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).

**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.

**Disclosures.** Mitchell DeKoven, PhD.

**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 by vaccination 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 safety and immunogenicity of TAK-003 in seropositive adult participants. Immunogenicity was demonstrated in 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 by vaccination 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.

**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.

**Disclosures.** Vianny Tricou, D Phil; Shibadas Biswal, MD; Mengya Liu, PhD

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