The Design and Use of a Health Status Index for Family Physicians

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This paper describes a Health Status Index (HSI) which is part of a patient encounter form in a family practice center. The Index, which is used to profile a patient's health status longitudinally, combines physical and psychosocial measures of health. Based on its use in the center and through the presentation of data on patient health status, the authors illustrate how the Index can facilitate the evaluation of care and the management of practice. More specifically, they suggest that such data assist physicians in: (1) evaluating the effect of different modes of treatment on the duration and severity of ill-defined symptoms and complaints; (2) identifying high-risk patients for special attention; (3) indicating treatment modalities which produce more desirable outcomes; (4) determining the efficiency of different modes of treatment and of continued care; and (5) addressing chronological, as well as interpersonal and interprofessional, questions of providing continuous care for the chronically ill.

The family physician has responsibility for first contact, continuous care, and the management of available health resources on behalf of his patients.[1-3] In this paper we describe a Health Status Index (HSI) and discuss how it can assist family physicians in discharging these responsibilities. First, we define the component measures of the HSI and report the way in which it is completed in a family practice center. Then, using data collected via the Health Status Index, we discuss how it can assist physicians in the evaluation of care and the management of their practices.

Work on the Health Status Index, and the Health Information System of which it is a part, was conducted by the Office of Health Services Education and Research of the College of Human Medicine, Michigan State University, under a subcontract with the Michigan Cooperative Health Information System of the Michigan Department of Public Health, pursuant to a contract No. HRA 106-74-35 between the National Center for Health Statistics and the Michigan Department of Public Health. Requests for reprints should be addressed to Dr. Charles W. Given, Office of Health Services Education and Research, College of Human Medicine, Michigan State University, East Lansing, Mich 48824.

Description of the HSI

The Health Status Index is one element of a patient encounter form which provides data for a health information system in a family practice residency training center. This center has a staff of 21 residents and two board-certified family physicians who manage over 1,000 patient visits per month. The HSI, which is used to profile a patient's health status longitudinally, combines physical and psychosocial measures of health (Figure 1). Symptoms are a physical measure of illness based upon the physician's observations and examination of the patient. Discomfort and inability to perform major activities are psychosocial measures of the existence of morbidity based upon the patient's reports. The definitions and classification of the psychosocial measures were adapted from those used by the National Center for Health Statistics in the United States National Health Survey.[4]

The categories of health included in the HSI are used to evaluate patient health status at three points in time: prior to the onset of the illness for which care is sought, at the time of the visit to the center, and three months after the visit. The first patient visit for an illness is considered to mark the onset of that condition. The patient's usual status prior to this onset is used as his baseline measure of health.

The severity of the patient's illness is defined by the degree of change in his status over two or more points in time. Comparing status prior to the onset of an illness with status at the time of each visit summarizes the impact of the illness on the patient.

The duration of an illness is defined by the length of time between onset and recovery or, in the case of long-term, continuing conditions, from onset to death. For an acute illness, recovery may be defined as the time when a patient resumes that status prior to the onset of illness. For chronic conditions, the HSI may be used to define the progression of the illness over some period of time. It is up to the judgment of the physician to determine if the observed changes in status for an individual patient represent an acceptable progression for that illness.

Completion of the Health Status Index

The HSI is completed by the attending physician for all patients at the time of each visit to the center (Figure 2). The patient is asked his usual health status prior to the onset of the present illness and his status at the time of the visit. These are recorded by the physician, along with his estimate of the patient's expected status in three months. This estimate is based on information available to the physician, including data from the patient's history, physical examination, laboratory and/or x-ray procedures, and diagnosis.

For the purposes of the HSI, the physician's estimate of the patient's status in three months is used to differentiate acute, short-term illness

from chronic, long-term problems. The use of a three-month time period to separate acute from chronic conditions is based on a convention established by the National Center for Health Statistics in their surveys of the health status of the United States population. In these studies, illnesses or conditions first noticed more than three months before an interview are considered chronic. Thus, a chronic, long-term problem is not subject to clinical definitions of resolution within three months and an acute, short-term problem is. Though acute conditions may be exacerbated by co-existing chronic conditions, they are considered to be etiologically separate from chronic conditions in the HSI. Therefore, a urinary tract infection in a diabetic patient would be considered a short-term problem, while an acute episode of the diabetic condition, such as ketoacidotic shock, would be considered to be related to the chronic condition.

When the physician decides a problem is short-term, he checks "short-term problem," notes whether a prescription drug was ordered, and estimates the number of days required for the patient to return to his functional status prior to the onset of the present illness. When the physician decides that an illness is not subject to resolution within three months, he checks the box labeled "long-term problem," indicates whether or not a prescription medication is being used to manage this problem, and estimates the patient's expected status in three months.

Table 1 describes the completion rate of the time components of the HSI for patients diagnosed as having one of ten common diseases at the time of their first visit to the center in 1975. The Table also includes the rates for patients with all other diseases and for those with no disease at the time of their first visit in 1975. These completion rates are based on a total of 2,674 patient visits. Exclusive of patients with no disease at first visit, status prior to visit had an average completion rate of 89 percent. Status at time of visit had a slightly lower rate of completion, but the average percent completed, exclusive of patients with no disease, was 87 percent. The third component of the HSI, expected status in three months, was completed on an average of 87 percent of the time for all groups of patients except those without disease at the time of their first 1975 visit. This high rate of completion suggests that even where residents were asked to estimate or predict future outcomes, they generally were willing to provide an assessment. Thus, we have received reasonably good compliance among the residents in completing the HSI.

Uses of the Health Status Index

Studies of general and family practice indicate that a significant proportion of patients seeking care present with ill-defined symptoms and complaints which do not fit standard classifications of disease.[5,6] The Health Status Index can assist family physicians in assessing and treating these problems by providing a collection of integrated observations on the course of patients' illnesses. Katz and colleagues,[7] and Akpom, Katz, and Densen,[8] for example, have shown how measures of function can be combined with symptoms, clinical indicators of disease (laboratory tests and x-rays) and risk factors to create meaningful classifications of patient illnesses. The family physician can use such classification schemes to categorize ill-defined problems into homogeneous groupings in order to describe changes in the course of these illnesses and to evaluate the effect of different modes of treatment on the duration and severity of these problems. These schemes need not exclude standard disease classifications, but can provide additional information to assist the family physician in defining the course of and in treating ill-defined problems.

The HSI can also assist the physician in defining the course of long-term continuing conditions. For example, during a five-month period of observation, the health status of nine of 20 patients with essential hypertension improved, the status of one patient deteriorated, and the status of ten patients remained unchanged. Of the ten patients whose status remained unchanged, five had no coexisting chronic condition, two had osteoarthritis, two were obese, and one had diabetes mellitus. Three of the nine patients whose status improved had no other chronic condition, one had osteoarthritis, three were obese, one had ischemic heart disease, and one had mitral stenosis. The one patient whose status deteriorated had ischemic heart disease and osteoarthritis. None of the 20 patients, however, sought care for acute conditions which might have distorted observed changes in health status. The presence of coexisting chronic conditions, therefore, did not appear to have any systematic effect on changes in health status. The one exception, perhaps, was the case of the patient who deteriorated over the observation period. This patient was the only one with a coexisting condition (osteoarthritis), as well as evidence of target organ involvement (ischemic heart disease) associated with the hypertension.*

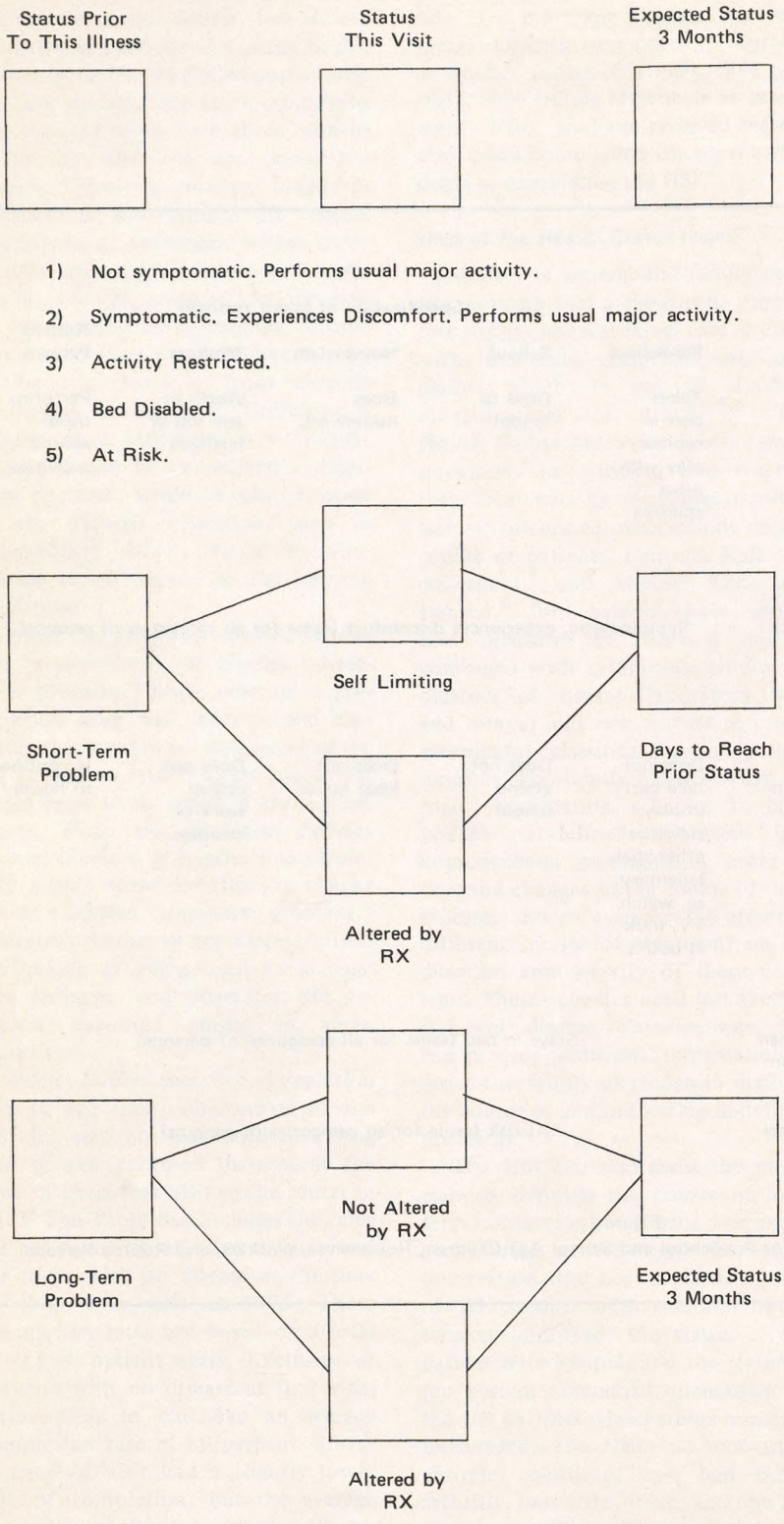
Data such as these can assist family physicians in managing their practices. As they are accumulated they describe a distribution of outcome status over time that establishes outcome norms or standards for different illnesses. These norms can be used to compare patients' courses of illnesses and to identify those who deviate from the norm. They can also be used to examine the appropriateness of patient care, and to identify treatment modalities which produce more desirable outcomes. For example, physicians may wish to question whether or not it is acceptable for patients with hypertension to be symptomatic at the beginning and end of an observation period. If such an outcome is suspect, the physician might review in more detail the care given those patients whose status remained unchanged. Based on an audit of the patients' medical records, he may conclude that care is adequate and that the patients' status could not be improved or, he may decide to alter some aspect of care for these patients to achieve more desirable outcomes. Equally important, when desired outcomes are compared with information describing the

*The validity of this HSI was examined in a recent study of hypertensive patients.[9] In this study measures were recorded on 99 hypertensive patients at the beginning and end of a five-month period using the Health Status Index and an Index of Severity which included systolic and diastolic blood pressure and involvement of target organs. Of the 99 patients studied, 40 improved on both measures. Twenty-one patients deteriorated and 38 remained unchanged on the Severity Index. Nineteen patients deteriorated and the status of 40 remained unchanged on the HSI.

Health Status	Definition	Specification of Major Activity				
		Pre-School	School	Housewives	Workers	Retired Persons
Not symptomatic: performs usual major activity	People who are asymptomatic	Takes part in ordinary play with other children	Goes to school	Does housework	Works at any job or business	Performs usual retired activities
Symptomatic: experiences discomfort, performs usual major activity	People in whom symptoms are pronounced (ie, affect comfort) so that person recognizes change in usual health status	Symptomatic, experiences discomfort (same for all categories of persons)				
Activity restricted	People who are unable to engage in major activity, confined to house, almost completely inactive, not bed disabled	Does not take part in play activities other than sedentary, eg, watch TV, look at books	Does not attend school	Does not keep house	Does not attend work or business	Is confined to house
Bed disabled	People who stay in bed all or most of the day — more than 1/2 of hours person is usually awake	Stays in bed (same for all categories of persons)				
At risk	People with terminal illness	At risk (same for all categories of persons)				

Figure 1.
Definition of Health Status by Major Activity for Pre-School and School Age Children, Housewives, Workers, and Retired Persons

Figure 2. Health Status Index



resources employed to produce them (eg, the cost of personnel and services), they enable the physician to determine the efficiency of different modes of treatment and of continued care. The Health Status Index, thus, helps the physician to successfully manage his practice not only by identifying those treatment modes that shorten the duration or reduce the severity of illness, but also by delineating the costs to himself and to the patient that are associated with producing desired outcomes (Table 2).

Finally, the Health Status Index can assist family physicians in providing continuous care, especially for the chronically ill, by describing the impact of the disease process on the patient and by indicating when additional health resources are needed to manage the patient. For example, as patients become restricted in their major activities and confined to bed for longer periods of time, physicians can plan with family members for the care of these patients. Can such patients continue to be cared for at home, or should plans be initiated to secure an appropriate level of institutional care? The measures included in the HSI not only alert physicians to these questions, but they also provide a common language which doctors, nurses, social workers, and representatives of community agencies can use to discuss the options available to the patient. Thus, the HSI assists the physician in addressing chronological, as well as interpersonal and interprofessional, questions of providing continuous care for patients.

In summary, we believe a Health Status Index such as that described can assist family physicians in providing first contact and continuous care for their patients. Further, the HSI can assist physicians in managing their practices and in allocating the resources available in the larger health system for the benefit of their patients. The HSI is extremely valuable for describing the course of most acute and chronic diseases seen within a family practice center and is a good measure of patient outcome. It provides a summary measure of patient health and a mode of communication of patient needs among different health-care providers. The HSI, thus, can be an important instrument in the delivery of family-oriented health care.

Table 1. Completion Rates of HSI January through December 1975, for First Visit in 1975 by Patients Having One or More of 10 Frequently Occurring Diseases, Other Diseases, and No Diseases

Disease	Number of Patients	Status Prior to Illness Complete		Status This Visit Complete		Expected Status Three Months Complete	
		#	%	#	%	#	%
Hypertension	139	125	90	128	92	117	84
Upper respiratory infection	140	127	91	120	86	112	80
Diabetes mellitus	65	56	86	58	89	52	80
Depression	28	25	89	24	86	22	79
Urinary tract infection	49	47	96	45	92	44	90
Arteriosclerotic heart disease	18	14	78	13	72	12	66
Vaginitis vulvitis	48	45	94	43	90	43	90
Bronchitis	48	45	94	43	90	43	90
Arteriosclerosis	12	11	92	10	83	9	75
Osteoarthritis	11	9	82	11	100	9	82
Other	1,557	1,422	91	1,393	89	1,311	84
No disease	569	370	65	376	66	312	54
Total	2,674						

Table 2.
Average Number of Visits April through August 1975 and Average Charge per Visit by Change in Health Status of 20 Hypertensive Patients

	Improved	Deteriorated	No Change
Average Number of Visits	4	6	5
Average Charge per Visit	$12.00	$25.00*	$10.00
Total Number of Patients	9	1	10

*The high average charge per visit for the one patient whose status deteriorated appears reasonable in view of the number of coexisting diseases which were identified.

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law permitted a taxpayer who was over 65 to exclude from his reported income the amount of gain received upon the sale of their personal residence that was attributable to the first $20,000 of the residence's selling price. For example, an individual who was over 65 and sold a residence for $60,000 that had cost him $30,000 would have a gain of $30,000 caused by the sale. However, only $20,000 of the gain would be included in the taxable income reported.

$$(30{,}000 \times \frac{20{,}000}{60{,}000} = 10{,}000)$$

The change in the Reform Act increases the amount of the selling price used in determining the excluded amount from $20,000 to $35,000. Using the same example, only $12,500 would be reported on the tax return.

$$(30{,}000 \times \frac{35{,}000}{60{,}000} = 17{,}500)$$

The tenth change contained in the Reform Act could have major impact on a number of physicians. The change limits the amount of deduction that can be claimed for expenses and depreciation related to rental property that is occupied by the taxpayer during some portion of the year. This section of the act exempts property used by the taxpayer as a residence from the limitation on deductions if the period of use by the taxpayer is less than 14 days, or less than ten percent of the number of days the property is rented at a fair price. If the taxpayer's use is greater than either of those amounts, the amount of deduction which can be offset against the rental income is limited. This is best illustrated by an example. Presume that a taxpayer had a home in the mountains that he rents for six months a year for $300 per month and uses the home for one month out of the year. The taxpayer incurs taxes of $300 per year and interest of $1,100 per year. He also incurs $400 for utilities and $500 for maintenance that are attributable to the rental period. The amount of depreciation attributable to the rental period is $800. The act requires the computation of deductions to be done as follows:

Income from rental	$1,800
Less Interest and Taxes	(1,400)
Amount available to offset rental expenses	400
Less Utilities and Maintenance Permitted	400

The result, in this example, is that the owner of the property is denied a deduction for the $500 in maintenance expenses and the $800 in depreciation expense because the rental income from the property is insuffient to cover these costs. If physicians own a second home that they use as a residence during part of the year and rent the property during the balance of the year, they will have to restrict their usage of the property or restrict the amount of deductions they claim for the property under this section of the act.

The eleventh change contained in this section of the act relates to claiming a dependency exemption for a child of divorced parents when the divorce decree does not establish the right to exemption. Under the prior law, a divorced parent who did not have custody of the children was given the exemptions for the children if they had provided $1,200 in support for all the children and the custodial parent could not show that they had provided more in support of the children. The law now requires that the non-custodial parent show that they provided $1,200 per child before they can require the custodial parent to show the amount contributed to the support of the children.

This section of the law also contains provisions which change the requirements related to the educational loans that are required to be included as portions of the individual's income if the loan is forgiven or are payments under the Uniformed Services Health Professions Scholarship Act. Also, there are changes which liberalize the tax provisions on money received under the 1972 disaster provisions of the law.

Future articles in this series will deal with the changes caused by the Reform Act in the areas of business operations, investments, foreign income, pension plans, trusts, and estate and gifts.

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contains references up to 1974. There are a number of black and white illustrations of good quality. The book has some relevance for family practice, but this reviewer came away disappointed because the introduction suggested that it would have much more. The book provides some useful and, at times, unique information and viewpoints. However, it cannot be recommended as a major rheumatologic reference work for the family practitioner's office. It is more likely to be of value in hospital and departmental reference libraries.

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Reporting Child Abuse And Neglect: Guidelines for Legislation. *Alan Sussman and Stephan J. Cohen. Ballinger Publishing Company, Cambridge, Massachusetts, 1975, 255 pp., $13.50.*

This is a scholarly work with an in-depth analysis of a very sharply circumscribed area, that of child abuse reporting and the legal structure which forms the basis for such reporting. The first chapter is the full text of the "Model Child Abuse and Neglect Reporting Law," which was written by the authors in conjunction with the Institute of Judicial Administration at the request of the Department of Health, Education, and Welfare. This model law is intended to serve as the legal guide from which governmental groups can formulate specific legislation. Subsequent chapters provide a section by section commentary on the law, a chronological review of the literature, a compilation of statistical data, a survey of attitudes and opinions, and an analysis of practices in four states. This body of supportive information is provided to clarify the intent of the model law, document the historical framework on which it was based, and explain the motives behind the philosophical decisions implied by its orientation.

This is a clearly presented, well-organized, and thoroughly referenced volume. In spite of its admittedly narrow focus, it is readable and is not overly technical or legalistic. It does not attempt to deal with the clinical aspects of child abuse, such as diagnosis and treatment, except where relevant to the reporting laws. This orientation makes this volume of interest primarily to lawyers, legislators, social workers, and others with a special interest in the legal aspects of child abuse reporting. To the majority of practicing physicians, residents, students and professionals with a clinical orientation it may serve as a useful reference, but will be of limited general interest.

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Family and Health: An Epidemiological Approach. *Edited by Berton H. Kaplan and John C. Cassel. Institute for Research in Social Science, Chapel Hill, North Carolina, 1975, 106 pp., $4.00.*

An individual may rise above or fall below the level of his family. All of his life, however, he is influenced by what they have said and especially by how they have interacted with him and with other persons inside and outside the family, and by their ability to maintain their heads above water (family competence).

The material in this book, essentially consisting of four theses, is well organized, maybe even too organized. Someone who revels in statistics will enjoy it. The material is occasionally very relevant to family practice, but much of it is experimental in nature, thought-provoking but not proven because of the small number of subjects involved.

In the first thesis, which attempts to prove that illness is often associated with distorted parent-child relationships, very sweeping conclusions are drawn from a study of 57 high school students. Thesis two attempts to demonstrate that family and individual

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either or any of the drugs acting alone.

It is clear that the avalanche of newly discovered antibiotics and other drugs upon the pharmaceutical market has spawned a new generation of drug reactions and interactions with deadly potential for the patient. This condition is aggravated by the growing tendency of physicians to administer several drugs concurrently in their approach to certain diseases and infections. Researchers, however, have identified these reactions and interactions and proliferated this information to the public through professional journals.

The mere availability of charts illustrating drug reactions and interactions does nothing to reduce their harmful effects unless procedures are devised to anticipate, control and present their occurrence. These procedures fall into three general groups and will be dealt with individually in the next three subsections.

C. National, Regional and Local Registries Make Information Regarding Drug Reactions and Interactions Available to Physicians. The medical profession has instituted international, national, regional and local registries of drug reactions and interactions which are now available to physicians. A well-organized reporting system is essential to measure the incidence and evaluate the significance of drug reactions and interactions.[27]

To stimulate and provide the vehicle for systematic observation of undesirable drug effects, the American Medical Association and the Food and Drug Administration (FDA) each established registries for reporting drug reactions in the 1950's.[28] The FDA has, by contract and consensual agreement, more than 1,000 hospitals reporting to it all adverse drug reactions. The FDA's Adverse Reactor Reporting Branch (ARRB) scans hundreds of medical journals and reviews 58,000 reports annually from other sources. The FDA leans on its statutory authority to require manufacturers to report all adverse reactions they discover in research.[29] The AMA and FDA systems are national sources of information regarding drug actions. The AMA also maintains separate records of blood dyscrasias.[30]

Independent regional registries also sprung up in the late 1960's and early 1970's. The Boston Collaborative Drug Surveillance Program (BEDSP) represents a regionally administered program for the discovery of drug interactions.[31] Each participating hospital records information on patients to whom the drugs are administered.

> Included for each patient is a record of all drugs ordered, which includes dosages, routes of administration, and starting and stopping dates. Suspected adverse reactions (defined as any undesirable or unintended effect of a drug) are detected in two ways. First, whenever a drug is discontinued, the attending physician is promptly interviewed by the nurse-monitor and asked why he stopped the drug. An adverse reaction is one of the reasons he may give. Second, even if he gives some reasons other than drug reaction, he is, . . . asked whether any suspected reactions occurred while the drug was being administered.
>
> *All suspected reactions are reported to the Clinical Pharmacology Unit and then investigated.* On the basis of the juvenile investigation, the investigating clinical pharmacologist makes a judgment on whether any drug or group of drugs in fact caused the alleged reaction.[32]

The Kaiser-Permanente Drug Reaction Monitoring System operates in the San Francisco-Oakland area, and according to its founders, is the first "epidemiologic adverse drug reaction study that has systematically monitored ambulatory patients."[33] The epidemiological approach analyzes groups of patients and associates patient and disease characteristics with drugs and their adverse reactions. By the use of statistical techniques, the risk that a specific drug presents to a specific patient is calculated.

Prescriptions dispensed and diagnoses made at the Kaiser-Permanente Medical Center in San Francisco for both inpatients and outpatients are fed into a computer. All outpatient visits are recorded on special forms listing the 300 most commonly used diagnoses of the Institute, and inquiring whether any adverse drug reactions have occurred. The computer then compares the physical characteristics of the user of a particular drug with the non-users. An appreciable increase in the rate of occurrence of any particular event will trigger a search for the cause of the increase. The introduction of a new drug is one thoroughly explored possibility.

This well-organized information gathering system has promoted:

> . . . a high standard of practice among its members (prescribing physicians), and by frequent and informal communication tends to discourage the inappropriate prescribing of dangerous drugs: For example, (the founders) found that only three prescriptions of chloramphenicol were dispensed from the pharmacy for the three months July to September 1969.[34]

In addition, examination of the age distribution of the usage of tetracycline reveals that the pharmacy did not prescribe the antibiotics to any pediatric patient under five years of age. "Thus," the founders of the Kaiser-Permanente conclude, "the danger of tooth staining and deformity seems to be universally recognized in the group."[35]

In summary, on the national and regional levels, the FDA, AMA and certain groups of physicians have recognized the dangers of drug reactions and interactions and have implemented drug registries to isolate specific dangerous drugs.

D. The Medical Profession Has Devised New Procedures to Control Reactions and Interactions After They Arise. The medical profession has responded to the problem of reactions and interactions resulting from the use of antibiotics by endorsing the use of specific procedures to avert the harmful consequences once a reaction or interaction has occurred. Prompt treatment is essential,[36] and epinephrine and a tourniquet should be close at hand.[37] After administering any antibiotic that may precipitate anaphylactic shock or other severe reactions, physicians are to instruct the patient to remain nearby for at least 15 minutes, so that any adverse reaction may receive prompt attention.[38] Additionally, medical authorities advise the clinically significant interactions between drugs are more likely to occur if large doses are administered, if they are given simultaneously, and if they are given in the presence of a renal or liver disease.[39]

The medical profession has devised

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a variety of easily administered tests to determine hypersensitivity to the following commonly used, but potentially reactive drugs: penicillin,[40] chloromycetin,[41] neosalvarin, tryparsimide, as well as a host of others.[42]

In short, physicians are advised by their peers to follow specific procedures to combat drug reactions and interactions, procedures that were devised in recognition of the potential dangers of an ill-administered drug.

E. The Medical Profession and the Government Have Sought More Vigorous Control Over the Prescription and Administration of Potentially Reactive or Interactive Drugs. Influential segments of the medical profession are calling for a higher standard of care in the area of drug therapy. Dr. Richard Dall, Regius Professor of Medicine at the University of Oxford, in calling for an "aggressive awareness"[43] of warning signals indicating drug reactions, cites examples of changing disease patterns that lead to the discovery of drug reactions. In England, an increase in the incidence of pulmonary hypertension observed at a cardiac center was traced to the use of antiobesity drugs; an escalating incidence of unexplained ulceration of the small bowel, occurring among people in Stockholm, was traced to the use of enteric-coated capsules containing a thiazide diuretic with potassium salt; and finally, eating cheese caused hypertension attacks in some patients taking monoamine oxidase inhibitors.[44] All of the foregoing reactions were discovered through the off-handed prescriptions of medical practitioners. Dr. Dall suggests that their conduct should set the standard for the medical profession; close observation is responsible for revealing the incidence of reactions among drugs commonly thought innocuous.

F. Leaders of the Medical Profession Have Recommended Certain Procedures to Anticipate, Control and Prevent Drug Reactions and Interactions. The medical profession has invented several ways to implement its innovations, reducing the threat of drug interactions.

At the outset, it should be emphasized that the following are the standards imposed by the medical profession upon itself; they are not specifically imposed by law.

The physician should take the patient's personal and medical history to detect drug hypersensitivities before administering drugs.[45] The physician should be particularly attentive to genetic factors that may cause an adverse reaction to a particular drug.[46] Dr. R.A. Keim has stated:

> A study of the records of all too many cases shows that some anaphylactic deaths could have been prevented by precautions so simple that they should have been undertaken routinely. *(The physician) must know his patient, his past history, his previous exposure to allergic drugs* and his experiences incident thereto and his family history for allergy.[47] (Emphasis added)

The physician must ask the patient specific questions about any adverse reactions he had, or thought he had, to medications administered to him in the past.[48] It is often difficult to ascertain certain drug reactions:

> because of their manifold appearance. In general, the frequency with which this diagnosis is made is a function of the suspicion of the physician. The first step is detailed repetitive questioning of the patient. Questioning proceeds on the basis that the patient has, at some time, taken a (potentially reactive) drug.[49]

The physician must test the patient for hypersensitivity to certain drugs.[50] Once a hypersensitivity is discovered, the physician has several alternatives.

> If an interaction is suspected, several choices of treatment are available to the physician depending upon the patient's disease and the type of interaction.
>
> He can eliminate the drug causing the interaction and, if possible, substitute an alternate drug (eg, replace a coumarin anticoagulant with another anticoagulant, a monamine oxidase inhibitor antidepressant); alter the dose of one or both drugs to compensate for the undesired effect (eg, when a coumarin is given with a coumarin anticoagulant); and readjust the dose when an interacting drug is discontinued.
>
> . . . *it is advisable for the physician to know well the actions of the drugs he uses and to limit the number of drugs to those that are essential.* This problem is important when one considers the number of patients who develop reactions causes by drug interactions and the relationship of these reactions to morbidity, mortality, hospitalization, and loss of income to the patient.[51] (Emphasis added.)

The medical profession also recommends that the physician specifically ascertain what other drugs the patient may be taking at the time of his treatment, either in the hospital or in the physician's office. Dr. Monroe Trout states:

> It is ironic that when a patient is admitted to the hospital we take all his valuables, his clothes, and his money but we neglect to look into his duffel bag for any medication he may take while in the hospital.[52]

This apparently basic procedure has long been neglected. Dr. Trout offers a laughable example:

> The (hospitalized) patient had a reaction to a drug and the physician thought that this was *the only drug that the patient was taking. On careful history taking,* not only from the patient herself, but also from the patient's family and from the previous doctors she had seen, *it was finally reconstructed that during the time this reaction occurred, she was taking 132 different drugs. I don't know when she had time to eat.*[53] (Emphasis added.)

The medical profession instructs the physician who administers potentially reactive drugs in his office to be trained and equipped to cope with any adverse reaction that may develop.[54] Proper counter therapy includes the prompt administration of epinephrine, oxygen, and antihistamines,[55] and if the foregoing prove ineffective, the implementation of supportive therapy, *viz,* the injective of certain intravenous fluids, aminophylline solution, and adreno-corticosteroids.

The medical profession has prescribed methods for minimizing the likelihood and severity of drug reactions and interactions. Limiting the potency,[56] avoiding parenteral administration,[57] limiting the use of multiple drug therapy,[58] having the patient remain in the doctor's office for at least 15 minutes for close observation,[59] and modifying the dosage at the outbreak of reaction:[60] these measures all reduce the incidence of interaction. The dental profession has imposed similar duties on its members.

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Classes of drugs most frequently prescribed by dentists are the analgesics, antibiotics, and sedatives. It is emphasized that although the interaction of these drugs may have been reported, they can be given together if adequate methods such as the monitoring of the therapy or dosage adjustments are made to compensate for the (adverse) responses.[61]

The profession imposes specific responsibility to weigh the benefit offered by a proposed medication to the danger it poses.

Practically all drugs may exert some toxic or hazardous effect.. "Practically useful drugs" ... are those that have exhibited a risk-to-benefit ratio clearly beneficial to the patient, and where the associated risk, hazard, or side effect is tolerable during and subsequent to the use of the drug.[62]

The physician is also duty bound to keep a record of past administrations and reactions,[63] and to maintain a "continuing alertness"[64] as to his patient's progress. Keeping accurate and current records has been deemed "an important aid"[65] by the AMA in the treatment of drug reactions and interactions.

When prescribing a drug with potential reactions or interactions, the physicial should inform the patient of the incipient risks,[66] and inform patients who are taking drugs of any adverse reactions or warnings that have come to their attention since the prescription was issued.[67] According to the professional literature, any information the physician may receive from drug manufacturers (typically in the form of "Dear Doctor" letters from detailmen) must immediately be passed to the patients taking the drug. The *Journal of The American Medical Association* has advocated placing drugs in labeled containers, which clearly indicate that the drug has caused reactions in the past.[68] The label could also include information about what foods and beverages the patient should avoid while ingesting the drug.

Finally, important journals of the medical profession obligate physicians to stay informed of the latest developments in drug therapy.

With the increased use of multiple drugs, the physician has the responsibility of expanding and keeping his knowledge of drug therapy up to date. He must be aware of the possible development of any unusual or suspicious reactions causes not only by the drugs prescribed but by their reactions with other drugs, including over-the-counter agents that a patient may be using, food and products that are eaten or drunk (eg, cheese, beer, wine) and agents that may be inhaled (eg, insecticides).[69]

In sum, the medical profession clearly regards adverse drug reactions and interactions as a serious widespread public health problem. To diminish the incidence of adverse reactions, important medical authorities have mandated the use of highly *specific* procedures, *viz*, the duty to take a history, to test for hypersensitivity, to warn the patient of possible adverse reactions, to weigh the benefits of a drug against its detriments, to keep records of all past administrations, and to notify all patients taking a drug of any adverse information about the drug that may come to the physician's attention. The *specificity* of the medical profession's approach to drug reactions and interactions creates a commendable consistency and predictability in the standards imposed by the profession upon its practitioners.

This writer intended in Part Two to profile the standards of knowledgeable and sophisticated medical researchers and practitioners regarding drugs whose administration is fraught with the perils of reactions and interactions. To lay the foundation for Part Three, it was necessary to indicate that the increase in the number of drugs in the last 20 years precipitated a geometric increase in the number of reactions and interactions, to note the "aggressive awareness" of the medical profession to the problem (as evidenced by their establishment of national, regional, and local drug registries, which serve as computerized reservoirs of information about reaction drugs), and finally to scrutinize with some detail the multifaceted approach that the medical profession has devised to combat the drug reaction problem.

Part Three will discuss the approach of the courts in lawsuits alleging negligence with respect to drug reactions and interactions, and whether common law standards are responsive to a public health problem that has emerged in the last 20 years.

III. The Path of the Law

The Physician's Legal Duty to Anticipate, Control, and Prevent Drug Reactions

The general rules that govern liability for medical malpractice control disposition of cases involving the liability of a physician for harmful reactions and interactions arising from drugs prescribed or administered by him. Consequently, a physician who prescribes and administers drugs is required to use reasonable skill and care for the safety of the patient. The physician is entitled to have his treatment tested by the rules and principles of established modes of practice, as characterized by the state of general medical knowledge, and by the standards of the school of medicine to which he belongs and the community in which he practices. Despite erosion in several jurisdictions, the "locality rule" still adheres in a majority of states.[70]

A physician's liability for a patient's reaction to a drug he has administered or prescribed is largely determined by general standards of due care. If he has used that degree of skill and knowledge which prevails in his community in prescribing the drug, as well as in managing reactive systems, he is normally not liable.[71]

In examining the approach of courts to the medical-legal problem of drug reaction or interaction, this writer posits four assumptions: that the physician has correctly diagnosed the ailment, that the drug he administered or prescribed was one which would be used to combat the diagnosed ailment by other members of the community, that the drug was prescribed or administered in the proper dose, and that is was properly injected into the patient.[72]

Part Three will consider the behavior of courts in imposing liability on physicians for the failure to adequately administer, control or prevent drug reactions and interactions. As much as possible, the analysis shall move away from the general negligence approach toward those cases in which the court has definitively set down standards of care regarding drug

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reactions. Obviously, a plaintiff can allege that a physician failed to use "due care" with respect to any drug reaction claim. This writer will discuss those cases in which the courts have imposed a *specific duty* to take a personal history, to test for hypersensitivity and to warn of potential reactions, among others, and have shunned reliance on the broad "due care" standards. The objective is to compare the *degree of specificity* adopted by the medical profession in its scholarly publications with the *degree of specificity* of judicial proclamations regarding drug reactions and interactions.

A. The Duty to Inquire With Respect to Past Drug Reactions. In *Sangari v Rosenfeld,*[73] the defendants, a group of dentists, replaced a filling in one of the plaintiff's teeth, using xylocaine in combination with epinephrine as an anesthetic. After the tooth was filled, the plaintiff arose from the chair, prepared to leave the room and fell, having suffered a cerebral hemorrhage or stroke, as a result of which he died three days later. Expert witnesses testified that the use of epinephrine is contraindicated where the patient suffers from high blood pressure. In a hypertensive patient, only minute quantities of epinephrine are necessary to raise the blood pressure to fatal levels. The defendants asked the plaintiff before filling the tooth "how her general health was." The court held on appeal that, as a matter of law, the dentist is under a duty to take a medical history from the patient before administering a potentially harmful drug, and that the physician was properly found negligent for not inquiring specifically as to the patient's health. A general, one question inquiry is inadequate as a matter of law, according to the New Jersey state court in *Sangari.*

O'Neal v State of New York[74] held that the admitting physician at a state hospital, who was told by the decedent that she was taking nembutal and who failed to consider available medical records in making his diagnosis and speak with the defendant's husband or contact her private physician to learn the decedent's addiction to barbiturates, did not observe proper and acceptable medical procedures. The physician diagnosed the patient's problem as epilepsy. The patient died from injections of thorazine and stelazine, which interreacted with residual barbiturates in her body.

The court first stated the physician's duty in the general terms of

> . . . reasonable and ordinary care, skill and diligence as physicians in good standing in the same general neighborhood, the same general line of practice, ordinarily have and exercise in like cases.[75]

Simple inquiry would have revealed in O'Neal, that barbiturate addiction, not epilepsy, was the source of the patient's problem. The court concluded that the entire procedure pursued by the attending physician was "palpably improper and not in accord with sound medical practice."[76] Liability emanated from that application of a general standard, not a specific duty to take a medical history.

Horace v Weyrauch[77] involved the subcutaneous injection of an iodine compound used as a medium contrast for x-raying the kidneys. Following the injection, the plaintiff developed an ulcer at the site of the injection. Surgery was required for its removal. The plaintiff was referred to the defendant-physician for a pyelogram (x-ray study of the urinary tract – kidneys, ureter, and bladder) Before the injection of the iodine, and after the plaintiff told him that others had had difficulty in giving him injections before, the defendant did not ask specific questions about whether the plaintiff had had any reactions or sensitivities to particular drugs. On appeal, the court held that "the jury could find that (it) is negligence . . . to fail to ask (the appropriate) questions."[78]

These cases are representative of a raft of authority interpreting the physician's duty to use "reasonable care and ordinary skill" as encompassing the duty to ask the patient fairly specific questions before administering certain drugs. Despite the clarity of the decisions, no court has specifically recognized a duty to take a medical history before treating the patient.

The courts have also construed the physician's general duty of "reasonable care and ordinary skill" to include the "specific" duty to respect the patient's statements indicating hypersensitivity to a particular drug.[79] Two cases are noteworthy.

In Yorsten v Pennell,[80] a hospital patient verbally indicated to doctors, interns, and nurses that he was allergic to penicillin and kept a note to that effect in his wallet. Despite the plaintiff's repeated admonitions and the wallet note, large doses of penicillin were administered after an operation to remove a bullet embedded in the patient's leg. When the plaintiff protested that he was allergic to penicillin, the defendant-physician simply walked away. The physician's failure to heed the plaintiff's statements was held to constitute actionable negligence.

In Decho v Shutkin, the plaintiff was treated by the defendant, a physician, for a ruptured intervertebral disc. The plaintiff told the defendant that he was allergic to adhesive tape. The plaintiff was placed in traction. Adhesive tape was affixed to the plaintiff's leg through the use of weights suspended from the end of the bed. The defendant applied "moleskin" – a type of adhesive tape – despite the patient's statements. The plaintiff immediately experienced pain in the leg. A nurse removed the moleskin and became nauseated by what she saw. The plaintiff completed the removal himself.

In holding that the foregoing evidence was sufficient to sustain a verdict for the plaintiff, the court held that the defendant failed to use the "care, skill and diligence ordinarily exercised by the other surgeons engaged in the same general neighborhood."[82]

B. *The Duty to Test for Hypersensitivity.* Courts are ready to impose liability upon a physician for failing to use "reliable" tests[83] to determine a patient's hypersensitivity to a drug prone to precipitate reactions and interactions, presuming that the test is economically "feasible."[84]

The cases supporting liability for failure to test for hypersensitivity are legion. In Love v Wolf,[85] a California intermediate appellate court held that a doctor who failed to conduct hyper-

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sensitivity tests before administering the drug chloromycetin was liable for malpractice. Mulder v Parke Davis & Co.,[86] a leading Minnesota decision, found liability on the part of a physican who failed to determine the plaintiff's susceptibility to chloromycetin by conducting blood tests. In a moment of specificity unusual for an appellate court dealing in the chimerical land of what a physician "should have done" to avert reaction, the court held that proper procedure would have included the counting of white blood cells before, during, and after the chloromycetin injections. The plaintiff ultimately suffered aplastic anemia, a recurrent reaction of the indiscriminate administration of chloromycetin.

Horace v Weyrauch[87] presented the issue of a physician's liability for a subcutaneous injection of an iodine compound used as a medium contrast for x-raying the kidneys as part of a pyelogram. Before injecting the iodine, the defendant-physician did not ask the plaintiff whether she had had any reactions or sensitivities to particular drugs, and did not make reliable, economical, and convenient tests to determine possible hypersensitivity to the iodine solution. The court held, as a matter of law, that the defending physician was negligent in not administering the hypersensitivity tests.

Perhaps the most often cited situation in the area of a physician's duty to conduct hypersensitivity tests is Yorsten v Pennell.[88] The plaintiff kept a note in his wallet indicating his allergies to penicillin and tetanus antitoxin. He was injured when a firearm discharged into his leg and fractured his fibula. Upon arriving at the hospital, the plaintiff showed the note to the nurse. Despite this disclosure, a junior intern failed to note the plaintiff's allergies on his hospital chart. Dr. Hatemic ordered 600,000 units of penicillin every four hours after the plaintiff's operation. The plaintiff testified he told all with whom he came into contact of his allergy to penicillin, but the penicillin injections kept coming. In one instance, the plaintiff told the defending physician of his penicillin allergy, and physician simply turned his back and walked away. An allergic skin reaction developed, and the jury found that the plaintiff suffered severe physical and personality changes as the result of the penicillin reaction. The court affirmed the trial court's holding that a physician is under a special duty to test for hypersensitivity to penicillin after the plaintiff repeatedly advises the defendant and his staff of the allergy.

The Pennsylvania Supreme Court determined in Incollingo v Ewing[89] that the administration of the antibiotic chloromycetin, without conducting blood tests or throat cultures to determine hypersensitivity, indicated negligence on the part of the physician.

The courts have carved two exceptions to the physician's duty to test for hypersensitivity. First, the physician is not under a duty to test where expert testimony adduced at trial indicates that such testing is not "economically feasible."[90] Second, the physician is not liable if he was aware of certain tests that could have been administered, but were generally unreliable and not ordinarily used in connection with the drug involved.[91]

C. *The Physician's Duty to Warn of Potential Reactions and Interactions.* As an outgrowth of the "informed consent" doctrine, the courts have declared that the physician must warn patients of potential reactions and interactions before administering medications.[92] On this point, the cases are numerous; their holdings are clear.

Liability has been imposed for failure to advise the patient of the risks of insulin and electroshock therapy.

Foley v United States[93] presents an interesting, indeed bizarre, factual situation. The plaintiff, a black man, was an outpatient at a veteran's administration hospital for treatment of a peptic ulcer. The plaintiff alleged certain pills prescribed by a physician employed by the hospital to induce sleep and relieve the ulcer produced exfoliative dermatitis which, in turn, precipitated the plaintiff's latent disposition to total depigmentation. Because of the medication, the plaintiff alleged, his hair and skin changed in color from black to white. The court, while unable to affirm the jury's findings because of insufficient evidence, indicated that the physician is obligated to warn the patient of potentially harmful reactions and interactions before administering or prescribing a particular drug.

Forrest L. Tozer and John E. Kasik, writing in the *1970 Legal Medicine Annual,* announced the existence of a *specific duty* to inform the patient of the possibility of adverse reactions.

> What communication or lack of communication will constitute malpractice of the lack-of-informed consent variety will depend on the nature of the physician's duty to warn. *Natanson v Kline* establishes an absolute duty in the context of a procedure with known dangerous potentials . . . Once the doctor has received his warning from the insistent detail man, . . . he, not the drug manufacturer, will be the target of any future patient who suffers from its use. And, unless he has warned the patient in accordance with his knowledge and has obtained the patient's informed consent to treatment with the drug, the patient may recover damages from him.[94]

D. *The Physician's Duty to Control the Reaction and to Use Reasonable Care to Prevent Reactions.* The reader will recall the force with which the elite of the medical profession urged physicians to control and observe the administration of medication to abate the possibility of drug reactions and interactions. The courts have been sporadic and unpredictable in enforcing such duties.

Neely v Saint Francis Hospital[95] is an important case. The plaintiff was a 37-year-old woman who sustained a ½" cut on the middle finger of her left hand and was given a penicillin shot to combat infection. Doctors employed by the defendant-hospital then administered a test to determine the plaintiff's sensitivity to tetanus antitoxin. In the test, a minute quantity of serum was injected between the layers of the plaintiff's skin, and she subsequently received 1,500 units of tetanus antitoxin by hypodermic needle. The defendant left the hospital. Shortly afterward, the sensitivity test began to show a positive reaction. Two weeks later, a "roaring" developed in the plaintiff's ears, and she returned to the

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