

Proposing a Clinical Trials Network for Patients With Weakened Immune Systems [VIDEO]

The ImmunOptimize workshop convened stakeholders across disciplines to brainstorm an infectious disease clinical trials network for immunocompromised patients.

December 5, 2024 By Fred Hutch News Service and Sabrina Richards

The COVID-19 pandemic made plain what many patients, clinicians and researchers have known for decades: people with weakened immune systems are much more vulnerable to infectious diseases. But immunocompromised patients are usually left out of large clinical trials that assess new treatments and vaccines, leaving a data gap that hampers clinical care.

On September 10, experts across disciplines, from infectious disease clinicians to regulators to representatives from the pharmaceutical industry, convened at the inaugural [ImmunOptimize](#) workshop in Bethesda, MD, to brainstorm strategies to address the unmet needs of immunocompromised patients.

“We need roots, not parachutes,” said Fred Hutch Cancer Center infectious disease expert [Joshua Hill, MD](#), who headed the ImmunOptimize scientific committee. “We need a grassroots effort to address the unmet needs of immunocompromised patients. The time is right to bring the conversations to the forefront.”

According to the [National Health Interview Survey](#) conducted in 2021, about 7% of the U.S. population — or over 23 million people, a smidge more than the population of Florida — are immunosuppressed. A likely underestimation, this number has more than doubled since 2013.

But despite their swelling numbers, these patients are still shut out of lifesaving advances in infectious disease treatment and prevention.

“Our goal: How we can improve timely evidence generation for therapeutics to improve prevention and treatment of infectious diseases in immunocompromised individuals,” Hill said.

At the workshop, stakeholders from academia, industry and government, including the U.S. Food and Drug Administration and the National Institutes of Health discussed how to bridge the data gap that leaves immunocompromised patients and their clinicians unable to make evidence-based

treatment decisions.

A clinical trials network, dedicated to testing drugs and vaccines against infectious diseases in immunocompromised patients, is the most pragmatic solution, experts argued. Such a program would offer the funding and administrative support necessary to support the scientists and clinicians who design, conduct, recruit for and analyze clinical trials.

The day after the workshop, a cadre of infectious disease specialists, patient representatives, and operations experts also discussed the scale of the problem — and the potential power of a clinical trials network — with select congresspeople and congressional staffers.

“We have the passion ... these are the most vulnerable patients we see every day. We know the unmet need, we know there are a lot of gaps,” said workshop attendee and panelist [Roy Chemaly, MD, MPH](#), chair of Infectious Diseases, Infection Control and Employee Health at the University of Texas MD Anderson Cancer Center. “We want to make sure during our lifetime that we’re making a difference for our patients.”

A ‘discarded population’

In the first wave of the COVID-19 pandemic in 2020, bone marrow transplant (BMT) recipients, whose immune systems are severely weakened by their cancer treatments, faced an up to 30% chance of dying within a month of an infection with SARS-CoV-2.

“That’s both striking and shocking,” Hill noted. “It was higher than the risk for 70- to 80-year-olds.”

BMT patients, whose immune systems must be reestablished after transplant, are among the most severely immunocompromised. But they’re not alone: solid organ transplant patients receive lifelong immunosuppressive drugs to prevent organ rejection. Advances in therapies for autoimmune conditions like rheumatoid arthritis and lupus, and some new cancer immunotherapies, can also leave patients with depressed immune function.

Although these patients need vaccines and antimicrobial drugs more than anyone, doctors often don’t have the data they need to make strong recommendations about regimens and dosage.

The COVID-19 pandemic highlighted this longstanding problem, said [Michael Boeckh, MD, PhD](#), who heads Fred Hutch’s Infectious Disease Sciences Program.

“There were fantastic vaccine trials conducted with unprecedented speed, but immunocompromised patients were left out,” he said. Without data, clinicians had to make up recommendations.

“COVID brought it to the forefront, but it’s what we who work in the field have been dealing with for a long time,” Boeckh said.

He recalled a young mother he successfully treated for a blood cancer a few years before SARS-CoV-2 swept the globe. After recovering from her bone marrow transplant, the woman returned to her home in rural Washington state. But when she became infected with a common cold virus, it quickly progressed into pneumonia. Despite being air-lifted to a major medical center, she died.

“I call this a tragedy, but it happens every day to immunocompromised patients,” Boeckh said.

As more people receive cancer treatment, organ transplants and immune-suppressive drugs for autoimmune disorders, the number of people who are highly vulnerable to infection is growing.

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