1046-M1-973 Paul H Schuette* (schuettep@gmail.com). A Mathematical Consideration of the Rule of Three. Preliminary report.

Researchers involved in clinical trials will sometimes employ a rule of thumb known as the "Rule of Three." Basically, the Rule of Three states that if no adverse affects have been observed in n trials, then the probability of an adverse effect should be no more than 3/n. An alternative formulation of the Rule of Three is that if an adverse event has probability p of occurring, we would need a sample of size 3/p to be reasonably assured of observing at least one occurrence. It will be shown that the Rule of Three can be derived from an approximation to a binomial distribution, and discuss an alternative derivation using a Poisson distribution. We shall also discuss the ease and appropriate use of the Rule of Three as well as some limitations. (Received September 13, 2008)