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Effect of study criteria on recruitment and generalizability of the results.

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Abstract

OBJECTIVE: Clinical trials are indispensable to drug approval process. This **research** examined the **effect** of a specific **study criteria** on **recruitment** and **generalizability** of the **results**.

METHODS: The following were reviewed: (a) the usual inclusion and exclusion **criteria** for the antipsychotic trials performed at the Institute; (b) epidemiologic data, to determine the **effect** of **study criteria** on the target population; and (c) the **recruitment** procedures/strategies used to identify potential candidates. A survey was conducted to determine the percentage of schizophrenic patients in a conventional outpatient psychiatric clinic conforming to the usual enrollment **criteria** for antipsychotic trials.

RESULTS: Intensive **recruitment** efforts in a general population of 3.6 million would have been expected to yield only 632 eligible subjects out of 36,000 suffering from schizophrenia. Out of 632, only 50 contacted the **research** site after an intensive **recruitment** effort. From those 50, 30 were excluded during a telephone interview. Of the 20 remaining, 6 were excluded for a variety of reasons during a face-to-face interview. Thus, only 14 subjects out of a population of 3.6 million met the **study criteria**.

CONCLUSIONS: These **results** emphasize the rarified nature of patients-volunteers who enter a clinical trial. Inclusion and exclusion **study criteria** can severely restrict the number of eligible subjects, dictate **recruitment** strategies, and in turn affect **generalizability** of the **results**.

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