PMC PERSONALIZED MEDICINE COALITION

PERSONALIZED MEDICINE IN BRIEF

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Developments in Brief

2021

MARCH 19

In an article published as part of an educational insert in the *USA Today*, PMC underlines the significance of nine personalized cancer treatments approved by the U.S. Food and Drug Administration in 2020. The article promises to improve public awareness about the benefits of personalized medicine for cancer patients.

PAGE 10

MARCH 12

The *Journal of Personalized Medicine* publishes a first-of-its-kind study applying a quantitative multi-factorial framework to assess the clinical adoption of personalized medicine among a representative sample of 153 health care providers. The study spotlights a system-wide but incomplete clinical integration effort, underlining the importance of generating additional evidence demonstrating the benefits of the approach.

PAGE 7

FEBRUARY 20

Prompted by the release of PMC's *Strategic Plan* and *Research Program* for 2021, *The Oncology Times* publishes an article outlining the obstacles that inhibit personalized medicine from improving care for as many patients as it should. The article promises to inspire additional efforts to improve the landscape for the field.

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2020

DECEMBER 17

A bipartisan group of Senators including Congressional Personalized Medicine Caucus Co-Chair Tim Scott (R-SC) introduces the *Medicare Multi-Cancer Early Detection Screening Coverage Act*. The bill would help health care systems deliver on personalized medicine's promise of earlier disease detection by providing a Medicare coverage pathway for liquid biopsy-based tests approved by the U.S. Food and Drug Administration.

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PRESIDENT'S BRIEF

Envisioning Personalized Medicine for a Post-Pandemic World

by Edward Abrahams, PMC President

As global leaders slowly permit themselves to imagine a post-pandemic world, this edition of *Personalized Medicine in Brief* describes an emerging effort to advance a new era of personalized medicine that absorbs the lessons learned from the emergence of COVID-19.

On pp. 4–6, PMC Senior Vice President for Public Policy Cynthia A. Bens discusses how advocates for personalized medicine are operating in the aftermath of a public health crisis that caught most of the world off-guard. In a public policy environment characterized by a renewed appreciation for how health care policies implemented today may affect our capacity for taking advantage of the opportunities and challenges that may be shaping the health care landscape in the future, PMC is advocating for increased investments in biomedical research, the withdrawal of a reimbursement policy proposal that may unintentionally disrupt access to personalized treatments, and the passage of a new law that would establish a pathway for Medicare coverage of liquid biopsy-based diagnostics that hold tremendous potential to improve cancer care and advance personalized medicine.

On pp. 7–8, PMC Senior Vice President for Science Policy Daryl Pritchard, Ph.D., considers the implications of a new study showing that United States-based health care providers, many of which were quickly overrun by patients seeking care for SARS-CoV-2 infections during the pandemic, are engaged in a broad-based but incomplete effort to adopt the personalized medicine tools that can assist in their efforts to target the most intensive treatments to those patients who need them most. Initiatives focused on building a roadmap for the implementation of personalized medicine, he notes, will prompt more widespread clinical adoption of the tests and treatments underpinning the field while informing policymakers who want to understand where the field can have its greatest impact.

And in two essays that appear on pp. 9–12, PMC Vice President for Public Affairs Christopher J. Wells reports on our progress in advocating for a broader understanding of personalized medicine that accounts for patients' circumstances and values, as well as their biological characteristics. With reference to lessons learned during the pandemic about the influence of health disparities and the potential of home-based health care paradigms enabled by telemedicine, PMC's educational campaigns are bolstering public enthusiasm for health care strategies that bring the right interventions to the right patients at the right time. The campaigns also promise to spur increased clinical adoption of personalized medicine by prompting patients to ask their physicians questions about the field.

In light of these and the many other developments that are shaping the landscape and outlook for personalized medicine as we begin to emerge from the pandemic, PMC is planning to convene *The 16th Annual Personalized Medicine Conference at Harvard Medical School* from November 17–18, 2021.

We hope to see you there for a discussion about the prospects for building a brighter future for patients and health systems in the aftermath of the horrible pandemic.

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Assistant Professor of Medicine
Columbia University

SHEZ PARTOVI, M.D.
Worldwide Lead, Business Development, Healthcare, Life Sciences, Genomics
Amazon Web Services

CHRISTI SHAW
CEO
Kite, a Gilead company

The 16th Annual Personalized Medicine Conference at Harvard Medical School will convene the world's leading researchers, investors, industry executives, policy experts, payers, clinicians, and patient advocates to explore how the emergence of COVID-19 as well as the latest developments in science, business and policy are influencing the landscape and outlook for personalized medicine.

16TH ANNUAL
PERSONALIZED MEDICINE CONFERENCE

PUBLIC POLICY BRIEF

With Policymakers Focused on Health Care, Personalized Medicine's Advocates Spotlight Key Opportunities in Personalized Medicine

by Cynthia A. Bens, PMC Senior Vice President, Public Policy

As a new Presidential Administration and Congress consider their approaches to combatting escalating health care costs and mitigating the COVID-19 pandemic, personalized medicine's advocates in Washington are developing policy solutions that are designed to make health care more effective and efficient by targeting prevention and treatment strategies to patients who will benefit. PMC and its allies are supporting efforts to advance policies that allocate more funding for basic scientific research that drives the development of biomedical interventions; to encourage more sophisticated approaches to biopharmaceutical pricing that protect patient access; and to ensure that tests approved by the U.S. Food and Drug Administration (FDA) for their potential to detect multiple cancers in their earliest stages do not experience delays in coverage.

To bolster the National Institutes of Health (NIH)'s ability to sustain its investment in biomedical research, PMC joined 360 other organizations in asking policymakers for a funding level of at least $46.111 billion in Fiscal Year 2022. Led by the Ad Hoc Group for Medical Research, the letter outlines that this inflation-adjusted increase of five percent in the NIH's budget will help "improve our understanding of fundamental life and health sciences" and "prepare us to combat unprecedented health threats including the COVID-19 pandemic." By increasing governmental spending on science at a moment when groundbreaking technologies are giving us an unprecedented ability to understand the biological and environmental factors that drive disease and influence patients' responses to various treatments, an appropriated funding level for NIH along these lines would drive discoveries that can inform a new era of personalized medicine. President Joe Biden requested an even higher amount of $51 billion for NIH as part of a proposed government budget sent to Congress in April.

Proponents for personalized medicine are also recommending that the Centers for Medicare and Medicaid Services (CMS) withdraw its Most Favored Nation (MFN) Model interim final rule, which is intended to reduce the cost of prescription drugs in the United States by aligning the prices for the top 50 Medicare Part B drugs with the lowest prices available in economically similar countries. In a comment letter to CMS Acting Administrator Elizabeth Richter in January, PMC noted that the MFN Model would negatively impact providers' ability to utilize personalized medicine in practice and force some patients to rely on alternative therapies or forgo treatment. If implemented, the MFN Model could thereby unintentionally disrupt access to personalized therapies that patients need. The letter requested that CMS "withdraw the MFN rule and instead pursue policies that allow for the more

"PMC and its allies are supporting efforts to advance policies that allocate more funding for basic scientific research that drives the development of biomedical interventions; to encourage more sophisticated approaches to biopharmaceutical pricing that protect patient access; and to ensure that tests approved by the U.S. Food and Drug Administration (FDA) for their potential to detect multiple cancers in their earliest stages do not experience delays in coverage."

rapid adoption of personalized medicine into the health care system." A *Federal Register* notice published on March 31 shows that final action on the MFN Model has been delayed until November of 2023.

One policy intended to accelerate adoption of personalized medicine is the *Medicare Multi-Cancer Early Detection Screening Coverage Act*, which was first introduced in the House and Senate during the last Congress.

Personalized Medicine Caucus Co-Chair Sen. Tim Scott (R-SC) is one of four Senators who introduced the *Medicare Multi-Cancer Early Detection Screening Coverage Act*. By establishing a Medicare coverage pathway for FDA-approved liquid biopsy-based diagnostics, the bill would help facilitate an era in which the American health care system takes full advantage of personalized medicine to detect and treat cancers at more manageable and less costly stages. The bill's sponsors also include Sens. Michael Bennet (D-CO), Mike Crapo (R-ID), and Ben Cardin (D-MD).

By providing a Medicare coverage pathway for liquid biopsy-based tests approved by the FDA for use in detecting cancers in their earliest stages based on the presence of telltale biomarkers in patients' bloodstreams, the bill would help facilitate an era in which the American health care system takes full advantage of personalized medicine to detect and treat cancers at more manageable and less costly stages, thereby improving effectiveness and efficiency. The *Medicare Multi-Cancer Early Detection Screening Coverage Act* has bipartisan support, including from Congressional Personalized Medicine Caucus Co-Chair Sen. Tim Scott (R-SC).

To help cultivate support for legislative solutions positively impacting personalized medicine, Scott and the other co-chairs of the Personalized Medicine Caucus, who include Sen. Kyrsten Sinema (D-AZ), Rep. Eric Swalwell (D-CA), and Rep. Tom Emmer (R-MN), are circulating letters on Capitol Hill to invite their colleagues in the House and Senate to join the caucus. The language in the letters reflects an emerging understanding of the role policymakers can play in advancing a field that has long promised tremendous benefits for both patients and health systems.

"The use of personalized medicine is intended to address a problem many have long recognized," the Senate letter reads. "Treatment and prevention strategies that help some patients are less effective for others, and some medicines may cause side effects or adverse reactions in certain patients."

"We believe proactive engagement from Congress would be helpful in understanding and fostering the science that is driving progress in personalized medicine."

GROWING THE PERSONALIZED MEDICINE CAUCUS

To help cultivate support for legislative solutions positively impacting personalized medicine, the co-chairs of the Personalized Medicine Caucus are circulating letters on Capitol Hill to invite their colleagues in the House and Senate to join the caucus.

The Senate version of the letter is presented below.

Dear Colleague:

We invite you to join the bipartisan Congressional Personalized Medicine Caucus, a forum that seeks to engage Senate offices in a constructive dialogue about legislative and regulatory policies that can help realize the full potential of personalized medicine.

Personalized medicine, also called precision or individualized medicine, is a rapidly advancing field in which physicians use diagnostic tests to identify specific biological characteristics that help determine which medical treatments and procedures will work best for each patient. By combining this information with an individual's medical records and taking into account social determinants of health, personalized medicine allows doctors and patients to develop targeted treatment and prevention plans where appropriate.

The use of personalized medicine is intended to address a problem many have long recognized — that treatment and prevention strategies that help some patients are less effective for others, and that some medicines may cause side effects or adverse reactions in certain patients. Certain people may be more susceptible to particular conditions than others, due to genetic or environmental factors, or both.

Certain challenges, however, have slowed the adoption of many new personalized medicine technologies. We believe proactive engagement from Congress would be helpful in understanding and fostering the science that is driving progress in personalized medicine.

This bipartisan and bicameral caucus is being led by Senators Kyrsten Sinema (Arizona) and Tim Scott (South Carolina), and by Reps. Eric Swalwell (California) and Tom Emmer (Minnesota) in the House.

Sincerely,

Kyrsten Sinema
U.S. Senator

Tim Scott
U.S. Senator

Sen. Kyrsten Sinema
(D-AZ)

Sen. Tim Scott
(R-SC)

Rep. Eric Swalwell
(D-CA)

Rep. Tom Emmer
(R-MN)

SCIENCE POLICY BRIEF

Progress and a Path Forward: Documenting System-Wide But Incomplete Clinical Integration of Personalized Medicine

by Daryl Pritchard, PMC Senior Vice President, Science Policy

On March 12, the *Journal of Personalized Medicine* published a first-of-its-kind landscape analysis applying a quantitative multi-factorial framework to assess the clinical adoption of personalized medicine in health care throughout the United States. Based on a survey of a representative sample of 153 health care providers, the article shows that 83 percent of the institutions studied scored a two or higher on the five-point scale used to examine their integration efforts. The study, commissioned by PMC and led by a team of researchers at Health Advances, also showed that only 22 percent of the institutions studied scored a four or a five on the personalized medicine integration scale. By revealing a system-wide but incomplete push to implement personalized medicine in clinical settings, the study underlines both the momentum that the field has as well as the limitations associated with the utilization of new biomedical technologies and practices with extraordinary but understudied potential benefits. It shows that the vast majority of U.S. health care institutions are now integrating personalized medicine at measurable levels, thus suggesting that the field has moved firmly from concept to practice. Still, we have a long way to go to realize the full potential of personalized medicine for patients and health systems.

The systemic move toward personalized medicine likely reflects scientific and technological breakthroughs that are driving molecular diagnostics and personalized treatments to the market even in the midst of a global pandemic. In its annual report of tests and treatments cleared and approved by the U.S. Food and Drug Administration, titled *Personalized Medicine at FDA: The Scope & Significance of Progress in 2020*, PMC counts 19 new personalized medicine approvals, representing approximately 39 percent of the therapeutic molecular entities the agency approved in 2020. Personalized medicines have now accounted for more than a third of new drug approvals for three of the last four years. FDA's Center for Biologics Evaluation has also approved six cell-based or gene therapies over the last half decade, representing a significant advancement for this class of personalized treatments, which involve the transplantation of normal genes into a patient's own cells to modify specific cellular functions.

The availability of an increasing number of diagnostic tests and platforms is also driving the integration of personalized medicine into health care. For example, the FDA approval of the first comprehensive pan-tumor liquid biopsy next-generation sequencing-based test may allow for earlier detection of multiple cancer biomarkers in cell-free DNA isolated from plasma specimens. By guiding targeted treatment strategies with attention to the biological characteristics that influence how patients respond to certain drugs, these diagnostic tools promise to make health care more effective and efficient for molecularly selected subsets of patients with cancer as well as those with certain rare, common, and infectious diseases.

Still, as the relatively low number of health care institutions that scored highly on the integration scale as documented in the new study likely reflects, we still have a long way to go to realize the full potential of personalized medicine. Efforts to integrate novel personalized medicine technologies and practices are still in the early going, and health care providers face challenges. For example, although more than 30 percent of patients with non-small cell lung cancer (NSCLC) have tumors that are linked to genetic

"The vast majority of U.S. health care institutions are now integrating personalized medicine at measurable levels, thus suggesting that the field has moved firmly from concept to practice. Still, we have a long way to go to realize the full potential of personalized medicine for patients and health systems."

driver mutations, many patients still do not receive genetic testing. Furthermore, a 2019 PMC report published in the *Journal of Clinical Oncology — Clinical Informatics* estimates that only 65–75 percent of patients with an actionable mutation as determined by genomic testing actually receive targeted therapies. This practice gap may be attributed to implementation challenges such as limitations in the availability and interpretation of diagnostic test results; sample processing constraints; limited access to targeted therapies; and lagging awareness of the rapidly evolving field of personalized medicine. PMC, working with research partners from Diaceutics, is undertaking a new project to examine the practice gaps associated with personalized medicine strategies in cancer care and will develop recommendations for health care providers meant to help them optimize clinical implementation strategies.

The practice gaps study can help provide some direction for the integration of personalized medicine into the health care system, but there is a need for a larger roadmap to help providers navigate a course to fully implement the novel technologies and practices underpinning personalized medicine within a health system that is under increasing pressure to control health care spending and deliver maximum value to broad populations of patients.

In a manuscript titled "Strategies for Integrating Personalized Medicine into Healthcare Practice," which was published by the journal *Personalized Medicine* in 2017, PMC's Health Care Working Group laid out this roadmap based on strategies to overcome implementation challenges. This was followed by the publication of a set of case examples titled "Strategies For Clinical Implementation: Precision Oncology At Three Distinct Institutions" in the journal *Health Affairs* in 2018, outlining the strategies that were successfully employed by three health care delivery institutions that scored highly on the personalized medicine integration scale.

So, while "A Quantitative Framework for Measuring Personalized Medicine Integration into US Healthcare Delivery Organizations" has revealed tremendous progress, we must build on this momentum in order to raise all health care delivery institutions to the highest levels of personalized medicine integration. As it is implemented, the roadmap now being developed will bring us closer to an era in which every patient benefits from the right intervention at the right time.

In a new article published in the *Journal of Personalized Medicine* titled "A Quantitative Framework for Measuring Personalized Medicine Integration into US Healthcare Delivery Organizations," a team of authors led by Health Advances Vice President Arushi Agarwal examines the extent to which academic health systems, community health systems, and integrated delivery networks are implementing personalized medicine in clinical care.

PUBLIC AFFAIRS BRIEF

Wide-Ranging Focus on Equitably Targeted Health Care Should Facilitate More Complete Understanding of Personalized Medicine

by Christopher J. Wells, PMC Vice President, Public Affairs

As the world reflects on the tragically uneven effects of the COVID-19 pandemic, leaders in health care are increasingly emphasizing the importance of developing more sophisticated health care approaches that can guide interventions to the most vulnerable patient populations, leverage molecularly targeted treatments more consistently, and ultimately make better use of broad-based datasets that include biological, clinical and environmental information. By underlining a wide range of opportunities to develop targeted health care strategies, this dialogue should facilitate a more complete understanding of personalized medicine, which has long promised to tailor health care not only to patients' biological characteristics, but also to their circumstances and values.

The pandemic has taught us startling lessons about the need for a health system that deploys health care resources more equitably. A special report published on March 4 by the *Boston Globe*'s health care reporting affiliate, *STAT*, shows, for example, that although the Black and Hispanic people who are most likely to die from COVID-19 account for 18 percent of the residents living in Palm Beach County, Florida, they had respectively received just 4.1 and 4.7 percent of vaccine doses administered in the county as of March 1. The story corroborates national findings released in mid-March by the Centers for Disease Control and Prevention, which concluded that "COVID-19 vaccination coverage was lower in high vulnerability counties than in low vulnerability counties, a finding largely driven by socioeconomic disparities." Both reports underline the need to roll out future preventive measures with a focus on the historically underserved populations most affected by infectious disease outbreaks, a commonsense application of personalized medicine's principles.

This renewed emphasis on addressing systemic inequities also underlines the importance of correcting a lack of diversity among participants in clinical trials for new drugs and vaccines, which leaves patients from underrepresented populations with unanswered questions about how new interventions may work for them. When it comes to personalized medicine, this issue is a scientific necessity as well as a moral imperative.

"Personalized medicine depends on a diverse, equitable, and inclusive biomedical research enterprise to generate reliable evidence to inform health care interventions that affect subsets of heterogeneous patient populations differently," PMC President Edward Abrahams explained in an introduction to the Coalition's forthcoming virtual discussion titled *Advancing Personalized Medicine Through Inclusive Biomedical Research*, which is scheduled to take place on April 22. Moderated by former PMC board member and Director of the Duke University Center for Applied Genomics and Precision Medicine Geoffrey S. Ginsburg, M.D., Ph.D., the conversation is designed to inform a PMC report that enhances our understanding of the strategies we can adopt to facilitate the emergence of a more inclusive biomedical research enterprise. Given the obvious link between the principles of personalized medicine and the importance of developing and deploying medical interventions in an equitable manner, a focus

On April 22, former PMC board member Geoffrey S. Ginsburg, M.D., Ph.D., will moderate the Coalition's virtual discussion on *Advancing Personalized Medicine Through Inclusive Biomedical Research*. The conversation will explore the sociocultural, behavioral, and systemic factors impeding the advancement of the diverse, equitable, and inclusive biomedical research enterprise necessary to generate reliable evidence to inform health care interventions that affect subsets of heterogeneous patient populations differently.

on aligning targeted prevention and treatment strategies with the circumstances and values of vulnerable patient populations should help define public perceptions of the field in the coming months and years.

The continued evolution of personalized treatments will also contribute to the public's understanding of the field.

According to PMC's *Personalized Medicine at FDA: The Scope & Significance of Progress in 2020*, personalized medicines accounted for 39 percent of the new molecular entities approved last year and have made up more than a third of approvals for three of the last four years. To enhance public awareness about the potential of paradigm-shifting immunotherapies as well as targeted therapies that can inhibit the genetic drivers of cancer without damaging healthy tissue as chemotherapy does, PMC Senior Vice President for Science Policy Daryl Pritchard, Ph.D., recently wrote an article titled "New FDA-Approved Treatments Signal Shift to Personalized Cancer Care," which was published online and as part of a special educational insert included in the *USA Today* on March 19. The article, part of PMC's consumer-facing educational initiative titled *More Than a Number*, notes that the nine personalized cancer treatments approved in 2020 will "improve care for patients and health systems by targeting the right drug to the right patient at the right time." It promises to improve public awareness about the benefits of personalized medicine for cancer patients.

In an open-access commentary article titled "Precision Medicine in 2030," which was published on March 18 in the journal *Cell*, National Institutes of Health Director Francis Collins, M.D., Ph.D., and *All of Us* Research Program CEO Joshua C. Denny, M.D., summarize how emerging conversations about health equity combined with powerful new treatments and cutting-edge diagnostic tools may facilitate a new era in personalized medicine. Envisioning a broad-based future for the field in which computational technologies are deployed to assess data on each patient's biological characteristics, clinical factors, and environmental circumstances to inform personalized prevention and treatment strategies with attention to issues in health equity and data privacy, the article calls for "a bold plan to collaborate internationally, to engage diverse populations of participants and scientists, to deeply measure our populations, to make clinical and research data broadly available, and to implement this knowledge in clinical practice" in pursuit of "precision medicine for all populations."

We would do well to embrace this vision for a future that for the first time puts the needs of each patient at the center of health care decision-making.

"Leaders in health care are increasingly emphasizing the importance of developing more sophisticated health care approaches that can guide interventions to the most vulnerable patient populations, leverage molecularly targeted treatments more consistently, and ultimately make better use of broad-based datasets that include biological, clinical and environmental information."

PERSPECTIVE IN BRIEF

Home-Based Health Care Strategies Anticipate Welcome Era of Patient-Centered Personalized Medicine

by Christopher J. Wells, PMC Vice President, Public Affairs

During the COVID-19 pandemic, an increased reliance on telemedicine, decentralized clinical trials, and at-home cancer screening previewed a future in which patients can access health care without leaving their homes. By giving patients new ways to access doctors when in-person options are unsafe or inconvenient, home-based care paradigms can augment the health system's ability to ensure that every patient can benefit from the right intervention at the right time, the essence of personalized medicine.

During a PMC webinar in September titled *COVID-19 and Personalized Medicine: Current Status and Lessons Learned*, PMC Board Chairman Jay G. Wohlgemuth, M.D., Senior Vice President, Chief Medical Officer, Quest Diagnostics, emphasized how at-home testing paradigms give us "a new chance to put the needs of patients in their rightful place at the center of health care decision-making."

As we emerge from the pandemic with a renewed understanding of the importance of engaging historically underserved patient populations in ways that align with their needs and preferences, we would do well to embrace telemedicine and other home-based health care paradigms.

According to a study published in *Health Affairs* on February 1 about telemedicine usage among 16.7 million patients covered by commercial insurance or Medicare Advantage plans, the number of weekly telemedicine visits increased twenty-three-fold between January and June of 2020. By giving patients the option to visit their physicians by telephone or through video conferencing software, telemedicine can make health care more accessible to patients in remote areas who may have difficulty traveling to in-person appointments with their physicians.

Similarly, decentralized clinical trials, which allow patients and their physicians to use digital technologies to report medication usage and associated outcomes, can make it easier for minorities and patients in remote regions to participate in research regarding new therapies, thereby increasing access and making clinical trials more meaningful to patient groups that have historically been less engaged in drug development research.

Thoughtful approaches are required to ensure that telemedicine and decentralized trials deliver cost-effective benefits. A study from the *Journal of General Internal Medicine* (October 2018) suggests that around 15 percent of patients who utilize telemedicine would not have sought in-person appointments to address

> "By giving patients new ways to access doctors when in-person options are unsafe or inconvenient, home-based care paradigms can augment the health system's ability to ensure that every patient can benefit from the right intervention at the right time, the essence of personalized medicine."

their concerns, which underlines the importance of ensuring that any increased costs associated with expanded insurance coverage for audio-visual visits are offset by successful interventions downstream. To ensure that telemedicine and decentralized trials do not exacerbate the inequities associated with a growing digital divide, policymakers will need to bolster the telecommunications infrastructure in rural parts of the country. Cybersecurity concerns must also be addressed.

To be sure, these challenges underscore the need for carefully calibrated approaches to integrating telemedicine and decentralized trials into the health care system. But they do not erase the benefits these paradigms can offer for diverse groups of patients.

At-home tests present additional opportunities to improve care for underserved populations.

For example, according to the American Cancer Society, African Americans are 20 percent more likely to be diagnosed with colorectal cancer and 40 percent more likely to die from it, as compared to other racial and ethnic groups. The U.S. Preventive Services Task Force (USPSTF) has embraced the latest at-home tests for colorectal cancer, which are designed to detect blood and cancer-associated genetic changes in patients' stool, as a viable alternative to colonoscopies for some cancer patients.

"The data show the tests are equally effective at saving lives," USPSTF Chairman Alex Krist, M.D., told *The New York Times* in January.

Although at-home screening for colorectal cancer cannot replace colonoscopies in all circumstances, the pandemic has underlined the significance of an at-home screening option for African American patients who may be wary of hospital visits that could expose them to COVID-19, another disease they have an outsized risk of dying from. As Jay G. Wohlgemuth, M.D., Senior Vice President, Chief Medical Officer, Quest Diagnostics, emphasized last year during a PMC webinar titled *COVID-19 and Personalized Medicine: Current Status and Lessons Learned*, at-home testing paradigms give us "a new chance to put the needs of patients in their rightful place at the center of health care decision-making."

Home-based paradigms cannot completely replace physical examinations of patients. Nor are they a cure-all for a health system that has failed too many Americans for far too long.

But in the coming months and years, decision-makers in the public and private sectors will be remiss if they fail to recognize that we have learned valuable lessons in the wake of the horrible pandemic, including that the adoption of home-based health care paradigms — under the right conditions — can improve the lives of underserved patients and advance the frontiers of personalized medicine, which has long promised to not only tailor health care to patients' biological characteristics, but also to their circumstances and values.

MEDIA BRIEF

From the PMC News Desk

Drawing on Insights From PMC's *Personalized Medicine Report* and *Strategic Plan*, *PharmaVOICE* Concludes That One-Size-Fits-All Medicine 'Doesn't Work;' Article Promises to Bolster Pharmaceutical Industry's Already Robust Interest in Personalized Medicine

An article published on April 1 in *PharmaVOICE* draws on insights from PMC's *Personalized Medicine Report* and *Strategic Plan* for 2021 to conclude that it "has become more and more apparent that the traditional one-size-fits-all approach to medicine doesn't work." By outlining the rationale for pursuing personalized medicine, the article promises to further enhance the pharmaceutical industry's already robust interest in the field. The article also underlines how far PMC and its allies have come since 2004 in reshaping thinking about the future of health care, at least when it comes to genetically guided therapy.

"It is now well accepted that genetic makeup can affect the safety and effectiveness of a therapy," the article reads.

See *PharmaVOICE*: "Precision Medicine: Expanding the Frontiers of Precision Medicine" (April 2021)

Distributed in *USA Today* as Part of PMC's *More Than a Number* Educational Initiative, Article Explaining Significance of Nine Personalized Cancer Treatments Promises to Help Prompt Patient-Physician Dialogue About Personalized Medicine

In an article published on March 19 as part of an advertorial insert distributed in the *USA Today* to educate consumers about the trends shaping the future of cancer care, PMC Senior Vice President for Science Policy Daryl Pritchard, Ph.D., explains the significance of nine personalized cancer treatments approved by the U.S. Food and Drug Administration in 2020. As part of PMC's consumer-facing educational initiative titled *More Than a Number*, the article is designed to help prompt patients to ask their physicians about personalized treatment options.

"Personalized treatments help physicians improve care for patients and health systems by targeting the right drug to the right patient at the right time," the article reads.

See online version in Mediaplanet's *Future of Personal Health*: "New FDA-Approved Treatments Signal Shift to Personalized Cancer Care" (March 2021)

In Article About CMS Coverage of Blood-Based Colorectal Cancer Screening, *BioWorld* Spotlights Both Clinical Opportunities and Reimbursement Challenges Shaping Pace of Advancement for Liquid Biopsies With Tremendous Promise to Personalize Cancer Care

In an article for February 22, *BioWorld* describes a complex set of interactions between patient groups and the Centers for Medicare and Medicaid Services (CMS) leading up to CMS' recent decision to begin covering U.S. Food and Drug Administration-approved blood-based screening tests for colorectal cancer. With reference to comment letters written by leaders including PMC Senior Vice President for Public Policy Cynthia A. Bens, the article spotlights both the clinical opportunities and reimbursement challenges shaping the pace at which liquid biopsy-based testing, which holds tremendous promise to personalize cancer care through the early detection of cancer-associated biomarkers in the blood, is integrated into patient care.

"CMS has determined that the time has come to offer Medicare coverage for blood-based in vitro diagnostics as a screening tool for colorectal cancer, but there's one catch: At present, there is no such test approved by the FDA that qualifies under the terms of the coverage memo, making this a null coverage proposition, at least for the time being."

See *BioWorld*: "CMS to Cover Blood-Based Tests for CRC Screening, But No FDA-Approved Tests Qualify" (February 2021)

Emphasizing Need for Evidence Development, *Oncology Times* Overview on 'Realizing Full Potential of Personalized Medicine' May Inspire Additional Efforts to Advance Field

Prompted by the release of PMC's *Strategic Plan* and *Research Program* for 2021, *The Oncology Times* on February 20 published a new article outlining the obstacles that inhibit personalized medicine from improving care for as many patients as it should. By exposing the *Times*' audience of cancer care professionals to an in-depth overview of the challenges facing personalized medicine in education, advocacy, and evidence development, "The Need to Realize the Full Potential of Personalized Medicine" promises to inspire additional efforts to improve the landscape for the field.

"In brief, we need more evidence that personalized medicine works — that it can improve clinical outcomes while making health care more efficient and therefore less costly," the article reads, quoting from an introduction to the *Research Program* written by PMC President Edward Abrahams and Board Chairman Jay G. Wohlgemuth, M.D., Chief Medical Officer, Senior Vice President, Quest Diagnostics.

See *The Oncology Times*: "The Need to Realize the Full Potential of Personalized Medicine" (February 2021)

Chronicling Painful Experiences of Stage 4 Prostate Cancer Patient, *Wired* Magazine Highlights Shortcomings of Health Care System Still Transitioning Away From One-Size-Fits-All Paradigm

In an article published on November 19, 2020, *Wired* magazine chronicles the painful experiences of Bryce Olson, a stage 4 prostate cancer patient whose widely publicized struggle to access personalized health care has illuminated the shortcomings of a health care system whose transition away from a one-size-fits-all paradigm remains incomplete. With reference to insights from PMC's *Personalized Medicine Report*, the article highlights challenges in regulation, reimbursement, and clinical adoption that are slowing the pace at which personalized medicine reaches patients.

"As with any new technology, there are roadblocks to adoption: Clinicians need to master a steep learning curve that includes keeping track of new tests, drug approvals, clinical trials, and constantly changing treatment guidelines," the article reads.

See *Wired* magazine: "One Man's Search for the DNA Data That Could Save His Life" (November 2020)

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EQRx
Freenome
Helix
Immatics US
Legend Biotech
MacroGenics
PAREXEL
Regeneron
Tango Therapeutics
WuXiNextCODE

HEALTH INSURANCE COMPANIES
Harvard Pilgrim Health Care

INDUSTRY/TRADE ASSOCIATIONS
American Clinical Laboratory Association
BIO (Biotechnology Innovation Organization)
Biocom
PhRMA

IT/INFORMATICS COMPANIES
2bPrecise
Assurance Health Data
Change Healthcare
Concert Genetics
DNAnexus
Flatiron Health
GNS Healthcare
M2Gen
Medidata
P4-ML
Paige.ai
PathAI
PierianDx
Syapse
Translational Software
XIFIN, Inc.

LARGE BIOTECH/ PHARMACEUTICAL COMPANIES
AbbVie
Amgen, Inc.
AstraZeneca Pharmaceuticals
Bausch Health Companies
Bayer
Biogen
bluebird bio
Blueprint Medicines
Bristol Myers Squibb
Eli Lilly and Company
Genentech, Inc.
Gilead
GlaxoSmithKline
Johnson & Johnson
Merck & Co.
Novartis
Pfizer, Inc.
Takeda Pharmaceuticals, Inc.

PATIENT ADVOCACY GROUPS
Accelerated Cure Project for Multiple Sclerosis
AiArthritis
Alliance for Aging Research
Alport Syndrome Foundation
Alzheimer's Foundation of America
American Association of Kidney Patients (AAKP)
Bulgarian Association for Personalized Medicine
Canadian Organization for Rare Disorders
Cancer Commons
Colorectal Cancer Alliance
CureDuchenne
Emily's Entourage
EveryLife Foundation for Rare Disease
Fight Colorectal Cancer
Friends of Cancer Research
GI Cancers Alliance
Global Liver Institute
GO_2 Foundation for Lung Cancer
HealthyWomen
International Cancer Advocacy Network
KRAS Kickers
LUNGevity Foundation
Multiple Myeloma Research Foundation
National Alliance Against Disparities in Patient Health
National Alliance for Hispanic Health
National Health Council
Swellter
SynGap Research Fund
Team Trevor
The Assistance Fund

PERSONALIZED MEDICINE SERVICE PROVIDERS
CareDx
Coriell Life Sciences
Genome Medical
Michael J. Bauer, M.D., & Associates, Inc.
Sema4
Sengenics
Tempus

RESEARCH, EDUCATION & CLINICAL CARE INSTITUTIONS
American Association for Cancer Research (AACR)
American Medical Association (AMA)
Arizona State University
American Society of Health System Pharmacists (ASHP)
Association for Molecular Pathology (AMP)
Audubon Bioscience
Brown University
Business Finland
Cancer Treatment Centers of America
Cello Health BioConsulting
College of American Pathologists
Colorado Center for Personalized Medicine
CommonSpirit Health
Coriell Institute for Medical Research
Duke Center for Research on Personalized Health Care
Essentia Institute of Rural Health
European Infrastructure for Translational Medicine
Harvard Business School
Hospital Albert Einstein
HudsonAlpha Institute for Biotechnology
iCAN
Instituto de Salud Carlos III
Intermountain Healthcare
Johns Hopkins Individualized Health
King Faisal Specialist Hospital and Research Centre
MaineHealth Accountable Care Organization
Manchester University School of Pharmacy
Marshfield Clinic
Mayo Clinic
MD Anderson – Institute for Personalized Cancer Therapy
MITRE Corporation
Moffitt Cancer Center
Morehouse School of Medicine
National Pharmaceutical Council
Nicklaus Children's Hospital Research Institute
NorthShore University Health System
North Carolina Biotechnology Center
Precision Health Initiative at Cedars-Sinai
Qatar Biobank
Sanford Imagenetics, Sanford Health
Teachers' Retirement System of Kentucky
The Christ Hospital
The Jackson Laboratory
Thomas Jefferson University
Translational Genomics Research Institute (Tgen)
UC Davis Mouse Biology Program
University of Alabama, Birmingham
University of California, San Francisco (UCSF)
University of Pennsylvania Health System
University of Rochester
University of South Florida Morsani College of Medicine
Vanderbilt University Medical Center
West Cancer Center

RESEARCH TOOL COMPANIES
Illumina, Inc.
Thermo Fisher Scientific

STRATEGIC PARTNERS
Accenture
Arnold & Porter
Artisan Healthcare Consulting
Bioscience Valuation BSV GmbH
Blue Latitude Health
Boston Healthcare Associates
Bradford Power
Bruce Quinn Associates
Cambridge Cancer Genomics
Cambridge Healthtech Institute
ConText
ConvergeHEALTH by Deloitte
Defined Health
EdgeTech Law, LLP
Foley & Lardner, LLP
Foley Hoag, LLP
Goldbug Strategies, LLC
Health Advances, LLC
Hogan Lovells, LLP
Innovation Horizons
Innovation Policy Solutions
Jane Binger, Ed.D.
Jared Schwartz, M.D., Ph.D., LLC
KPMG
L.E.K. Consulting
Michael Stocum
McDermott Will & Emery
Neil A. Belson, LLC
Ogilvy
Priya Hays, M.D., Ph.D.
Real Chemistry
Reservoir Communications
S D Averbuch Consulting, LLC
Slone Partners
The Journal of Precision Medicine
The Synergist
TIGAR Health Technologies
Truc Nguyen, M.D., Ph.D.
United States Pharmacopeial Convention (USP)
William P. Stanford, M.D., Ph.D.

VENTURE CAPITAL
GreyBird Ventures, LLC
Health Catalyst Capital Management, LLC
Kleiner Perkins Caufield & Byers
Section 32
Third Rock Ventures, LLC

PMC's Newest Members

Alexion Pharmaceuticals
Alport Syndrome Foundation
Audubon Bioscience
GI Cancers Alliance
KRAS Kickers
MacroGenics
NuProbe, Inc.
Paige.ai
PathAI
Reservoir Communications
Swellter
The Assistance Fund
TIGAR Health Technologies

MISSION: The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.

PMC
PERSONALIZED MEDICINE COALITION

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