A METHOD FOR MONITORING ADVERSE DRUG REACTIONS

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1. Introduction

A recent international conference on Adverse Reactions Reporting Systems [6] has again underscored the great need for continuing surveillance of therapeutic drugs after they are marketed. Formal clinical drug trials and other premarketing studies are usually too small in scale and too formally structured to detect all of the problems that a drug may cause when it is employed in the varied and complex setting of actual patient care. These drug-caused problems, known medically as *adverse drug reactions*, consist of a wide variety of untoward effects, some of which occur quite rarely.

In the Kaiser-Permanente Department of Medical Methods Research, a computerized medical data system [9] is being developed which now records the essential medical data for patients seen in the Kaiser-Permanente outpatient department in San Francisco. In attempting to minotor the risks of untoward events due to therapeutic drugs, we have employed an analytic method that delves into a relatively unstructured situation in an effort to bring out some orderly and useful observations.

After describing the method we shall discuss the relationship of drug monitoring to studies of the effects on health of environmental pollution, the theme of this part of the Symposium.

2. Data currently available

In contrast to most other drug monitoring programs, we have been working with outpatient data, that is, information about what takes place in outpatient clinics rather than in a hospital ward [3]. Analytic methods applied to inpatient data have been described by others [1], [5], [7], [8].

Because outpatients are not under continuous observation as are hospitalized patients, outpatient data are necessarily imprecise and less complete than inpatient data. Regarding drug usage, in an outpatient setting, one can ascertain

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