national referral population.

Although potentially non-specific to the cancer patient population, the equity profiles for the top 10 ranked cancer hospitals or health systems with matrix cancer centers show that racial/ethnic minorities are also underrepresented at these institutions. Based on what you know of academic oncology, what are some possible explanations?

Winn, VCU: Many of our academic centers don't accept Medicaid and have structures in place that are unwelcoming to patients in their neighborhoods. Top academic centers have proven they are interested in research, but most

have undervalued research that directly investigates social and economic determinants and what causes the gaps. So there is a combination of the environment and not accepting types of insurance and not having a sufficient number of people interested in health disparities. It has all contributed to the lack of minorities.

Knudsen, ACS: This is a critical issue. It was a priority for me at Jefferson, as past president of AACI, and now at the American Cancer Society. We have to increase diversity of oncology care—and research—at all levels. ACS is partnering with minority-serving institutions like Morehouse to fund positions to build a stronger pipeline. This needs to be a priority for all of us, including cancer centers.

Mesa, UTHSCSA: These are great cancer centers impacting the cancer mission through their research, clinical trials, cancer care and education programs. Drivers of underrepresentation of minority patients at these centers is multifactorial.

Without question, finances are a major driver, where commercially insured cancer care—critical to generate care financial margins needed to fund the academic mission—is a huge factor.

Additional barriers including access, impact of social determinants of health and health literacy to seek care, hourly wage based employment discouraging seeking care during work hours all contributing to the disparity.

Additionally, sometimes the experience of presenting oneself to a massive academic cancer center can be intimidating with many aspects of the experience sometimes being far from welcoming to a patient of limited means (complex registration procedures, challenges with transportation or parking, assumptions of access to computer resources or smart phones).

Willman, UNM: All of the reasons I have discussed above: access barriers, lack of "cultural comfortableness" of a minority/underserved patient in entering a "premier" center, centralization of high quality, complex cancer care versus innovative means of dissemination of care to diverse and distributed populations, geographic and distance barriers, and variability in insurance status and "acceptability" of different forms of insurance at "premier" centers.

The data are largely based on Medicare claims, without Medicaid or private insurance. Does that make these findings particularly significant? Also, do you expect to see similar trends in Medicaid and private claims data?

Winn, VCU: It does. If the Medicaid population is added in, the findings may be even more augmented in terms of a lack of minority presence. I absolutely expect Medicare would track better because frequently private insurance and Medicaid are not as desirable. The data for private insurance and Medicaid would undoubtedly be grim.

Knudsen, ACS: Again, it's difficult to comment specifically on that without seeing the methodology and the data. In general, it's important to recognize that the patient population—including the population of underserved patients—also includes those who are insured privately or by other means, uninsured, on Medicaid, on Medicare, or dually covered by Medicaid and Medicare. To look at only one aspect could impact the overall accuracy of the data.

Mesa, UTHSCSA: I suspect these other data once included would only further highlight the gap in health equity, with significant disparities in both groups leaning toward underrepresented populations with Medicaid, and largely

more Caucasian and affluent amongst the commercially insured.

Willman, UNM: I do believe that the fact that all patients assessed were insured by Medicare, make the disparities and outcome differences seem even more profound.

And yes, I am sure that when individuals insured by Medicaid, the Medicaid Waiver, private insurance, and uninsured patients are examined, the differentials and disparities in patients served and outcomes will be tremendous and concerning.

What can cancer centers do in response to these findings from U.S. News?

Winn, VCU: We should all take a moment of pause and reflection. As we moved through the COVID crisis, we learned about health disparities and social structures that we need to address. But the greater conversation is recognizing that it is not just minorities in the community. There are problems with our health systems, and we have to be more mindful with how they are inadvertently contributing to the disparities.

Knudsen, ACS: Let's first recognize that health inequity is a systemic issue that demands collaborative solutions from the public, private, and nonprofit sectors, as well as the communities served:

Note that this ranking looks at patients served by the hospitals, so by design, it does not include those who were not able to access care to the level necessary to get to that point.

Insurance coverage alone will not solve these issues. We have to address social determinants of health and critical concerns such as health literacy, cultural and language barriers, and mistrust in the health care system There are specific strategies and action steps:

- Build trust in underserved communities. Note that ACS supports this through our educational awareness campaigns that build trust in screening, for example.
- II. Listen and incorporate these populations' lived experiences into their hospital experiences. We need to develop solutions together with underserved populations rather than develop solutions for them.
- III. Prioritize patient navigation to improve outcomes and to be able to demonstrate to underserved communities that health care systems will be there to support them every step of the way.

Mesa, UTHSCSA: I believe cancer centers, especially NCI Designated Cancer Centers, will be able to utilize this information (especially if incorporated into the rankings) to lobby for additional resources, programs, access strategies, outreach to the community to expand access and care to these underrepresented populations to match their communities if considered an important factor for their USNWR ranking.

Dr. Robert Winn and I have been working to gather a group of similar minded NCI Designated Cancer Centers, to join the Mays Cancer Center in San Antonio and Massey Cancer Center at VCU, to develop a collaborative effort to advance Cancer Health Equity across our communities, our states, our country. We look forward to sharing more with *The Cancer Letter* as these efforts mature.

Willman, UNM: We simply have to be committed to health equity; there is no other ethical path or more important ethical imperative.

I am thrilled that the national Cancer Center community is now engaged in deep consideration and discussion of Diversity, Equity, Inclusion (DEI) in all of our missions (including clinical care delivery, research, education and training, and our community engagement programs), and, of how we might attain health equity by lowering the access bar to more vulnerable and underserved populations, by partnerships, and by the development of innovative means to widely disseminate high quality care.

I also think we have to renew our commitment as cancer centers to not only training in cancer medicine and research, but to training public health care workforces and allied health care professionals who will be essential in the future on the front lines of clinical care delivery.

Other comments?

Winn, VCU: I'm glad this is being brought to the forefront. At Massey, we are rolling up our sleeves and understand even the miracles of science have limitations. Gaining the trust of our communities means we have to address and break down barriers to make cutting edge science and healthcare more accessible to all communities. All at-risk communities, both urban and rural.

Knudsen, ACS: Yes! ACS has some concepts for potential solutions: An <u>Equity Scorecard</u>.

The goal of the equity scorecard, which we created in alignment with other organizations, was to try to give some sort of benchmarking for how well any given system or cancer center is doing compared to standard, and to give recommendations. So, I think that that could be part of the learning community, if you will.

And an important role for ACS moving forward is to try to assist centers that are falling short and that could use a lit-

tle guidance. We've done the same thing with screening and return to screening, to try to assist by building toolkits for health systems and cancer centers to deploy, so that they can enhance their screening rate.

We see ourselves as doing the same role with regard to health equity.

Mesa, UTHSCSA: It's great to see *The Cancer Letter* continuing to advance important conversations in our cancer community—few are as important as advancing diversity, equity and inclusion in our cancer care (prevention, screening, care, and survivorship), our research and clinical trials, and in our cancer training and education programs.

Willman, UNM: It is an interesting time to reflect on this data as I am in transition from leading the UNM Comprehensive Cancer Center in New Mexico for 20 years—with a tremendously underserved, diverse minority population—to leading the Mayo Clinic Cancer Programs nationally, starting August 2, in Minnesota/Midwest, Florida, and Arizona and globally.

I must say we have been having deep discussions at both institutions about how to "lower the access bar" and about DEI and Health Equity Issues. As the Mayo Clinic serves very diverse and different communities at each of its three U.S. Sites, it has a great opportunity to make a difference.

Health equity and improving access "for all" to Mayo's great clinical care are challenges that I personally and the Mayo Clinic are deeply committed to achieving. We are also developing exciting new programs and highly innovative platforms for virtual/digital care within one's home environment: Mayo Clinic Care@Home and Mayo Clinic Cancer Care@Home.

I believe these programs have the potential to revolutionize high quality care delivery in a very cost-effective fashion, to enhance the dissemination of high quality care across large geographic regions, and to achieve health equity by assuring access to these care models and programs to diverse and underserved communities.



I believe cancer centers, especially NCI Designated Cancer Centers, will be able to utilize this information (especially if incorporated into the rankings) to lobby for additional resources, programs, access strategies, outreach to the community to expand access and care to these underrepresented populations.

– Ruben Mesa

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CANCER HISTORY PROJECT

Hait and Libutti in conversation;

Rutgers Cancer Institute founder and its current director talk history

In 1993, when William Hait came to New Jersey to start work toward the NCI designation for Rutgers, the place had one office and three cubicles.

our years later, in 1997, the Cancer Institute of New Jersey received the NCI Cancer Center designation, and on the next review cycle, in 2002, it received the Comprehensive Cancer Center designation.

The Cancer History Project invited Hait, the first director of Rutgers Cancer Institute of New Jersey to sit down for a conversation with Steven K. Libutti, the institution's current director.

"That's almost unprecedented today, to be able to achieve that, and so, that's an amazing accomplishment," Libutti said to Hait.

How did Hait get it done?

"I was given some very sound advice from my colleagues at Yale. They said, 'Your instinct will be to build the basic science programs first.' They said, 'Build the clinical programs first, because that's what the center at first will be known for.'

"So, I tried my best to recruit outstanding clinical people, clinical researchers, master clinicians, people who could really be dedicated to giving incredibly high-level care to the people in New Jersey."

Rutgers, now a part of a health system and a scientific consortium with Princeton University, recently <u>started</u> <u>construction</u> of a \$750 million cancer hospital in collaboration with RWJBarnabas Health.

The text of the conversation follows.

A video recording is posted here.





Steven K. Libutti, MD, FACS
Director, Rutgers Cancer
Institute of New Jersey
Senior vice president of oncology
services, RWJBarnabas Health;
Vice chancellor for cancer programs,
Rutgers Biomedical and Health Sciences;
Professor of surgery, Rutgers Robert
Wood Johnson Medical School;
Affiliated Distinguished
Professor in Genetics, Rutgers
School of Arts and Sciences.

Steven K. Libutti: Well, Bill, first, I want to start by thanking you for taking the time out of what I know is a very busy schedule to join me today to talk a bit about the Rutgers Cancer Institute in New Jersey, both the history of the cancer institute, and where we're going as we move towards the future.



William N. Hait, MD, PhD Global Head, Johnson & Johnson External Innovation.

William N. Hait: Thank you, Steve. It's great to be here. Absolutely great.

Libutti: So, can you tell me a little bit about how your vision formed for the Cancer Institute of New Jersey? When you joined in 1993, coming from Yale, the cancer institute was really in its infancy.

Hait: The actual cancer center was physically in its infancy. We had one office and three cubicles, but the planning had gone on for several years, by the dean and by the associate dean for research, and Mike Gallo respectively, who had put together a planning grant, with faculty across the medical school and Rutgers, to plan for an NCI-designated cancer center, at least one that could be capable to even compete.

Because back then, there was no place in New Jersey that could even compete for NCI designation, because none would have the eligibility criteria.

Libutti: And so, when you arrived, after that initial planning had taken place, what was your vision, and what were your first steps in terms of trying to operationalize that vision?

Hait: I was given some very sound advice from my colleagues at Yale. They said, "Your instinct will be to build the basic science programs first." They said, "Build the clinical programs first, because that's what the center at first will be known for."

So, I tried my best to recruit outstanding clinical people, clinical researchers, master clinicians, people who could really be dedicated to giving incredibly high-level care to the people in New Jersey.

Libutti: And how long would you say it took for you to kind of get that center of gravity in place as you were doing those recruitments?

Hait: It's a very good question. In retrospect, it seemed overnight, but it was

a lot of hard work to convince people of a vision.

We didn't have a building, we had some cubicles, we had some lab space over across the river, but I was very fortunate to have been involved with training many outstanding fellows at Yale, who went on to join faculty at other places, who I sort of pulled in the chit, and I said, "Come on, we're going to start a cancer center in New Jersey. Let's give it a try."

And a few fantastic people joined, and they recruited their friends, and before you knew it, we had some people who were actually very good at seeing patients, and then we built the relationships on the basic science campus to start building out the basic science programs.

Libutti: When I think about it, you joined in 1993 and you successfully obtained NCI designation in 1997, then moving on in the next cycle in 2002 to get comprehensive designation, which is truly remarkable.

I mean, that's almost unprecedented today, to be able to achieve that, and so, that's an amazing accomplishment. Why did you think at that time it was so important to achieve an NCI designation for the cancer institute?

Hait: I really felt that the designation by the NCI was the highest standard you could reach, and it was clear to me, for a variety of reasons, that New Jersey needed at least one cancer center, maybe more, that could compete at that level in terms of patient care, clinical research, basic research, population research, and then not just say ourselves that we've done it, but have the highest authority, like the NCI and their peer review say, "You guys make the grade, and now you have the designation."

And I think that has been, as you know, Steve, the key differentiating factor for the Rutgers Cancer Institute of New Jersey.

Libutti: Absolutely.

Hait: So, as we celebrate the 50th anniversary of the National Cancer Act, how important, Steve, do you think the Cancer Centers Program is in the fight to ultimately someday eliminate cancer?

Libutti: So, that's a great question, and I truly believe that the Cancer Centers Program is critical to continued progress in our fight against cancer.

I think when you look back at the progress we've made over the last 20 years, many of those seminal discoveries, discoveries leading to checkpoint inhibitor therapy, or discoveries leading to CAR T-cell therapy, or discoveries leading to sort of molecularly targeted therapies or precision medicine, really had their birth in cancer centers across the United States.

Libutti: And it was the National Cancer Act, back in 1971, when that was signed, that gave birth to the Cancer Centers Program, and I think that that program continues to evolve and adapt to changing landscapes.

It has, particularly, over the last five to 10 years, taken a new focus on the community, on the importance of cancer centers reaching out into their communities, in their catchment area.

The Cancer Centers Program has put a premium now on diversity and inclusion, which I think is of incredible importance as we better understand unique aspects of the cancer burden in different communities.

So, I think the Cancer Centers Program continues to play a critical role, and will continue to do so as we implement many of the findings over the next 20 to 50 years.

Hait: Well, I do think the new approach to the community and to the broad aspects of preventing, intercepting, and curing cancer is so critical. I know that, having taken care of patients for so many years, you and I never saw someone come in and say, "I'm so happy I've been diagnosed with cancer, so you can treat me."

It's always, "What could I have done differently, so I wouldn't have to wind up with this very difficult disease?" And I think your focus and the focus of the Cancer Centers Branch, to really look at prevention, and screening, and intercepting the disease, and maintaining health is absolutely essential.

Libutti: Absolutely.

Hait: Steve, you were <u>recruited</u> to become the director of the Rutgers Cancer Institute and senior vice-president of oncology services for RWJBarnabas Health in 2017. That dual appointment was really a first, and showed the commitment and partnership of the health system.

Can you talk a little bit about that partnership and what it means for cancer patients in New Jersey?

Libutti: So, yes, stepping into that role in 2017 was an interesting experience, and I often, when I talk about this, you like to look back and think that all of these entities were well-established, etc., at that time, but the RWJBarnabas Health system had really only become a health system a year before in 2016, and Rutgers Cancer Institute had existed as a Rutgers entity for only four years at that point.

And so, coming into that role, it was interesting in that it was bringing together two newly formed cultures to create a new culture around cancer care and cancer services, but it's been a tremendous opportunity, and very exciting.

The health system is the largest in the State of New Jersey, and cares for over half of the New Jersey population, approximately five million people, and sees about 11,000 new cancer cases a year, analytic cancer cases. And so, there's

a tremendous amount of opportunity for an NCI-designated cancer center to partner with a health system of that size.

It was also incredibly important to me that the health system is very focused on patient health, not just patient healthcare, and I think that's of critical import for cancer care as well, cancer prevention.

Cancer screening is a critical aspect of what we do as NCI-designated centers, and we serve a very diverse community, and New Jersey is the fourth most ethnically diverse state in the United States.

And so, being partnered with a health system that takes that diversity as a real important focus and enables us to impact so many patients, was really key. And the integration into Rutgers has been truly enabling as well.

There are so many outstanding schools and investigators at Rutgers that provide this very ripe and fruitful environment for the cancer institute to do its work in terms of studying the biology of cancer, and then trying to translate those findings.

So, while it was challenging, wearing those two hats, I think the position allows a much greater ability to deliver the outcome of those research efforts to the largest population we can possibly touch.

Hait: What were some of those challenges? I mean, the opportunity sounds fantastic, but integrating into two new systems, both large, must've been an experience. What were some of the challenges that you had to overcome, and how did you do it?

Libutti: Well, any time you're coming into a new environment, you have to be careful to try to listen and appreciate what the cultures are, and as I had said already, these were forming cultures between the two, with an underpinning of legacy culture from the prior UMD-NJ, where CINJ had been based, and

the two health systems that ended up forming RWJBarnabas.

And so, there were differences of scale of vision and focus at the individual hospital sites, but I think in fairly short order, it became very clear to me that the leadership, both at the system level and the level of the hospitals, were really passionate about leveraging the strength of this system to care for as many folks as we could.

And so, what originally seemed daunting, quickly became a very supportive environment, and I came in the middle of these conversations between Rutgers and RWJBarnabas Health about executing this new MAA, or master affiliation agreement, between the two entities, and I sort of look at us at the cancer institute as sort of being at the tip of the spear for that relationship. And we'd learn things a bit by trial and error.

There's a certain amount of freedom in not having to follow a script, but you also do a little bit of recon by fire.

You go in one direction, you hit a speed bump, or you fall in a pothole, and you have to readjust a bit, but because both institutions really wanted the cancer program to succeed, even when there were some of those missteps early on, the support was there that we could continue to carry on.

Hait: As you know, Steve, one of the great aspects of a cancer center and what makes the cancer center so successful was the ability to create collaborations with the medical school, with the entirety of Rutgers, and now with the health system, and most recently, the consortium partnership with Princeton University. Can you tell us a little bit about that?

Libutti: We're especially proud of the fact that we are an NCI-designated consortium cancer center, and that partnership is with Princeton University.

It brings together the largest private research university in Princeton, and the largest public research university at Rutgers, together with one cancer center program. And it really drives tremendous, both basic and translational research, some examples of which are around our studies of cancer metabolism.

Eileen White at Rutgers and her collaborator, Josh Rabinowitz at Princeton, have made some seminal discoveries in understanding the metabolic processes in cancer cells, and within the tumor microenvironment, that can be leveraged as potential targets for cancer therapeutics.

Recently, the Ludwig Cancer Research Institute, has established a new branch at Princeton University, the Ludwig Princeton branch, which has focused on cancer metabolism, and is directed by Josh Rabinowitz and co-directed or associate directed by Eileen White, and it's another example of the power of this collaboration that manifests itself through the Rutgers Cancer Institute of New Jersey.

Libutti: I think being at Rutgers gives us the opportunity to collaborate with many of the other schools and institutes. We have robust collaborations with the School of Pharmacy, with the School of Nursing, with the School of Public Health, with both medical schools, and with the School of Arts and Sciences.

And so, there's a tremendous opportunity for investigators in different disciplines to combine their intellect and their knowledge around the cancer problem. And so, those collaborations, I think, are key to our success, and what one would hope would happen with an NCI-designated cancer center.

Hait: One of the really important aspects of this cancer center has been the unwavering support of the state of New Jersey. Going back to the original announcement that there would be an effort to build an NCI-designated center, back to Governor Florio, and

then the governors thereafter all were very supportive. Can you talk a little bit about that support, including the State Cancer Registry that brought forth Screen New Jersey?

Libutti: Absolutely. So, we, as you've mentioned, have incredible support both from the executive branch, from the governor's office, as well as from both houses of the legislature, the Assembly and the Senate have been incredible supporters of the Cancer Institute throughout those years.

And this manifests in a variety of ways, it manifests in real dollars in terms of their commitment to the Cancer Institute of New Jersey each year in the governor's budget, but also to particular programs, as you mentioned.

And our New Jersey State Cancer Registry, which is actually the home of a national SEER database, is co-managed between the New Jersey Department of Health and the Cancer Institute in New Jersey, and that gets competed competitively every five years for the SEER grant, and we've been very successful in maintaining that.

And then our ScreenNJ program, which is a program that focuses on screening for colon and lung cancer, and we're hoping to expand to other tumor types, was launched in fiscal year 2018 through the support of the state of New Jersey, and continues to be supported by the state moving forward.

So, without the state support, we would not be successful.

Hait: Steve, we started the cancer Institute with one office and three cubicles, and you have just a broken ground for New Jersey's first freestanding cancer hospital. Can you tell us a little bit about this incredible facility?

Libutti: So, I'm very excited about this project that also is a joint effort between

the health system, RWJBarnabas Health, the city of New Brunswick, the county of Middlesex, state of New Jersey, and Rutgers University, all coming together.

The New Brunswick Development Corporation, DEVCO, is instrumental in this activity, as is the New Brunswick School Board. Part of this project, building a 510,000 square foot, 12-story cancer pavilion, complete with inpatient and outpatient activity, advanced imaging capabilities, multidisciplinary clinics, operating rooms, 10 brand new state-of-the-art research laboratories.

In addition to that project, which I think is going to have incredible positive impact, not only on New Brunswick and the surrounding community, but on the entire state, having a destination cancer hospital within New Jersey, as a part of that project, we're building a brand new school for the City of New Brunswick, a \$55 million school, with no taxpayer dollars being expended to build that school.

And we believe that that's an investment in the future cancer researchers and physicians that may go through that school, and then ultimately decide to pursue a career in cancer research and cancer care, and may wind up practicing or performing research in the new pavilion.

And so, how can you not be excited about being a part of a project that's covering all the spectrum of activity like that?

Hait: Fantastic.

Libutti: So, Bill, as we wrap up our discussion, what would you say is the thing you were most proud of accomplishing in your tenure as the director of the Rutgers Cancer Institute of New Jersey?

Hait: It's a tough question. Certainly, we're proud of getting the NCI comprehensive designation, that was very im-

portant, proud of the faculty and people, the staff we were able to attract to New Jersey, but the most proud I think we would all say, was that we were really able to deliver extraordinary care to people in New Jersey and from beyond New Jersey, but really, fundamentally for the people of New Jersey, who really needed a center of this quality.

And I think to this day, as I look back at the cancer center and I think about the thousands of patients that we cared for, that I think sticks with me as perhaps the greatest accomplishment. There's no better place in the world to get cancer care today than at the Rutgers Cancer Institute of New Jersey.

From my perspective, Steve, and I know I speak for many of the people who had this idea that we could create a cancer center of extraordinary quality for the people of New Jersey, I think where you've taken it was to previously unimagined places, and I know, on behalf of all of us who were here some years ago, and all the people in New Jersey that this institution has touched, we owe you and your team a tremendous debt of gratitude, so a big thank you.

Libutti: So, Bill, thank you for those kind words, but I owe you, as does the rest of the Cancer Institute, a tremendous thank you, to you and the original team, many of whom are still here at the cancer institute, as a testament to that loyalty to what you built.

Without your vision, without the foundation that you built here, all that we're trying to accomplish now and what we want to continue to accomplish into the future, would not have been possible.

And I am truly indebted to you for all you did in launching this great center, and I hope to make you proud as the team continues to move forward.

Hait: Well, thank you, Steve, and the feelings are mutual.

IN THE ARCHIVES



The National Cancer Act of 1974: Expanding "Comprehensive"

Spotlight article

Rauscher "Identifies" Four More Comprehensive Centers
TCL Archives | June 21, 1974

[NCI director Frank] Rauscher still has authority to "identify" (the term NCI prefers over "recognize" or "designate") two more comprehensive centers under the terms of the National Cancer Act of 1971, which would bring the number so identified to 18. When the extension of the act becomes law, the limit of 18 will be removed, and Rauscher expects to eventually name as many as 30.

Best guess for the next two centers would be San Francisco, if organizational problems there can be overcome, plus either Ohio State, the budding consortium in Philadelphia, or one of four programs in Oklahoma, Kansas and Missouri. UCLA is a long-shot possibility.

The distribution of comprehensive centers by location now is:

- Northeast (4) Boston Children's, Yale (New Haven),
 Sloan-Kettering (New York),
 Roswell Park (Buffalo).
- Mideast (2) Hopkins-Maryland, Georgetown-Howard.
- South (3) Duke (Durham), Univ. of Miami, Univ. of Alabama (Birmingham).
- Southwest (1) M. D. Anderson (Houston).
- Midwest (3) Illinois (Chicago), Univ. of Wisconsin (Madison), Mayo (Rochester, Minn.).
- Mountain States (1) Colorado (Denver).
- Pacific Coast (2) Univ. of Southern California(Los Angeles), Hutchinson-Univ. of Washington (Seattle).

The Cancer Letter's founding editor Jerry Boyd's predictions were mostly right. The next two centers to receive Comprehensive designation were:

- #17, Fox Chase, aka "the budding consortium in Philadelphia" (The Cancer Letter, Oct. 11, 1974)
- #18, Ohio State (The Cancer Letter, April 16, 1976).

UCLA followed in 1977 (*The Cancer Letter*, <u>Jan. 7</u>, 1977).

Today, there are 51 NCI-designated Comprehensive Cancer Centers.

Recent contributions

Aiming at cancer, we hit bonus targets
By Roswell Park Comprehensive Cancer
Center | July 29, 2021

Subha Barry: A Strength to Pay Forward By Rutgers Cancer Institute of New Jersey | July 29, 2021

Prateek Sharma: Understanding Barrett's esophagus, a global influencer
By The University of Kansas Cancer Center | July 29, 2021

Seattle Cancer Care Alliance celebrates 20 years of innovation in cancer treatment and care

By Seattle Cancer Care Alliance | July 28, 2021

This column features the latest posts to the <u>Cancer History Project</u> by our growing list of <u>contributors</u>.

The Cancer History Project is a free, web-based, collaborative resource intended to mark the 50th anniversary of the National Cancer Act and designed to continue in perpetuity. The objective is to assemble a robust collection of historical documents and make them freely available.

Access to the Cancer History Project is open to the public at <u>CancerHistoryProject.com</u>. You can also follow us on Twitter at <u>@CancerHistProj</u>.

Is your institution a <u>contributor</u> to the Cancer History Project? Eligible institutions include cancer centers, advocacy groups, professional societies, pharmaceutical companies, and key organizations in oncology.

To apply to become a contributor, please contact admin@cancerhistoryproject.com.

IN BRIEF



Lakshmanan Krishnamurti named chief of pediatric hematology, oncology, and bone marrow transplant at Yale



Lakshmanan Krishnamurti was named chief of pediatric hematology, oncology, and bone marrow transplant at Yale New Haven Children's Hospital and Leader of the Smilow Cancer Hospital Pediatric Hematology/Oncology Program.

Krishnamurti is a pediatric hematologist oncologist and an expert in bone marrow transplant and the treatment of hemoglobinopathies.

Krishnamurti joins Yale from Emory University School of Medicine, where he is director of the Bone Marrow Transplantation Program and professor of pediatrics and holds the Joseph Kuechenmeister Aflac Field Force Chair at Children's Healthcare of Atlanta.

Krishnamurti begins his role Oct. 1.

Stephanie Graff named director of breast oncology at Lifespan Cancer Institute



Stephanie Graff was named director of breast oncology at the Lifespan Cancer Institute.

Graff is board certified in medical oncology, hematology, and internal medicine.

Graff comes to Lifespan from the Sarah Cannon Cancer Center of HCA Healthcare, where she was director of the breast program for HCA Midwest in Kansas City and both the National

Breast Lead and Associate Director of Breast Cancer Research for the entire Sarah Cannon network.

She is the medical director of the Dr. Susan Love Foundation for Breast Cancer Research.

Jay T. Bishoff named regional director of urology at Northwell Health



Jay T. Bishoff was named director of urology for Northwell Health's Central Region, with oversight of urology sites in Nassau County and parts of eastern Queens.

He also is a professor of urology at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. His appointment is effective Aug. 2.

Based at Northwell's The Smith Institute of Urology, with affiliations at North Shore University Hospital and Long Island Jewish Medical Center, Bishoff treats urological cancer patients using robotic and laparoscopic techniques.

He is an expert in developing programs for quality improvement to increase better health outcomes. His areas of research and interest include cancer of the prostate, kidney, adrenal gland and testis.

Prior to joining Northwell, Bishoff was director of Intermountain Urological Institute at Intermountain Health Care in Salt Lake City, where he also held other clinical leadership positions over a 15-year span.

Earlier, Bishoff was a U.S. Air Force surgeon, serving from 1998 to 2006, including during Operation Iraqi Freedom, treating patients at Balad, Iraq. He is also the author of Boots of War: Unforgettable Experiences from a Front Line Surgeon During Operation Iraqi Freedom.

Ray Bailey, John Mills named to new leadership roles at Florida Cancer Specialists & Research Institute



Ray Bailey was named senior vice president of Pharmacy Services, and John Mills was named vice president of Pharmacy Services at Florida Cancer Specialists & Research Institute.

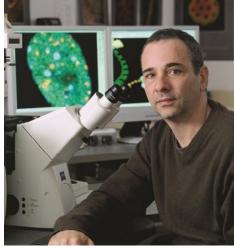
Bailey will maintain and expand pharmaceutical and trade partnerships to support the statewide practice's long-term

growth initiatives for pharmacy services, including pharmacy operations and Rx to Go, its oral oncolytic specialty pharmacy.



With daily oversight of all pharmacy services for Rx to Go, Mills actively supports pharmacy operations and future expansion activities. He joined FCS in 2019 as director of payer relations and business strategy and was promoted to senior director of pharmacy the following year.

Andre Nussenzweig receives 2021 Basser Global Prize



Andre Nussenzweig, of NCI, has received the ninth annual Basser Global

Prize from the Basser Center for BRCA at the Abramson Cancer Center of the University of Pennsylvania.

Nussenzweig is branch chief of the Laboratory of Genome Integrity in the NCl's Center for Cancer Research.

Each year, the Basser Global Prize recognizes a leading scientist who has conceptually advanced BRCA1/2-related research. Individuals with mutations in the BRCA1 and BRCA2 genes are at an increased risk of breast, ovarian, pancreatic and other cancers.

Nussenzweig's work on the fundamental aspects of DNA repair, replication, and genome integrity in cells has led to important discoveries that have applications for the development of biomarkers and targeted therapeutics for the treatment of BRCA-mutated cancers.

Nussenzweig will give the keynote address at the 10th annual Basser Center for BRCA Scientific Symposium on May 10 and 11, 2022.

The Basser Global Prize provides \$100,000 in unrestricted support of the winner's BRCA1/2-related research efforts, a Basser sculpture, and a \$10,000 personal prize, which will be awarded at the symposium.

The Basser Center was established in 2012 with a \$25 million gift from University of Pennsylvania alumni Mindy and Jon Gray in memory of Mindy Gray's sister Faith Basser, who died of ovarian cancer at age 44. To date, Mindy and Jon have donated more than \$55 million to the Basser Center in support of research and education to improve treatment and prevention strategies for hereditary cancers.

The Basser Global Prize was established and subsequently endowed by Shari Basser Potter and Leonard Potter.

UCLA's Beth Karlan receives IGCS's lifetime achievement award



Physician-scientist Beth Karlan, professor of obstetrics and gynecology in the David Geffen School of Medicine at UCLA and director of cancer population genetics at the UCLA Jonsson Comprehensive Cancer Center, has received the Lifetime Achievement Award from the International Gynecologic Cancer Society for her contributions to gynecologic cancer research and clinical practice.

The award is bestowed annually.

Karlan is being recognized for advancing the understanding of hereditary cancers and molecular drivers of ovarian cancer and her commitment in seeking better ways to prevent and eradicate deadly cancers.

In the laboratory, Karlan has identified subtype-specific biomarkers for early detection, prognostication and personalized therapies. She established a human tissue biorepository to collect fresh frozen tissue, serum, and germline DNA from women with ovarian and other gynecologic cancers in order

to study cancers' biologic differences and develop improved treatments.

This resource has been used in national and international collaborations including The Cancer Genome Atlas project, Consortium of Investigators of Modifiers of BRCA1/2 and Ovarian Cancer Association Consortium — partnerships that have helped to shape current standards of care for gynecologic oncology.

She is also a co-PI on a national effort using a digital platform to implement population-based genetic testing for BRCA1 and BRCA2 mutations.

The award will be presented to Karlan at the IGCS annual global meeting in Rome Sept. 1.

NJ appropriates \$10M for pediatric cancer research

New Jersey Governor Phil Murphy signed the fiscal year 2022 state budget, which included a \$10 million appropriation to support pediatric cancer research.

This legislation, which was sponsored by Senate President Stephen M. Sweeney and Sen. Anthony M. Bucco, will support the establishment of the Pediatric Cancer Center at Rutgers Cancer Institute of New Jersey.

Dana-Farber uses \$10M gift to establish the David Liposarcoma Research Initiative

Dana-Farber Cancer Institute has received \$10 million from the Rossy Foun-

dation to establish the David Liposarcoma Research Initiative.

The five-year initiative will spearhead research into liposarcoma at Dana-Farber and external collaborating partner institutions, with the aim of transforming the treatment of this rare, underfunded, and understudied disease in order to improve care of patients through research.

This commitment from The Rossy Foundation will focus on collaborative research among various departments at Dana-Farber—including liposarcoma biology, biochemistry, immunology, metabolism, genomics, and epigenetics.

The overall research initiative will be led by George Demetri, director of the Sarcoma Center, senior vice president for Experimental Therapeutics, and Quick Family Chair in Medical Oncology at Dana-Farber.

The David Liposarcoma Research Initiative collaboration brings together the teams of 11 principal investigators from four institutions—Dana-Farber, Harvard Medical School, Brigham and Women's Hospital, and the Broad Institute of MIT and Harvard. These investigators will work togeth

Dana-Farber will be the lead and coordinating institution for this new initiative.

The initiative will also include engagement of a panel comprising the international scientific advisory board. The commitment also establishes the David Liposarcoma Research Initiative International Scientific Symposium in basic, translational, and clinical liposarcoma research.

This symposium will enable the team to share results, guide the development of clinical trials in years three through five, and have a global influence to stimulate new collaborations in this field.

AACR establishes Cancer Evolution Working Group

The American Association for Cancer Research has established the Cancer Evolution Working Group.

The mission of the AACR Cancer Evolution Working Group is to advance cancer diagnostic, therapeutic, and prevention strategies by fostering a fundamental understanding of cancer evolution amongst its members and the broader cancer research community. Membership in the AACR Cancer Evolution Working Group is free and open to all members of the AACR interested in cancer evolution.

The AACR Cancer Evolution Working Group will strive to accomplish its mission by working to:

- Facilitate transdisciplinary approaches to the study of cancer evolution and translate novel cancer evolution insights into new early detection, diagnostic, therapeutic, and preventive strategies to improve outcomes significantly and sustainably for cancer patients.
- Promote the incorporation of multiomic molecular (genetic, epigenetic, genomic, karyotype, transcriptomic, proteomic, epiproteomic, metabolic), cellular, and tissue-based concepts and techniques, as well as novel data science tools into well-designed cancer evolution studies of multiclonal cancer cells and of host immune system and tumor microenvironment co-development.
- Recommend scientific and educational programs to provide ongoing forum(s) for the scholarly discussion and development of

effective approaches to the conduct and interpretation of cancer evolution studies, including an annual Cancer Evolution Special Conference, an ongoing monthly Cancer Evolution Seminar Series, and cancer evolution sessions at AACR Annual Meetings.

- Foster collaborations with individuals interested in this scientific area and with relevant AACR scientific working groups that are engaged in other scientific disciplines.
- Assist with the professional advancement of early- and mid-career investigators engaged in cancer evolution research.
- Establish a community of cancer evolution experts and other individuals interested in advancing progress in cancer evolution.

AACR Cancer Evolution Working Group Executive Committee members are:

- Frank H. Laukien, PhD (co-chair)
- Charles Swanton, MBPhD, FRCP, FMedSci, FRS, FAACR (co-chair)
- Anna D. Barker, PhD, FAACR (co-chair elect)
- Jeffrey P. Townsend, PhD (co-chair lect)
- Denis Noble, CBE, FRS, FMedSci, MAE
- Kenneth J. Pienta, MD
- George H. Poste, DVM, PhD, FRCPath, FMedSci, CBE, FRS
- Susan M. Rosenberg, PhD
- Jason A. Somarelli, PhD

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- Chan Soon-Shiong Professor of Medicine; Director, Myelodysplastic Syndrome Center, Columbia University, New York, NY
- Andrea Sottoriva, PhD
- · Danny R. Welch, PhD
- · Jonathan Weissman, PhD

SU2C to host roadblock televised fundraising special Aug. 21

Stand Up To Cancer will hold its seventh biennial roadblock televised fundraising special August 21.

This year's show will air on Saturday, Aug. 21 at 8 p.m. ET & PT / 7 p.m. CT. Reese Witherspoon and Jim Toth, a media industry entrepreneur and investor, will come on board as co-executive producers, working alongside the renowned live-event producing team Done + Dusted and Stand Up To Cancer's production team.

Anthony Anderson, Ken Jeong & Tran Ho, and Sofia Vergara will also join as cohosts. Common and Brittany Howard are the first of many to be announced as performers during the special evening.

Stand Up To Cancer's biennial special will broadcast from Los Angeles and air simultaneously on more than 60 participating media platforms across the United States and Canada, including all four major broadcast networks in the U.S. Broadcasters carrying the show are donating one hour of simultaneous commercial-free prime time. The

telecast will also be available to stream live and on-demand on several streaming platforms.

SU2C's biennial specials have been supported by hundreds of celebrities over the past 13 years. The names of participants, as well as additional musical performers, for the 2021 special will be announced in the weeks leading up to the telecast.

House approves language to protect 340B Program

The House of Representatives has approved bipartisan language "to highlight the need to protect the integrity of the 340B program by halting pharmaceutical manufacturers' unlawful actions that have resulted in overcharges to 340B covered entities."

The appropriations bill amendment, authored by Reps. Abigail Spanberger (D-Va.) and David McKinley (R-W.V.), pertains to drug companies that have stopped offering required discounts to safety-net hospitals, health centers, and clinics on drugs dispensed at community-based pharmacies.

"My 340B-related amendment sends a message to big pharmaceutical companies: Stop hiking drug prices on consumers and discriminating against our 340B providers and pharmacies," Spanberger said in a House floor speech.

"The actions of several drug companies to deny 340B discounts for drugs dispensed at community pharmacies are harming safety-net providers and the patients they serve while increasing drugmakers' profits," 340B Health President and CEO Maureen Testoni said in a statement.

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP



ASTRO issues clinical guideline on radiation therapy for soft tissue sarcoma in adults

A clinical guideline from the American Society for Radiation Oncology provides guidance on the use of radiation therapy to treat adult patients with soft tissue sarcoma.

Recommendations outline optimal radiation dosing, techniques and treatment planning for patients with localized, operable STS of the trunk (i.e., chest wall, abdominal wall) and extremities (i.e., arms, legs), with a focus on preserving long-term functionality through individualized care. The guideline additionally addresses the role of radiation therapy for retroperitoneal sarcoma.

The guideline, ASTRO's first for sarcoma, is published in *Practical Radiation Oncology*.

Management of STS requires nuanced and coordinated care from a multidisciplinary team of surgical, orthopedic, medical and radiation oncologists, as well as specialized pathologists and radiologists. Because not all patients are able to receive treatment at high-volume centers where physicians have experience managing these rare tumors, comprehensive guidelines are essential to guide treatment decisions.

"Management of soft tissue sarcoma can be complicated, with the potential for poor outcomes and significant morbidity if treated suboptimally. The addition of radiation therapy to surgery reduces the chance of local recurrence," Kilian E. Salerno, vice chair of the guideline task force and a radiation oncologist at NCI, said in a statement.

"This guideline stresses the importance of multidisciplinary input prior to initiation of treatment and provides detailed recommendations on indications for radiation therapy, dose and planning techniques. ASTRO developed this guideline to provide clear guidance on the role of radiation therapy in patient-centered, multidisciplinary oncologic care," Salerno said.

Standard treatment for STS involves surgical resection, with radiation therapy for patients who are at increased risk of recurrence. In the past, radiation generally followed surgery, but this paradigm has shifted to favor preoperative radiation therapy. While local recurrence rates are similarly low with preoperative and postoperative approaches, long-term side effects vary depending on when radiation is given relative to surgical resection.

"When radiation is indicated, it generally should be given before surgery because the long-term side effects are less severe," B. Ashleigh Guadagnolo, chair of the guideline task force and a professor of radiation oncology at tMD Anderson Cancer Center, said in a statement. "The side effects of preoperative radiation therapy can be serious, but they are reversible. Postoperative radiation therapy side effects, however, are, in many cases, permanent because more radiation dose is required when given after surgery, and it often needs to be given to a larger area of the body."

"Research on patterns of care in the U.S. indicates that most radiation therapy for STS continues to be given postoperatively, however. Therefore, there is a need for clear clinical guidance on modern treatment approaches that can have less impact on patients' long-term quality of life," she said.

Recommendations in the guideline address patient selection for radiation therapy and outline best practices for dosing, sequencing, planning and image guidance for extremity and superficial truncal STS, as well as for retroperitoneal sarcomas, which offer a worse prognosis than those in the extremities. The guideline also calls attention to the fundamental role that cooperation between the multidisciplinary care team has in the design and delivery of patient care.

Key recommendations follow:

 Radiation therapy is recommended for patients with primary, localized extremity and truncal soft tissue sarcomas who are at increased risk of local recurrence, based on multidisciplinary evaluation of the tumor's pathology, location and size; final or expected surgical margins; and other factors that are detailed in the guideline. Radiation therapy generally is not recommended for patients at low risk of local recurrence.

- For patients where surgery and radiation therapy are indicated, preoperative radiation therapy is recommended. Postoperative radiation therapy is recommended only in specific clinical circumstances, such as the discovery of unanticipated adverse pathologic features following oncologic resection or unplanned excision, or when the risk of wound healing complications outweighs the risk of longterm, permanent side effects. The guideline also includes treatment algorithms for initial local management and local management following an unplanned excision.
- For patients with primary localized retroperitoneal sarcomas, the routine use of radiation therapy in addition to oncological resection is conditionally not recommended. Selective use of radiation therapy may be considered for patients with RPS at high risk of local recurrence. When radiation therapy is indicated in these select cases, preoperative radiation is preferred.

The guideline addresses optimal dosing, fractionation, target delineation and delivery techniques for preoperative and postoperative radiation therapy, including recommendations for image guidance and patient positioning, with specific attention to patients' long-term functional outcomes.

Patients with advanced bladder cancer could benefit from immunotherapy regardless of gene mutation status

A study has demonstrated that patients with advanced bladder cancers whose tumors have a mutated FGFR3 gene respond to immunotherapy treatment in a manner that is similar to patients without that mutation, a discovery that runs counter to previous assumptions.

This research, led by scientists at the University of North Carolina Lineberger Comprehensive Cancer Center, has important implications for patients who have not been offered immunotherapy because of their genetic profiles.

The findings are published in the British Journal of Cancer.

"Despite prior work suggesting that FG-FR3-mutated bladder cancers should not be treated with immunotherapy, our study demonstrates the opposite, so we believe that immunotherapy should be offered without hesitation," said corresponding author UNC Lineberger's William Y. Kim, Rush S. Dickson Distinguished Professor of Medicine and professor of genetics.

There have been several recent significant treatment advances for bladder cancer. In 2019, the FDA approved a drug, erdafitinib (Balversa), that targets FGFR3 and prolongs survival. Additionally, immune checkpoint blockade drugs, commonly known as immunotherapies, have recently been approved for advanced bladder cancer. Prior to this decade, treatment was primarily

limited to systemic, platinum-based chemotherapy.

"Clinical trials have shown that bladder cancers with FGFR3 mutations have fewer immune cells, primarily T cells, than cancers without the mutation. Because tumors with low levels of immune cells tend to respond poorly to immune checkpoint blockades, it has been hypothesized that those patients would have low response rates to immunotherapy," said co-first author UNC Lineberger's Tracy Rose, assistant professor at the UNC School of Medicine.

To test the hypothesis, UNC Lineberger researchers designed a study to compare tumor tissue samples and clinical trials data from 17 patients with FGFR3-mutated bladder cancer to 86 patients whose tumors did not have the mutation.

The investigators found that patients with FGFR3 mutations responded to immunotherapy equally as well as those without the mutations. At a cellular level, they also found equivalent diversities of T cell receptors and a similar balance of immune suppression and immune activation signals in tumors with and without FGFR3 mutations. This equivalency, or balance, indicates a similar chance of benefiting from immunotherapy.

The researchers hope to establish a clinical trial to test whether patients with FGFR3 alterations benefit more from erdafitinib or immunotherapy.

"Our study does not rule out the possibility that erdafitinib will synergize with immunotherapy," said William Weir, cofirst author and an MD-PhD student at UNC-Chapel Hill. "If anything, the fact that FGFR3-altered patients benefit from immunotherapy argues that this may be a reasonable approach."

DRUGS & TARGETS



Keytruda receives FDA approval for highrisk early-stage TNBC

Keytruda (pembrolizumab) received FDA approval for high-risk, early-stage, triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

Keytruda is sponsored by Merck.

FDA also granted regular approval to pembrolizumab in combination with chemotherapy for patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA approved test.

FDA granted accelerated approval to pembrolizumab for this indication in November 2020.

The following trial was the basis of the neoadjuvant and adjuvant approval, as well as the confirmatory trial for the accelerated approval.

The efficacy of pembrolizumab in combination with neoadjuvant chemotherapy followed by surgery and continued

adjuvant treatment with pembrolizumab as a single agent was investigated in KEYNOTE-522 (NCTo3o36488), a randomized, multicenter, double-blind, placebo-controlled trial conducted in 1174 patients with newly diagnosed previously untreated high-risk early-stage TNBC (tumor size >1 cm but ≤2 cm in diameter with nodal involvement or tumor size >2 cm in diameter regardless of nodal involvement). Patients were enrolled regardless of tumor PD-L1 expression.

Patients were randomized (2:1) to pembrolizumab in combination with chemotherapy or placebo in combination with chemotherapy. Details of the chemotherapy regimen are in the drug label linked below.

The main efficacy outcome measures were pathological complete response rate and event free survival. The pCR rate was 63% (95% CI: 59.5, 66.4) for patients who received pembrolizumab in combination with chemotherapy compared with 56% (95% CI: 50.6, 60.6) for patients who received chemotherapy alone. The number of patients who experienced an EFS event was 123 (16%) and 93 (24%), respectively (HR 0.63; 95% CI: 0.48, 0.82; p=0.00031).

BMS withdraws Opdivo for liver cancer indication

Bristol Myers Squibb is withdrawing from the U.S. market the indication for its immune checkpoint inhibitor Opdivo (nivolumab) as a single agent for patients with hepatocellular carcinoma who were previously treated with sorafenib.

The move follows the FDA's Oncologic Drugs Advisory Committee voting down Opdivo for this indication in April while scrutinizing checkpoint inhibitors

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or sign-up at: https://cancerletter. com/news-alerts/ with "dangling" accelerated approval that have not met their post-marketing requirements demonstrating confirmatory benefit (*The Cancer Letter*, April 30, 2021). The committee voted five to four not to keep Opdivo's indication after it failed to show clinical benefit in a trial..

The committee also gave the thumbs down to Merck's Keytruda (pembrolizumab) as a third-line treatment for patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 protein and whose disease has progressed with two or more prior lines of therapy.

Merck announced July 7 that it would withdraw this indication for Keytruda.

Opdivo was the first immunotherapy agent to be approved for use under the FDA's accelerated approval program. Its 2017 accelerated approval was based on tumor responses from its phase 1/2 trial, but a subsequent randomized study of Opdivo vs. sorafenib didn't achieve statistical significance for its primary endpoint of overall survival.

FDA issues alert about increased risk of death associated with Pepaxto

FDA issued an alert stating that a clinical trial (OCEAN, Study OP-103) evaluating Pepaxto (melphalan flufenamide) with dexamethasone to treat patients with multiple myeloma showed an increased risk of death.

The trial compared Pepaxto with low-dose dexamethasone to pomalido-mide with low-dose dexamethasone in patients with relapsed or refractory multiple myeloma following two to four lines of prior therapy and in patients

who were resistant to lenalidomide in the last line of therapy.

FDA encourages health care professionals to review patients' progress on Pepaxto and discuss the risks of continued administration with each patient in the context of other treatments. Patients currently receiving Pepaxto should also discuss with their health care professional the risks and benefits of receiving Pepaxto.

In February 2021, FDA approved Pepaxto under Accelerated Approval for use in combination with dexamethasone to treat adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease was refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

The manufacturer, Oncopeptides AB, was required to conduct the OCEAN trial as a post-approval requirement under the accelerated approval program.

Due to the detrimental effect on overall survival in the OCEAN trial, FDA is requiring the manufacturer suspend enrollment in the trial. FDA has also suspended enrollment in other ongoing Pepaxto clinical trials.

Patients receiving clinical benefit from Pepaxto may continue treatment in the OCEAN trial provided they are informed of the risks and sign a revised written informed consent.

FDA continues to evaluate the OCEAN trial results and may hold a future public meeting to discuss these safety findings and explore the continued marketing of Pepaxto. The agency will update patients and health care professionals when new information is available.