

Researchers mobilizing global resources to test new treatments for severe H1N1 infection

November 11 2009

An important, ground-breaking initiative is unfolding in the global critical care community in response to the H1N1 pandemic.

While front-line [health care workers](#) and infectious disease experts around the world are working round the clock to control, treat and prevent [H1N1](#) infection, those who deal with the most severely ill patients—physicians working in hospital intensive care units (ICUs)—have joined forces to develop a more coordinated, long-term approach to H1N1.

In a commentary published today in the medical journal the *Lancet*, St. Michael's Hospital's Dr. John Marshall describes this unprecedented initiative, which is called the International Forum for Acute Care Trialists (InFACT) H1N1 Collaboration. While the coalition against H1N1 is led by Canadians, dozens of groups whose members are involved in the care of critically ill influenza patients from every continent on the planet have already signed on.

"A core element of our initiative is to undertake [clinical trials](#) of simple, readily available and biologically plausible interventions that can be used to treat patients with severe H1N1 infection," says Dr. Marshall, a senior scientist in the Li Ka Shing Knowledge Institute at St. Michael's Hospital in Toronto who chairs the InFACT collaboration.

Will the clinical trials and the other initiatives planned by InFACT—such as a global registry of influenza victims and a "biobank" of blood samples—benefit people who are already sick or will fall ill over the next few months?

"Probably not," Dr. Marshall says. "But H1N1 isn't going away any time soon. We need to take a coordinated, evidence-based approach to understanding the natural history of the disease, to cataloguing current resources and gaps, and to looking for new and better treatments which may prevent or shorten hospitalization among those most seriously affected."

Proposed clinical trials to test new treatments

Canadian researchers are organizing several clinical trials aimed at finding new and more effective treatments for H1N1 infection.

One of these trials—the Collaborative H1N1 Adjuvant Treatment (CHAT) trial—seeks to enroll 1,400 patients, most of them Canadians, who are being treated in a hospital ICU for severe H1N1 infection and are on a ventilator. The mortality rate for these patients currently ranges from 10% to 20% over the first month. On average, those who survive spend two weeks in the ICU.

Right now H1N1 infection is treated with anti-viral drugs and other supportive measures. But researchers want to evaluate two classes of common, readily available drugs which have shown promise in limiting the severity of H1N1 infection.

"Anecdotal reports and data from animal studies suggest that corticosteroids and statins may dampen the inflammatory response that leads to severe illness and death from H1N1," says Dr. Marshall. "None of these drugs has been adequately studied for efficacy."

Even though no specific data show them to be effective, right now more than half of patients with severe H1N1 infection are treated with corticosteroids—hormones given to reduce swelling and decrease the body's immune response. This is based largely on the observation that corticosteroid drugs have proven useful in treating severe acute lung injury.

A recent study of patients with seasonal influenza found that those who were taking statins when they got sick had a better prognosis than those who were not. These drugs are currently taken by millions of people to help control cholesterol levels and prevent heart disease.

This accelerated "bench-to-bedside" approach is key to success against pandemic [influenza](#) and other infectious diseases, says Dr. Marshall. "Research during a pandemic poses unique ethical and logistical challenges. It usually takes years to mount a major clinical trial. But in the case of H1N1 our goal is to drastically shorten this to a period of weeks or a few months without compromising scientific and ethical integrity," he explains.

While funding is needed for the clinical trials to proceed, that time is too short to achieve this through conventional means. "Instead, we've adopted an incremental funding strategy. This means we're seeking money that will allow us to launch the trials and moving ahead with confidence that additional funds can be found," he says.

Source: St. Michael's Hospital

Citation: Researchers mobilizing global resources to test new treatments for severe H1N1 infection (2009, November 11) retrieved 26 April 2024 from <https://medicalxpress.com/news/2009-11-mobilizing-global-resources-treatments-severe.html>

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