STROKE
REGISTRIES

Report of Subcommittee Task Force on Stroke Registries
to the Joint Council Subcommittee on Cerebrovascular Disease
and the Division of Regional Medical Programs

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Feasibility and Value

for Regional Medical Programs

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September 15, 1967

SUBCOMMITTEE TASK FORCE ON STROKE REGISTRIES

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TABLE OF CONTENTS

The Subcommittee Task Force on Stroke Registries was appointed to assist the Joint Council Subcommittee on Cerebrovascular Disease and the Division of Regional Medical Programs. Increasing knowledge about precursors of stroke, possible preventive and diagnostic aids, and more accessible medical care have served to intensify interest in controlling this nation's third leading cause of death. Since many stroke victims do not die, but experience prolonged, often profound disability, salvage through rehabilitation and service innovations places new responsibilities upon communities and their health resources. The advent of government-financed health insurance for the aged and of liberalized health services for persons of low income strain our already insufficient medical manpower and facilities. The Regional Medical Programs are focused on closing the gap between health needs and available knowledge. The Joint Council Subcommittee is supporting research efforts on stroke. Together, they are concerned with all factors which might prevent and treat stroke in our population.

Precedents in other disease areas are hardly sufficient to justify indiscriminate proliferation of stroke registries to aid either research or service. As the number of such applications is sizeable, and the need to establish policy on support is immediate, the Subcommittee Task Force was given this general question:

To what extent should registries, for heart, cancer, and particularly stroke, be supported?

The Subcommittee Task Force was asked to examine this pragmatic question in light of the need for stroke registries as they may relate to research, community planning and service, and in light of various techniques used in the past and at present to enrich knowledge of stroke and its more effective management. (Appendix A)

The Subcommittee Task Force attempted to develop policy by asking itself some provocative questions:

What type of quantitative information is needed by a community program addressed to combating stroke?

Once the purpose of a community program is delineated, what is the most effective data system to employ?

What is a registry?

The Subcommittee recognized that registries are but one form of statistical data management. All general safeguards to insure quality of data are as applicable to registries as to any other form of statistical data collection (e.g., specificity of definition, completeness of reporting, accuracy of diagnosis).

The recommendations of the Subcommittee Task Force, summarized below, pertain to the underlying questions which must be answered before allocations are made, and to some of the operational risks and scientific dividends incumbent on registry development.

If some recommendations seem obvious, they reflect experience with other disease registries. Restatement in this context may reinforce the complexity of detail essential to the development of registries for stroke.

If the recommendations appear guarded, it is because the Subcommittee was in accord that while the concept of a registry for stroke may have merit in the hands of an experienced, resourceful staff, the wholesale encouragement of stroke registries is unwarranted. Both the experience of registries conducted primarily for case management, as in the infectious diseases, and that for research, as in cancer, suggests that the registry is not necessarily an ideal data system. It is only as good as the conception and consistency of operation; it is only as complete as the unflagging persistence of its managers; and while the full creative potential of a registry may not as yet have been realized, for both service and research goals, application of this instrument to stroke should be made cautiously.

The guidelines advanced in this report are intended to provide general direction for the planning and support of stroke registries by the Regional Medical Programs. The Subcommittee Task Force does not feel it could do more, at this time, for there is insufficient experience with stroke registries to formulate highly specific rules about their development and operation. In fact, it would be presumptive to do more than encourage experimentation and flexibility, based on individual regional capabilities. Nonetheless, based on registry experience with other diseases, and examining some of the inherent differences presented by stroke, these guidelines should be of value to those concerned with stroke registries.

The Subcommittee Task Force is in accord that such development deserves close observation. Provision should be made to monitor developments, evaluating these guidelines as experience bears them out.

SUMMARY OF RECOMMENDATIONS

Support Policies

1. The needs of a regional program should dictate the extent and type of data system developed.

2. Stroke registries should be supported, discriminately, on a demonstration and evaluation basis, before a major commitment to a large-scale program of registry support is made by the Regional Medical Programs. Regions unable to develop stroke registries might consider performing one-time surveys or studies to delineate the extent of stroke in a given region or community.

3. Development of stroke registries exclusively for epidemiologic research purposes should be carefully considered. It is hoped that the potentials of epidemiologic research may be integrated into service-oriented registries.

4. Development of "stroke awareness" should accompany any organized program concerned with stroke. Plans for regional stroke programs should include educational and promotional elements. There are such potentials inherent in any stroke record-keeping system--and particularly in registries--which should be exploited as an integral part of any regional stroke program.

5. If registries are to be supported, the Regional Medical Programs must consider concurrent support of adequate manpower training, to develop personnel qualified to deal with the data collection and maintenance problems.

6. Given support, the financial commitment of stroke registries must be adequate to meet the stated goals of the program, and must be long-term--even for as long as five to ten years.

Registry Principles

7. The definition of stroke adopted for any data system should be designed to serve regional program needs.* A broad definition will yield more cases for inclusion in a system, from which pertinent cases can be selected for special study.

8. Specific dividends which are anticipated for participating patients, physicians and community agencies, should be delineated, and the methods of securing them should be built into stroke registry proposals to the Division of Regional Medical Programs.

Operational Guidelines

9. In any proposal for new experimental data systems, such as stroke registries, methods for the evaluation of the proposed system should be incorporated, including specific methodology for quality control of data.

10. The confidentiality policy of a stroke registry must be clearly specified in advance of establishing a registry--and it must be scrutinized throughout the operation to assure compliance.

11. Data requirements should be geared to the minimum needed by the program; "nice to know about" items that cannot be obtained uniformly in a mass data system, and items without identified purpose, should not be collected.

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* If there is an intent to make comparisons between regional programs, comparability of initial broad definitions is essential.

BACKGROUND

Functions of the Regional Medical Programs

The primary goal of the Regional Medical Programs is to upgrade the level of patient care for individuals with heart disease, cancer and stroke, and other related diseases. Through a network of integrated regional resources, diagnostic, therapeutic and rehabilitative services can be concentrated, for example, on stroke patients (though not to the exclusion of the other two disease entities). While opportunities will undoubtedly arise secondarily for research and training, the primary emphasis is on rendering the highest quality of service to ill and potentially ill persons in a given region.

Present State of Epidemiologic Knowledge Concerning Stroke

Information on the incidence of stroke is very limited. It is based almost entirely on three community studies and covers chiefly white populations. Mortality from stroke is high, as these studies confirm; roughly 50 percent of those persons reported as experiencing a major stroke die within a month, 66 percent within 6 months.

Prevalence information is extremely incomplete. Neither the National Health Interview Survey or Health Examination Survey provided prevalence information on cerebrovascular disease.

Data on cerebrovascular cases might be obtained by a survey of physicians and hospitals. However, data on TIA's (transient ischemic attacks) cannot be so obtained, since many persons experiencing such symptoms do not seek medical attention. The usefulness of population surveys for obtaining information concerning the occurrence of TIA's should be explored.

Existing information suggests that the incidence of ischemic stroke is higher among whites than nonwhites, who are influence more by hypertension, thus resulting in more hemorrhage and less thrombosis. This may indicate that stroke is a different disease among nonwhites. Regional programs should confirm whether such difference does exist and recognize the implications of this possible difference.

Data deficits concerning stroke are substantial. The community surveys yield small numbers of strokes. Complete classification as to type of stroke does not appear in these data. Prevalence data are incomplete. Incidence and other information regarding the TIA syndrome are not included (except for a survey currently being planned).

Disease Registries

Of the many record-keeping systems employed to describe or scrutinize health status, registries are possibly the oldest. John Graunt examined the London Bills of Mortality, which were records of births and deaths based on parish registers, as early as 1662. Parish registers had existed in England, many of her colonial possessions, and other European nations for more than a century when Graunt made his "natural and political observations." In France, the keeping of parish registers--serving as basic census rolls--was made compulsory in 1539; from 1670 on, they were used by Colbert as a source of statistics for Paris.[1]

The utilization of registries can improve the understanding and the estimate of the extent of epidemic disease. Scientific, epidemiological methodology has relied increasingly on the use of registers. The sophisticated application of registers, for management or epidemiological purposes, has spawned what we know as disease registries. The health sciences are recognizing new uses of registries--to grapple with projections of manpower and facilities, for example. As a fundamental tool in recording information upon which medical and public health judgments can be made, the registry concept has been applied with varying degrees of success.

Registries to assist in the management of infectious diseases were developed in the last century; tuberculosis, encephalitis, leprosy, venereal disease come to mind. Their current value lies in keeping track of cases and recording information leading to identification and treatment of disease contacts. Several types of registries dealing with cancer were developed in recent decades.

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[1] Gear, H. S., Biraud, Y., Swaroop, S. International Work in Health Statistics, 1948-1958. Geneva, World Health Organization, 1961, p. 5.

There is the "special purpose" cancer registry, limited to collection and analysis of data on a single type of cancer, whose purpose is chiefly educational and reference. The epidemiological or central cancer registry may contain information from which the incidence and prevalence of various forms of cancer can be determined. The emphasis of such a centralized cancer registry, depending on a large volume of information--preferably population-based--is on epidemiology, a basis for understanding survivorship, identifying etiological clues, giving directions for basic research. A hospital evaluatory cancer registry, designed to measure the quantity and quality of medical care for cancer patients in a given institution, is chiefly for case management, occasionally only for survival follow-up purposes. Such a registry may meet accreditation standards set by the American College of Surgeons, which defines the hospital registry as "a repository of records containing pertinent information on diagnosis, treatment, follow-up, and end results on all patients . . . admitted as inpatients or to the outpatient department of a given hospital."

An exhaustive study of registry practice was not undertaken by the Subcommittee. However, a number of recent endeavors were identified. In recent years, a special purpose registry has been established for beryllium disease, by which voluntary submissions of biopsy and autopsy material assist in differentiating this condition and evaluating the effects of treatment. The American Medical Association's voluntary registers on blood dyscrasias (1953) and on adverse drug reactions (1964) are also special purpose, chiefly to enhance practitioner knowledge. Registries are developing in the field of mental health, based in part on the lengthy record-keeping heritage of mental hospitals.

In 1950-51, the Public Health Conference on Records and Statistics noted:

> "In the operation of health service programs
> (for example, in cancer control), one of the
> most useful administrative tools is a register
> of all cases or suspects. If it is set up to
> provide a continuous case history in abstract,
> and a mechanism for scheduling follow-up, it
> can be well worth the effort and personnel
> required to keep it going. In the recent
> mushrooming of registers, however, they have
> sometimes been operated for their own sake, or
> in the vague belief that they might lead to
> interesting statistics or to epidemiological
> clues to illness factors.

"During the past two years our Conference, with
the aid of some 44 individuals and agencies
that reviewed a preliminary draft, spelled out
a set of principles and recommended practices
to serve as a general guide to statisticians
and health directors in the purposes and
operation of program registers.

"In essence, we recommended that registers
should be intimately tied to the actual provi-
sion of services to patients and that they
should be operated at the same administrative
level where the service program is operating.
It would seem unnecessary to maintain 'super-
registers' that contain the same information
as local or hospital registers. For statisti-
cal purposes and for maintenance of a clearance
system, selected items of information may be
forwarded to a higher, central system--as for
example from a local health unit to the State
level."

The value of disease registries--"super registers" or
other species--varies appreciably with the original goals, and
the abilities to satisfy them. The apparent popularity of this
form of record system, as reflected in the more than 30 appli-
cations to date to fund stroke and multi-disease registries
received by the Division of Regional Medical Programs, makes it all
the more important to understand what a register and a registry
can and cannot do--by defining their potential capabilities and
limitations. Whether registries, singly or collectively, can
not only reflect health status, but also be instrumental in improv-
ing it, depends in part on such definition.

DEFINITIONS

Register, Registry

The Subcommittee considered two definitions of a registry. The first was felt to be too restricted in its health orientation and too encompassing of operational features. It defined a registry as:

> a system of data collection and retrieval
> concerned with the characteristics, diagnosis,
> treatment and follow-up of patients in a
> particular disease category.

This definition describes the registries currently operating for cancer, and, less explicitly, for tuberculosis and mental illness.

A more generalized definition was felt to be more practical:

register: a listing of persons or the accumulated body of data recorded on these persons

registry: the system and process involved in the support, management and operation of a register. A registry may be within an institution, within a program area, or may pertain to a geographic area.

In redefining a register and a registry, the Subcommittee took cognizance of the limitations of existing centralized chronic disease registries. They were not designed primarily as management tools, assisting the patient who is enrolled. Their use is substantially statistical, epidemiologic, and for the good of future patients rather than those currently under care. Individual hospital registries, with medical management as a primary purpose, may be integrated into a central, epidemiologically-oriented registry. The meticulously maintained confidential nature of central cancer registry information, for example, while not jeopardizing hospitals, may, strangely, mitigate against the best interests of the patient. In present practice, if a patient seeks treatment outside of the hospital in which his case is enrolled, useful historical information on his registry file may not necessarily be forward by the central cancer registry in that form. Confidentiality is preserved--but optimum medical care may not be.

The Subcommittee agreed that if stroke prevalence data or estimates of the incidence of stroke are the principal pieces of information desired, a survey will achieve the goal quicker and more economically than a registry which must be supported over a long period of time.

Stroke

The Subcommittee did not attempt to assume the task of the Stroke Nomenclature Committee (NINDB), which has been attempting to characterize stroke for many months. Of value to the Subcommittee discussions was the fact that stroke is not easy to define or characterize, and that no hard and fast word description would be acceptable to all persons working with the condition. Definition was discussed as it related to specifying input for any data system adopted which pertains to stroke.

The Subcommittee considered several definitions, varying in specificity. The most explicit describes a stroke as being "a neurological deficit or cerebral dysfunction caused by a disturbance of the blood supply of the brain." Further characterization, which may be valid in both management and research uses of data, includes:

1. Duration

   a. transient
   b. prolonged
   c. permanent

2. Etiology

   a. ischemia
   b. infarction
   c. hemorrhage

3. Extent

   a. focal dysfunction
   b. general dysfunction

4. Temporal Description (by history)

   a. TIA
   b. prolonged neurological deficit with eventual complete recovery
   c. persistent neurological deficit with partial recovery
   d. persistent neurological deficit without significant recovery

e. persistent neurological deficit or
   persistent stroke prior to TIA symptoms
f. prior persistent defect with present
   TIA symptoms

5. Temporal Description (by examination)

   a. actively improving
   b. actively worsening
   c. actively changing deficit
   d. not changing

Another working but less precise definition is: recording any case that a physician says is stroke (since he is treating it as such). For many purposes this looser definition might be quite adequate. However, this definition eliminates persons experiencing transient symptoms, who might well not be under a doctor's care, let alone be diagnosed as "stroke prone." Nor would this definition be entirely sufficient in developing indices to measure the need for specific services and facilities.

An equally loose definition, which would bring far greater numbers into the "net" of data system cases, is all persons having "whatever people call stroke." Registry personnel would then, it is hoped, have the opportunity to further categorize these reported cases. A loose definition requires collection of sufficient information to categorize with respect to diagnostic reliability--differentiating diagnoses made by a physician from cases identified by information supplied by an individual patient.

If the purpose of the data system is to provide measurable information, as well as be an "information and referral" focus, this latter definition is the most embracing. The Subcommittee feels that over-refinement of definition may supersede the purposes for which the data system is designed. If a definition of stroke which is overly precise is adopted by a data system, the uses of the data system may be prematurely contracted--and not be comparable with another system's "overly precise" definition. It was felt more productive to use a reasonably loose definition of stroke initially--one specifically designed to capture the cases meeting program objectives. Categorization could be performed by a central bureau, according to fixed definitions. When many persons, such as all physicians in a community and all nursing homes, are asked to categorize potential cases, the decisions tend to become less objective. Greater numbers of persons would benefit from inclusion in the data system, if the initial net is not finely woven by tight definitions. In stroke, where characterization cannot be based on a supportive clinical test, such as an EKG or a biopsy, selective bias becomes likely. Moreover, the average

practitioner is not sophisticated enough to make hard classifications for stroke.

It is believed that a short-range objective of a registry should sacrifice a degree of specificity for sensitivity. Refinement and definition will come by careful studies of registry samples identified through this form of reporting.

As information is generated on all suspect stroke cases, and the relationship of such matters as earlier diagnosis and use of specific therapeutic measures is documented, fewer patients will be misdiagnosed, characterization of the disease will be enhanced, and the data system might eventually provide information to describe the natural history of specific stroke entities.

Recommendation: The definition of stroke adopted for any data system should be designed to serve regional medical program purposes.* A broad definition will yield more cases for inclusion in a system, from which pertinent cases can be selected for special study.

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* If there is an intent to make comparisons between regional programs, comparability of initial broad definitions is essential.

DATA SYSTEMS TO ASSIST A REGIONAL PROGRAM ON STROKE

It would be useful for conducting an effective regional program on stroke to have better knowledge of the disease:

- the natural history* of stroke as a disease

- incidence and prevalence of stroke in the region

- opportunities for earlier detection and prevention

- evaluation of various treatment modalities in various medical facilities

- the rehabilitation process

- cases included in the region's program

To provide a partial description of the natural history of stroke as a disease, cross-sectional surveys conducted periodically (possibly by a national office) might be one means. Not only would an initial survey describe the prevalence of stroke in a given population, but it would initiate a reservoir of individuals for in-depth analysis. Surveys, with certain limitations of validity, can provide estimates of incidence. Although follow-up is difficult, repeated surveys can also provide survival information.

Opportunities for earlier detection and application of preventive measures are enhanced by a data system with substantial input over time--a type of registry, for example, as we know registries today. Our approach to stroke prevention in the past has been tertiary--chiefly after the fact of disease assault. Primary and secondary prevention** could be practiced among the "stroke prone," high-risk individuals identified as experiencing TIA's. If a system delineated the "stroke prone" individual, and referred him

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* Natural history is defined as the description of an illness from onset through outcome, including treatment. It constitutes descriptive epidemiology, as opposed to analytical.

** Primary prevention - absolute avoidance of a disease.
Secondary prevention - early detection and prompt, adequate treatment after disease has occurred, to prevent disability or premature death.

for detailed clinical study, earlier detection and prevention could
be effective.

. Evaluation of both treatment modalities and the rehabili-
tation process could be enriched by a data system which followed
stroke patients over time, systematically. A mechanism which
retained considerable information on stroke patients, such as a
registry, could be used in taking discrete samples for in-depth
study.

For several program needs, then, a data system which
identifies and keeps track of persons displaying symptoms, exper-
iencing massive strokes, and ultimately dying of stroke--or other
causes--has considerable merit. In evaluation of program efforts,
there can be too much reliance on retrospective information ob-
tained in a second or sequential survey. A registry with a built-in,
follow-up mechanism permits evaluation of the experience of persons
brought into the cohort at different times in a region's stroke
program. For example, persons in a given region registered in
1966, prior to development of regional cooperative arrangements,
constitute one cohort whose survivorship and whose ability to
obtain service in the community may differ from the cohort
registered in 1969.

Specific program needs, in a particular region, ultimately
must dictate the types of data and the degree of refinement desired.
The magnitude of stroke prevalence in a given region (or community)
might best be derived by a one-time survey for base line information
at the beginning of the regional program. This information could be
correlated with already existing data such as demographic character-
istics of the population, manpower and service resources available
in the community.

No single system of data collection and analysis will
achieve all desired goals of a regional stroke program. The merits
of surveys, registries, and other data systems must be carefully
gauged--with such factors as cost, availability of experienced
personnel, and capable direction balanced against ultimate program
goals.

It is hoped that needed information can be collected on
a variety of suitable techniques, so that the usefulness of a registry
system can be measured against that of a survey or other method.
Means of performing such critical evaluation should be carefully
specified in any proposal for new experimental data systems, such
as stroke registries.

Recommendation: The needs of a regional program should dictate the extent and type of data system developed.

Recommendation: In any proposal for new experimental data systems, such as stroke registries, methods for the evaluation of the proposed system should be incorporated, including specific methodology for quality control of data.

FUNCTIONS OF A STROKE REGISTRY

Service Functions

Accepting the definition that a register is essentially a listing of names, and a registry the system and process to support, manage and operate registers, some of the potential merits of a stroke registry can be appraised.

The Subcommittee concurred that, for the purposes of Regional Medical Programs generally, the service (management) functions of a stroke registry outweigh the research functions, by having both short-range impact on patient care and by meeting long-range community and regional goals.

A stroke record-keeping system should be based on what the particular regional program aims to do for its population. A service-oriented registry system, for example, could provide specific information to the regional program pertaining to:

- the early detection of the high-risk stroke individual (persons experiencing TIA's; perhaps the hypertensive or diabetic individual, etc.)

- improved quality of diagnosis, through better definition and characterization of the disease, with implicit feedback to physician

- proper management--keeping the patient alive to receive rehabilitative and restorative measures

- adequate follow-up, minimizing permanent dysfunction and serving the needs of the long-term stroke patient

Other dividends to the community of a primarily service-oriented stroke registry include:

- stimulation of "stroke consciousness"

- maximal effectiveness of skilled personnel and resources available for intensive stroke care

- identification of stroke cases amenable to
  specialized techniques or meriting intensive study

- informational material from which program
  evaluation can be made

Case identification may be one of the most valuable dividends
of a stroke registry. More important, the registry encourages case
keeping. It provides a mechanism for follow-up, a potential resource
of persons for whom diagnosis and treatment may be lifesaving. A
registry may not only identify and hold a potential stroke patient,
but it may also serve the needs of the patient with the completed
stroke--the patient who may be identified only after initial
hospitalization. All too often, after initial hospitalization and
some restorative services, the completed stroke patient deteriorates
quickly from various degrees of neglect. If the registry is an
effective management tool, the completed stroke patient with profound
disability may be referred to a center where he can continue to
receive essential services.

Once the purposes of a stroke registry are identified, input
data must be selected accordingly. For example, to meet individual
regional goals the following sources of input, among others, would
have to be considered:

- all physicians reporting on all suspicious
  and recognized stroke patients

- all individuals in a community, reached first
  by questionnaire and then screened according to
  symptoms

- hospital data only

- persons coming to the attention of a regional
  center

- individuals enrolled in recognized rehabili-
  tation facilities

- death certificates, for incidence and
  prevalence data.

With time, and careful analysis of input data, knowledge concerning various treatment modalities could be enriched, and clinical diagnostic skills improved. The registry may not be initially as useful to the stroke center specialist. However, what is learned from a registry incorporated as an evaluation instrument at a stroke center can be diffused to clinicians generally; the load placed on stroke centers could lighten, local services could be upgraded, the management of stroke could generally improve.

The dividends to the community and its people of a service-oriented central stroke registry are potentially numerous--and more immediate than realized by today's cancer registries, for example. If the purpose of a community (or regional) stroke registry is to provide information, referral and follow-up, the data system forges links between community resources expressly meeting the intent of the Regional Medical Program. It brings together the pertinent agencies and individuals, cooperatively, for a concerted venture in which benefits are promptly forthcoming. The experience of patients in the community and the services they use are detailed and evaluated. The research dividends of a stroke registry--even if the preeminent purpose is service-oriented--may be many years in the making. The management dividends are immediately evident--and immediately useful in maximizing the limited supply of manpower and facilities, in fostering innovations in delivery of services, secured by a careful record system which is geared to help living members of a community.

The educational dividends of a stroke registry which is service-oriented are substantial--and of especial importance. The public needs to develop a stroke consciousness, as achieved for cancer, alerting both physicians and laymen to symptoms recognized as likely precursors of stroke and to preventive measures which could mitigate the severity of stroke. Any record-keeping system, the Subcommittee believes, should include built-in educational and promotional elements. The service-oriented stroke registry offers a means to narrow the time gap between knowledge and its application; but the proposals for stroke registries should clearly delineate the means by which this new, often unfamiliar type of knowledge can be transmitted effectively. A stroke registry which is community- and service-oriented will generate statistics, fairly promptly, to bring resource deficiencies to light. Such findings will have an influence on legislative activities in the region, providing sound information upon which allocations might be awarded on a priority basis to correct deficiencies. It is expected that this type of stroke registry will stimulate initiative and imaginative use of existing resources, keeping the Regional Medical Program's focus on stroke vital and viable.

For the physician, the education can also be subtle. Just by completing and signing periodic follow-up forms on cases he has diagnosed or treated, he becomes more aware of stroke management. If he is given feedback which is useful to him, he is even more motivated to cooperate. A service-oriented registry, which has stated benefits to the persons enrolled (both patients and physicians), is apt to be more complete than a registry established chiefly for "statistical" purposes. The Subcommittee endorses the concept that whatever record system is established, for the good of a regional program, it must offer some tangible, relatively prompt benefit to the participants.

The Subcommittee was reminded that in Saskatchewan, Canada, where health services are wholly financed by the government, annual recall of registered patients is highly successful. If the patient is recalled through a registry for a costly work-up, his view of the registry might be jaundiced. Recall might not pose a problem for persons receiving government-financed health insurance. But for individuals who cannot easily afford medical attention, cooperation might be poor unless the recall was coupled with reasonable fees or even partially defrayed costs. Arousing stroke consciousness through an active service- and education-oriented registry should include an appreciation of factors, such as costs of personal health services, which could deter successful program operation.

The registry could be a source for differentiating various types of stroke and give management clues to identify cases amenable to surgery, angiography, anticoagulants, for example. Groups of cases experiencing bizarre symptoms could be selected from the registry and referred to stroke centers for intensive clinical study and management. Hence, a stroke registry could systematically assist in maximizing the effectiveness of limited personnel and resources performing highly specialized diagnosis and work-up on stroke patients.

It is clear, however, that the registry itself does not provide "service." It functions as a record-keeping mechanism which, by its very recording capacity, can keep track of services rendered to persons enrolled, and can alert the service-giving agencies, when services are desirable.

A service-oriented registry is a way of "keeping your finger on and being in contact with all of the community whom you may eventually want to reach." It provides a continuing follow-up scheme which could answer such questions as:

Is the stroke program functioning?

What is the service experience of persons enrolled?

What is the survivorship of registry patients
first entered via hospital emergency services
compared with that of persons first entered
via nursing homes?

What are the transportation needs of completed
stroke patients?

What is the rehabilitation accomplishment?

Using the registry as a logical means to "keep your finger"
on the pulse of all community endeavors related to stroke is favored by
the Subcommittee. The establishment of stroke registries merely for
status or accreditation is recognized as a dubious practice. Whatever
record system is selected to implement a regional program for stroke,
the benefits to the contributors should be foremost.

It is quite probable that some of the regions may not have the
need, interest, personnel or experience to organize and operate a
complete, service-oriented stroke registry, as described here. The
type and amount of record keeping in each of the regions will vary
with the needs and capabilities of the program. Regions which do not
include a full-scale registry operation might consider a simple
alphabetic index card system, limited to demographic and referral
information on all patients included in the program. Even without
follow-up, the index could provide basic counts of patients which would
be useful to the program. The register could be used as the basis for
a more complete registry system, if that was indicated at a future time.

Recommendation: Stroke registries should be supported,
discriminately, on a demonstration and
evaluation basis, before a major commit-
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support is made by the Regional Medical
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Recommendation: Specific dividends which are anticipated
for participating patients, physicians
and community agencies, should be delineated,
and the methods of securing them should be
built into stroke registry proposals to the
Division of Regional Medical Programs.

Research Functions

The Subcommittee was in accord that a stroke registry designed exclusively for epidemiologic or research purposes would be of limited use in the Regional Medical Programs. Depending on regional program goals, the research dividends of a stroke registry might be modest or elaborate.

The advantages of a stroke registry over repeated cross-sectional surveys in providing incidence data are substantial. A registry, which has some reasonably prompt feedback to the supplying practitioner, for example, is apt to contain more complete information, given more willingly. The follow-up aspects of a registry system may reduce the degree of bias introduced in surveys by uneven interviewing techniques.

Another cogent asset of a registry over repeated cross-sectional surveys is maintaining information on defined cohorts. No "true cohort" exists in a cross-sectional survey, since individuals who have died just prior to the survey cannot be surveyed. In a registry, which has input on a continuing basis, from a variety of sources, information tends to be more complete and immediate. The reliability of retrospective data, as collected in surveys, may be poor.

A central registry which does not cover an entire population can be used to describe only the patients served by the program, their disease and treatment, and their survival. It can also be used as a source of cases for evaluative studies.

A registry based on a specified denominator population will enable incidence and prevalence data to be generated. However, it is important to recognize that even a population-based registry is representative only of experience in that population--and will not necessarily yield data that can be generalized to other populations.

The payoff on the epidemiologic potential of a registry, especially that relating to survival, may not be evident for as long as five or even ten years after the system begins. Maintaining enthusiasm of contributors is difficult, if dividends, such as discussed in the Service section, are not forthcoming sooner.

It was pointed out that a regional stroke registry should not be developed without full consideration of the epidemiological and clinical research potentials. For example, in Baltimore, where a service-research stroke registry is being developed, a probability

sample of the general population over age 45 is being independently conducted to determine the prevalence of TIA symptoms. Such studies will be used to refine definitions of high-risk individuals to be included in the registry program.

While a community or regional registry can only represent the experience of that locale, it goes beyond the scope of individual hospital-based registries. A community-based registry would not contain the selective bias of single hospital registries. This would be especially true if the reporting sources included physicians and other community sources. For stroke, this breadth of reporting input is especially important. A community-based stroke registry, for both service and research ends, should probably include reporting from physicians, nursing and convalescent homes, the Visiting Nurse Association and other resources brought to bear on management and rehabilitation of stroke patients. In fact, a desirable byproduct of a registry is to keep people engaged in rehabilitative services, by the very information a registry can provide.

Clinical research will also be assisted by a properly established record system. Provided that pertinent information is specifically incorporated into the system, the fruits of epidemiological analysis will eventually give clues for understanding the relationship of stroke to associated diseases, for relating treatment modalities to end results, and for studying the etiologic and prognostic significance of demographic and other factors. The long-term research findings of a stroke registry certainly will have an impact on the clinician in the community--who is ultimately charged with the greatest responsibility in managing stroke.

In summary, the unique research opportunities of a regional stroke registry as a data system organized to obtain such information include:

- avoiding selective biases inherent in most information on stroke today

- improved incidence data, if characteristics of stroke are well defined and the registry includes all cases in a defined population area

- improved survivorship information

- correlation of incidence, survivorship and mortality data, to make interpretation of stroke mortality data more meaningful

- a resource for in-depth investigations, using sampling methods (to explore factors of race, sex, family history, etc.)

- a resource for evaluating community efforts, program success

- an active referral system for keeping track of individuals needing available services (screening, diagnosis, treatment, rehabilitation, supportive services)

- strengthened lines of communication between clinical researchers at "stroke centers" and local clinicians

Recommendation: Development of stroke registries exclusively for epidemiologic research purposes should be carefully considered. It is hoped that the potentials of epidemiologic research may be integrated into service-oriented registries.

OPERATIONAL GUIDELINES AND REQUIREMENTS

The Subcommittee recognized that, while the nature of each regional stroke record system might be quite distinctive, there are operating guidelines which all such systems should observe:

1. There must be a careful delineation of the functions or uses of the particular record system (stroke registry) as they relate to the purposes and goals of the region's program.

2. The sources of input information should be carefully selected to relate to the regional program's overall goals--in turn, dependent on the prevalence of stroke and availability of resources in the given community. Physicians, for example, may be a substantial source of information. Since many hospitals do not presently take long-term stroke patients, other appropriate community resources--therapists, nursing homes, rehabilitation centers--should be seriously appraised to contribute to the data system's "input."

3. The active cooperation of participants (pro-viders of input information) must be enlisted. A personal visit to the individual physician, explaining the features of the program, might be augmented by community activities informing participating agencies and individuals of the program goals.

4. The physician (who may be the chief contributor of input data) should be given a guaranteed dividend for his time--either a clearly-specified form of data feedback, a nominal payment, or both.

5. Responsibility and authority for the conduct of the registry should be vested in a competent, full-time staff. Medical and statistical staff are essential; librarians and social workers may be desirable for follow-up. Performance of this activity by voluntary efforts, a committee, or other less committed personnel should be avoided.

6. Training centers should be established and function in conjunction with registry development, to create adequate supplies of skilled manpower.

7. A central registry staff should be well schooled in records management, statistics and epidemiology, to maximize using the data generated.

8. Establishment of a stroke registry, whether primarily for service or research goals, is usually a long-term commitment. Unless 5 to 10 years' involvement is anticipated, the dividends may be modest for the enormous effort in mounting this type of record system.

9. A group of competent, respected physicians should be enlisted to influence receptivity to a stroke registry in the professional community (both individual practitioners and community agencies). Offering consultation for confirmation of the diagnosis and patient management might be an incentive to program participation by community practitioners.

10. In both development and promotion of a stroke registry, program merits should be emphasized over those of the registry mechanism itself. The comparatively prompt dividends to the community, and to the practicing physician, are clearly more acceptable--if not more justifiable--than the distant reward of statistical analysis. The registry should be conceived and developed as an active, service mechanism (both for the management of the patient and the study of the data generated)--not as a static repository of data.

11. The educational component of a regional stroke program should be advanced simultaneously, creating stroke consciousness. The educational component should help dispel the fatalistic approach of the public that stroke is a natural, unavoidable event, and pave the way for greater acceptance of preventive measures in part revealed through analysis of registry data.

Confidentiality

Each regional stroke program should assess the nature of confidentiality to meet program goals. The welfare of the patient under management is paramount, but confidentiality should be considered in relation to potential benefits accruing to physicians, and to hospitals providing care. Each program should ask these questions, before a commitment to a stroke registry is made: What degree of confidentiality best serves ultimate program purposes? What might have to be sacrificed to assure more active use of information fed into the registry? If the goals are chiefly service, strict standards of confidentiality presently used in cancer multi-hospital-based registries might not be suitable.

The Subcommittee reviewed the confidentiality safeguards being observed by the California Tumor Registry. Here, transmittal of information via the central registry is not permitted from hospital to hospital. If a physician or hospital desires information on a specific patient who has been admitted to another hospital, he cannot use the central California Tumor Registry to extract it or even to determine the names of other hospitals where a registered cancer patient received other services unless the permission of the patient or his family has been obtained. While this policy creates some obstacles toward efficient care, the system maintains the full trust of participating hospitals.

The Baltimore project, involving a community program on stroke, uses an optical scanner to read and select cases--deliberately to minimize the numbers of persons having access to the information. The scanner selects and codes the clinical record, and cards are punched from this code sheet, mechanically. The final data file is a computer tape.

The greater the detail of information collected, the greater the need to preserve confidentiality. The ethical questions become pointed, inescapable. It was suggested that the stringent confidentiality maintained in cancer or mental health registries might not be suitable for stroke. But overly free access to information on stroke patients, other committee members stated, is not desirable. If the registry information is available to anyone in the community, the victim of stroke might well face discrimination in purchasing insurance, in being hired for work, in obtaining a driver's license. It was pointed out that, in states where cancer is a legally reportable disease, the law is unenforceable and the reporting of cancer cases is generally incomplete.

The Subcommittee concurred that a fundamental principle
pertaining to the confidential nature of a registry is to convince
the reporting agencies and individuals that there will be no patient
contact without specific prior approval--nor indiscriminate use of
the information assembled. The physician who voluntarily agrees
to submit information may or may not ask the patient's permission
to do so. If the physician is to preserve the confidence of his
patient, he must be assured that the patient will not in any way
be exploited, through such a record system. It is felt that volun-
tary reporting of information--safeguarding the physician-patient
relationship--will not only yield more complete reporting, but
ultimately yield more usable results for the patient, the physician,
the community.

It will be absolutely necessary to obtain the approval
and cooperation of the medical and hospital community. One viola-
tion could destroy the entire labor invested and lose the confidence
of the physicians and public who nourish the registry.

Recommendation: The confidentiality policy of a
                  stroke registry must be clearly
                  specified in advance of estab-
                  lishing a registry--and it must
                  be scrutinized throughout the operation
                  to assure compliance.

Demands on a Physician's Time

Experience has indicated that a registry may have a "snowball" effect, each year increasing its burden on contributors to complete follow-up forms on enrolled registrants. There is apt to be less "snowball" effect with stroke than with cancer, however, since a large proportion of strokes currently prove fatal within 6 to 12 months. The Subcommittee concurred that a physician should be asked only to provide a reasonable minimum of information, simplified as much as possible by checklists. He will still have the educational experience of checking his records on given registrants, possibly using the follow-up form as a means of recalling patients. If only a reasonable minimum of information is elicited, physician cooperation is sustained. If feedback dividend is part of the physician's relationship to the registry, his cooperation may be strengthened. This "minimum" must be enough to meet all the predetermined purposes of the registry, or some information will have to be obtained in some supplementary fashion.

It is believed that salient, minimal information given on a follow-up basis will provide ample data from which special studies for more extensive information can be performed. It is not essential to have the physician complete elaborate dossiers annually, or more frequently, on all his referred cases. If the information he is asked to provide is selected carefully, related to the regional program's ultimate goals, evaluation can detect avenues for in-depth investigations, leads for service requirements and clinical inquiry.

Recommendation: Data requirements should be geared to the minimum needed by the program; "nice to know about" items that cannot be obtained uniformly in a mass data system, and items without identified purpose, should not be collected.

Manpower Requirements

Persons trained to do registry work, either in a central registry or transcribing from institutional records, are in very limited supply. At present, only one source of registry training is known: The Cancer Research Institute of the University of California, San Francisco. The present program is geared to instruct registry methods especially for individuals working in hospitals, abstracting cancer cases. (Expansion to central registry operation and more sophisticated statistical methods in obtaining registry data has been requested.)

It is imperative, therefore, that if registries for stroke-- where there is no registry experience--are to be developed, training resources must be developed concurrently. Training should be sponsored and supported on a national level. For certain recognized functions, training should precede or at least accompany registry development. Unique and new skills, for which training will need to be devised and supported, will become apparent, based on pilot operations. The potential resources for eliciting registry data for stroke are far more numerous and varied than hospitals, chiefly used for cancer registries, and health departments, chiefly used for infectious disease registries. It is believed that it will be several years before adequate supplies of qualified registry workers will be available--and that only if training is supported, planned, tested and conducted promptly.

Despite the assists of computer technology, considerable manipulation of data involves human beings. A proliferation of stroke registries in this country couldn't possibly produce valid qualitative or even quantitative results, unless considerable effort is expended in advance, instructing registry statistical and records personnel, and generating a "registry-thinking" supply of personnel to operate them. Recruiting of capable, motivated persons to develop and maintain useful registries will be difficult. It is possible that the new service orientation, while challenging, will present far more frustra- tions in both policy and operational matters than presently exists in data-oriented registries. Most crucial, perhaps, will be the medical management of the registry, since this will require physicians who are interested and knowledgeable in working with record systems oriented toward service and research.

Recommendation: If registries are to be supported, the Division of Regional Medical Programs must consider concurrent support of ade- quate manpower training to develop per- sonnel qualified to deal with the data collection and maintenance problems.

Machine (technology) Requirements

Those members of the Subcommittee experienced in large-scale data systems were agreed that the assists of machine technology, chiefly our modern computers, are invaluable. Computers and other machines can do a great deal, saving laborious hand operations which volumes of data would defeat. The potential of computers in this field is very great. But the paucity of experience and the rapid changes occurring in the computer field demand caution. Plans which offer "computer solutions" to complex records problems of input storage and retrieval should be evaluated very critically. Experimental programs in some regions should be encouraged, but wholesale adoption of systems which have not been proved operational should be avoided. Planning, collecting and processing information, evaluating quality, cleaning up errors, and analysis of data will still require trained personnel, using their hands and their brains. The operation of the California Tumor Registry, which contains over 300,000 individual cases followed from diagnosis through death, still requires considerable hand processing and coding before the data can be put on tape for computer use.

A system which is highly computerized increases the potential--and the appetite--for retrieval and analysis. This advantage, in absolute terms, must be balanced by available funds. The more data consumed and retrieved through greater reliability on computers--the greater budget needed to operate. Translating output into patient care, clinical research, or preventive measures takes considerable budget--and technical skill--both augmented by computer capabilities.

Costs

The costs of developing and operating a registry are substantial. No concrete estimates were made by the Subcommittee, but those experienced in registry development indicated that the costs are high--and they must be seriously balanced against the program needs. The California Tumor Registry (CTR) estimates that a hospital registry which includes life-time follow-up of a cancer case costs the contributing hospital a total of about $10 - $15. The CTR reimburses the hospital $3.10 per newly admitted case. In Baltimore, the developing stroke registry is considering reimbursing practitioners not for their own time but for secretarial service in abstracting the desired information.

It is difficult to predict the cost of a central stroke registry operation, since it will depend on the exact nature, size,

scope and diversity of a regional program. The guidelines offered by
the Subcommittee, in light of the very limited knowledge on this subject,
are:

- cost relates to the size and methodology
  of the operation (i.e., number of reporting
  institutions, methods used to obtain cases,
  number of cases)

- cost relates to the complexity and detail of
  information required

- cost relates to the definition of stroke
  used (e.g., including TIA's implies long
  survival, years of follow-up)

- cost relates to the expectations of analysis

- cost relates to the interest in and capability
  for performing special, in-depth studies

- cost, by necessity, will rise somewhat each year,
  for while the number of new cases may remain
  relatively stable, follow-up tends to "snowball"
  annually

What cannot be estimated at all are ultimate savings to
the community by having a registry which enables stroke patients to
be referred to services, to stimulate the development of needed
services, to control stroke by application of new knowledge. While
the costs of a stroke registry might spiral--and the commitment must
be a major commitment--if a regional program knows how it can use
the data system and its output for the betterment of the community,
the ultimate cost might not be so unreasonable.

It should be asserted that cost is only one factor in making
a commitment for a registry. The service dividends may be forthcoming
within a few years. But the scientific output, upon which new under-
standing of stroke and its influence in the community are based, may
be many years in the making. A commitment to a stroke registry must
be long-term. It is not the data system to produce instant knowledge
nor instant management assists. It is complex. It is as sensitive
and effective as the skill in its planning and operation. It is use-
ful only as it serves the purposes for which it is intended--and a

stroke registry will be useful only if it can be adapted or even sacrificed when those purposes change.

> Recommendation: Given support, the financial commit-
> ment of stroke registries must be
> adequate to meet the stated goals of
> the program and must be long-term
> --even for as long as five to ten years.

Tri-Part Disease Registries

Since a number of regional applications have proposed individual and collective registries for all three diseases--heart disease, cancer and stroke--the Subcommittee briefly considered policy guidelines on this point. Depending on the regional program's goals, combining the collection and storage functions of a tri-part registry might be feasible. One Subcommittee member felt that the collection process should be clearly separated for the three disease entities, although a follow-up and storage system could be centralized. Coding, especially, would have to be kept distinct by disease entity. Another member did not concur. If the intent is chiefly to have a centralized reporting system service of all hospitals (not physicians), competent medical records staff, not registries, may be the requisite components of a data system. If the objective is adequate follow-up --keeping the finger on the pulse of these three diseases in the community--three distinct reporting systems might not be required. The complexity of information sought by the system would certainly determine whether combinations would be feasible. If the information collected is relatively simple--and more detailed categorization is performed by a centralized staff--synthesis might be manageable.

APPENDIX A

Charge to Subcommittee Task Force on Stroke Registries

February 24, 1967

The intent of the Task Force on Stroke Registries would
be to examine the question of the need for stroke
registries as they may relate to research, community
planning, and service; examine the various techniques
utilized in the past and at the present time for regis-
tries in other disease areas; and make recommendations
about the need for stroke registries and what their
scientific and administrative characteristics would be.

It is expected that the Task Force's report will be
useful to not only the Joint Council Subcommittee on
Cerebrovascular Disease in its program planning activities,
but also to the Regional Medical Programs in
consideration of planning and operational grants for
the development of stroke registries.