procedures coded as trauma and non-trauma. As a proxy for patients with penetrating trauma, SIR for patients coded as trauma who had a surgical wound class noted as dirty was compared to SIR for patients coded as trauma with surgical wound class coded as contaminated or clean-contaminated.

Results. For the CMS model, there was a statistically significant difference (p = 0.0003) between SIR for trauma (SIR = 3.451) and non-trauma (SIR = 1.071) procedures. There was also a statistically significant difference (p=0.0014) between trauma procedures with dirty surgical wound class (SIR = 6.608), compared to those with wounds categorized as contaminated or clean-contaminated (SIR = 2.235).

NHSN Adult Complex 30 Days SIR comparison for COLO SSI with and without trauma

National Healthcare Safety Network
Adult Complex 30 Day SSI (CMS Model)
As of: April 23, 2021 at 11:03 AM

	COLO Trauma	COLO Non Trauma
Observed Infection	34	11
Predicted Infection	9.852	10.269
SIR	3.451	1.071

Relative ratio of SIRs (data column 2 / data column 1): 1.071/3.451 = 0.31 (31%)
Two-tailed p-value: 0.0003
95% Conf. Interval: 0.151, 0.601

NHSN Adult Complex 30 Days SIR comparison for trauma COLO procedures with dirty wound class description, against COLO procedures with wound class described as clean or clean-contaminated

National Healthcare Safety Network
Trauma COLO Wound Class
As of: April 23, 2021 at 11:37 AM

	Trauma COLO - D	Trauma COLO - CO, CC
Observed Infection	21	15
Predicted Infection	3.178	6.712
SIR	6.608	2.235

Relative ratio of SIRs (data column 2 / data column 1): 2.235/6.608 = 0.338 (33.8%)
Two-tailed p-value: 0.0014
95% Conf. Interval: 0.171, 0.657

Conclusion. Risk factors currently included in the model for COLO SSI may not adequately account for the increased risk from penetrating trauma with fecal spillage. Trauma and wound class should be added to the CMS IQR risk model for SIR.

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96. Relative Vaccine Effectiveness Against Influenza-Related and Any Respiratory-Related Hospital Encounter During the 2019/20 High Influenza Activity Period: A Comprehensive Real-World Analysis to Compare Quadrivalent Cell-based and Egg-based Influenza Vaccines

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Session: O-21. Innovations and Advancements in Vaccines

Background. Changes in the influenza hemagglutinin protein during replication of influenza in eggs during vaccine production may contribute to low vaccine effectiveness (VE). This phenomenon, egg adaptation, can explain VE differences between egg-based (QIVe-SD) and cell-based (QIVc) quadrivalent influenza vaccines. This research evaluated the relative vaccine effectiveness (rVE) of QIVc versus QIVe-SD in the reduction of influenza-related and any respiratory-related hospitalizations/emergency room (ER) visits among subjects 4-64 years old during the 2019/20 influenza season.

Methods. A retrospective cohort analysis was conducted among subjects 4-64 years old vaccinated with QIVc or QIVe-SD using administrative claims data in the U.S. (IQVIA PharMetrics® Plus). The adjusted number of events and rates of influenza-related hospitalizations/ER visits and respiratory-related hospitalizations/ER visits were assessed using inverse probability of treatment weighting (IPTW). Poisson regression was used to estimate relative vaccine effectiveness (rVE). In the main analysis, the study period was from Aug 4, 2019 to Mar 7, 2020 (ending early to avoid any influenza outcome misclassification with COVD-19 infection). In the assessment of the high influenza activity period (HIAP), the analysis period was restricted to Dec 8, 2019 to Mar 7, 2020.

Results. During the 2019/20 influenza season, 1,150,134 recipients of QIVc and 3,924,819, of QIVe-SD were identified following IPTW. In the main analysis, adjusted results show that QIVc was associated with a significantly higher rVE compared to QIVe-SD against influenza-related hospitalizations/ER visits (5.3% [95%CI: 0.5%-9.9%]) and respiratory-related hospitalizations/ER visits (8.2% [95%CI: 6.5%-9.8%]). Similarly, in the HIAP analysis, QIVc was associated with a significantly higher rVE compared to QIVe-SD for influenza-related hospitalizations/ER visits (5.7% [95%CI: 0.8%-10.4%]) and respiratory-related hospitalizations/ER visits (7.3% [95%CI: 5.4%-9.2%]).

Conclusion. QIVc was more effective in preventing influenza-related and respiratory-related hospitalizations/ER visits compared to QIVe-SD, using either a broad influenza season definition or restricting to the HIAP.

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97. Tetravalent Dengue Vaccine (TAK-003) Development Program: A Bird's Eye View

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Session: O-21. Innovations and Advancements in Vaccines

Background. Dengue fever is a mosquito-borne viral disease endemic in 128 countries. An unmet clinical need remains for an effective vaccine that can be used more broadly than the vaccine presently available. A clinical development program has evaluated the long-term safety, immunogenicity, and vaccine efficacy (VE) of TAK-003, a live attenuated tetravalent dengue vaccine with a DENV-2 backbone engineered to elicit immune responses to all 4 dengue serotypes.

Methods. 18 clinical trials in 13 countries have involved 28,175 seropositive/seronegative participants aged from 1.5-60 years from endemic/non-endemic regions. In the ongoing pivotal phase III study, 4–16-year-old healthy children (N=20,099) were randomized 2:1 to receive two doses of TAK-003 or placebo, 3 months apart for an evaluation of VE and safety over a multi-year period stratified pre-vaccination dengue serostatus. Active surveillance throughout the trial detected symptomatic dengue. The trial will continue up to 4–4.5 years post 2nd dose, and for another 25 months after a booster dose. Data up to 3 years after the second vaccination are currently available.

Results. Safety and immunogenicity data from Phase I/II studies established the final formulation and dosing schedule. Overall VE in the pivotal phase III study was 80.2% [95% CI: 73.3–85.3] against virologically confirmed dengue (VCD) at 12 months post 2nd dose. At 18 months, VE was 66.2% (95% CI: 49.1–77.5) in dengue-naive and 76.1% (95% CI: 68.5–81.9) in dengue pre-exposed participants, with VE of 90.4% (95% CI: 82.6–94.7) and 85.9% (95% CI: 31.9–97.1) for prevention of hospitalized VCD and dengue hemorrhagic fever, respectively. Cumulative VE against VCD from first dose to 3 years post 2nd dose was 62.0% (95% CI: 56.6–66.7) and 83.6% (95% CI: 76.8–88.4) in prevention of hospitalized VCD. Some decline in VE was observed over time mainly driven by outpatient dengue. Two doses of TAK-003 3 months apart were well-tolerated with no important safety risks identified up to 3 years after completion of the vaccination schedule.

Conclusion. TAK-003 is immunogenic against all 4 dengue serotypes and continues to be efficacious, well-tolerated, and with no evidence of disease enhancement in seronegative population up to 3 years post-vaccination.

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98. COVID-19 Vaccine Breakthrough Hospitalizations and Deaths in the Veterans Health Administration

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Session: O-21. Innovations and Advancements in Vaccines

Background. A COVID-19 vaccine breakthrough infection is defined as SARS-CoV-2 RNA or antigen detected ≥ 14 days after completion of a final vaccine dose.