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## Original Contributions

# The Stroke Data Bank: Design, Methods, and Baseline Characteristics

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**The National Institute of Neurological and Communicative Disorders and Stroke initiated the Stroke Data Bank, which is a multicenter project to prospectively collect data on the clinical course and sequelae of stroke. Additional objectives were to provide information that would enable a standard diagnostic clinical evaluation, to identify prognostic factors, and to provide planning data for future studies. A brief description of the structure and methods precede the baseline characterization of 1,805 patients enrolled in the Stroke Data Bank between July 1983 and June 1986. Two thirds of these patients were admitted within 24 hours after stroke onset. Medical history, neurologic history, and hospitalization summaries are presented separately for the following stroke subtypes: infarction, unknown cause; embolism from cardiac source; infarction due to atherosclerosis; lacune; parenchymatous or intracerebral hemorrhage; subarachnoid hemorrhage; and other. The utility and limitations of these data are discussed. (*Stroke* 1988;19:547-554)**

Stroke is the third leading cause of death in the United States; only coronary heart disease and cancer are more prevalent causes of death. In 1985, there were 153,050 deaths attributed to cerebrovascular diseases and a crude death rate of 64.1 per 100,000 resident population.<sup>1</sup> Cerebrovascular diseases are also a major cause of chronic disability, affecting millions of Americans. In 1978, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) initiated a data bank project to provide prospectively and consistently recorded information on stroke to address some of the many unresolved research issues in cerebrovascular disease. The Stroke Data Bank (SDB) had four major objec-

tives: 1) to obtain information on the clinical course and outcome of stroke, 2) to provide information that would enable a standard diagnostic clinical evaluation, 3) to identify factors predictive of outcome following stroke, and 4) to provide planning data for future controlled, randomized, clinical trials in the treatment of stroke patients.

The purpose of our report is to provide a comprehensive description of the project background, design, and methods and a description of the patients enrolled. Additional details (including copies of the data collection forms) are available in the *SDB Manual of Operations*.<sup>2</sup> Previous communications have reported on the pilot phase,<sup>3</sup> reliability studies,<sup>4,5</sup> and nursing implications<sup>6</sup> of this project. The primary analytic publications from the main phase of the SDB are now in preparation.

### Design and Methods

#### Project Organization

Cooperative clinical projects require an organizational structure that will both facilitate efficient operation and at the same time provide a mechanism to ensure participation of all collaborators in the decision-making process. Toward these goals, the organizational structure developed for the SDB fostered careful and uniform adherence to the procedures for data collection and effective communication and cooperation among the various constituents.

In addition to the requirement for recruiting more patients in a shorter period than would have been possible in a single center, the advantage of a broader geographic representation of patients and a diversity of referral and treatment patterns led to the multicenter collaborative structure of the SDB. The four clinical centers participating were the University of Maryland, Baltimore; Boston University; Michael Reese Hospital

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and Medical Center, Chicago, Illinois; and New York Neurological Institute of Columbia University. The NINCDS Biometry and Field Studies Branch acted as the statistical coordinating center.

A monitoring committee advised NINCDS regarding overall project policy and reviewed operational aspects, monitored the accumulating data, and reviewed the scientific content of research in progress. The monitoring committee comprised scientists appointed by the NINCDS. No member of this committee participated in the project as an investigator, and members of the committee were drawn from institutions or programs that were not participating in the project.

### *Design Features*

Stroke was defined as a sudden, nonconvulsive, focal neurologic deficit persisting for >24 hours. This definition excluded cases of transient ischemic attacks (which had been included in the pilot project). Patients were eligible for entry into the SDB if they were at least 15 years of age, had a diagnosis of stroke, and if the stroke onset was within 7 days of initial SDB contact. Patients were ineligible for entry into the SDB if the patient or family refused informed consent, if the patient died or was discharged before initial SDB contact, or if there were other coincident severe illnesses such as cancer, sickle cell disease, hematologic disease, or head injury affecting short-term survival. Enrollment in the SDB was affected by early poststroke mortality, as patients had to survive long enough after admission to be seen for a SDB neurologic examination. All patients from each clinical center who met the eligibility criteria were asked to participate in the SDB; those who agreed and signed an informed consent were enrolled.

The nurse coordinator at each center was responsible for finding cases through hospital admissions and screening records. The screening procedures included a daily review of the hospital admitting records, including admissions to intensive care or the emergency room, and a review of neurology consults, operating room schedules, angiograms, and computed tomography (CT scan) reports. Case finding also resulted from daily contact with the neurology staff and residents, the neurosurgery service and, where applicable, the pediatric service for possible new patients. There was no central recording of the number of cases screened who were subsequently found to be ineligible. Although 100 patients/yr was the expected enrollment per center, no specific enrollment goal or total sample size was specified. Patient recruitment began in July 1983 and was completed in June 1986. A total of 1,805 patients were entered during this 36-month period.

### *Methods*

*SDB Manual of Operations*<sup>2</sup> was developed as an integral part of the conduct of this project to ensure that the data were collected according to predetermined standards, definitions, and schedules. The information recorded within the SDB included a medical history, a

description of the onset of disease, initial and follow-up diagnostic and neurologic evaluations, therapy, and outcome recorded throughout the patient's clinical course as a part of routine patient care.

The diagnosis of stroke was further detailed by classifying each patient as to stroke subtype on the basis of CT scan, clinical syndrome, angiogram, surgical, and/or autopsy results. The specific stroke subtype diagnoses defined include 1) infarction, cause unknown, 2) infarction with normal angiogram, 3) infarction with tandem arterial pathology, 4) embolism from cardiac source, 5) infarction due to atherosclerosis, 6) lacune, 7) parenchymatous or intracerebral hemorrhage, 8) subarachnoid hemorrhage, and 9) all others. These stroke subtype diagnoses are presented in detail by Mohr and Barnett.<sup>7</sup>

The neurologic examinations took place at least once during the first 7 days after onset, at least once during Days 7–10, and 3, 6, 12, 24, and 36 months after onset. The preenrollment examination, in which the SDB neurologist verified the stroke, coincided with getting the patient's consent and served as the initial SDB neurologic examination. This initial examination consisted of an assessment of the patient's Glasgow Coma Scale (GCS) score,<sup>8</sup> their Hunt and Hess grade<sup>9</sup> (for subarachnoid hemorrhage patients only), two assessments of weakness, assessment of sensory deficits, extraocular and visual field abnormalities, language, and nonlanguage cognitive function abnormalities.

The weakness scales measured weakness bilaterally for the tongue, face, shoulder, hand, hip, and foot. The codes for weakness for each component were 0, normal; 1, slight weakness overcome with relatively great force; 2, weakness against resistance, overcome with minimal force; 3, weakness against gravity, able to affect movement and maintain position only against gravity; 4, weakness without gravity, able to affect movement only if the force of gravity is removed; 5, no movement or only a flicker in the muscle; and 5.01, untestable. For tongue and face, only codes 0, 2, 5, and 5.01 apply. The first weakness score (A) was simply the sum of all the components and ranged from 0 to 60.12. A second weakness score (B) avoided assuming that any untestable component was worse than all others by scoring only those components that were testable, and weakness known to be unrelated to the present stroke was ignored. Weakness score B was therefore the proportion of the total testable score and ranged from 0 to 1.

Codes for the sensory deficit score were 0, normal; 1, subjective only, the patient reports a difference in feeling but objective testing is normal; 2, partial, slight to moderate loss of sensation but stimulus still felt by the patient; 3, severe, severe objective loss to pin, touch, or position sense; and 3.01, untestable. The sensory deficit score was therefore the sum of the components and ranged from 0 to 36.12.

Performance on the modified Barthel Index of activities of daily living was assessed and scored.<sup>10</sup> The Barthel Index quantifies functional status as totally dependent (0–39), partially dependent (40–59), inde-

pendent (60–84), and totally independent (85–100). Functional assessment later in the patient's course also included level of depression as assessed on the Center for Epidemiologic Studies Depression Scale.<sup>11</sup>

Based on the results of both the neurologic and functional assessments, each patient received a stroke severity score that provided an additional baseline measure from which improvement over time could be gauged. The SDB Stroke Severity Scale ranged from 0 (independent in functional ability, no impairment in swallowing, self-care, walking, communication, or comprehension, and no neurologic symptoms or signs) to 13 (reduced consciousness) or 14 (death).

CT scan and angiogram data included number, side, pathology, anatomy, volume, density, and mass effect of lesions related to the stroke, edema, cortical atrophy, hydrocephalus, intra-arterial studies, and digital subtraction angiography studies. Neither CT scans nor angiograms were mandated at any time by the SDB; these were done at the instigation of the treating physician and were recorded in the SDB whenever available. Lesion volumes were recorded by sketching each lesion on the SDB CT scan form,<sup>2</sup> which displayed 10 CT levels or sections. Sketches were drawn in all the sections in which the lesion appeared on the CT scan, in the appropriate anatomic location and relative size. If there was extensive mass effect or distortion, the brain structures involved were drawn as if they were not displaced. Blood in the ventricles was indicated by shading the ventricles, and a high- or low-density descriptor was assigned to each lesion. Once the sketch was complete, a plastic transparency with a cartesian grid of boxes was placed over each section. The grid elements involved in the sketch were then coded as either high or low density. Each specific grid element was converted to relative brain volume; the average volume per grid element was 1.822 ml. Adding volumes for each grid element involved resulted in an estimate of the total lesion volume.

Special occurrences (including complications, evolving, recurrent, or worsening strokes, pure motor syndrome, and death) were reported as necessary. The data recorded on patients diagnosed with subarachnoid hemorrhages was minimal, and these patients were followed for only 30 days after onset.

The data quality assurance measures included clinical center site visits, monthly reports from the clinical and coordinating center, distributed data entry with distributed error detection capabilities, reediting the entire dataset at the end of new patient accrual, and evaluations of interobserver variability.<sup>4,5</sup>

### Baseline Results

Although the SDB patients cannot be considered a random sample from a defined population, they represent a wide spectrum of patients with acute stroke. Therefore, it is of interest to examine in detail the characteristics of these patients.

Only data from the initial neurologic examinations are presented in this article. Since one eligibility criterion was that the patient be enrolled within 7 days

after the stroke, these data reflect information recorded within 7 days after the stroke. If information for a given variable was not available for all patients, the number of patients from whom the data was obtained is given. Missing values occurred as a result of technical problems, failure to follow established procedure, lack of recollection on the part of the patient, or failure to report values. Statistical tests of significance are not reported. The large number of patients suggests that relatively small differences may be statistically significant without having substantive meaning. The tabulation of percentages exclude missing values from both the numerator and denominator. The distribution of time from stroke onset to hospital admission is given in Figure 1. Half the patients were admitted within 12 hours after their stroke, two thirds within 24 hours, and many infarctions occurred in patients already in the hospital. The patients with hemorrhages were admitted to the SDB hospital slightly later after onset than those with infarcts and the patients with subarachnoid hemorrhages later than those with intracerebral hemorrhages.

Of the 1,805 patients enrolled in the SDB, 1,273 were diagnosed as having had cerebral infarctions and 480 as having had hemorrhages. For this report, the diagnoses of infarction, cause unknown ( $n=459$ ), infarction with normal angiogram ( $n=49$ ), and infarction with tandem arterial pathology ( $n=69$ ), that is, ipsilateral carotid bruit with carotid artery stenosis, will be combined as infarct, unknown cause.

The median age of the SDB patients was 65 years; 47% were male and 54% were black (Table 1). Only 30% of these patients were still gainfully employed, either full- or part-time, at the time of their stroke. The majority of patients had less than a high school education, and 46% of patients were married at the time of their stroke. The patient populations (stroke subtype diagnoses) within each clinical center differed slightly (Table 2).

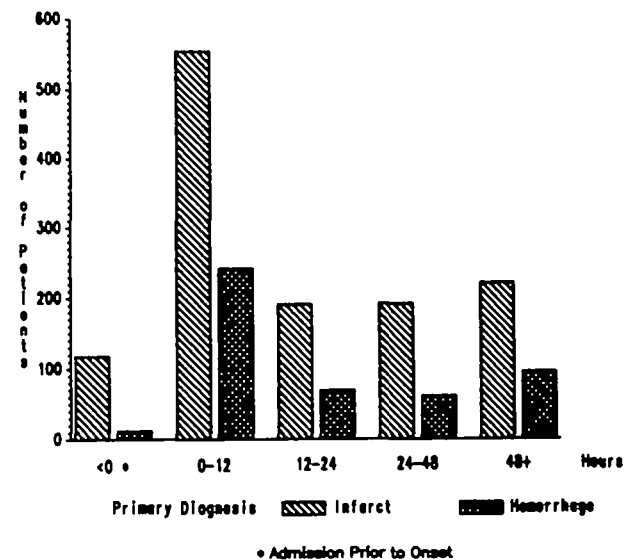


FIGURE 1. Time to admission from onset by primary diagnosis, Stroke Data Bank.

**TABLE 1. Descriptive Characteristics of Stroke Data Bank Patients**

	Category							Total (N = 1,805)
	Cerebral infarctions				Hemorrhages			
	Infarct, un- known cause (n = 577)	Embolic (n = 246)	Athero- sclerotic (n = 113)	Lacune (n = 337)	Intra- cerebral (n = 237)	Subar- achnoid (n = 243)	Other (n = 52)	
<b>Age</b>								
Median (yr)	69	70.5	67	66	61	52	58.5	65
≤50 (%)	11	10	9	9	26	45	36	18
51-60 (%)	17	12	29	24	24	27	23	21
61-70 (%)	28	28	31	31	24	18	29	27
71-80 (%)	26	30	23	26	18	8	6	22
81+ (%)	17	20	8	9	8	1	6	12
Male (%)	45	46	65	46	57	31	52	47
Black (%)	61	53	47	59	53	43	37	54
Employed full- or part-time* (%)	22	19	31	27	41	48	45	30
Married† (%)	42	48	61	38	49	55	59	46
<High school education (%)	64	51	58	60	53	35	39	56
No.	501	194	96	315	171	147	46	1,470

\*Missing data for 5% of patients.

†Missing data for 3% of patients.

The characteristics of the medical and neurologic history are given in Table 3. The first available poststroke systolic and diastolic blood pressures show that, on average, patients with intracerebral hemorrhages had the highest blood pressure. From the patients' medical histories, hypertension was the most frequently reported cardiovascular disease, affecting 38-75% of patients in each stroke diagnostic subtype. Of those reporting a history of hypertension, patients with lacunar strokes or hemorrhages had the highest proportion of untreated hypertension at the time of their stroke. The majority of SDB patients reported some cardiovascular disease (including hypertension, myocardial infarction, atrial fibrillation, other arrhythmias, systemic emboli, angina, congestive heart failure, and claudication), although the proportion varied across

subtypes from 47% among patients with subarachnoid hemorrhage to 87% among patients with embolic infarcts. Overall, 21% of SDB patients had been diagnosed or treated for diabetes and 6% for cancer. Only 14% reported any history of transient ischemic attacks (TIAs), with 7% of those reporting TIAs within 1 week of the current stroke, 10% within 1 month, and 12% within 6 months. One fifth of the patients with infarcts due to atherosclerosis had prestroke TIAs. The majority (78%) reported no previous strokes, but for those reporting previous strokes the subtype of stroke was predominantly ischemic infarction. Antiplatelet agents and/or anticoagulants were being used at the time of stroke by 11-25% of the patients with cerebral infarctions, 10% of those with intracerebral hemorrhages, and only 1% of those with subarachnoid hemorrhages.

**TABLE 2. Distribution of Diagnosis Subtype by Center, Stroke Data Bank**

Stroke subtype diagnosis (%)	Center				Total (N = 1,805)
	University of Maryland (n = 460)	Boston University (n = 259)	Michael Reese Hospital (n = 496)	New York Neurological Institute (n = 590)	
<b>Cerebral infarctions</b>					
Infarct, unknown cause	34	32	33	29	32
Embolic	13	24	14	9	14
Atherosclerotic	1	7	7	9	6
Lacune	7	20	24	23	19
<b>Hemorrhages</b>					
Intracerebral	19	7	11	13	13
Subarachnoid	22	7	10	13	13
Other	4	2	1	4	3

TABLE 3. Medical and Neurologic History of Stroke Data Bank Patients

	Category						
	Cerebral infarctions				Hemorrhages		
	Infarct, unknown cause (n = 577)	Embolic (n = 246)	Atherosclerotic (n = 113)	Lacune (n = 337)	Intracerebral (n = 237)	Subarachnoid (n = 243)	Other (n = 52)
<i>Blood pressure after stroke</i>							
Systolic	161 ± 1.4	151 ± 1.9	156 ± 2.8	167 ± 1.8	183 ± 2.8	154 ± 2.4	147 ± 5.0
No.	571	242	108	330	235	231	50
Diastolic	93 ± 0.9	88 ± 1.3	91 ± 1.5	97 ± 1.1	105 ± 1.8	90 ± 1.3	82 ± 2.8
No.	571	240	108	330	234	231	50
<i>Medical history (%)</i>							
Hypertension (treated and untreated)	66	59	73	75	64	42	38
Untreated of total hypertensives	28	27	28	40	48	43	25
Myocardial infarction	17	33	15	11	9	3	8
Atrial fibrillation	3	39	3	2	4	1	2
Other arrhythmias	7	20	7	4	1	1	2
Systemic emboli	1	3	0	1	2	<1	2
Angina	17	28	19	9	5	4	17
Congestive heart failure	12	36	7	6	8	2	6
Chronic obstructive pulmonary disease	4	5	4	5	4	2	6
Any cardiovascular disease	76	87	81	82	69	47	54
Diabetes	29	17	29	27	9	5	10
Cancer	6	6	4	8	4	4	8
<i>Neurologic history</i>							
Transient ischemic attacks (%)	19	13	20	13	3	1	24
No.	515	222	103	324	205	218	49
Previous stroke (%)	25	29	39	20	13	4	31
No.	547	240	109	332	220	220	51
Antiplatelets/anticoagulants (%)	11	17	25	11	10	1	8
No.	567	244	108	335	228	228	52

The median time from onset to first SDB neurologic examination (Table 4) varied across stroke diagnostic subtypes, with those patients diagnosed with infarctions due to atherosclerosis and with intracerebral hemorrhages examined earlier than others. The initial GCS scores also varied slightly across subtypes, with most patients at the maximum score (GCS = 15). The components of the GCS showed that most patients were oriented to time, place, and person, were conversant, exhibited spontaneous eye opening, and exhibited appropriate motor responses to simple commands. Right hemiparesis was noted somewhat more frequently than left hemiparesis within most diagnostic subtypes. Patients with intracerebral hemorrhages showed the most severe weakness by either weakness score. Ataxia was absent in 83% of all patients, and right and left ataxia were equally frequent in the remaining patients. Sensory scores were lowest among patients diagnosed with either lacunar infarctions or subarachnoid hemorrhages. Sensory deficits were not apparent for the great majority of patients diagnosed with subarachnoid hemorrhages, but deficits were distributed approximately equally as to side where present. The visual field examination revealed

no abnormalities in the majority of patients. A variety of aphasias were noted, global aphasia most frequently.

The first functional assessment was generally recorded at the time of the first neurologic examination. The median Barthel Index scores within the cerebral infarction category ranged from 20 to 57 (totally to partially dependent), whereas the median scores within the hemorrhage category were 0 (totally dependent), with 65–68% of patients at the minimum score. This initial score will be used as a baseline for measurement of recovery of functional ability over long-term follow-up. The median initial Stroke Severity Scale scores ranged from 8 to 10 across all diagnostic subtypes, indicating some dependence in functional abilities and some additional impairments. The proportion of surviving patients at the maximum recorded score (13, reduced consciousness) was 21% for the intracerebral hemorrhage cases, 14% for the subarachnoid hemorrhage cases, and much less for the cerebral infarction category. This indicated that the patients who had suffered a hemorrhage, in general, were much more severely disabled at the time of initial assessment than patients with cerebral infarctions.

TABLE 4. Patient Status at First Neurologic Examination, Stroke Data Bank

	Category						
	Cerebral infarctions				Hemorrhages		
	Infarct, un- known cause (n = 577)	Embolic (n = 246)	Athero- sclerotic (n = 113)	Lacune (n = 337)	Intra- cerebral (n = 237)	Subar- achnoid (n = 243)	Other (n = 52)
<i>Median days onset to initial neuro- logic examination</i>	2	2	1	2	1	2	2
<i>Initial Glasgow Coma Scale score (%)</i>							
Normal (15)	57	47	68	93	28	55	48
9-14	32	39	29	7	31	23	33
6-8	8	11	1	0	18	8	11
3-5	2	3	2	<1	23	14	8
<i>Weakness score</i>							
A median	11	14	12	10	24	0	21
B median	0.17	0.22	0.20	0.17	0.37	0	0.33
No.	577	246	113	337	237	243	52
<i>Sensory score</i>							
Median	5	8.5	2.5	0	17	0	8
No.	574	244	112	337	232	242	51
<i>Sensory deficits (%)</i>							
None	38	37	39	63	33	87	30
Left	29	32	37	20	35	8	30
Right	29	28	22	15	28	2	34
Both	3	2	2	2	4	3	6
No.	520	211	103	334	155	194	44
<i>Language (%)</i>							
Normal	60	48	71	97	65	95	46
Broca	4	6	9	1	3	0	8
Wernicke	6	7	0	0	5	1	5
Global	16	24	9	0	11	1	16
Anomic	5	5	3	<1	7	0	3
No.	460	189	94	290	106	146	37
<i>Barthel Index score</i>							
Median	32	20	37	57	0	0	28
% at minimum	25	40	28	6	68	65	34
No.	574	246	112	329	234	17	50
<i>Stroke Severity Scale score</i>							
Median	9	10	9	8	10	10	10
% at maximum	7	12	2	1	21	14	9
No.	574	244	110	330	231	14	50
<i>Cervical bruit</i>							
Absent (%)	93	97	83	93	99	100	94
No.	568	243	111	334	224	231	48
<i>Anamnesis on awakening (%)</i>	25	24	23	36	15	12	31
<i>At onset</i>							
Severe headache (%)	11	10	11	5	41	87	21
Vomiting (%)	7	5	8	1	29	45	8
Seizures (%)	2	3	3	<1	9	7	4
Focal deficit (%)	98	96	97	99	78	33	92
Decrease in consciousness (%)	18	29	14	2	57	48	37
Coma (%)	1	4	1	<1	21	12	4

TABLE 5. Hospitalization Summary, Stroke Data Bank

	Category						
	Cerebral infarctions				Hemorrhages		
	Infarct, unknown cause (n = 577)	Embolic (n = 246)	Atherosclerotic (n = 113)	Lacune (n = 337)	Intracerebral (n = 237)	Subarachnoid (n = 243)	Other (n = 52)
<i>Computed tomography</i>							
At least one (%)	99	98	100	98	100	95	92
First normal (%)	38	24	28	50	<1	15	15
Median time to first (hr)	22	12	21	26	10	22	27
Fatalities within 30 days (No.)	59	28	15	2	71	71	6
<i>% discharged to</i>							
Home	57	52	54	77	30	53	54
Nursing home	11	12	4	3	12	6	6
Rehabilitation center	19	17	20	18	22	8	21
Died	12	16	18	1	34	31	15
All other	1	3	4	1	2	2	4
<i>Days to discharge</i>							
Median	17	16.5	20	12	18	24	18.5
<i>Patients who died in hospital</i>							
Median	13	13	18.5	30	6	11	14
No.	67	39	20	5	80	75	8
<i>Patients discharged alive</i>							
Median	17	17	20	11	24	29	19
No.	510	207	93	332	157	168	44
<i>Medications in hospital and/or at discharge (%)</i>							
Heparin	38	54	73	31	8	2	29
Steroids	13	20	22	2	81	86	48
Dehydrating agents	4	7	8	1	37	32	10
Narcotics	8	12	4	3	22	39	27
Warfarin	15	37	27	4	2	1	13
Aspirin	50	29	30	56	3	1	25
Dipyridamole	14	20	14	16	2	0	17
Diuretics	36	50	30	34	32	21	25
Antihypertension	43	44	42	46	59	58	40
Anticonvulsants	12	11	9	2	46	80	33
Insulin	18	10	19	12	19	9	10
Antidepressants	5	4	1	3	4	7	10

Presence of a cervical bruit was reported for only 5% of the patients. At onset, the majority of patients reported a focal deficit. Decreased consciousness and/or coma at onset were reported primarily among patients with hemorrhages.

Ninety-seven percent of all patients (Table 5) had at least one CT scan performed during hospitalization. For the cerebral infarction category, 24–50% of first CT scans were normal. Virtually all first CT scans were positive for patients with intracerebral hemorrhages. The median time from onset to first CT scan ranged from 10 to 27 hours after onset. The 30-day case fatality rate (Table 5) is consistent at 30% within the hemorrhage category. Within the cerebral infarction category, patients diagnosed with a lacunar stroke had a much

lower (1%) case fatality rate than the remaining subtypes (10–13%). They also had a much shorter hospitalization and were more frequently discharged to their home rather than to an institution. The case fatality rate in this population may be somewhat lower and the duration of hospitalization somewhat shorter than expected due to the fact that the participating institutions are all teaching hospitals and their referral patterns may differ from other institutions; also, early deaths were, by eligibility criteria, excluded from the SDB.

The medications given during hospitalization and/or as a discharge prescription are also summarized in Table 5. Aspirin, diuretics, and antihypertension agents were the most frequently reported medications



given. There was considerable variation in medications prescribed across diagnostic subtypes.

### Discussion

The SDB provides a resource for the study of the clinical course and outcome of stroke, the development and comparison of diagnostic classifications, and the development of prognostic models. The SDB may serve to verify or discredit historically held neurologic theories in these areas and may provide new insights into stroke mechanism and course. The SDB could facilitate planning of clinical trials in the treatment of stroke patients, particularly but not exclusively providing patient accrual estimates for specific eligibility criteria for the participating institutions. Therapeutic efficacy questions cannot be addressed by the SDB. Observational studies of this type are subject to bias in absence of a treatment protocol, in physicians, in patient selection, and in treatment selection. Additionally, institutional confounding would result in groups of patients receiving different treatments, and the observed differences between groups might be related to factors (primarily unknown) other than the prescribed treatments. While the SDB centers are not population-based, which may limit the ability to generalize the results, the availability of a prospectively and consistently collected data set of this magnitude offers a wealth of information on the characteristics and sequelae of stroke. The data from newer diagnostic procedures, such as CT, result in a much broader scope of issues that can be addressed by the SDB. The long-term follow-up of these patients also provides information on institutionalization after stroke, functional and neurologic recovery, and prognosis for long-term survival.

### Appendix 1. Participating Institutions and Investigators

#### *Clinical Centers and Principal Investigators*

Boston University, Boston, Massachusetts, Philip A. Wolf, MD; Duke University, Durham, North Carolina (pilot phase only), Albert Heyman, MD; Michael Reese Hospital, Chicago, Illinois (main phase only), Daniel B. Hier, MD (formerly Louis R. Caplan, MD); New York Neurological Institute, New York, New York (main phase only), J.P. Mohr, MD; University of Maryland, Baltimore, Maryland, Thomas R. Price, MD; and University of South Alabama, Mobile, Alabama (pilot phase only), J.P. Mohr, MD.

#### *NINCDS Project Office and Coordinating Center*

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PhD, Project Director (formerly Selma Kunitz, PhD).

#### *Data Processing Unit*

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Michael D. Walker, MD (NINCDS, Bethesda, Maryland), Chairman; Neal F. Kassell, MD (University of Virginia, Charlottesville, Virginia); Nathan Mantel (American University, Bethesda, Maryland); and H.J.M. Barnett, MD (University of Western Ontario, London, Ontario, Canada).

#### *Advisory Committees*

H.J.M. Barnett, MD; William K. Hass, MD (New York University Medical Center, New York, New York); and Neal F. Kassell, MD.

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