



Update on Immune Thrombocytopenia Following Janssen COVID-19 Vaccination

Vaccine Adverse Event Reporting System (VAERS)

Methods of Analysis

Search criteria:

- Any of the following Preferred Terms: *Autoimmune thrombocytopenia, Idiopathic thrombocytopenic purpura, Immune thrombocytopenia, Immune thrombocytopenic purpura, Thrombocytopenic purpura, Thrombocytopenia*
- Platelet count < 150,000 or diagnosis of thrombocytopenia/ITP
- onset \leq 28 days
- US reports

VAERS: Method of Analysis

- Numerators are based on the aforementioned search strategy
- US reports
- Hematologists have NOT yet adjudicated the cases
- Observed-to-expected analysis (O/E) was performed based on vaccine administration data and published background rates of ITP

VAERS: Overview of ITP Reports

Through 9/30/21, we identified and retained 150 reports in VAERS:

- Age in years
median 51.0 (interquartile range 39-63)
- Sex
female 86 (57%)
- Serious
134 (89%), including 15 deaths

VAERS: Platelet Count

Platelet Count* per μL	n (%)
plt < 10,000	31 (21%)
$10,000 \leq \text{plt} < 20,000$	16 (11%)
$20,000 \leq \text{plt} < 50,000$	30 (20%)
$50,000 \leq \text{plt} < 100,000$	32 (21%)
plt $\geq 100,000$	25 (17%)
platelet count not reported	16 (11%)

mean 51,690

median 38,000

interquartile range 12,000-79,000

*Nineteen cases had a diagnosis/assessment of thrombocytopenia, but the platelet count was missing (n=16) or the only available count was normal (n=3).

VAERS: Observed-to-expected Analysis

Time Window	n (%)	O/E Ratio (95% CI) *
onset \leq 7 days	48 (32%)	5.17 (3.81, 6.85)
onset \leq 14 days	107 (71%)	5.76 (4.72, 6.96)
onset \leq 21 days	134 (89%)	4.81 (4.03, 5.70)
onset \leq 28 days	150 (100%)	4.04 (3.42, 4.74)

*Based on background rate of 3.3/100,000

Terrell et al. The incidence of immune thrombocytopenic purpura in children and adults: A critical review of published reports. Am J Hematol. 2010 Mar;85(3):174-80.