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| **Evidence Table 6. Vaccinated versus unvaccinated: Mixed population** | | | | | | | |
| **Author- Year- Country** | **Study Design** | **McHarm Score** | **Population** | **Vaccine1** | **Timing1** | **Adverse Event1** | **OR, 95% CI, versus unvaccinated group** |
| Mallory R. M et al,2010 US[107](#_ENREF_107) | Controlled Clinical Trial | 3 | Mean age: 9, Age range: 2 - 17, Percent female: 51% | Influenza - monovalent H1N1, not reported, MedImmune, derived by genetic reassortment of the hemagglutinin and neuraminidase genes from the wild-type A/California/7/2009virus and the remaining 6 gene segments from an attenuated master donor virus (in sucrose phosphate buffer and egg allantoic fluid, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intranasal | Dose1: 1 Days Dose2: 29 Days | Event: # with any AE Dose 1: 18.1% Event: # with any AE Dose 2: 13.7% Event: Blood and lymphatic system Dose 1, Syscat: 1 Event: Blood and lymphatic system Dose 2, Syscat: 1 Event: Ear and labyrinth Dose 1, Syscat: 4 Event: Ear and labyrinth Dose 2, Syscat: 4 Event: Eye Dose 1, Syscat: 6 Event: Eye Dose 2, Syscat: 6 Event: GI Dose 1, Syscat: 7 Event: GI Dose 2, Syscat: 7 Event: General disorders and administration site conditions Dose 1, Syscat: 8 Event: General disorders and administration site conditions Dose 2, Syscat: 8 Event: Immune system Dose 1, Syscat: 10 Event: Immune system Dose 2, Syscat: 10 Event: Infections and infestations Dose 1, Syscat: 11 Event: Infections and infestations Dose 2, Syscat: 11 Event: Injury, poisoning, procedural complications Dose 1, Syscat: 12 Event: Injury, poisoning, procedural complications Dose 2, Syscat: 12 | # with any AE Dose 1: OR 1.103 (0.537-2.267) # with any AE Dose 2: OR 0.985 (0.448-2.167) Ear and labyrinth Dose 2: OR 0.251 (0.015-4.066) GI Dose 1: OR 1.017 (0.367-2.818) GI Dose 2: OR 0.882 (0.281-2.774) Infections and infestations Dose 1: OR 0.756 (0.149-3.834) Infections and infestations Dose 2: OR 1.821 (0.404-8.219) Injury, poisoning, procedural complications Dose 2: OR 0.759 (0.078-7.414) |
| Vesikari T. et al.,2004 Belgium, Germany[174](#_ENREF_174) | Controlled Clinical Trial | 5 | Sample size: 59, Age range: 1 - 44 | Rotavirus, Rotarix, GlaxoSmithKline, Derived from the parent strain 89-12single dose of a minimum of 10(6.1) focus forming unit (ffu) of RIX4414 or placebo, with prior administration of Mylanta® as buffer, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral | Dose1: 0 Days | Any adverse event: 0% Any SAE: 0% |  |

| **Evidence Table 6. Vaccinated versus unvaccinated: Mixed population** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Author- Year- Country** | **Vaccine2** | **Timing2** | **Adverse Event2** | **Control group** | **Adverse Events Control** |
| Mallory R. M. et akl.,2010 US[107](#_ENREF_107) |  |  | Event: Musculoskeletal and connective tissue Dose 1: 2%, Syscat: 15 Event: Musculoskeletal and connective tissue Dose 2, Syscat: 15 Event: Nervous System Dose 1, Syscat: 17 Event: Nervous System Dose 2, Syscat: 17 Event: Respiratory, thoracic, and mediastinal Dose 1 Event: Respiratory, thoracic, and mediastinal Dose 2 Event: Skin and subcutaneous tissue Dose 1, Syscat: 23 Event: Skin and subcutaneous tissue Dose 2, Syscat: 23 Syscat: 1 |  | Event: # with any AE Dose 1: 16.7% Event: # with any AE Dose 2: 13.6% Event: Blood and lymphatic system Dose 1, Syscat: 1 Event: Blood and lymphatic system: 0%, Syscat: 1 Event: Ear and labyrinth Dose 1: 0%, Syscat: 4 Event: Ear and labyrinth Dose 2: 1.52%, Syscat: 4 Event: Eye Dose 1: 0%, Syscat: 6 Event: Eye Dose 2: 0%, Syscat: 6 Event: GI Dose 1: 7.58%, Syscat: 7 Event: GI Dose 2: 6.1%, Syscat: 7 Event: General disorders and administration site conditions Dose 1: 0%, Syscat: 8 Event: General disorders and administration site conditions Dose 2: 0%, Syscat: 8 Event: Immune System Dose 1: 0%, Syscat: 10 Event: Immune System Dose 2: 0%, Syscat: 10 Event: Infections and infestations Dose 1, Syscat: 11 Event: Infections and infestations Dose 2: 3.03%, Syscat: 11 Event: Injury, poisoning, procedural complications Dose 1: 0% Event: Injury, poisoning, procedural complications Dose 2\*\*\*: 1.5%, Syscat: 12 |
| Phonrat, B. et al. 2013[254](#_ENREF_254) Thailand |  |  |  | Placebo Placebo includes same adjuvants, preservatives, formulations as the active group | Any adverse event : 69.5% Any SAE : 0% Event: SAE : 0% Event: Arthalgia (1st immunization) : 2.07(ofcases)% , Syscat: 15 Event: Arthalgia (2nd immunization) : 2.41(ofcases)% , Syscat: 15 |
| Vesikari T. et al.,2004 Belgium, Germany[174](#_ENREF_174) | Rotavirus, Rotarix, GlaxoSmithKline, Derived from the parent strain 89-12. 10.7 ffu or 10.4 ffu of RIX4414 or placebo administered with prior administration of Maalox® as buffer., Adjuvant: Not Reported, Preservative: Not reported, Delivery: | Dose1: 0 Days | Event: At least 1 solicited AE (10.7 ffu group) Event: At least 1 solicited AE (10.4 ffu group): 0% AE: 0% | Placebo Unsure of adjuvants, preservatives and formulations | Event: at least 1 solicitied SAE (1-3 yr): 100% Event: Any SAE (18-44 yr): 0% |