Institute for Patient Access

VALUE OF INNOVATION

Policy Forum

APRIL 28, 2022 • WASHINGTON, DC

Overview

How do patients, health care providers and society determine the value of medical innovation?

On April 28, 2022, the Institute for Patient Access welcomed health policy stakeholders to explore the issue. This forum covered:

- Innovation, COVID-19 and public health
- Medical breakthroughs for Alzheimer's and dementia
- Federal legislation and initiatives.

Michelle Winokur, DrPH

Executive Director, ***Institute for Patient Access***

opened the event by challenging attendees to consider the value of medical innovations that most people appreciate, but probably take for granted. Dr. Winokur shared how overcoming three serious medical events in a year was only possible "because of advancements I'd never before considered. Now, I'm routinely awe-struck by the innovations that save, treat and prevent an untold number of ailments."

David Charles, MD

Medical Director, ***Institute for Patient Access***

also shared thought provoking opening remarks about how patients and providers define value. When Dr. Charles asks his patients about the value of medical innovation, "they never come out with a dollar figure," he explained. They instead share how new treatments and therapies help them manage their conditions and improve their quality of life. And the value a medication brings to a patient, ultimately, is what matters.

A common theme of resilience connected the event's discussions. The amount of time necessary to take an idea and transform it into a fully tested and approved treatment requires both patience and persistence. When medical innovations fall through, it can be devastating for everyone involved. But when new treatments and therapies are proven successful, it can be life-changing for patients.

Keynote Address:

Making the Longshot

David Heath

Author of "Longshot: The Inside Story of the Race for a COVID-19 Vaccine"

David Heath covered how the COVID-19 vaccine was developed in a record-setting 338 days. Many vaccines have taken years, if not decades, to develop. And this medical innovation saved many lives throughout the pandemic.

> **"The reason we're even able to talk about whether the pandemic is over is because of the vaccines."**

The innovation that enabled the coronavirus vaccines dates back to 2013. Research on developing vaccines for respiratory syncytial virus and Middle East respiratory syndrome led to advancements that made the mRNA vaccine possible. What that work uncovered about changing antibodies made it possible for researchers to develop the COVID-19 vaccines quickly.

Heath highlighted that there are many great challenges associated with combating public health threats like the coronavirus. One of the most pressing is the distrust of science. Popular belief held that, when vaccines became available, COVID-19 would be eradicated. A lack of public trust in the vaccines and the science behind them, however, has left many people vulnerable.

Given these challenges, Heath explained, another public health threat of COVID-19's scale is possible. "Scientists say it's inevitable that we'll see another novel strain of coronavirus in the future. It means we need a new generation of vaccines," Heath concluded.

To best prepare for the potential health threats the nation may face, public health requires robust investment, innovation and the support of the public.

A Look Behind the Curtain

Few diseases demonstrate the urgent need for medical innovation like Alzheimer's and dementia do. These disabling and degenerative conditions impact six million Americans.

Erin G. Doty, MD

Eli Lilly and Company

Alzheimer's patients have many unmet needs, and the lack of available and disease-modifying therapies makes caring for these patients difficult. From research to recruiting for a clinical trial, it takes years and typically has a massive financial investment.

When therapies don't work, it's devastating for everyone involved, from researchers to patients and their families. "But really, to call it a failure doesn't do it service," Doty emphasized. Even treatments that don't make it from the lab to the clinic still help researchers better understand the disease and how to detect it.

Howard Fillit, MD

Alzheimer's Drug Discover Foundation

Medical innovation has been working to support Alzheimer's patients for many years. Research and diagnostics made it possible to find the biological indicator, amyloid, that doctors now regularly use to diagnose if a patient has Alzheimer's.

As more proteins are identified in connection with Alzheimer's, the opportunities for innovation are also growing. "The number of targets being explored in human beings with this disease is just exploding," Dr. Fillit shared.

And research done in one area can help propel advancement in other areas. Biomarkers and prior research on them have led to accelerated approval in other fields and will be key to Alzheimer's innovation.

Ian N. Kremer, JD

Leaders Engaged on Alzheimer's Disease Coalition

Policies that limit access to the few treatments available are one of the more pressing difficulties Alzheimer's patients and their caregivers must face. The Centers for Medicare and Medicaid Services recently refused to cover an FDA-approved treatment, the first in many years, that could help Alzheimer's patients.

"It does no one any good to innovate and get something approved by the FDA if it is blocked from reaching clinicians and their patients," Kremer stated.

The key to innovation is investment. Funding for Alzheimer's research has seen a significant increase in recent years, and this bodes well as the research community moves forward and develops solutions.

This panel was moderated by **Josie Cooper**, the executive director of the *Alliance for Patient Access*.

Setting the Stage

As medical breakthroughs provide patients with new options, policies in turn can directly impact innovation. The intersection of policy and innovation plays a key role, especially as policy often gives innovation the boost it needs to succeed.

Pam Traxel

American Cancer Society Cancer Action Network

Innovation is particularly important for treating cancer. The Cancer Moonshot, originally introduced under the Obama administration, was relaunched by President Biden earlier this year. The initiative seeks to reduce the death rate of cancer significantly over the next two decades through supporting innovation.

But the field of oncology faces many challenges, especially following the pandemic.

"The single most important thing that policymakers can do is really understand their role," Traxel emphasized. They can provide both funding and incentive for innovation to occur at many levels and in many different fields, which can lead to improved health outcomes for patients.

Gavin Clingham, JD

Alliance for Patient Access

Few legislative packages have been as important to innovation in recent years as the 21st Century Cures law, which provided funding for medical innovation. The CURES 2.0 bill, sponsored by Rep. DeGette and Rep. Upton, builds off the previous legislation by supporting innovation and makes preparing our nation for future unknown public health threats a top priority.

"In 2.0, they're building upon the successes in 21st Century Cures, but also recognizing that there are a lot of players that come into whether or not the therapy makes it to the patient, and how can they encourage that pipeline," Clingham explained.

This new bill is also particularly valuable because it will transform Medicare coverage when it comes to new treatments.

Patricia A. Gibson, MSSW

Epilepsy Alliance America

For many diseases, having a hub for researchers, providers, policymakers and patients is a powerful tool to advance innovation and connect with others. When it comes to innovation, centers of excellence can help coordinate scientific understanding, share resources and broaden a field's reach to lesser-known conditions.

When everyone – from policymakers funding innovation to the researchers running clinical trials – share aligned goals, innovation can progress faster and have a powerful impact. "Misalignment is really stifling innovation," Gibson pointed out, emphasizing that a lack of common goals detracts from patient care.

This panel was moderated by **Amanda Conschafter**, the *Alliance for Patient Access*' communications director.

Conclusion

What is innovation worth?

Assigning value to innovation is more than just the cost it takes to manufacture a drug. For many patients, innovation's value lies in the hope, peace of mind and improved health that it offers.

To learn more about the value of innovation, visit the Institute for Patient Access' website.

IfPA | Institute for Patient Access

instituteforpatientaccess.org