

Public Health Ontario Reports 100+ Youth Hospitalizations Involving Heart Problems Post COVID-19 mRNA Vaccination

TrialSite Staff, September 6, 2021

Public Health Ontario (PHO) released a thus far largely unnoticed report aggregating COVID-19 immunization adverse events following immunization or (AEFI) in Ontario reported in the Public Health Case and Contract Management Solution. For the period of Dec. 13, 2020, to August 7, 2021, PHO reports a significant cluster of vaccine safety activity associated with the ongoing COVID-19 program. Based on vaccines associated with both Pfizer-BioNTech and Moderna, the report reveals that by August 7 106 cases of myocarditis/pericarditis were reported in Ontario residents under the age of 25, representing over fifty percent of the total incidents. Segmented by age, 31 of the total cases were reported in young people 12 to 17 years old while 75 of the total were in the 18 to 24-year-old group. Put another way 80% of the total AEFIs were young people 24 and below; 80% of the entire group were made.

Warnings Noted

While the U.S. Food and Drug Administration (FDA) recently, and controversially approved the Pfizer-BioNTech product, or as *TrialSite* discussed, essentially established two parallel approved and EUA pathways, the agency also reported increased risk for males over 40 for myocarditis and/or pericarditis following administration of the Pfizer-BioNTech vaccine.

The world's regulators are on notice. An accelerated vaccine product, seemingly safe and effective, but waning in effectivity over time now becomes associated with the need for three shots (an additional booster) and now Israel's COVID czar has come out and declared be ready for a fourth booster and perhaps even more.

What does this mean in terms of risk when so little data is known—these products are still very young. Thus, PHO issued a directive in the summer instructing public health agencies of Canada to direct surveillance efforts toward these particular conditions, with a recognition that similar AEFIs were recorded in both the United States and Israel.

Some Findings

PHO shows that rates of cases associated with myocarditis/pericarditis were higher following the second dose of mRNA vaccine than after the first dose, particularly for those receiving the Moderna vaccine as the second dose of the series (regardless of the product received for the first dose).

The Canadian public health agency furthermore conveyed that the total rate of case reports associated with the Pfizer-BioNTech vaccine was 6.4 million doses administered following the first dose and 8.7 per million doses administered following the second dose when combining age groups and gender.

Breaking out vaccines PHO reveals that the Moderna vaccine reporting rate was 6.6 million doses administered following the first dose and a noticeable spike of 28.2 per million doses administered following the second dose, for all age groups and genders combined.

One particular group—those aged 18 to 24—when receiving the second dose of an mRNA COVID-19 vaccine were more at risk with a 37.4 per million doses associated with Pfizer-BioNTech and a noticeable 263.2 per million following the Moderna vaccine as the second dose.

While these rates are high, according to the Canadian Immunization Guide a rare AEFI occurs at a frequency of 0.01% to less than 0.1%. The Canadian POH continues a march forward with a full-throttle vaccine-centric strategy discounting these cases as rare given the vaccine's high effectiveness at preventing symptomatic infection with severe outcomes, which is also associated with the risk of myocarditis.

The key for any true risk-based effort would be to understand what the risks of myocarditis and pericarditis are associated with COVID-19 and compare that to the risks of these adverse events occurring via vaccination.