



# *Protocol Considerations for Adult and Elderly Vaccines*

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# Protocol Considerations for Adult and Elderly Vaccines

- ▶ Must show safety in healthy adults first
  - ▶ Understand if there is pre-existing immunity to disease you are preparing a vaccine in the population. May need less doses
  - ▶ Vaccines for sexually transmitted diseases typically given in pre-teen years, so may need to test in naive adults first.
  - ▶ Immune responses less robust in the elderly so may need novel adjuvants and/or higher doses.
  - ▶ Safety studies fewer, typically involve 2,000-5,000 individuals unless there is a safety signal
  - ▶ Payment may be an issue if risk/benefit calculations not compelling, i.e. herpes zoster vaccine in the elderly
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