Cystic Fibrosis: A Community Challenge

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CYSTIC FIBROSIS of the pancreas, a relatively new disease entity, was brought to official recognition through the classic work of D. H. Andersen in 1938 (*1*). Today a confirmation of the diagnosis of this disease is no longer postponed until postmortem examination, but may be established within a matter of hours, and the life prolonged for years. The classic pattern of this disease has also changed, since many of the clinical manifestations are conditioned by modern medical care which in many instances prevents or delays the appearance of manifestations or at least ameliorates the severity of the disease.

In experienced centers and hands, meconium ileus, an early complication of the disease, is diagnosed and treated at once, gastrointestinal symptoms are corrected promptly, and pulmonary infection is prevented or treated adequately. On the other hand, in many regions this disease is still unknown, and it may serve as an excellent example of how many clinical and research contributions are needed to alert the medical world to its existence. Among several hundred papers dealing with cystic fibrosis, those of Andersen (*2*), Baumann (*3*), Bodian (*4*), di Sant' Agnese and Vidaurreta (*5*), and Shwachman and associates (*6*) are regarded as comprehensively informative. In addition to the references in this paper, the National Cystic Fibrosis Research Foundation can be consulted for the detailed literature on the clinical, laboratory, and research aspects of the disease.

Like many other diseases of infancy, childhood, and adolescence and the chronic diseases which afflict adults, cystic fibrosis is gaining increasing recognition as a public health problem which envelops the family unit. The community is concerned because the family may have to fall back upon it for assistance and, indeed, is likely to do so because of economic factors. Communities and health departments in the United States have met such problems before with considerable imagination, ingenuity, work, and public support. It is our purpose to present evidence that cystic fibrosis requires such tactics.

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Incidence

The facts are still being accumulated on the incidence of this disease among the people of the United States. Andersen and Hodges (*7*) calculated in 1946 an incidence of cystic fibrosis of 1.73 per 1,000 live births in the New York area; in 1958 Andersen (*2*) estimated the prevalence of cystic fibrosis in the United States as 0.7 to 1.7 per 1,000 live births. Goodman and Reed (*8*) give a rate of 0.7 to 1.0 per 1,000 live births, and our own data for the Massachusetts area (*9*) indicate an even greater incidence, as high as 1 in every 600 newborn infants. Baumann (*3*) calculated the incidence for the Swiss population as 7.22 new cases per 10,000 births per year. A national hospital survey of cystic fibrosis (*10*) indicates that 2,525 persons were hospitalized in the United States in 1957 because of cystic fibrosis, and one out of every six or seven died. The annual number of deaths attributed to this disease during the 1952–57 period ranged from 295 in 1952 to 475 in 1955 to 359 in 1957. In the bigger pediatric hospitals cystic fibrosis may represent 3 percent of autopsies and 0.2 percent of hospital admissions (*2*, *10*).

The real extent of this disease, cystic fibrosis

of the pancreas, and its distribution among the general population is still unknown. Several factors are partially responsible for this. Official medical statistical listings omit this fairly young pathological entity. For example, the Standard Nomenclature of Diseases and Operations included cystic fibrosis of the pancreas for the first time in the 4th edition (1952), but without recognizing the modern interpretation of the disease, that is, as a systemic disease involving not only the pancreas but many other organs, particularly the respiratory system, paranasal sinuses, liver, rectum, and sweat glands.

The Manual of International Statistical Classification of Diseases, Injuries, and Causes of Death (seventh revision, 1955) codes only fibrocystic disease of the pancreas. It should be emphasized that fibrocystic disease of the lung (congenital), fibrocystic disease of other organs, and cystic disease of the lung, liver, or other organs are quite different clinical and pathological entities and should not be confused statistically, or otherwise, with cystic fibrosis of the pancreas. Indeed the name, cystic fibrosis of the pancreas is now an obsolete, misleading, and completely inadequate term for describing the clinical and pathological picture of this disease entity.

Several other misnomers are also being used for cystic fibrosis: fibrocystic disease, mucoviscidosis (Farber), mucosis (Bodian), mucositis (Michalowicz), dysporia entero-broncho-pancreatrica familiaris (Glanzmann), and exocrinosis (di Sant' Agnese). The monthly *Index Medicus* uses pancreatic cystic fibrosis with cystic fibrosis, fibrocystic disease of the pancreas, and mucoviscidosis as cross references.

Until a better name is coined, clinician, pathologist, and statistician should be familiar with this clinical pathological entity as described in different countries by these various names. With the present medical and official international statistical listings, this disease, even when diagnosed, is not being reported statistically or may be coded under "other diseases of pancreas."

Many cases are diagnosed late or misdiagnosed, particularly when the predominant signs and symptoms point to organs other than the pancreas. Frequently, an incomplete and symptomatic diagnosis is made, such as bronchitis, emphysema, bronchopneumonia, bronchiectasis, atelectasis, sinusitis, nasal or intestinal polyposis, rectal prolapse, malnutrition, anemia, vitamin deficiency, intestinal obstruction, congenital intestinal abnormality, portal hypertension, heat prostration, or hypoproteinemia. All these conditions may occur as one or more complications of cystic fibrosis but as such are not yet included in the statistical coding with direct reference to cystic fibrosis, as the disease is understood either in modern teaching or clinical experience or both.

Even if diagnosed and treated correctly the disease may not be enumerated in the vital statistics, since this entity is not a reportable disease. Only hospitals with a large pediatric service, taking a particular interest in this disease, may provide pertinent mortality and morbidity statistics for cystic fibrosis in the area they serve. Cystic fibrosis may be responsible for as much as 5 percent of all deaths in these hospitals. Some State departments of health (Massachusetts, Connecticut, Rhode Island, and Maine), which supervise health programs for persons with this disease, may have accurate and up-to-date data of the incidence of cystic fibrosis among the population in their jurisdiction (*11*).

Characteristics of Cystic Fibrosis

Increasing knowledge of the disease indicates that cystic fibrosis is inherited (*3*, *4*, *7*, *12*) and may originate during fetal life. About 10 to 15 percent of the patients are born with intestinal obstruction (meconium ileus) (*13*). Apparently the effect of the absence of pancreatic enzymes is that undigested, tenacious meconium blocks the ileum or some other part of the intestine. Nowadays this emergency is usually corrected surgically, but absence of pancreatic enzymes leads to nutritional and growth disturbances that must be corrected continuously by dietetic supplements of enzymes and vitamins. Even when such replacement therapy is successful, pulmonary changes may still appear, or they may occur independently. The accumulation of bronchial secretions fre-

quently precipitates severe pulmonary phenomena, leading to persistent bronchitis, atelectasis, emphysema, bronchiectasis, and peribronchial and generalized pulmonary involvement (*14*).

Clinical manifestations of cystic fibrosis vary according to age of the patient at onset, progress of the disease, and response to therapy (*2, 5, 6*).

Diagnosis

The diagnosis of cystic fibrosis is based on clinical manifestations and laboratory results. These include a complete or partial deficiency of pancreatic enzymes (*15*), abnormal concentrations of sweat electrolytes (*9*), pulmonary obstructive phenomena, and other important features supplemented by a detailed clinical and family history (*16*). No single clinical manifestation or laboratory test can absolutely determine the presence or absence of this disease or rule out other possibilities (*4–6,17,18*). Currently, analysis of sweat electrolytes is probably the most reliable single test to confirm the diagnosis when other manifestations are present (*9*).

The lack of pancreatic enzymes is prevalent in approximately 80 percent of the patients, many of whom have some signs of malnutrition in spite of replacement therapy. History of rectal prolapse is present in about 25 percent (*19*), and intestinal complications including meconium ileus, intussusception, and fecal impaction in about 20 percent (*2,13*). Other conditions of cystic fibrosis found not infrequently are portal hypertension, biliary cirrhosis, congestive heart failure, nasal polyposis, diabetes mellitus, heat prostration, and hypoproteinemia (*5*). Shwachman and Kulczycki have also noted similar findings in their series of cases (unpublished data).

Some cases, however, present a diagnostic challenge and require considerable clinical experience and a searching interpretation of the laboratory tests. We are aware of patients who were treated for psychiatric conditions or for tuberculosis, allergy, or rectal prolapse or who have had segments of the lung removed (*14*), but in whom the true nature of the disease was not recognized for many years. In some cases, the physician or surgeon overlooks this disease completely, and incorrect diagnoses will continue to be made until cystic fibrosis is more widely recognized. We are also aware that postmortem findings may be wrongly labeled if the pathologist is not aware of the disease (*20*).

Genetic Aspects

Genetic studies indicate that cystic fibrosis is a hereditary disease and that the genetic makeup of each parent may contribute to the appearance of this disease in the offspring (*3,7,8,16,21,22*). Andersen and Hodges (*7*) point out that cystic fibrosis is transmitted as an autosomal recessive gene.

The work of Lowe and co-workers (*18*) in 1949 with 95 families indicated that some heterozygotes may eventually survive and reproduce. Goodman and Reed (*8*) stated in 1952, "Fibrosis of the pancreas is a simple recessive trait which causes the eventual death of infants and children, and genetically speaking, is a lethal gene." These authors assume that the lost gene is replaced by mutation from the normal to abnormal allele; their calculation of the mutation rate for cystic fibrosis is expressed as 0.7 to 1.0×10^{-3}. According to their investigation, 1 in every 16 to 20 persons carries this gene. Baumann (*3*) thinks that the gene balance is maintained because of an increased instinct of progeniture in individuals with these genes; that is, Swiss families with mucoviscidosis have 4.27 children each, while "healthy" families have only 2.48. Baumann's conclusion is that the gene does not behave in a purely recessive way and "the genotypically homozygous individuals are affected phenotypically; the parents of homozygous patients are heterozygous, genotypically sick but phenotypically healthy individuals showing rarely microsymtoms (increased electrolytes in perspiration)." Hsia (*21*) includes cystic fibrosis in the group of heterozygotes "for which the evidence appears to be reliable and has received independent confirmation."

Much clinical and laboratory observation is being accumulated supporting the view of partial gene penetration and an incomplete expression of the disease in many patients (*3,23*).

More than 80 percent of the patients lack pancreatic enzymes; others have various degrees of pancreatic insufficiency, and a few have sufficient enzymes (*5,15*). More than 80 percent of the patients have pulmonary involvement of different degrees of severity. A few are free of pulmonary manifestations, or show mild pulmonary changes only at a later age (*14,23*).

The symptoms and signs of cystic fibrosis may appear singly or in combinations, early or relatively late in life. Koch (*24*) stated that hereditary mucoviscidosis is more frequently noticed among adults than infants and children. Peterson's study (*23*) and our own observation indicate a possibility of many cases of unrecognized cystic fibrosis among adults. Baumann (*3*) confirmed an observation by di Sant' Agnese (*25*) and Shwachman (*6*) stating that a significant percentage of parents and siblings may have elevated sweat electrolytes without clinical manifestations of the disease. All observations point to the fact that birth order has no correlation with affected siblings. In some families only the 9th or the 11th offspring has been affected, and in others all three, four, or five siblings are affected (H. Shwachman and L. Kulczycki, unpublished data). There is no sex predominance (*3, 6*). Steinberg and co-workers (*22*) analyzed 141 families and found known consanguineous mating in only one. But Baumann's geneological research in Switzerland showed siblings in closely related families.

The statement made in the past that the disease is usually fatal within the first year of life reflected only helplessness, stated so vividly in 1942 by Attwood and Sargent (*20*): "Cystic fibrosis of the pancreas is seldom correctly diagnosed prior to death, and may be even missed at autopsy." The proper management of the patient may suppress the progress of the disease, change its clinical pattern, and extend the life of the patient (*26, 27*). The influence of parental intelligence and socioeconomic factors is evident and may be of significance.

Apparently both genetic and environmental factors may affect the transmission of the gene and the expression of the disease. There is a possibility that this disease may be transmitted as a dominant trait with low penetrance, or as a recessive, with partial expression (*3, 23*). Many more studies of the family, the patients, and their offspring are required to establish the specific genetic pattern of cystic fibrosis.

Survival beyond adolescence is increasingly frequent. In the few instances when the parent of a child with cystic fibrosis remarried a partner with no history of the disease, the offspring were free of cystic fibrosis. Baumann advises avoidance of marriage between members of families with known history of cystic fibrosis and suggests voluntary limitation of reproduction after the appearance of the first case. Some of the data from clinical observations and genetic studies may support consideration of their practical application, but much more research and evidence are needed before cystic fibrosis gene tracing becomes part of the premarital consultation.

Public Health Interest

Public health is concerned with this disease not only because of the need for providing essential clinical service and medical care for the patient but even more so because of the adverse economic factors. So serious a disease in the advanced stage usually requires a highly specialized regimen for the individual. An adequate program must be readily available to the family and to the patient. It should include casefinding; a center for evaluation, diagnosis, and treatment; social referral; public assistance; and other followup services. Public health has an important role to play in all these aspects. The Commonwealth of Massachusetts and other States (*11*) have already recognized this function by including patients with the disease in the State crippled children's program and by making available to them essential clinical services. Public health planning and action in this matter are conditioned by experience in handling other crippling conditions of children such as rheumatic fever, nephrosis, poliomyelitis, and chronic orthopedic conditions.

In many instances it is necessary to aid the family with cystic fibrosis in meeting its economic problems. The recently formed citizen organizations and the campaigns for public understanding of this problem may have a special value in furthering support for this concept. Parents and families directly concerned with

this disease in particular have formed local chapters of the national organization.

Summary and Conclusions

Cystic fibrosis weighs heavily upon the afflicted families. It warrants a program of aid for the individual patient and assistance to the family income to meet the expenses of necessary and continuous medical care. The community, acting through existing public health services, must help by providing for the early detection of the disease and developing facilities for casefinding, diagnosis, and treatment. A standardized nomenclature of this disease and proper pathological and statistical coding are needed. Uniform channeling of the statistical data currently available and continuously developing through followup studies is urgent.

Owing to the complexity of the disease and the difficulty in the correlation and interpretation of the clinical and laboratory findings, it is postulated that the diagnosis and management of the patient affected with cystic fibrosis should be supervised by physicians who have specialized knowledge of this relatively new clinicopathological entity. Several pediatric centers have accumulated much experience in handling the overall problem of cystic fibrosis. But any such service, particularly the supervision of nutrition, rehabilitation, breathing therapy, proper bronchial drainage, and adequate use of mist and aerosol spray, requires considerable cooperation on behalf of the patient by the parent, properly trained physician, nurse, and physiotherapist. The voluntary organization of parents and interested citizens has an important function in the development of these needed services.

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Reports From the White House Conference on Children and Youth

Proceedings and background material of the 1960 White House Conference on Children and Youth are available in two collections of booklets and on a set of recordings.

Both collections contain the chartbook, "Children in a Changing World"; the resumé of national organizations' reports, "Focus on Children and Youth"; the summary of States' reports, "The States Report on Children and Youth"; and the "Conference Proceedings," which includes additional background descriptive material, condensations of selected papers, and a composite report of the forum recommendations. Library No. 1 includes, in addition, three volumes of background papers entitled "The Nation's Children." Library No. 2 contains, in addition to the basic publications, "Reference Papers on Children and Youth" and the survey papers, "Children and Youth in the 1960's." Each library is available for $10 plus $1.30 for postage and handling.

Six 12-inch double-face recordings of excerpts from 12 of the major speeches and discussions may be obtained for $12.75. Each excerpt lasts 20 minutes and can be played on any 33⅓ rpm record player. Speakers are President Eisenhower, Secretary of Health, Education, and Welfare Arthur S. Flemming, Marion D. Hanks, Abraham J. Heschel, Reuben Hill, Irene M. Josselyn, Roy E. Larsen, Robert B. Lawson, Lawrence J. McGinley, Liston Pope, Milton G. Rector, and Abram J. Sachar.

The libraries and recordings may be ordered or prices on individual printed items may be obtained from the National Committee for Children and Youth, 411 Association Building, 1145 Nineteenth Street NW., Washington 6, D.C.

A separate booklet on "Recommendations" may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington 25, D.C., single copies 35 cents, quantities of 100 or more 25 percent less.

Federal Publications

Atmospheric Emissions From Petroleum Refineries. A guide for measurement and control. *PHS Publication No. 763; 1960; by Bernard J. Steigerwald and Andrew H. Rose, Jr.; 50 pages; 30 cents.*

Directed to petroleum refinery operators and air pollution control officials, this manual discusses petroleum refining procedures in relation to air pollution control. Methodology for estimating atmospheric emissions from refineries, an introduction to refinery terminology, equipment, and processes, and details on sources and magnitude of emissions are presented.

This book implements the nine reports of the Joint Project, a study initiated in 1955 to determine the quantity and nature of emissions from oil refineries in Los Angeles County. Control procedures adopted by the county are described.

Poultry Diseases in Public Health. Review for epidemiologists. *PHS Publication No. 767; 1960; by Mildred M. Galton and Paul Arnstein; 40 pages; 25 cents.*

Developed as a guide for epidemiologists, this review discusses and evaluates some of the reported outbreaks and sporadic cases of human diseases traceable to poultry, especially chickens. It summarizes current public health aspects of about 25 bacterial, viral, fungal, and parasitic diseases involving man and fowl.

Medical Research in the USSR. A selected and annotated list of references. *PHS Publication No. 710; 1960; by Elizabeth Koenig; 45 pages.*

Abstracts of monographs, research reports, and personal accounts by Western scientists, written as early as 1947 but mainly between 1954 and 1959, deal with medicine and medical research in the Soviet Union.

Cited are about 100 research reports or literature reviews and approximately the same number of reports on medical institutes and laboratories, clinics, hospitals, and talks with Soviet scientists. This compilation is designed to assist those who cannot read Russian to acquire background information on the status of Soviet medical research.

Living Longer. Questions and answers on the health of our older citizens. *PHS Publication No. 733; 1960; 47 pages; 25 cents.*

Background information is provided for participants in State and local forums on aging in preparation for the White House Conference on Aging, January 1961. The booklet may also be useful in developing local health programs and services for the aged.

Text and illustrations present summary information on population estimates, life expectancy, leading causes of death, limitation of activity associated with acute and chronic conditions and injuries, disability, cost and financing of medical care, marital and income status, visits to physicians, length of stay in general and mental hospitals, nursing homes, and related facilities, and the Nation's need for hospital beds.

Health Statistics from the U.S. National Health Survey.

ACUTE CONDITIONS, incidence and associated disability, United States, July 1958–June 1959. *PHS Publication No. 584–B18; 1960; 34 pages; 30 cents.*

VOLUME OF PHYSICIAN VISITS, United States, July 1957–June 1959. *PHS Publication No. 584–B19; 52 pages; 40 cents.*

ARTHRITIS AND RHEUMATISM reported in interviews; United States; July 1957–June 1959. *PHS Publication No. 584–B20; 1960; 26 pages; 25 cents.*

DIABETES reported in interviews, United States, July 1957–June 1959. *PHS Publication No. 584–B21; 22 pages; 25 cents.*

LOSS OF TEETH, United States, July 1957–June 1958. *PHS Publication No. 584–B22; 1960; 26 pages; 25 cents.*

ACUTE CONDITIONS, geographic distribution, United States, July 1958–June 1959. *PHS Publication No. 584–B23; 1960; 30 pages; 30 cents.*

OLDER PERSONS, selected health characteristics, United States, July 1957–June 1959. *PHS Publication No. 584–C4; 1960; 76 pages; 45 cents.*

Staphylococcal Disease. Selected materials on nursing aspects. *PHS Publication No. 764; 1960; 174 pages; $1.*

Reprints from professional and scientific journals have been collected to make available in one volume recent information on the nursing aspects of staphylococcal disease.

This book also contains a specially prepared article on bacteriophage typing and a selected list of audiovisual training aids with information as to where each may be obtained.

Recommendations for the control of staphylococcal disease and a detailed bibliography are provided.

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