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**COORDINATED RESEARCH ON
CONGENITAL MALFORMATIONS:
REPORT OF A PLANNING CONFERENCE**

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PAN AMERICAN HEALTH ORGANIZATION
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COORDINATED RESEARCH ON CONGENITAL MALFORMATIONS:
REPORT OF A PLANNING CONFERENCE*

Introduction and Specific Aims

The XVI Pan American Sanitary Conference (August-September 1962) recommended specific action by the Member States and by the Organization in regard to the reporting of congenital defects, current tabulation and analysis of data to bring together the experience of countries. The three principal recommendations of the Resolution are: (1) adoption of measures to ensure notification of defects by attendants at birth and of those discovered later; (2) standard procedures for the rapid compilation of such data by the PASB; and (3) effective methods of analysis of data to enable the health authorities to initiate necessary measures for the protection of the public health where indicated.

The initial discussion in the Pan American Sanitary Conference leading to the Resolution followed the Report on the Research Program on Mortality Statistics in the Americas. The Inter-American Investigation of Mortality is a collaborative project already underway in which research centers have been established in Schools of Medicine and Public Health and Ministries of Health in 10 countries.

A system of notification of congenital malformations to health agencies already exists in some areas and studies based on the results so obtained have contributed to present knowledge of

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congenital malformations. However, recent events have indicated the need for more comprehensive methods of surveillance and for more intensive search into causes of malformations. Recently in England and in Denmark procedures for notification of congenital malformations in the same way as for communicable diseases are being established.

Because of the problems involved in establishing a satisfactory system for collection of data on congenital malformations in the Americas, it is proposed that the Resolution of the Pan American Health Organization be implemented by a research program so that sound methods may be tested, definitions and procedures may be developed and data may be collected on an experimental basis. Such a research program will serve as the initial step in collecting and analyzing data which may furnish clues to environmental causes of malformations.

The principal objective is the establishment of a program to determine incidence of specified malformations in selected areas, associated with a monitoring system to alert health officials to an unusual incidence of malformation in time or space and to serve as a starting point for ad hoc research into etiology of specific malformations.

Method of Procedure

A Planning Conference supported by a grant from NIH,

Division of General Medical Sciences GM 10967-01, was held from 3-7 January 1963 to advise the Organization on how the Organization should develop and implement a collaborative program for the Americas. The group included health administrators, pediatricians, epidemiologists, geneticists, obstetricians, maternal and child health specialists, pathologists and statisticians. Several members of the staff of WHO and NIH as well as of PAHO participated. A draft proposal for research on congenital malformations had been made as a framework for discussion. The list of participants of the Planning Conference is attached as appendix A.

It was agreed that the proposed research was significant as a step toward recognition of detrimental effects of newly introduced potentially teratogenic agents by detecting unusual groupings in time and space. The present report incorporates recommendations of the Planning Conference and is a part of the application submitted on February 25, 1963 to the National Institutes of Health for a grant to the Pan American Health Organization.

The method of procedure will be to select several study areas widely dispersed in the Americas for participation in this program. The careful selection of these areas will require considerable exploration and visits by staff of the Bureau, short-term consultants and central staff of the research project. Selection of principal collaborators in these study areas and design of the projects in those areas will be carried on in 1963. Each one of these principal collaborators would submit a research proposal for

consideration by the Bureau within the framework of the proposed research program.

Exploration of participation in the cities of the Americas will be carried out in 1963. Hospitals will be selected in communities where the preponderance of births (minimum of 80 per cent) were delivered in hospitals. Whenever under such circumstances all hospitals within the jurisdiction could be included in the study, essentially community-based data would result. Although it may be practicable to start with a single hospital in a selected community, with other hospitals added progressively, the necessary support should be made available to draw in the remaining hospitals as rapidly as possible. It was agreed that special reasons such as an unusually high frequency of a specific malformation, or exceptional environmental circumstances such as high altitude or poor nutritional status of the population would justify the inclusion of selected hospitals or areas requiring efforts to strengthen existing services.

At this time, the following requests or interests in participation can be reported which indicate that implementation of this proposal is practical. Three health administrators in the United States participated in the Planning Conference and requested inclusion of a hospital or all hospitals within their jurisdictions in a specific area.

Two of these administrators, Dr. Malcolm Merrill of California

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and Dr. Robert Barr, of Minnesota, were consulted in regard to the scheduling of the research program and they recommended strongly that the application be submitted in order that funds would become available for pilot testing and the research program as soon as possible.

United States

California

Dr. Malcolm Merrill served as general chairman of the Planning Conference and has expressed interest in the inclusion of an area in California. He stated that the Human Population Laboratory in Alameda County and Contra Costa which has approximately 30,000 live births per year would be the area for preliminary consideration. This laboratory which is supported by an NIH grant would have about one million and one-fourth population. A study of this type has already been started in Los Angeles General Hospital and thus Los Angeles might be considered for inclusion. Almost all births are delivered in hospitals in California (over 99 per cent).

New York City

Reporting of congenital malformations has been carried on for many years with confidential information recorded on the back of the birth and fetal death certificates in New York City. For the two years 1958-1959, using a base of 1,000 live births, the total rate of malformations was 15.3 but only 10.6 from the live birth

certificates. Although staff of the New York City Health Department has had special interest in this field, the investigation of the condition at birth has not been approached in terms of research and of developing comparable and complete data from each hospital. Dr. George James, the Commissioner of Health, has expressed his interest in the establishment of a Study Area in New York City. The size of the Study Area and the inclusion of the hospitals in the study will be explored both for the pilot testing and for continuation into the research program. Brooklyn, with a population around 2,600,000, has been suggested for the Study Area. In New York City 99.8 per cent of births occur in hospitals or on ambulance service of hospitals.

Minnesota

Dr. Robert Barr, Executive Officer of the Department of Health of Minnesota, has already started exploratory work in the Twin Cities (Minneapolis and St. Paul) with a physician employed to improve accuracy of recording. He wishes these cities included in the research program. The work will be expanded gradually from a few hospitals to the entire state. In Minnesota there will be additional studies but with other funds provided. Dr. Barr definitely wishes the investigation in the Twin Cities included in the collaborative research program. In these cities there are approximately 40,000 births each year with 99.9 per cent in hospitals.

Canada

Reporting of congenital malformations is carried on routinely in the provinces of Alberta, British Columbia and Ontario. In Ontario for the period 1952-1958, the rate of infants born with abnormalities averaged 11.0 per 1000 live births. Thus, a start has been made and with the development of a research project to promote complete reporting with standards as for other areas, data of the necessary high quality could become available. Dr. Basil D.B. Layton, of the International Health Section of the Department of National Health and Welfare of Canada, has requested our consideration for the inclusion of a Study Area in a city of Canada depending on suitable arrangements being worked out through the Health Services of the province and municipality concerned.

Venezuela

In Caracas, over two-thirds of the live births occurred in one hospital, Maternidad Concepcion Palacios, and an additional 6.6 per cent in the University Hospital. The data which show that 98.3 per cent of the live births were delivered in hospitals (including clinics) are given below:

Hospital and Attendance at Birth in Caracas, Venezuela, 1960

Hospital or attendance at home	<u>LIVE BIRTHS</u>	
	Number	Per Cent
Total	46,683	100.1

(Table continued next page)

"Maternidad Concepción Palacios"	32,096	68.8
Private Clinics	9,089	19.5
"Hospital Universitario"	3,091	6.6
Red Cross	999	2.1
"Clinica Santa Ana"	631	1.4
Midwives	636	1.4
Private Physicians	9	0.0
Unknown	132	0.3

A medical report on each birth is already filed with the health department and in the two largest hospitals the form is completed after a pediatric examination of the newborn infant has been made. About one per cent of births at the Hospital Concepción Palacios are diagnosed as having a malformation with one third confirmed by autopsy. The principal problem would be completion of records of fetal deaths, extension of pathological services, and promotion of complete recording of malformations according to standards. Thus, the situation in Caracas is unusually favorable for introduction of this research program. Interest in participation has been expressed by Dr. Pastor Oropeza and Dr. Dario Curiel. The large maternity hospital would be an excellent place to initiate pilot testing.

Colombia

Medellin, Colombia, is a city of around 700,000 population in which the Medical School of the University of Antioquia is located. Dr. Hector Abad Gomez, the professor in charge of the Department of Preventive Medicine and Public Health, is a potential principal collaborator.

It has been estimated that over 90 per cent of the total births occur in the Social Security Hospital, "Luz Castro" Hospital and the University Hospital with an additional 4.6 per cent in 4 smaller hospitals. Only 4.3 per cent occur in homes. Thus the research could be started in one of the large hospitals and extended to the others as the program produces data of the desired quality.

Brazil

Dr. Nelson de Araujo Moraes (Fundação Serviço Especial de Saúde Pública) of Brazil has requested inclusion of one or two cities in the investigation. Because of the major developments in the Northeast (through bilateral program with the United States) it seems desirable that a Study Area be established in a large city with a medical school in that area. Recife in the State of Pernambuco has two Medical Schools, Faculdade de Medicina da Universidade do Recife and Faculdade de Ciências Médicas de Pernambuco. A medical statistician of the Bureau is stationed in Recife and thus could render consultant service in the establishment of this research project. Such a project could be established first in a large hospital in Recife.

Chile

The Faculties of the Medical School and of the School of Public Health in Santiago, Chile, are interested in participating

in research projects and have well-qualified potential collaborators. The WHO study was initiated in the Hospital El Salvador and could well be extended to include a medical report on each delivery. Santiago has a population of over one million and a high proportion of births occur in hospitals. For the province of Santiago which includes the city, approximately 88 per cent of the 88,000 live births occurred in hospitals in 1961. The city would have a much higher proportion. The system of medical care is such that records will be available from out-patient clinics as well as hospitals.

Others

In addition to these four Latin American cities, exploration would be carried on for inclusion of a Study Area of at least one hospital in a city in a high altitude area and one with problems of protein malnutrition. La Paz, Bolivia, is a city at a high altitude in which Dr. Cecilio Abela, a well qualified pediatrician who received training in New York, is a possible principal collaborator. Because of the problems of protein malnutrition in Central America, the inclusion of a large maternity hospital in San Salvador, Guatemala City, or San José, Costa Rica, will be investigated. Also Study Areas in other countries will be explored.

During 1963 the research program will be promoted and records and procedures recommended by the Planning Conference will be

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tried out in a few pilot areas. Throughout, strong emphasis will be placed on quality of data for use for epidemiological studies. This emphasis on careful recording of data in a coordinated research program principally in medical centers is needed to provide basic data on the condition at birth for many purposes. A medical report of delivery and its outcome and an autopsy report were recommended for information regarding every product of conception counted in the study (28 weeks or more) and examined by a physician. As a minimum, each product of conception would have at least a complete physical examination. The autopsy report would be used for all those receiving an autopsy.

There was general agreement that a check list of specific malformations would be a part of the report form. A narrative description will be given of the defects also for detailed classification. In order to consider the final inclusions, their definition and description, it was recommended that an ad hoc committee of experts be assembled. Dr. Samuel Z. Levine has agreed to assist in this additional preparatory work. The recommendations of such a committee would be included in a Manual of Procedures which would be used in the pilot phases of the program in 1963. Also during 1963, the machinery would be set up for current coding and analysis of data received in the pilot phases so that a monitoring system would be in operation.

Although the main activities in the initiation of the project will be (1) a monitoring or a surveillance system and (2)

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collection of data for study of incidence of malformations observable at birth, the Planning Conference viewed as imperative that a plan of operation be devised also for prompt ad hoc investigations concerning causation of any unusual frequencies to which the system alerts. To develop this plan of operation a small advisory committee will be asked to consult with the Central Staff on special investigation of potential teratogenic agents and other etiological factors.

Thus, work in 1963 will be essentially preparatory to initiation of the research program early in 1964. In order to develop standard procedures to be followed in each area, a Planning Conference of the selected principal collaborators and a few experts in the field would be scheduled for early 1964.

Monitoring or Surveillance System

In each Study Area records would be collected currently of congenital malformations observable at birth on live birth or fetal death on the special form for Medical Report of Delivery. This report would be prepared at the time of discharge of the infant from the hospital and its completion would be supervised and signed by a physician in charge. (Exceptions to this procedure would be made for reporting, as soon as a medical examination has been made, of conditions diagnosed on premature births or malformed infants remaining in the hospital for care and treatment).

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The Planning Conference suggested that selected sources of data regarding malformations not readily recognizable at birth might be tapped to feed information into the system. This would provide an additional safeguard against an increase in malformations which might pass unrecognized.

Reports of congenital malformations would be sent currently (once a week) to the Central Office in Washington for immediate processing.

Once a week on a given day a report will be issued by the Bureau giving the numbers of malformations reported according to a detailed classification. Each malformation would be counted separately. The base, namely the total live births and fetal deaths in the same period, would be given also for use in evaluating the frequency of occurrence of specific malformations. It is recognized that during the first few weeks of such a system, evaluation will be difficult due to the lack of knowledge of the differences existing at present. However, with the accumulation and analysis of data currently, the situation will be clarified. The system may then serve to alert health officials to unusual occurrence of malformations requiring investigation.

Incidence of Congenital Malformations

In addition to the monitoring system a program would be established to determine incidence of individual malformations in

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the Study Areas of the Americas. Standard procedures will be established for the recording of congenital malformations discovered by examination at birth (or fetal death) on or before discharge of the infant from the hospital or of death. Autopsy findings on these infant and fetal deaths would be included. The ad hoc committee asked to define and describe malformations will delineate the method of examination of the infant at birth.

Data for each Study Area would be analyzed on an annual basis. Data on all fetal deaths and live births would be obtained either from tabulations made locally or in the Central Office from duplicate sets of punch cards supplied to the Bureau from the Study Areas.

Special Investigations

A significant increase in a specific type of malformation will have immediate ad hoc investigation by the principal collaborator in the Study Area and the assignment of a consultant if advisable. Differences in the incidence of malformations which are discovered in the various Study Areas may lead to special investigations.

Provisions are made for consultants to render assistance for basic investigation into etiology, which may include animal experimentation.

Research projects to test precisely defined hypotheses are expected to arise either as the result of observations made by individual collaborators or from a review of the total material in the study. Such projects would be developed as independent projects or as a collaborative project.

SCHEDULE OF OPERATIONS IN THREE YEARS OF COORDINATED RESEARCH
ON CONGENITAL MALFORMATIONS

A schedule in outline form has been prepared of the necessary steps to establish the program in the first year and to collect data in monitoring system and in the study of incidence and for special investigations in the following two years. It is possible that the monitoring system can be expanded to include data from additional reporting systems being established. However, the standards as developed in this program are needed for development of comparable data to lead to special investigations.

First Year, July 1, 1963 - June 30, 1964

1. Exploration of Study Areas and selection of principal collaborators by PASB staff, consultants, and central staff of project - beginning March 1, 1963.
2. Meetings of Advisory Committee for development of definitions and description of malformations during summer 1963.
3. Selection of Four Study Areas for pilot testing to begin September 1, 1963.
4. Pilot Testing, September 1, 1963 and continued.
5. Meeting of Advisory Committee for Plan of Operations for Special Investigations.

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6. Planning Conference, February 1964 for discussion and introduction of standard procedures and Manual.
7. Monitoring system established effective March 1, 1964. Continuation of reporting in pilot testing.
8. Release of Weekly Report on Congenital Malformations beginning November 1, 1963 from pilot testing and monitoring system.
9. Special ad hoc investigations due to unusual occurrences as indicated by monitoring system.
10. Collection and processing of data for study of incidence beginning March 1, 1964.

Second Year, July 1, 1964 - June 30, 1965

1. Monitoring system continued with Weekly Report issued regularly.
2. Special ad hoc investigations resulting from unusual occurrences in monitoring system.
3. First annual report from study of incidence for year March 1, 1964 - February 28, 1965.
4. Special investigations resulting from persisting differences noted in study of incidence.

Third Year, July 1, 1965 - June 30, 1966

1. Planning Conference, November 1965, for evaluation and reorientation of program based on experience in first year.
2. Completion of two years of monitoring, March 1, 1966.
3. Responsibility for local procedures gradually taken over by local and national health departments and central routine procedures by the Pan American Sanitary Bureau.

4. Analysis of incidence data for two years (March 1, 1964 - February 28, 1966).
5. Plans for additional collaborative or independent studies.

Significance of this Research Program

The Planning Conference agreed that the proposed research was significant as a step toward recognition of detrimental effects of newly introduced potentially teratogenic agents by detecting unusual groupings in time and space with investigations as to the causes while events are still fresh in the minds of those involved. Additional significance is attached to the recognition of persistent differences as well as of sporadic fluctuation in the incidence of congenital malformations related to geographical areas.

In addition, availability of good basic data on deliveries can yield many useful by-products. For example, the introduction into the system of infant records will permit analyses of perinatal and post-neonatal mortality data not hitherto possible in some areas. An important by-product may also be the stimulation of medical research in other areas of maternal and child health.

It is anticipated that the system of medical reporting of the condition at birth will be taken over by local health authorities. The value of standard procedures will be evident as incidence data become available. Reporting to the Pan American Health Organization can be continued as a routine procedure.

At present only limited information is available concerning the incidence and distribution of congenital malformations. As pointed out in the presentations at the Conference, it seems difficult to get an accurate estimate of the incidence of all congenital malformations from records published. The best estimate was probably two to three per cent. In New York City as recorded in the notification system the rate was 15.3 per 1000 for 1958-1959. Recording of malformations at birth will be definitely improved by introduction of this research program as proposed.

The extent of the influence of environmental factors and the manner of their interaction with genetic factors are not well known. It is the initial purpose of this program to supply more reliable epidemiological information than is presently available.

A hemispheric study will provide extensive data on the incidence of malformations which are essential as the basis for studies to identify possible external agents which may act upon the fetus to produce malformations.

In the Seminar on the Use of Vital and Health Statistics for Genetic and Radiation Studies in 1960, sponsored by the United Nations and the World Health Organization, repeated statements were made regarding the need for improvement of the quality of vital statistics with general references to the reporting of congenital defects on birth certificates. Also participants stressed the importance of the development of the International Classification

of WHO for study of rare events for genetic purposes. Many references were made to the value of collaboration of the geneticists and vital statisticians and to the shift in the epidemiological approach from infectious diseases to conditions labelled constitutional or congenital in whose etiology genetic factors are often of paramount importance. The geneticists have raised many challenging questions on which vital statistics of improved quality may provide basic information.

This proposed research would be an initial step toward improvement of the essential data regarding births and malformations observable at birth for use in many programs by geneticists, epidemiologists and health officials. At present community-based research is being carried out for development of comparable mortality statistics (Inter-American Investigation of Mortality). The proposed research directed to the collection of comparable data on the condition at birth is a similar collaborative program. Both endeavors in the fields of birth and death statistics will benefit many kinds of scientific programs.

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LIST OF PARTICIPANTS
TO THE
PLANNING CONFERENCE FOR RESEARCH ON CONGENITAL MALFORMATIONS
January 3-7, 1963

- Dr. Guillermo Adriasola, Prof. Cátedra Higiene Materno-infantil,
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- Dr. Roberto Caldeyro Barcia, Professor, Departamento de Fisiología
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- Dr. Heinz W. Berendes, Chief, Perinatal Research Branch, National Institute of Neurological Diseases and Blindness, National Institutes of Health, Bethesda, Md.
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