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Trials of prophylactic agents for the control of communicable diseases: a guide to their organization and evaluation

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Preamble

This is the first of several monographs and technical reports on clinical trials that the World Health Organization would produce over many years.

Aims

It is now generally agreed that the ideal procedure before employing a vaccine or other prophylactic agent on a large scale is to institute a controlled field trial. In such a trial fully comparable individuals or groups of individuals are chosen at random and some are vaccinated and some left as controls (they may be vaccinated, and often are, with a control vaccine); but all are exposed to the same risk of contracting the disease. This may appear on the surface to be a relatively simple preliminary to the wide-scale use of a vaccine, but experience has shown that it is an ideal that cannot always be attained, and that a trial must always be conducted with much care and with a full knowledge of the many pitfalls awaiting the unwary investigator. The purpose of this monograph is to outline the general principles on which controlled field trials of prophylactic agents should be based, and to point out how errors can be avoided and sources of bias eliminated. The World Health Organization is publishing this guide in the hope that it will be of assistance to health authorities in conducting field trials of prophylactic agents whenever needed (Preface, page 6).

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