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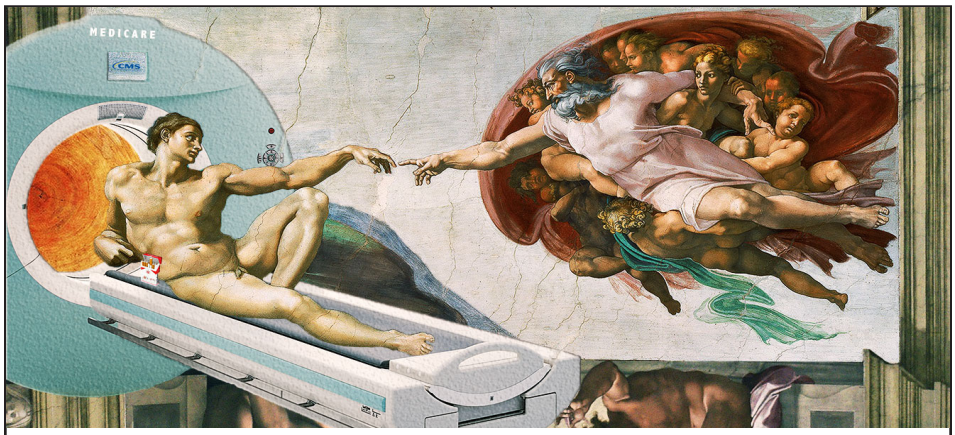

CMS Inserts Unprecedented Conditions Into Medicare Coverage of Lung Screening

By Paul Goldberg

CT screening of the lungs of current and former heavy smokers is about to become a Medicare benefit.

A proposed decision published Nov. 10 has inserted some unprecedented conditions into its decision to cover screening:

Beneficiaries would have to go through counseling, and health professionals would be required to provide documentation that "shared decision-making" took place. The Centers for Medicare and Medicaid Services has never mandated shared decision-making as a gateway to paying for a service.

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Guest Editorial

Brawley: CMS Got it Right

By Otis W. Brawley

This week the Centers for Medicare & Medicaid Services issued a proposed rule stating that the scientific evidence was sufficient to support reimbursement for counseling on the risks and benefits of lung cancer screening as well as lung cancer screening with low dose computed tomography in high risk individuals and once per year. CMS will pay for such services when provided to beneficiaries at high risk for lung cancer and when provided by physicians and centers with specific qualifications.

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In Brief

Susan O'Brien to Move to UC Irvine Health

SUSAN O'BRIEN will join **UC Irvine Health** as associate director for clinical science for the Chao Family Comprehensive Cancer Center and medical director of the Sue and Ralph Stern Center for Cancer Clinical Trials and Research. Her appointment is effective Jan. 1, 2015.

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Policy Mimics NLST Population; Mandates Collection of Data

(Continued from page 1)

For providers, this means meeting eligibility criteria, providing services that meet technical specifications set by the government, and collecting data and submitting it to a national registry that would be approved by CMS.

The agency's challenge was to put together a payment policy that would take the results of a clinical trial conducted primarily in the academic setting and apply them in the community, where standards of care may be different.

"It sets a useful precedent for cautious translation of results that were derived from academic centers or experienced centers out into the community," said Barnett Kramer, director of the NCI Division of Cancer Prevention, who took part in designing and running the National Lung Screening Trial, which provides basis for screening.

"CMS has set an appropriately high bar, because I do think that screening tests in general involve enough complicated decision-making that we ought to get away from the traditional history of sound bites in recommending screening to one of informed decision-making and explicit discussion of the tradeoffs, both the benefits and the harms," Kramer said to The Cancer Letter.

Technically, the agency's plan proposes standard coverage, but contains some elements of another category used to provide payment: coverage with evidence development.

The decision is in many ways also a landmark case in setting payment policy:

• It translates the findings of the NLST, a large randomized trial conducted by NCI into payment policy and standards of care in the community (The Cancer Letter, Nov. 5, 2010).

• It draws on the recommendation of the U.S. Preventive Services Task Force (The Cancer Letter, Aug. 2, 2013, Aug. 9, 2013, Jan. 10, 2014). With the B grade from USPSTF, lung screening became an Essential Health Benefit under the Affordable Care Act, which means that private insurers will have the obligation to cover the service next year.

• It's informed by the clinical judgment of a CMS advisory committee, called the Medicare Evidence Development & Coverage Advisory Committee, or MEDCAC (The Cancer Letter, May 9, 2014),

• It rejects several key aspects of a proposal for broader coverage, advanced by patient groups, researcher Claudia Henschke's International Early Lung Cancer Action Program, and some professional societies (The Cancer Letter, March 21, 2014, April 18, 2014, June 13, 2014, Jan. 9, 2009, March 28, 2008, March 14, 2008, Nov. 3, 2006).

The age eligibility is a telling feature of the CMS decision. To qualify for screening, beneficiaries must be between the ages 55 and 74, the age group screened in NLST. By limiting the screening benefit to this age group, CMS rejected the USPSTF analysis, which relied on modeling to project benefit to a larger age group: 55 to 80.

Similarly matching NLST, the Medicare policy restricts availability of screening to people who are either current smokers or who have quit smoking within the last 15 years, have a tobacco smoking history of at least 30 pack-years, and receive a written order from a physician or qualified non-physician practitioner. A pack-year equals one pack of 20 cigarettes smoked each day for one year.

David Howard, a member of MEDCAC and a professor at the Emory University Department of Health Policy and Management, estimates that in 2012 there were 3.2 million Medicare-eligible persons between ages 55-74 who have at least 30 pack years of smoking history and are current smokers or quit within the past 15 years.

By way of comparison, there were 3.9 million persons ages 55-80 who have at least 30 pack years of smoking history and are current smokers or quit within the past 15 years. These figures were calculated using the Health and Retirement Study, a national survey of persons 50 years and older.

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Data Required to Get Coverage of Lung Screening

Data Type	Minimum Required Data Elements
Facility	Identifier
Radiologist (reading)	National Provider Identifier (NPI)
Patient	Identifier
Ordering Practitioner	National Provider Identifier (NPI)
Demographics	Date of birth, gender, race/ethnicity.
Indication	Lung cancer LDCT screening – absence of signs or symptoms (y/n)
Smoking history	Current status (current, former, never), If former smoker, years since quitting, Pack-years as reported by the ordering practitioner.
CT scanner	Manufacturer, Model.
Effective radiation dose	CT dose index, tube current-time, tube voltage, scanning time, scanning volume, pitch, slice thickness (collimation).
Screening exam results	Baseline or repeat screen; Screen date; Clinically significant non-lung cancer findings (y/n), if yes, list; Nodule (y/n), if yes: number, type (calcified or non-calcified; solid or semi-solid), size and location of each nodule.
Diagnostic follow-up of abnormal findings within 1 year	Low dose chest CT, Diagnostic chest CT, Bronchoscopy, Non-surgical biopsy, Resection (with dates), Other (please specify).
Lung cancer incidence within 1 year	Incident cancers, Date of diagnosis, Stage, Histology, Period of follow-up for incidence.
Health outcomes	All cause mortality, Lung cancer mortality, Death within 60 days after most invasive diagnostic procedure.

Source: The proposed decision memo for screening for lung cancer with low-dose CT (CAG-00439N)

The agency's final version of the coverage decision is expected by Feb. 8, 2015.

"I think it's very well reasoned and obviously shows the results and assimilation from a lot of input from a variety of constituents, and I think it's in keeping with the discussion at the MEDCAC—that is a way to offer screening, but to make sure that once the technology disseminates into the community, it's done carefully and data are collected to make sure that results are similar to those found in the National Lung Screening Trial," Kramer said.

Otis Brawley, chief medical and scientific officer of the American Cancer Society, agrees.

"I am very glad that CMS decided to pay for this service," Brawley said. "A prospective randomized trial has shown that screening causes a 16-percent decrease in relative risk of death among people at high risk for lung cancer.

"We have to realize that in order for this to be a true benefit, high quality screening, diagnosis and treatment have to be given, and that's why I am thrilled that (1) there is a registry, and (2) CMS is only covering it when knowledgeable, well-trained, and operating in centers that are well-equipped to provide this service.

"My concern is that there is a benefit, but there is also a harm, and we have to work hard to maximize the benefit and minimize the harm. Our work is only starting. It is up to us to make sure that this is done right."

A guest editorial by Brawley appears on page 1.

The proposed decision largely follows the elements of a letter requesting that the agency conduct "a national coverage analysis" for lung screening, submitted by Peter Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center.

Some of the elements Bach proposed that now appear in the proposed decision include using the age range in the NLST, qualifying facilities for expertise, including shared decision making and putting in place a registry to monitor outcomes and quality.

"CMS seems to have gone just about as far as they could towards coverage given the negative rating screening got from the MEDCAC," Bach said to The Cancer Letter. "Seeing the draft decision, I think it's fortuitous that the ACA did not mandate that a task force rating of A or B guaranteed coverage by CMS, which is what they did for commercial plans.

"This allowed CMS to craft a thoughtful policy that has a good chance of delivering benefits while minimizing harms through their requirements for various safeguards. Meanwhile, people from age 55 to 64 will have policies that cover any type of screening from any imaging center.

"This makes no sense once you realize that the younger age range of people are at lower risk of lung cancer, meaning the risk-benefit tradeoff is less favorable for them on average," Bach said.

The policy is also consistent with joint guidelines from the American College of Chest Physicians and the American Thoracic Society. Bach is a co-author of those guidelines.

Though the CMS decision requires collection of data, this decision isn't made under the agency's Coverage with Evidence Development, or CED.

Here, the distinctions are important:

• The CED mechanism requires collection of data for the purposes of formulating a coverage decision in the future. In this case, the coverage decision has been made.

• In the context of CED, participating cites operate under approval of the Institutional Review Board, as a clinical experiment, which requires formal informed consent and is subject to rules and regulations governing research.

• In the case of this coverage decision, consent is replaced by documentation that demonstrates that shared decision-making has occurred and that the provider meets the criteria for providing the service. The two parties involved in this are the patient and the healthcare provider. Had this been a CED, a research investigator would be involved in the interaction.

The CMS decision doesn't fully meet the requests of some advocacy groups and professional societies.

In a joint letter and a 43-page paper addressed to CMS, a group of professional societies and advocacy groups pressed for broader coverage (The Cancer Letter, Oct. 3, 2014).

They sought:

• Unrestricted broad national coverage of LDCT lung cancer screening for the patient population recommended by the USPSTF with standards and a clinical practice registry, plus

• Coverage with Evidence Development for other high-risk individuals where evidence is promising to inform future coverage decisions. This would include "category 2" patient groups identified in the National Comprehensive Cancer Network screening guideline.

This category of current and former smokers includes individuals with a 20 pack year history who have at least one additional risk factor for lung cancer, such as self-reported occupational exposure, previous cancers, chronic obstructive pulmonary disease or pulmonary fibrosis, high radon exposure, a family history of cancer.

Though the informal coalition failed to convince CMS to broaden coverage beyond the NLST population and the USPSTF recommendation, groups that spearheaded this effort applauded the agency's proposed decision, in effect accepting a partial victory, or downplaying what was a clear signal from the agency that their request was beyond the evidence.

"The American College of Radiology will apply to be a Medicare recognized registry and will work with stakeholders to submit comments regarding the details of the CMS coverage announcement," the group that represents the subspecialty said in a statement. "Significant lung cancer screening infrastructure is growing quickly to meet the need for this important public health measure."

Ella Kazerooni, chair of the ACR Lung Cancer Screening Committee and American College of Radiology Thoracic Imaging Panel, said screening should begin right away. "We strongly advise older current and former heavy smokers to speak with their doctors about whether CT lung cancer screening is right for them," Kazerooni said in a statement. "If they and their doctor decide that screening is warranted, we encourage patients to seek out an ACR lung cancer screening center."

Laurie Fenton-Ambrose, president and CEO of Lung Cancer Alliance, similarly applauded the CMS decision, saying that it's "aligned with" the proposal of her organization and professional societies involved in screening. "By issuing this decision, CMS has avoided creating a perplexing two tiered system of coverage, where lung cancer screening is an essential health benefit for some but not for those at even higher risk for lung cancer—our nation's seniors," she said.

A study published in the Nov. 6 issue of The New England Journal of Medicine estimates that screening based on the results on NLST costs $81,000 for each quality-adjusted year of life it produces.

The metric, known as Cost per Quality-Adjusted-Life-Years (QALYs), considers the overall costs of a medical intervention to a selected population to produce one year of perfect health. A widely used benchmark for cost-effectiveness is $100,000-$150,000 QALY.

"The takeaway from this study is that there is potential for lung cancer screening to be done in a cost-effective manner, particularly for adults 65-75 years of age," said William Black, chair of the Lung Cancer Screening Group at Dartmouth-Hitchcock Medical Center and professor of radiology, of community & family medicine, and of The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth.

Black is principal author of the NEJM paper.

When the researchers looked at specific subgroups of study participants, they found lung cancer screening was most cost-effective for current smokers, women, and for people in their sixties.

"Although precision with subsets is not as good as overall, people at higher risk seemed to benefit more from screening, so, for example, current smokers benefited much more than people who had quit," Black said.

Guest Editorial

ACS's Brawley: CMS Got it Right

(Continued from page 1)

The CMS position acknowledges that if implemented wisely, lung cancer screening eventually has the potential to prevent the deaths of several thousand Americans per year. It also realizes that lung cancer screening is not without significant inconvenience and risk.

The emphasis on counseling, informed decision-making, and qualifications for medical professionals and medical centers who perform the screening is ground breaking. When it comes to a number of cancer screening tests, American medicine is starting to emphasize patient self determination and true shared decision making. This CMS policy will catalyze the movement.

These proposed policies are based on sound science. The National Lung Screening Trial is one of the best designed and best conducted screening studies ever. It documents the benefits and limitation of this screening intervention. The study shows that low dose CT when done well has the potential of reducing relative risk of lung cancer death by about 20 percent; it also has a high false positive rate, requiring a significant proportion of those screened to undergo follow-up studies. The NLST shows that screening is most effective among those at greatest risk of lung cancer. Unfortunately, a relative risk reduction of 20 percent means that 80 percent of those destined to die of lung cancer, still die of lung cancer. Most importantly, this randomized demonstrates that screening causes interventions that lead to some premature morbidity and is even associated with some premature deaths. In the original publication, one death occurred within 60 days of a screening related invasive procedure for every 5.4 deaths prevented.

The CMS policy not only mandates counseling and shared decision-making, but attempts to minimize the risks, maximize the benefit by mandating establishment of a registry to follow patient outcomes and setting minimal qualifications of radiologists and screening centers. This is a challenge to and opportunity for the

numerous professional and healthcare organizations that urged CMS to pay for lung cancer screening. It is now their responsibility to teach the complexities of screening to the medical professionals who will be involved in the shared decision-making.

The complexities of screening are immense and often counterintuitive. Those of us who engage in health education have a responsibility to understand and teach both the potential benefits and limitations of screening.

To just say one should get screened is a terrible oversimplification. As a colleague is fond of saying, "For us to oversimplify the message that screening saves lives is no different than a financial planner oversimplifying the message that investing in stock makes people wealthy."

Accurate, understandable information is especially important when working with disparate populations. Disparate populations generally have the the highest risk of cancer death and are at greatest risk of complications from medical interventions.

They are often concerned that they are not being told the truth. Those who advocate screening and do not acknowledge the potential for harm actually justify the distrust and contribute to health disparities.

Screening can be lifesaving but without quality controls it can cause more harm than benefit. Lung cancer screening can be very lucrative for screening centers, but quality assurance programs can be quite costly. Those organizations that lobbied for CMS payment for screening now must work to solidify and enforce the standards to assure widespread availability of quality screening, diagnosis, and treatment.

The medical community was slow to do this when breast and prostate cancer screening began decades ago and we are still seeing the harms from this inaction. We cannot afford such delays in lung cancer screening.

The CMS lung cancer screening proposal is a harbinger that informed decision making and patient choice will be an important element of cancer screening. Its importance is growing for a number of cancer screening interventions.

This proposal is a unique opportunity for CMS, professional societies and health advocacy organizations to work together. We have a moral imperative to teach true fact about screening. We have a solemn obligation to organize ourselves so that we can provide high quality screening, diagnosis and treatment and save lives.

The author is the chief medical officer of the American Cancer Society and is a professor at Emory University.

FDA News

Avastin Combination Approved In Recurrent Ovarian Cancer

FDA approved Avastin in combination with chemotherapy for the treatment of women with platinum-resistant, recurrent ovarian cancer.

The new indication of Avastin is in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan chemotherapy for the treatment of women with platinum-resistant, recurrent, epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received no more than two prior chemotherapy regimens.

With this approval, Avastin is approved in the U.S. to treat six distinct tumor types.

The approval was based on results from the phase III AURELIA study that showed Avastin plus chemotherapy reduced the risk of disease worsening or death by 62 percent compared to women who received chemotherapy alone. The median progression-free survival was 6.8 months in the Avastin arm compared to 3.4 months in the control arm (HR=0.38; $p<0.0001$).

Overall survival was 16.6 months in the Avastin arm compared to 13.3 with chemotherapy alone (HR=0.89 [95% CI: 0.69, 1.14])

AURELIA is a multicenter, randomized, open-label study in 361 women with platinum-resistant, recurrent, epithelial ovarian, primary peritoneal, or fallopian tube cancer, who had received no more than two anticancer regimens prior to enrollment in the trial. Participants were randomized to one of six treatment arms (paclitaxel, topotecan or pegylated liposomal doxorubicin with or without Avastin). Avastin is sponsored by Genentech, a member of the Roche Group.

ODAC Votes Against Approving Farydak in Multiple Myeloma

The FDA Oncologic Drugs Advisory Committee recommended against approval of the Novartis agent Farydak (panobinostat), a pan-deacetylase inhibitor, for the indication of previously treated multiple myeloma when used in combination with bortezomib and dexamethasone.

ODAC voted 5-2 against approval Nov. 6, noting that while the agent had demonstrated an improvement in progression-free survival, its side effects were too severe to warrant approval.

The application was based on a phase III randomized, double-blind, placebo-controlled, global registration trial called PANORAMA-1 (PANobinostat

ORAl in Multiple MyelomA) and a phase II multicenter, single-arm, open-label study in the U.S. named PANORAMA-2.

PANORAMA-1 enrolled 768 patients with relapsed multiple myeloma in a pivotal, add-on design trial that used bortezomib and dexamethasone as backbone therapy. The primary endpoint was investigator-assessed progression-free survival. The secondary endpoint was overall survival. PFS was also assessed by an independent review committee in a sensitivity analysis, due to large amounts of incomplete response assessment data.

According to FDA briefing documents, Farydak produced an improvement in median progression-free survival of 3.9 months as assessed by investigators, or 2.2 months as assessed by independent review committee.

However, there was an increased incidence of deaths not due to progressive disease—7 percent vs. 3.5 percent—and the observed adverse events of myelosuppression, hemorrhage, infection, gastrointestinal toxicity, and cardiac toxicity.

ODAC was asked to determine whether the benefit of treatment with Farydak, also known as LBH589, in combination with bortezomib and dexamethasone outweighs the risks for patients with relapsed multiple myeloma.

"We are disappointed by this voting outcome and believe the results from our clinical trials provide strong evidence to support LBH589 as a potential first-in-class treatment option for multiple myeloma, a cancer where an unmet patient need exists," Bruno Strigini, president of Novartis Oncology, said in a statement.

Farydak seeks to restore cell programming in multiple myeloma. If approved, Farydak would be a first-in-class therapy for patients with previously treated multiple myeloma, according to the drug's sponsor.

"Access to a treatment like panobinostat can make a significant difference, slowing progression of the disease and perhaps offering an additional therapy option to patients in greatest need," Walter Capone, president and CEO of the Multiple Myeloma Foundation, said in a statement. "We encourage the FDA and Novartis to work together to identify a path forward and stand ready to support their efforts."

According to FDA documents, recent regular approvals for drugs in multiple myeloma have been supported by improvements in time-to-progression or progression-free survival. (Both include objective tumor progression in time from randomization; TTP does not include deaths.)

"For approved products, differences in median PFS or TTP ranged from 2.8 to 9.2 months in add-on design trials. A 9.2 months difference occurred when dexamethasone alone was used as the comparator regimen," the agency's briefing documents state.

"In more recent approvals, an add-on design to a standard chemotherapy regimen, i.e., to bortezomib or to melphalan and prednisone, led to smaller incremental improvements in PFS or TTP. Accelerated approvals have been supported by overall response rate results from single-arm trials."

CPRIT Sets Funding Priorities For Rare and Pediatric Cancers

By Matthew Bin Han Ong

The Cancer Prevention & Research Institute of Texas is adding rare cancers and childhood cancers to its list of funding priorities, according to a draft program report.

The Texas legislature requires the oversight committee of the $300 million state-funded program to establish funding priorities on an annual basis. This is the first time these priorities are articulated and vetted in a public setting, officials say.

"The oversight committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, scientific research and product development," the Oct. 3 draft report reads.

CPRIT's mandate has three major points: research new approaches to prevention and early detection; fund initiatives that bridge basic research, product development and preventive measures research; and enhance Texan research superiority by increasing applied science and technology research capabilities and recruiting high-quality cancer scientists and clinicians.

This round of proposed research program priorities for CPRIT includes:

- "A broad range of innovative, investigator-initiated research projects,
- Prevention and early detection,
- Computational biology and analytic methods,
- Rare and intractable cancers, including childhood cancers,
- Cancers of importance in Texas,
- Research to move basic science toward its application, and
- [Recruitment of] outstanding cancer researchers to Texas."

According to the report, these priorities do not exclude funding in areas outside of the identified priorities.

The institute awarded 101 new grants in August—a total of $107 million—to cancer researchers, prevention initiatives and product development projects.

"CPRIT funds provide needed support for individuals and organizations working to reduce the burden of cancer," CPRIT CEO Wayne Roberts said in a statement at the time. "Through our merit-based peer review, we identify a wide range of high-quality, innovative projects that positively impact the lives of Texans—both now and into the future.

"These new grants, plus the more than $970 million CPRIT has already invested in research, prevention and product development projects, will make new discoveries to cure and prevent cancer a reality."

The product development grants invested $13.5 million in brain cancer treatment and advanced imaging and diagnostic research.

The prevention awards, totaling $17.5 million, will support prevention services for underserved populations, increasing HPV vaccination rates, tobacco cessation efforts, and colorectal cancer screening.

Over $76 million in research grants will support the recruitment of eight cancer scientists and clinicians at various career levels to academic institutions in Texas, as well as an additional 76 cancer research grants.

CDC: About 8 Million Women Skipped Cervical Cancer Screening in the Past 5 Years

About eight million women ages 21 to 65 years have not been screened for cervical cancer in the past five years, according to the Centers for Disease Control and Prevention. More than half of new cervical cancer cases occur among women who have never or rarely been screened.

Researchers reviewed data from the 2012 Behavioral Risk Factor Surveillance System to determine women who had not been screened for cervical cancer in the past five years.

They analyzed the number of cervical cancer cases that occurred during 2007 to 2011 from CDC's National Program of Cancer Registries and the National Cancer Institute's Surveillance, Epidemiology and End Results Program.

Cervical cancer deaths were based on death certificates submitted to the National Vital Statistics System.

The report's key findings include:

• In 2012, 11.4 percent of women reported they had not been screened for cervical cancer in the past five years; the percentage was larger for women without health insurance (23.1 percent) and for those without a regular health care provider (25.5 percent).

• The percentage of women not screened as recommended was higher among older women (12.6 percent), Asians/Pacific Islanders (19.7 percent), and American Indians/Alaska Natives (16.5 percent).

• From 2007 to 2011, the cervical cancer incidence rate decreased by 1.9 percent per year while the death rate remained stable.

• The southern U.S. had the highest rate of cervical cancer (8.5 per 100,000), the highest death rate (2.7 per 100,000), and the largest percentage of women who had not been screened in the past five years (12.3 percent).

Using the human papillomavirus vaccine as a primary prevention measure could also help reduce cervical cancer and deaths from cervical cancer.

Another recent CDC study showed that the vaccine is underused; only 1 in 3 girls and 1 in 7 boys had received the three-dose series in 2013. The HPV vaccine is recommended as a routine vaccine for children 11-12 years old. Modeling studies have shown that HPV vaccination and cervical cancer screening combined can prevent as many as 93 percent of new cervical cancer cases.

Even with improvements in prevention and early detection methods, most cervical cancers occur in women who are not up-to-date with screening, CDC officials said.

The findings appeared in Vital Signs, part of the CDC's Morbidity and Mortality Weekly Report.

2015 Breakthrough Prize Winners Announced at Gala

The Breakthrough Prize Foundation announced the recipients of its prizes in life sciences and fundamental physics, who will receive awards of $3 million.

The recipients of the 2015 Breakthrough Prizes in Life Sciences are:

• **Alim Louis Benabid**, of Joseph Fourier University, for the development of high-frequency deep brain stimulation, which has revolutionized the treatment of Parkinson's disease.

• **C. David Allis**, of The Rockefeller University, for the discovery of covalent modifications of histone proteins and their roles in the regulation of gene expression and chromatin organization.

• **Victor Ambros**, of University of Massachusetts Medical School, and **Gary Ruvkun**, of Massachusetts

General Hospital and Harvard Medical School, for the discovery of genetic regulation by microRNAs. Each received a $3 million award.

• **Jennifer Doudna**, of University of California, Berkeley, Howard Hughes Medical Institute and Lawrence Berkeley National Laboratory, and **Emmanuelle Charpentier**, of Helmholtz Center for Infection Research and Umeå University, for harnessing a mechanism of bacterial immunity into a general technology for editing genomes. Each received a $3 million award.

The Breakthrough Prize in Fundamental Physics recognized a collaboration of 51 total prize recipients that discovered that the expansion of the universe is accelerating, rather than slowing. The team included **Saul Perlmutter**, of the University of California, Berkeley and the Lawrence Berkeley National Laboratory; **Brian Schmidt**, of Australian National University; and **Adam Riess**, of Johns Hopkins University and the Space Telescope Science Institute; and members of the Supernova Cosmology Project and the High-Z Supernova Team.

The awards were presented at a gala at NASA's Ames Research Center. The ceremony will air on Discovery Channel and Science Channel Nov. 15, and on BBC World News the weekend of Nov. 22.

In Brief

O'Brien Named Asso. Director For Clinical Science at UC Irvine

(Continued from page 1)

She will focus on increasing both the number and complexity of innovative, outcomes-focused clinical trials.

O'Brien comes to UC Irvine from MD Anderson Cancer Center where she was the Ashbel Smith Professor in the Department of Leukemia. She is chair of the National Comprehensive Cancer Network Chronic Myelogenous Leukemia Guidelines Committee, a member of the NCCN Acute Lymphoblastic Leukemia Guidelines Committee and is the hematology member of the Southwest Oncology Group Executive Committee.

ROSEMARIE HENSON will join the **American Cancer Society** as senior vice president for prevention and early detection, effective January 2015.

Henson is senior advisor to the assistant secretary for health at the U.S. Department of Health and Human Services. She will serve as a member of the society's Cancer Control team.

She co-led preparations at HHS for the 2011 United Nations High-Level Meeting on Non-Communicable Diseases, and led the HHS team that published the 50th Anniversary Surgeon General's report: The Health Consequences of Smoking-50 Years of Progress. In May 2014, the team received the Secretary's Award for Meritorious Service for their work.

Henson has also held a variety of leadership positions at the Centers for Disease Control and Prevention, and was deputy director of the National Center for Chronic Disease Prevention and Health Promotion. She served as the director of CDC's Office on Smoking and Health from 2001 to 2004 and directed CDC's National Breast and Cervical Cancer Early Detection Program.

MICHAEL BISHOP will receive the Daniel Nathans Memorial Award for his contributions to biomedical research from the **Van Andel Research Institute.**

Bishop, a Nobel laureate, will give a scientific lecture and a lay lecture during his visit to the Institute on December 1-2.

Bishop was awarded the Nobel Prize in Medicine or Physiology in 1989 along with his colleague Harold Varmus, director of the NCI, for their discovery of proto-oncogenes that can give rise to cancer after incurring genetic damage. Bishop and Varmus also received the Albert Lasker Basic Medical Research Award and the National Medal of Science for their discovery.

Bishop currently serves as a university professor and director of the G.W. Hooper Research Foundation and as chancellor emeritus at the University of California, San Francisco. He has been elected to numerous organizations including the National Academy of Sciences and the Institute of Medicine.

ANTJE HOERING was named CEO of **Cancer Research and Biostatistics**, effective Jan. 1, 2015.

Hoering serves as chief scientific officer at CRAB, is the lead statistician for the SWOG Myeloma Committee and, is an active member of the Myeloma Steering Committee for the National Clinical Trials Network.

She also serves as the director of the Biostatistics Core for a SPORE grant funded through the Sarcoma Alliance for Research Through Collaboration, and is the co-director of the Biostatistics Core for a Program Project through the Myeloma Institute for Research

and Therapy.

Hoering will succeed John Crowley, CRAB's founder, and CEO since 1997, who will continue to serve as CRAB's chairman of the board.

NANCY HESSE was named chief nursing officer of **Cancer Treatment Centers of America.**

Hesse will be responsible for leading the development and execution of system-wide programs and best practices for safety outcomes and clinical quality.

She previously held the position of senior vice president of patient care services at CTCA - Eastern Regional Medical Center and will continue in that role while assuming her new position.

Hesse joined CTCA in January 2014 after serving as chief nursing officer at Abington Health, Lansdale Hospital, a position that she held for four and a half years. She was also a system director of emergency services and director and nurse manager of the Emergency Trauma Center.

KATHLEEN GREEN was appointed associate director for basic sciences research at the Robert H. Lurie Comprehensive Cancer Center of **Northwestern University.**

Green is the Joseph L. Mayberry, Sr., Professor of Pathology and Toxicology and Professor of Dermatology at the Feinberg School of Medicine.

Green will report to center director Leonidas Platanias, and will be responsible for the development and coordination of the center's basic science research programs, as well as fostering interdisciplinary and inter-programmatic collaborations.

In addition, she will serve on the Executive Committee and Leadership Group and oversee the development and operation of the basic research laboratory facilities on the Chicago and Evanston campuses.

Green replaces **Thomas O'Halloran**, the Charles E. and Emma H. Morrison Professor of Chemistry and Professor of Molecular Biosciences at the Weinberg College of Arts and Sciences, and director of the Chemistry of Life Processes Institute, who will serve as senior advisor to the director.

Green's research focuses on the molecular basis for how cells stick together, not only to provide mechanical strength to tissues, but also to regulate chemical signals for development and differentiation. She has a particular interest in tissues such as skin and heart that are major targets for adhesion-related diseases, including inherited, autoimmune and bacterial-toxin mediated disorders and cancer.

Green has served as co-leader of the center's Tumor Invasion, Metastasis and Angiogenesis Program. She also serves as director for Northwestern's PhD training Cluster in Cancer Biology and the NCI-funded Carcinogenesis Training Program, which provides interdisciplinary research training for eight pre-doctoral students in cancer biology.

She currently serves as secretary of the American Society for Cell Biology, deputy editor-in-chief of the Journal of Cell Science, and principal investigator on three grants from the NIH, including a MERIT Award.

NANCY WEIGEL was named editor-in-chief of the Endocrine Society's journal **Hormones and Cancer**, beginning Jan. 1, 2015. Weigel is a professor at Baylor College of Medicine.

The journal was founded in 2010 and is published on a bimonthly basis. It is produced in partnership with Springer, an international publisher of clinical and research books.

She has previously served as associate editor for the society's journal Molecular Endocrinology and was an editorial board member for Hormones and Cancer, Endocrinology, Steroids, Nuclear Receptor Signaling and the Journal of Biological Chemistry.

Weigel's research has focused on co-activators and androgen receptors in prostate cancer as well as vitamin D receptor target genes.

She is chairwoman of the society's Laureate Awards Committee and has served on the society's council as well as the Publications Core Committee. Weigel has been honored with the society's Roy O. Greep Award for Outstanding Research and the Society of Women in Urology/Society for Basic Urology Research Award for Excellence in Urologic Research.

THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY formed a clinical affairs department focused on to providing services, education, and resources to support oncology practices.

This new department will offer assistance practice management, quality care assessment and improvement, efficiency and business intelligence.

The new department will be active by the end of 2014. The society plans to house existing practice management resources in the new department and, over the next year, will expand these offerings to include support in the following areas: business of oncology; practice management (staffing, technology, services, etc.); practice transformation to medical home, to certification, etc.; and market analysis.

THE COMMUNITY ONCOLOGY ALLIANCE documented an 82 percent increase in cancer clinic closings and a 143 percent increase in consolidation into hospitals in a new report since its first in 2010, which reported on activity from 2008 to 2010.

COA's Community Oncology Practice Impact Report states that over the past eight years, 313 cancer treatment facilities have closed and 544 community cancer practices have been acquired by or affiliated with hospitals.

THE HARRINGTON DISCOVERY INSTITUTE at University Hospitals and the **University of Oxford** formed an affiliation focused on drug discovery projects.

The affiliation will include the Oxford-Harrington Scholarship Program, which plans to expand throughout the United Kingdom. The program will provide support for preclinical drug research and early-stage clinical trials that may not be far enough along in the drug development pipeline to receive financial support from the pharmaceutical industry.

Scholars will have access to the institute's Innovation Support Center for strategic project management, which will help oversee drug development efforts. The new model will include an Oxford presence for BioMotiv, a for-profit commercialization company, aligned with the nonprofit Harrington Discovery Institute.

DANA-FARBER CANCER INSTITUTE and **Astellas Pharma Inc**. announced a three-year collaboration to research and develop small molecule inhibitors of oncogenic K-Ras for the treatment of cancer, including lung cancer.

Nathanael Gray, of the Cancer Biology Department at Dana-Farber and professor at Harvard Medical School, will lead this collaborative research. In collaboration with other Dana-Farber investigators, Gray published an article about a novel approach to developing inhibitors to the G12C mutation of K-Ras earlier this year and detailed the inhibitor's structural interaction with the K-Ras target in a second publication in June.

In addition to providing research support, Astellas has an option to obtain from Dana-Farber an exclusive, worldwide license to novel K-Ras inhibitors obtained from the research collaboration, and upon exercise of the option, would conduct further preclinical research and development on such K-Ras inhibitors, and subsequent clinical development and commercialization.

In this collaboration, Gray's laboratory and the Dana-Farber Medicinal Chemistry Core will be joined by the laboratories of **Pasi Jänne** and **Kwok-Kin Wong** of the Thoracic Oncology Program and co-directors of the Belfer Institute for Applied Cancer Science at Dana-Farber and professors at Harvard Medical School.

ASTRAZENECA, **Pharmacyclics Inc**. and **Janssen Research & Development LLC** entered into a clinical trial collaboration to evaluate the efficacy and safety of AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Imbruvica (ibrutinib).

Imbruvica is an oral Bruton's tyrosine kinase inhibitor co-developed and commercialized by Pharmacyclics and Janssen Biotech. The study will assess the combination as a treatment for patients with hematologic cancers including diffuse large b-cell lymphoma and follicular lymphoma, which are investigational uses for both compounds.

MEDI4736 blocks the signals that help tumors avoid detection by the immune system. Imbruvica blocks signals that tell malignant B cells to multiply and spread uncontrollably. Preclinical evidence suggests that the combination of these two agents may lead to an enhanced anti-tumor immune response.

Under the terms of the agreement, the trial will be conducted by Pharmacyclics. The financial terms of the agreement have not been disclosed.