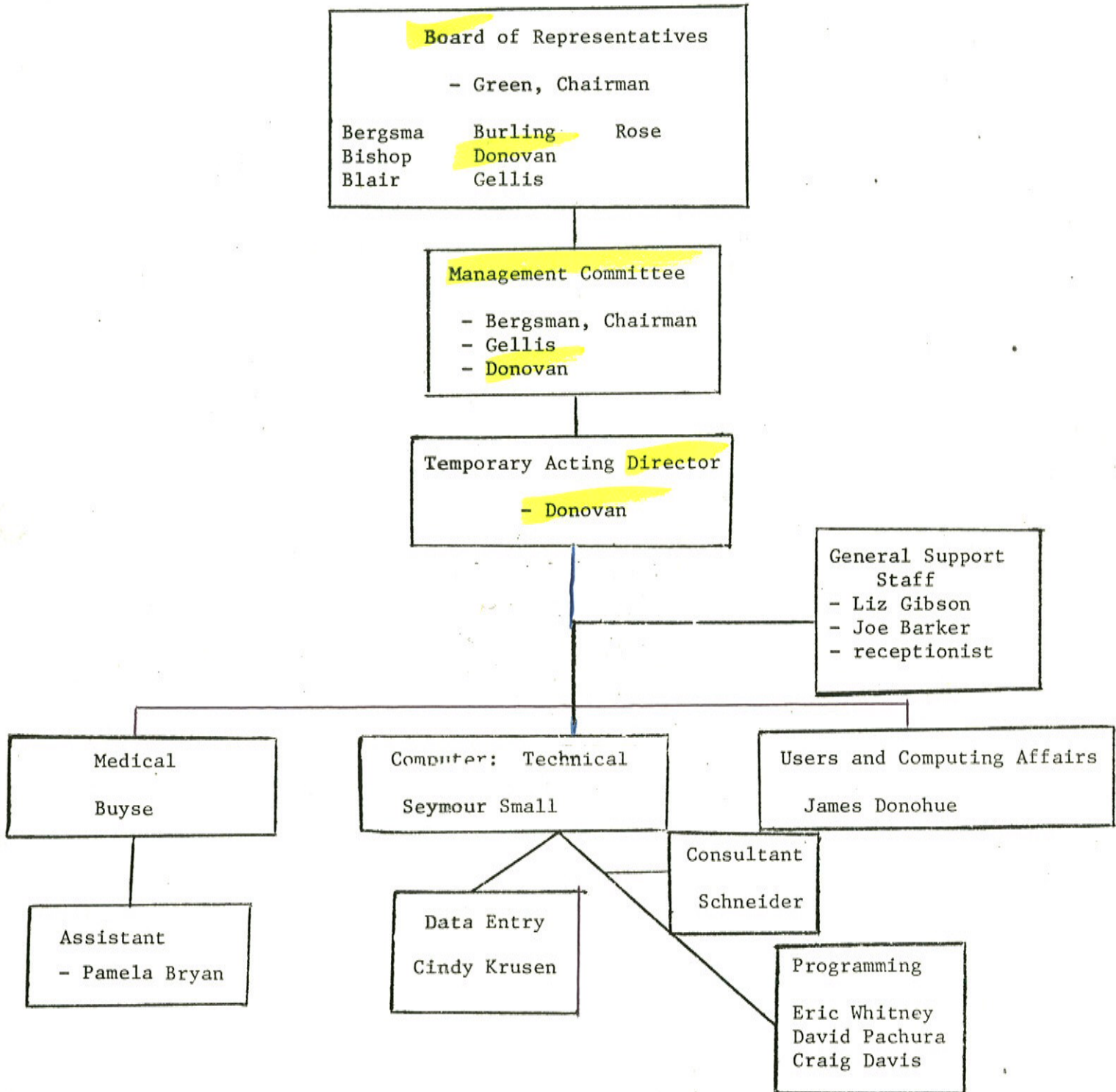


PERSONNEL AND ORGANIZATION OF THE CENTER FOR BIRTH DEFECTS



FROM: Science Information Division
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San Francisco, June 13 -- A computer system which quickly provides the latest information on all kinds of birth defects was demonstrated at the 1978 Birth Defects Conference here today.

The computer offers physicians and researchers instant retrieval of birth defects information gathered from leading medical institutions around the world.

The system was developed jointly by The National Foundation-March of Dimes, Tufts-New England Medical Center, and the Massachusetts Institute of Technology.

"Access to continually updated data is of inestimable value to the practicing physician, especially in the area of unfamiliar defects," said Arthur J. Salisbury, vice president for medical services, The National Foundation-March of Dimes.

"Many birth defects are so rare that a physician may see only one case in his entire career. By using the computer, the doctor is assured of recent information on the syndrome selected," Dr. Salisbury said.

Accessible 24 hours a day, the computer will operate through the public telephone system, making it possible to dial the central processing unit from computer terminals in hospitals or medical centers. A physician can now request information about more than 1000 different birth defects, and the computer responds by displaying all the most recent available information. New genetic and birth defects data are continually being entered.

"We envision an eventual national network providing information to all researchers and clinicians who need it," said Dr. Salisbury.

Data comprising the core of the information retrieval system have been assembled and verified by some 436 physicians from 22 countries and coordinated under the direction of Daniel Bergsma, M.D., editor of the March of Dimes Birth Defects Compendium, and chairman of the management committee of the Center for Birth Defects Information Services. Collaborators with Dr. Bergsma in development of the Birth Defects Information System and members of the Center management committee are Drs. Sydney Gellis, chairman, department of pediatrics, Tufts University School of Medicine, and John Donovan, associate professor, Sloan School of Management, Massachusetts Institute of Technology.

The system has other potential uses, among them diagnostic assistance. It is anticipated that when clinical testing is completed in the near future, a physician with a diagnostic dilemma will be able to present the computer with signs and symptoms observed in a patient.

The system will then help narrow down the possible diagnosis through a series of questions suggested by the physician's initial observations. The questions and answers continue until the system has received enough symptoms, signs and test results to suggest one or more probable diagnoses.

Eventually, the system will also operate as a birth defects registry, classifying previously unknown birth defects and matching scattered reports to identify "new" syndromes. In this capacity it may also help prevent birth defects by pointing to environmental causes which may be avoidable. Information collected, analyzed and then provided by the computer may play a role in prevention by alerting health professionals to an increase in certain birth defects, giving them valuable extra time to trace causes before many children are affected.

The system also has potential as an educational tool to help train medical students in diagnostic procedures, birth defects medical terminology and other aspects of medical practice relating to birth defects.

FROM: Science Information Division
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MARCH OF DIMES CHAPTERS TO FUND USE
OF BIRTH DEFECTS COMPUTER SYSTEM

San Francisco, June 13 -- March of Dimes chapters throughout the United States will assist local medical centers with funds for equipment or personnel to initiate access to a new computerized Birth Defects Information System demonstrated at a press conference here today.

Depending on uncommitted funds available, chapters may make grants for terminal-leasing costs, training personnel in use of the Information System, or for computer time charges.

The first grants will be made to major medical centers to which the most baffling birth defects cases are usually referred. One center in each of the 50 states is expected to be so equipped by early 1979.

"Although most of the nation's diagnostic experts in birth defects are in major medical centers, none of them know all there is to know about every one of more than a thousand congenital disorders," said Dr. Arthur J. Salisbury, vice president for medical services of The National Foundation-March of Dimes.

"We believe that feedback from them as they gain experience in using the computerized information system will enable the computer experts to make their experience more universally applicable at all levels," Dr. Salisbury said.

Community hospitals and other institutions are expected to be gradually phased into the network as experience in using the system advances.

If the widely-predicted "personal computer" explosion grows, some enthusiasts predict that private practitioners may someday consult the March of Dimes Birth Defects Information System through terminals in their offices.

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BACKGROUND

BIRTH DEFECTS INFORMATION SYSTEM (BDIS)

In the United States alone, more than a quarter of a million children are born with birth defects each year. In addition to the children's lives, the emotional, financial, and spiritual lives of their immediate families are greatly affected. Birth Defects have an impact on the daily lives of more than 15 million Americans. The Birth Defects Information System is directed toward helping children, their families, the community, and ultimately, future parents and their relatives.

In the past, it has been extremely difficult to locate complete, up to date information on any given birth defect. This information usually has been scattered among journals and textbooks in different medical specialties, with no centralized source.

The National Foundation-March of Dimes initially attempted to resolve this problem by compiling the Atlas & Compendium of Birth Defects, which contains known information on birth defects in a standardized format for efficient reference. The first edition of the Compendium appeared in 1972, with more than 300 physicians from various medical specialties as contributors. Soon it became obvious that printed editions of the Compendium could not keep abreast of rapidly increasing information in the vast field of birth defects. This led to the conclusion that only computer technology could provide the instantaneous update of information when required.

What is the Birth Defects Information System?

The Birth Defects Information System is a computer-based system that can assist physicians, patients and their parents and relatives in obtaining information about birth defects for clinical and research uses. BDIS is operated by the Center for Birth Defects Information Services, a division of Tufts-New England Medical Center, funded by The National Foundation-March of Dimes. It is expected that in the future other universities and institutions may become involved with the Center.

The basic data for the system consists of information on most known birth defects and has been gathered and assembled by The National Foundation-March of Dimes. Initial clinical testing of the system is being performed at the Tufts-New England Medical Center. The computer implementation is based on research performed at the Massachusetts Institute of Technology Sloan School of Management.

Access to the System

The Birth Defects Information System consists of a computing facility that can be reached through practically any computer terminal connected to a telephone line anywhere in the world. Using a telecommunications network, access to the system can be gained through a local telephone call from most major cities within the United States and Europe.

After a user has called the computer by telephone and identified himself, using his terminal, the computer guides him through a sequence of questions and prompts. There is no need for a user to learn a special computer language or to read a large instruction manual to use BDIS. To make the system easier to use, a HELP facility has been implemented that allows a user to type ? at any time while using BDIS to activate a detailed explanation of what he should do next. By typing ? repeatedly during the first session, a novice user can learn to use BDIS through self-instruction obtained with the HELP facility.

Uses of the System

Providing information about birth defects. Every day more than 600 babies are born with birth defects. Some are immediately apparent, while others are hidden and may not reveal themselves until later in life. Some of them are rare. Many others defy diagnosis. Some are genetic in origin, while others have obscure origins.

Parents want all available information. Some common questions are: What is the risk of occurrence of the birth defect in other members of the existing family? What would be the effects on future generations? What is the prognosis for the afflicted child's recovery, or what are the child's special needs? Parents usually consult local physicians. Due to the specialized nature of birth defects, the physician often refers them to a birth defects center. Until now, the birth defects center performed the slow and arduous task of research to attempt to answer the parents' questions.

Information also may be sought by prospective parents after learning about a birth defect in the family. What are the chances that one of their children will be so afflicted?

The BDIS provides information through queries via computer terminal. A summary of all known medical information about more than 1,000 of the known birth defects is presently in the computer and can provide many types of medical information, ranging from the minimal diagnostic criteria for a birth defect to other known references and experiences relating to it. Work to gather data is continuing on the remaining known birth defects.

Potential Future Uses

Assisting in diagnosing birth defects. It is extremely important to associate a name, pertinent historical information, and all other available information on an observed abnormality in a child. Once the abnormality is so identified, meaningful diagnostic treatment, prognosis for the future, and preventive mechanisms can be undertaken in the child as well as in relatives to protect future generations. However, many pediatricians do not encounter birth defects as frequently as they encounter more common childhood diseases. Therefore, the pediatrician often refers the child to a birth defects center. But even in a birth defects center, it is difficult and often unproductive to try to identify a particular combination of abnormalities in a child and associate it with a known syndrome. Since the computer system can look at many combinations of facts related to the patient in question, it rapidly assists the physician in focusing on possible syndromes for differential diagnosis. It does this by asking the user to specify the observed signs and symptoms in the patient. It then challenges the user with questions concerning other possible signs, symptoms, and tests. The system then presents a list of possible syndromes that the physician should consider in the diagnosis decision. The physician can then use the system to obtain more information about those syndromes.

Protecting the Patient's Privacy

To ensure the confidentiality of all information, a patient's name will never be recorded by the BDIS. The only recorded facts (other than medical information) is patient's sex, date of birth, place of birth, mother's date of birth, and name of the patient's physician. A patient's and family's name will remain known only to their personal physician.

Assisting in recognition of new birth defects. Attaching a name (hence a history, prognosis, etc.) to an abnormality exhibited in a patient is important since it allows a physician to recommend treatment and to predict the future course of events for the afflicted child and the child's family. This name allows a pool of information that has been accumulated over the years to be brought to bear on the child. Before the computer system was developed, however, a physician, medical team, or birth defects center in one area might observe a particular abnormality, but be unable to match it with an existing known birth defect. The case might then be filed away as an unknown syndrome. At some later date, a physician in another community may recognize the same abnormality, but since he also realizes it is not one of the known birth defects, he also has no choice but to file it away. Only by coincidence would those two physicians ever get together. Further, with the number of such unknown birth defects being observed every day (over 40 per cent of birth defects patients at Tufts-New England Medical Center have been classified as unknowns), it is impossible for a team of physicians to recognize groupings and patterns.

With the aid of the computer, the problem of classifying new (or previously unknown) birth defects will be greatly alleviated, and the system itself assists in recognizing unknowns. For example, a physician inputs the signs and symptoms observed in a patient, and the computer then suggests possible syndromes that match those signs and symptoms. If the physician determines that these suggested syndromes are not applicable, he or she declares to the computer that those signs and symptoms are associated with an unknown syndrome. The computer stores this information in its memory. At some later date, when similar signs and symptoms are recorded by another physician, the computer can recognize the similar pattern and outputs a message to the center, noting that the two unknowns are similar. It keeps track of all physicians who have observed unknowns so they may contact each other and discuss their cases.

In the future, the BDIS will assist the March of Dimes in publishing Syndrome Identification, its periodical on unknown birth defects. The National Foundation-March of Dimes will be able to publish similar "unknowns" that appear to have been recognized by several people.

Printing of updated Birth Defects Compendium. Over the past several years, the March of Dimes has drawn together an enormous amount of information on birth defects, in the Birth Defects Atlas and Compendium. Since the BDIS has all this information, as well as more updated information stored in its memory, subsequent versions of the Compendium can be produced by the computer, using computer-based phototypesetting techniques. This greatly reduces the cost of producing updated versions of the Compendium. The March of Dimes will continue to sponsor the ongoing data-gathering to maintain the updated Compendium.

Training medical students. The information system may be used to assist in the teaching of diagnostic procedures and medical terminology and to provide information on birth defects to future physicians.

Acting as an early warning system. Since this information system can gather information on birth defects throughout the entire country and for the input of unknowns throughout the country and perhaps the world, it potentially will be able to recognize clusters of abnormalities, either high occurrences of known birth defects or new birth defects, occurring in the area.

Assisting in research of causes of birth defects. The programming tools used to construct this information system may also be used to construct other databases and statistical analyses. That is, if a pool of data exists on a number of patients with a particular birth defect, the pool of data can be readily input into this facility, and various statistical tests can be performed to trace possible causes of that birth defect.

TECHNOLOGY

The data that has made this system possible has been verified and assembled with the assistance of some 100 physicians coordinated by the March of Dimes. The computer technology used to develop this system is the interactive timesharing facilities of the IBM System/370 computer using the VM/370 operating system. The major files of the system consist of some 10 million characters of information and are stored primarily on disks. The system is connected to the TYMNET international telecommunications network, which permits access to the system through a local telephone call from most major cities in the United States and in Europe.

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RELATIONSHIPS IN DEVELOPMENT OF THE BIRTH DEFECTS INFORMATION SYSTEM

HISTORY

OF DEVELOPMENTAL CONTRIBUTIONS

DATA

More than 400 experts in a wide range of medical specialties contributed to the basic data on more than 1,000 birth defects.

FINANCING AND COORDINATING

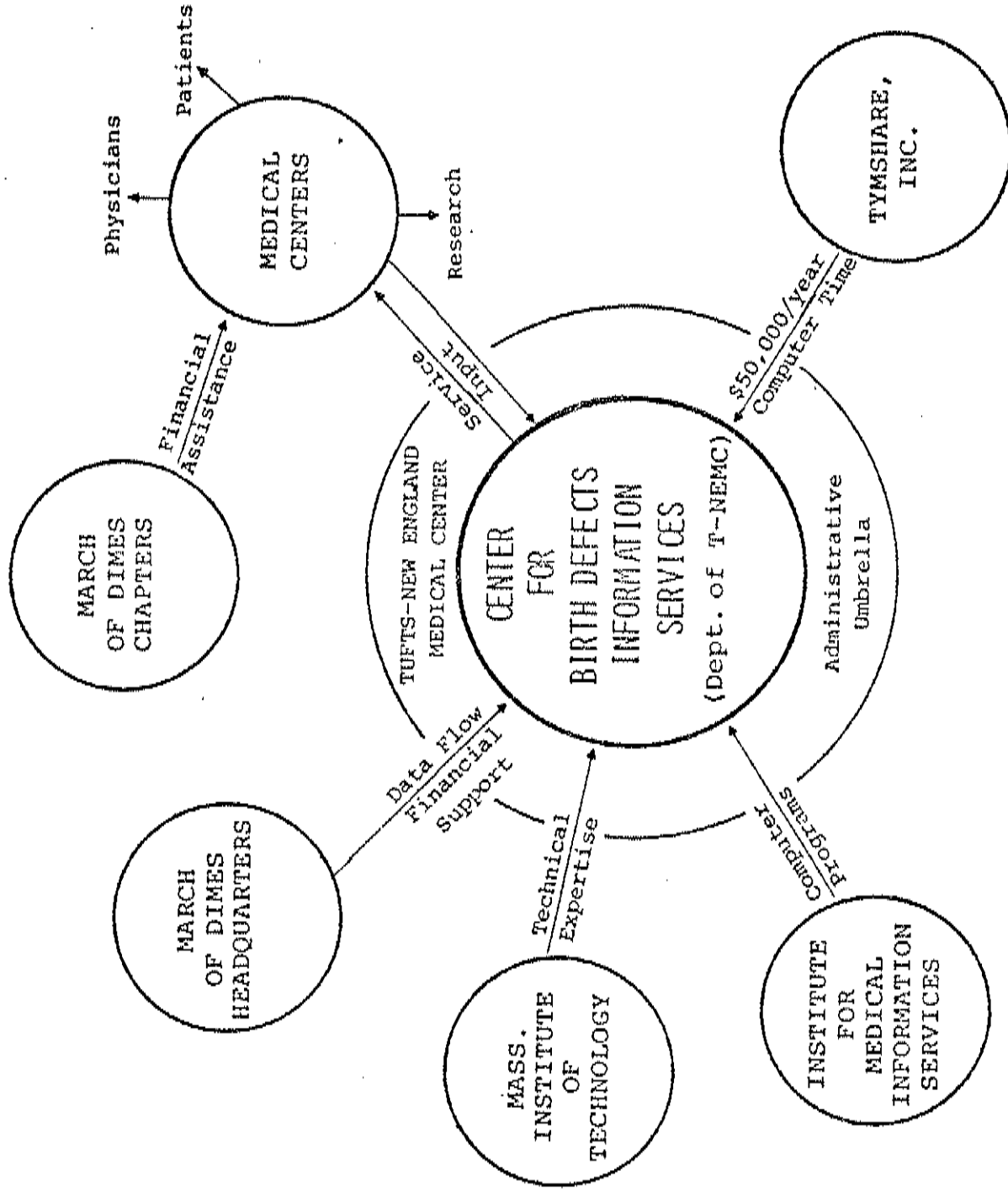
More than a half-million dollars invested by The National Foundation-March of Dimes in data collection, coordination of system development and clinical testing.

COMPUTER SYSTEM DESIGN

A team of computer specialists at M.I.T. designed and implemented BDIS. Using advanced technologies resulting from computer research in excess of \$4 million sponsored by organization from the private and public sectors.

CLINICAL TESTING

Manpower and time at medical centers participating in clinical testing of BDIS.



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CENTER FOR BIRTH DEFECTS INFORMATION SERVICES

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I. PURPOSE

The Center for Birth Defects Information Services (Center) will be operated as a division of Tufts-New England Medical Center, Inc. (T-NEMC) in collaboration with The National Foundation-March of Dimes. It is expected that in the future other universities and institutions may become involved in the Center. The purpose of the Center is to assure that a capability for assisting in the diagnosis, prevention, control, warning, research, education and communication of birth defects is made available to institutions and the medical community as a major attack on the problems associated with all birth defects for the benefit of children and parents.

The Center will provide the following:

- Birth defects information retrieval to provide known information on birth defects in a centrally located, up-to-date and computerized readily accessible system.
- Diagnostic assistance for medical professionals in identifying possible birth defect syndromes that a particular patient may have.
- Cluster signs and symptoms to assist in unknown syndrome identification.
- Ability to publish future editions of the Birth Defects

Compendium.

- Early warning system to alert the medical community to, and thus help prevent, another thalidomide-like catastrophe.
- Research vehicle to provide a database and statistical capability to analyze data on patients; for example, to determine causes of birth defects.
- Educational tool for assisting the medical community in training, diagnosis, and human genetics.

II. PLAN

The Center's objective will be:

- To offer programs for providing birth defects and related information and diagnostic assistance; and
- To inform and negotiate with institutions, agencies and personnel to assure that long-term financial support is available.

To accomplish the first objective, the Center's three-year plan is to offer these services to medical centers throughout the country. Financial support to these centers would come in part from local National Foundation-March of Dimes Chapters.

To accomplish the second objective, the Center's three-year plan is to initiate a program of education in the following areas:

1. Insurance companies as to the benefit to patients and to themselves through better or quicker services at reduced costs.
2. Medical and research community as to the use of the facility.
3. State and federal agencies as to the value of adding

these services to their repertoire.

4. Legislators as to the value of these services to their constituencies.
5. General public as to the value and knowledge of existence of those programs.

III. STRUCTURE OF THE CENTER

The center will be comprised of four components:

A. Board of Representatives

Membership

The Board of Representatives will consist of the three persons appointed to the Management Committee (the ex officio members), three persons appointed by The National Foundation, three persons appointed by T-NEMC. It is anticipated that the Board may be increased to include additional representatives from the business, legislative, professional and public sectors, giving preference to one from the Massachusetts Institute of Technology.

B. Management Committee

Membership

The initial members of the Management Committee will be Dr. Daniel Bergsma, Dr. Sydney S. Gellis, Dr. John J. Donovan and the Director of the Center, who shall serve as an ex officio member of the Management Committee with full power to vote. Thereafter, appointments will be made by the Board of Representatives.

Responsibilities

The Management Committee shall insure that the Center is administered consistently with this Agreement. It will be responsible for executing policies, guidelines and directions for the Center,

based on advice from the Board of Representatives. Subject to the preceding sentence, the Management Committee will be responsible for approving all formal agreements, budgets, contracts and grants of the Center. It will report on its activities to the Board of Representatives annually and at other times as requested.

Working Committees of professionals

It is anticipated that leading professionals will be appointed to these committees for such purposes as certifying or validating existing data, identifying new birth defects, interpreting related research results, maintaining confidentiality of databases and advising on ethical issues.

D. Center Staff

A Director will be appointed by the Management Committee to administer the Center.

An Associate Director of Medical Affairs and an Associate Director of Computing Affairs will also be appointed by the Management Committee.

Other staff will be hired by the Director in accordance with the budget approved by the Management Committee.

The Center will immediately draw upon five resources:

1. Medical Centers throughout the country for providing service, education and research.
2. The National Foundation for working closely with Center staff in publishing, informing legislators, and implementing the plan.
3. Faculty and resources of MIT and T-NEMC for ensuring the quality of the work.
4. Under the direction of the Vice President for Chapters, The National Foundation-March of Dimes Chapters throughout

the country for providing support and liaison between Medical Centers and local parents and children, and assisting in the educational programs in their area for clients, legislators and state agencies.

5. Institute for Medical Information Services, Ltd., providing and maintaining systems software.

IV. COMMITMENTS

1. The National Foundation will commit itself to a level of funding of not more than \$450,000 per year for the calendar year beginning January 1, 1978. For the following two calendar years, The National Foundation has indicated that it will give favorable consideration to the same level of funding.
2. A formal agreement will be entered into between the Center and The National Foundation concerning the data owned by The National Foundation.
3. A formal agreement will be entered into between the Center and the Institute for Medical Information Services Ltd., concerning use of the system software owned by the Institute.
4. If human subjects are used by the Center, the protocol shall be approved by the human subjects committee of the participant and submitted to T-NEMC for ratification by its Human Investigation Review Committee.

V. GENERAL

The Center will be operated as a division of the Tufts-New England Medical Center, Inc. with its operations subject to the administra-

tive policies and financial procedures of T-NEMC which shall not be obligated to provide funding.

This agreement shall be effective after signing thereof by The National Foundation-March of Dimes and Tufts-New England Medical Center, Inc. for a term of three years certain from January 1, 1978 and will continue in effect thereafter on an annual basis unless and until either party cancels this agreement with one year's prior written notice to the other party.