



## XL COMU Awards 2021 – Clinical

### Safety of an inactivated SARS-CoV-2 vaccine in elderly persons

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**ABSTRACT:** *Introduction.* Brazil has the 2nd highest number of COVID-19 deaths (more than 530,000) and the 3rd highest number of confirmed cases (more than 19 million) worldwide. COVID-19 vaccination is the most effective strategy to prevent new cases and illness, reducing hospitalizations and deaths. The 1st vaccine used in Brazil was the Sinovac/Instituto Butantan CoronaVac, an inactivated SARS-CoV-2 vaccine. Elderly persons (EP) were among the first groups eligible for immunization, after healthcare workers, indigenous people and *quilombolas*. *Objective.* To evaluate adverse events following immunization (AEFI) with CoronaVac in EP. *Methods.* This observational retrospective study was conducted at the Reference Center for Special Immunobiologicals (CRIE) of the Hospital das Clínicas (HC-FMUSP), a tertiary/quaternary hospital attached to the University of São Paulo Medical School (FMUSP), in São Paulo city, from February to April 2021. EP, who searched or were referred to CRIE to receive the COVID-19 vaccine were asked for authorization for follow-up calls to evaluate AEFI. The on phone follow up was made by healthcare workers who conducted AEFI forms on day 4 and day 8 after the first and second vaccine doses; a sociodemographic questionnaire; and a modified functionality scale for EP based on the Independence in Activities of Daily Living index (ADLi), Instrumental Activities of Daily Living scale (IADLs) and Study of Osteoporotic Fractures index (SOFi). *Results.* During the study period, CoronaVac was used; 159 EP received the first dose and 155 EP were fully vaccinated at CRIE; 152 participants were contacted after the first dose and 142 participants were contacted after the second dose. The participants' age ranged from 53 to 101 years (mean, 84 years), 65.4% were females, and 73.7% were white. 148 (93.1%) participants have at least one comorbidity, the most common was hypertension (59.8%) followed by heart disease (30.2%) and dyslipidemia (25.2%). 70/152 (46.1%) participants were classified as independent in IADLs, 117/152 (77.0%) in ADLi and 66/152 (43.4%) according to SOFi. 47 participants (30.2%) reported at least one AEFI at first dose. The most common local AEFI was pain at the injection site (13, 8.6%) and the most common systemic AEFI was fatigue (8, 6.0%), followed by headache (6, 4.0%). Thirty participants (21.1%) reported at least one AEFI at the second dose. The most common local AEFI was pain at the injection site (6, 4.3%) and the most common systemic AEFI was myalgia (11, 7.9%), followed by fatigue (9, 6.5%). Most AEFI were mild and had no or little interference in daily activities. There were five severe AEFI: two deaths after the first dose (a sudden death and another following a hemorrhagic stroke) and three hospitalizations (one after the first dose and two after the second dose). None of them were considered related to the vaccine. *Discussion and conclusion.* This unique studied population was composed of EP with comorbidities and some level of dependency. The participants reported few and mild AEFI, suggesting CoronaVac is safe in EP.

**Keywords:** Vaccine; COVID-19; Elderly.