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**Background:** Evidence is limited for influenza vaccine effectiveness (VE) against laboratory-confirmed influenza among young children. Using test-negative design (a modified case-control study) which minimizes confounding by health care-seeking behavior and misclassification of diseases, we aimed to monitor influenza VE among young children in Japan where all approved influenza vaccines are egg-propagated, inactivated formulations (IIV).

**Methods:** For seasons spanning 2013-14 to 2017-18 in Osaka and Fukuoka Prefectures, Japan, we employed prospective, active, and systematic recruitment of children aged <6 years who visited collaborating pediatric clinics within 7 days of influenza-like illness onset. Nasal aspirates were tested for influenza by real-time RT-PCR. Date of vaccination was confirmed by medical records or maternal and child health handbooks. Cases and controls were defined as being PCR-positive and -negative, respectively. Conditional logistic regression models were used to calculate adjusted VE ([1 - adjusted odds ratio]  $\times$  100%).

**Results:** We analyzed 4,614 subjects including 1,917 cases. VEs of IIV with 2 doses approximated 50%, ranging from 41% (95% confidence interval [CI]: 14 % to 60%) in 2016-17 season to 63% (95% CI: 45% to 76%) in 2017-18 season. Significant VEs were also shown for predominant circulating strains every season, irrespective of their antigenic match to vaccine strains (56% and 65% for A[H1N1]pdm, 37% and 50% for A[H3N2], and 60% for B[Yamagata]).

**Conclusions:** IIV provided modest and significant protection against laboratory-confirmed influenza in young Japanese children.

Key messages: Test-negative design is useful for monitoring influenza VE.

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Influenza vaccine effectiveness in young Japanese children over five seasons

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