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Title: **Safety & immUnogenicity of COVID-19 vaCcines in systEmic immunE mediated inflammatory Diseases (SUCCEED): Preliminary Results on Severe Adverse Events**

Objective(s): SUCCEED was funded by the Canadian government's COVID Immunity Task Force to study SARS-CoV-2 vaccination in participants with immune-mediated inflammatory diseases (IMID). One of our primary objectives was to describe vaccine safety, particularly severe adverse events (SAE) defined as events associated with emergency department (ED) visits and/or hospitalizations.

Method(s): In Vancouver, Calgary, Winnipeg, Montreal, Quebec City, Sherbrooke, Toronto, and Hamilton, data were collected from adults with rheumatoid arthritis (RA), ankylosing spondylitis/spondyloarthritis (SpA), systemic lupus erythematosus (SLE), psoriasis/psoriatic arthritis (PsA) and inflammatory bowel disease (IBD), who received SARS-CoV-2 vaccination. Participants filled out questionnaires reporting SAE experienced within 31 days following each vaccine dose.

Result(s): About two-thirds (63%) of 1556 participants were female; mean age was 52.5 years. BNT162b2 (Pfizer) vaccine accounted for 75% of first/second doses, 67.8% of third doses, 63.3% of fourth doses and 62% of fifth doses. mRNA-1273 (Moderna) was the second most common vaccine. Forty-nine percent of participants had IBD, 27.4% had RA, 14.3% had PsA, 5.3% had SpA, and 4% had SLE.

There were 12 (0.8%) self-reported SAEs leading to ED visit or hospitalization, occurring in 11 participants; one participant reported 2 SAEs. There were 6 ED visits (including one Bell's Palsy that occurred 31 days after the first vaccine) and 6 hospitalizations (including one Guillain-Barré syndrome that occurred 15 days after the first vaccine). Other causes for ED visits included an allergic reaction of hives, an episode of labyrinthitis, a case of severe menstrual bleeding and a case of pericarditis. There was only one serious disease flare in a SLE patient who presented to ED with pericarditis. Other reasons for hospitalizations included one new-onset migraine with aura, a case of idiopathic thrombocytopenia purpura, one case of atrial fibrillation, one transient multifactorial renal failure, and one diverticulosis flare. There were two additional hospitalizations not specifically labelled by the participant as vaccine-related; one case of shingles and a case of epiploic appendagitis.

Among the 12 self-reported vaccine-related SAEs, 7 were experienced by participants <65 years old. Three events occurred after the first vaccine dose, 3 after the second dose, 5 after the third dose, and 1 after the fourth dose. No deaths occurred in the 31 days after vaccination.

Conclusion(s): In the 31 days after SARS-CoV-2 vaccination in IMID, there were relatively few serious AEs, and no deaths. Additional analyses will consider all other non-severe AEs that did not require an ED visit or hospitalization (including flares).