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Sex Differences in Endocrine-Related Pre-existing, COVID-19- and COVID-19 Vaccine-Related Health Conditions and Adverse Events

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COVID-19 illness-related symptoms and outcomes are highly variable, with reported sex differences. mRNA vaccines were deployed for the first-time on a large scale for COVID-19, and the endocrine effects of Pfizer's and Moderna's mRNA vaccines, remain to be elucidated. Associations between COVID-19 illness and/or COVID-19 vaccines and reproductive disturbances have been reported based on large nation-wide surveys and targeted studies. Yet, none of the studies have directly ascertained similarities and differences between reproductive adverse outcomes from COVID-19 illness in unvaccinated individuals versus COVID-19 mRNA vaccines in individuals without COVID-19 illness. Here, we report preliminary findings endocrine systems from a global survey on of ~8,000-10,000 participants collected between February 2022 and October 2023. Approximately 62.5% of the participants were from the United States, and the remaining were international. Nearly 1.49% of respondents reported hospitalization after COVID-19, whereas 5.69% of the respondents reported hospitalization after vaccination in our cohort. SARS-CoV-2-related severe symptoms were reported by ~9.3% of COVID-19 vaccinated versus 6.7% of unvaccinated individuals (p<0.001). Women reported more vaccine-related adverse events (AEs) than men; 30% of men and 19% of women reported no AEs after any vaccination dose. After the first dose, 60% women and 48% of men reported some AEs, whereas after the second dose, 46% of women and 40% of men reported experiencing

several AEs. Sex differences were present in endocrine and autoimmune pre-existing health conditions, including thyroid disease (13%F vs 3%M), osteoporosis (6%F vs 1% M), elevated cholesterol (M>F), and hypertension (M>F). Nearly 5% of women reported pre-existing irregular menstrual cycle irregularities and hormonal changes, whereas only 2% of men reported hormonal irregularities. In unvaccinated individuals, after COVID-19 illness, nearly 6% of women reported experiencing hot flashes, whereas 7.5% reported irregular menstrual cycles. In COVID-19 vaccinated individuals without SARS-CoV-2 infection, 94.6% of men and 62.5% of women respondents reported no reproductive changes. Of those reporting reproductive AEs included hormonal changes in 5% of women and 3.5% men, hot flashes in 8.5% women and 1.9% men, heavy periods and/or dysmenorrhea in 16.7% of women, and irregular periods in17.1% of women. In summary, reproductive AEs in vaccinated individuals without COVID-19 illness were more frequent than in unvaccinated individuals with COVID-19 illness. A detailed and thorough follow-up is needed to better understand if pre-existing health conditions exacerbated vaccine-associated AEs.

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