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PROFILE ON OPEN-HEART SURGICAL FACILITIES IN THE NEW YORK CITY AREA

In 1973 there were only about 3,000 open-heart operations performed in the New York City metropolitan area out of the many tens of thousands of surgical procedures. Open-heart surgery doesn't begin to appear on any list of the twenty five most frequently performed operations in the United States. Why then is it a cause for concern to the average consumer? Why is this issue of Health Perspectives devoted to the subject?

There is no such thing as minor heart surgery or an inexpensive heart operation. In one institution today the total charges to a patient for open-heart surgery run between ten and twelve thousand dollars. Of every 100 patients undergoing open-heart surgery, under the best of conditions, approximately ten of them will die. When both costs and risks are this great it is imperative that every effort be made to exercise vigilance and control to ensure high quality efficient services.

OPEN-HEART SURGERY: WHAT IS IT?

Conditions requiring open-heart surgery may be regarded as divided into two general groups: congenital heart disease (which exists when a baby is born) and acquired heart disease. In congenital heart disease the blood vessels and connections of the heart do not develop normally in the unborn baby and surgical repair of the resultant defect is the only treatment possible. Acquired heart disease may be of several kinds, but the two most common conditions for which surgery is recommended are those resulting from rheumatic heart disease or from coronary artery disease. The coronary by-pass operation, for patients with severe angina and intractable pain, is relatively new, but in 1972 it accounted for approximately one third of all open-heart operations in New York City.

All open-heart surgery requires the use of an "extra-corporeal pump oxygenator" or heart-lung machine. This pump is used as a substitute for the patient's own heart and lungs, and not only gives oxygen to the blood but also circulates the blood through the body to maintain vital functions while the heart is allowed to stop beating so that the surgeon has

a non-moving organ to work on. Special x-rays are also required, so that diagnoses of the heart and blood vessels can be pin-pointed and the proper type of surgery decided in advance of operation. Many other instruments and kinds of equipment are needed, as well as a staff of specially trained personnel to use them.

The first 48 to 72 hours after a heart operation are crucial, and all heart surgery patients must spend these hours in an intensive care unit where they can be constantly watched. The ratio of staff to patients in these units is much higher than on a normal hospital floor, often as high as one staff member for each patient.

PROFESSIONAL STANDARDS AND ACCREDITATION

There are three sources of standards for open-heart surgical units.

- 1) The Joint Commission on Accreditation of Hospitals (JCAH), a Chicago based non-profit agency, was given a contract by HEW to develop criteria for the identification of hospitals capable of providing the most advanced techniques and methods for the diagnosis and treatment of heart disease, cancer, stroke, and end-stage kidney disease.
- 2) The Inter-Society Commission for Heart Disease Resources was created under the same auspices to develop guidelines for the optimal medical resources for the prevention and treatment of cardiovascular diseases.
- 3) The New York State Health Department, under State Public Health Law, administers the State Hospital Code which sets the standards defining the regulations under which hospitals are licensed.

Standards apply to the staffing of units, the equipment deemed essential for a unit, and the general hospital support services, such as blood banks, cardiac catheterization units, laboratories able to do special tests, etc. Both the JCAH and the Inter-Society Commission recommend that qualified medical, surgical, anesthesiologic, radiologic, nursing, and technical personnel be available for emergency duty at all times (24 hours a day.)

In addition, specifications as to the work-load of a unit are given:

The JCAH: "Numerical criteria for optimal care must consider the following factors: (1) the recommen-

dation by recognized experts on how much of a work load would be sufficient to allow professional and technical staff an opportunity to develop and maintain their skills, motivation, and morale; (2) published and unpublished data on the frequency with which certain diagnostic and therapeutic procedures are performed in selected hospitals and the morbidity and mortality associated with those procedures at each of those hospitals; and (3) the inverse relationship between the cost of a procedure and the frequency of its performance."

The Inter-Society Commission: "We believe the smallest practical unit to qualify as a cardiac center should perform four to six cardiac operations with extracorporeal circulation weekly, an increase over the widely held opinion in this country that two open-heart cases per week constitute the irreducible minimum for maintaining an effective open-heart program."

The State Hospital Code: "There shall be sufficient utilization of a center to insure both quality and economy of services as determined by the commissioner."

All experts in the field say that unless a minimum number of open-heart procedures are regularly performed in a unit, there will be more deaths from surgery and a stormier post-operative course. A study is now planned by the National Heart and Lung Institute to examine mortality rates and quantify the risks according to the size of a unit. Because the mix of operations is so different from hospital to hospital, and the pre-operative condition of patients also varies greatly, it is difficult to say exactly how many more patients will die in a unit performing less than the optimal number of operations. There are, however, studies from related situations where there is less built-in variation. In coronary care units treating myocardial infarcts there were higher mortality rates in smaller units, and all hospitals that had mortality rates of 20 per cent or greater treated fewer than 200 patients per year. Another study considered coronary arteriography, the radiologic examination always done prior to open-heart surgery. The mortality rate in institutions performing fewer than 200 examinations over a two year period was **eight times higher** than in institutions performing more than 800 examinations in two years. Thus there appears to be a direct correlation in care of heart patients: fewer procedures, more deaths.

OPEN-HEART SURGICAL PROGRAMS IN THE NEW YORK METROPOLITAN AREA

At the present time, 200 open-heart operations per year (or roughly four per week) is considered the optimal number for a unit in order to maintain staff skills and minimize mortality. Table I shows those hospitals in the greater New York City Metropolitan Area doing 200 or more procedures in 1973. There were seven hospitals in this category, four of them

in Manhattan, and one each in the Bronx, Queens and Nassau County. Figures are given for a five year period (1969-1973) so that trends may be seen and those hospitals with developing programs may be identified.

TABLE I
OPEN-HEART SURGICAL PROCEDURES IN NEW YORK HOSPITALS
(Hospitals doing 200 or more procedures in 1973)

HOSPITAL	1969	1970	1971	1972	1973
University (NYU-Manhattan)	308	393	531	579	761
Presbyterian (Manhattan)	271	292	294	319	348
St. Lukes (Manhattan)	52	154	264	311	331
Montefiore (Bronx)	226	314	282	339	321
New York Hospital (Manhattan)	230	178	282	304	319
Long Island Jewish (Queens)	38	70	206	236	262
St. Francis (Nassau County)	212	204	137	80	221
TOTAL	1337	1605	1996	2168	2563

Table II shows those hospitals in the greater New York City Metropolitan Area doing more than 50 procedures in 1973, but fewer than 200. There were eight hospitals in this category, five in Manhattan, and one each in the Bronx, Brooklyn, and Nassau County.

TABLE II
OPEN-HEART SURGICAL PROCEDURES IN NEW YORK HOSPITALS
(Hospitals doing more than 50 but less than 200 procedures in 1973)

HOSPITAL	1969	1970	1971	1972	1973
Mt. Sinai (Manhattan)	110	123	147	149	137
Albert Einstein Division (Montefiore - Bronx)	NA	NA	115	125	NA
Downstate (Brooklyn)	34	55	69	51	102
North Shore Hospital (Nassau)	9	1	22	58	93
Lenox Hill (Manhattan)	24	17	28	76	90
St. Vincent's (Manhattan)	57	55	51	67	89
Roosevelt (Manhattan)	-	50	62	70	60
Flower 5th (Manhattan)	80	36	32	59	NA
TOTAL	314	337	526	655	571

Table III shows those hospitals in the greater New York City Metropolitan Area doing fewer than 50 procedures in 1973. There were twelve hospitals in this category, six in Brooklyn, two in the Bronx, two in Nassau County, and one each in Manhattan and Westchester County.

TABLE III
OPEN-HEART SURGICAL PROCEDURES IN NEW YORK HOSPITALS
(Hospitals doing less than 50 procedures in 1973)

HOSPITAL	1969	1970	1971	1972	1973
Nassau Hospital (Nassau)	-	21	38	NA	48
St. Barnabas (Bronx)	46	62	89	70	41
Bellevue (Manhattan)	34	23	34	41	NA
Maimonides (Brooklyn)	-	-	NA	NA	29
Jewish Hospital (Brooklyn)	58	69	74	40	NA
Nassau Cy. Medical Center	27	20	19	27	17
Grasslands (Westchester)	NA	NA	NA	NA	41
L.I. College (Brooklyn)	0	0	55	19	0
Kings County (Brooklyn)	20	21	18	NA	NA
Brooklyn	16	30	26	0	0
Wyckoff (Brooklyn)	13	9	9	8	0
Bronx Municipal	6	4	2	NA	NA
TOTAL	220	259	364	205	176

Using the totals for 1972, where figures are more complete, it can be seen that the seven hospitals shown in Table I account for 2168 operations, or 72 per cent of the total 3028. The twelve hospitals performing fewer than 50 operations per year accounted for only 205 procedures, or 6 percent of the total.

COSTS

Open-heart surgery is an expensive procedure. Even when the physician's fees are not included, the hospital charges to the patient will run at least seven or eight thousand dollars per open-heart operation.

No hospital makes a profit on open-heart surgery. The initial investment the hospital must make may approach half a million dollars, even if the hospital already has many of the specialized support services such as respirators, defibrillators, and a coronary care unit. It is difficult to give reliable figures, particularly in an inflationary period, but some numbers may be cited as examples.

Dr. C. W. Lillehei, who performed the first open-heart operation in America in 1954, estimates the cost of a heart-lung machine at \$30,000 and of a needed supply of valves for surgery at about \$10,000. Monitoring equipment for postoperative care would cost at least \$10,000. Dr. Don Frederickson of the Inter-Society Commission has estimated the cost of equipping a catheterization and cardio-vascular diagnostic laboratory as between \$300,000 and \$500,000, the higher figure applying if the laboratory is computerized.

The cost of the equipment is only the beginning. The largest part of hospital overhead is spent on staff salaries, and an open-heart surgical unit requires large numbers of highly trained staff. The New York Times has reported that one survey showed that open-heart surgery, if properly done with modern equipment and supplementary personnel, can push a hospital's operating costs up as much as 9 per cent.

This total package of costs is only partially covered by the charges made to the patient actually undergoing the surgery. If the true costs were passed on only to those patients benefitting from the special staff and equipment, the charges would be prohibitive. Since no one individual can pay the true costs, these are therefore allocated among all patients entering that hospital and, in effect, the patient undergoing an appendectomy is also underwriting the patient with open-heart surgery. This principle is exemplified in the formula used by Blue Cross to reimburse hospitals. Blue Cross pays each hospital a daily rate which is related to the cost of running the hospital divided by the number of days of patient care the hospital dispenses. If this total cost is pushed up by the expenses of an open-heart surgical unit the daily rate Blue Cross has to pay would be higher.

WHO IS MINDING THE STORE?

It would seem obvious that by any standard, either

of cost or of quality, there are too many open-heart surgical units in the greater New York City Metropolitan area. There are more than ten units doing fewer than one procedure per week, with no indication that these units are in a growth stage of development.

Many involved organizations have expressed concern over this expensive duplication of facilities. In April, 1973, Blue Cross announced that it would discontinue payment for open-heart surgery at five hospitals in Brooklyn and Nassau County whose programs were not approved by the State Department of Health. This would not close the programs, but would exclude the costs of such programs from the formula which determines how much Blue Cross pays the hospital for a day of patient care. These hospitals were Long Island College, Wyckoff Heights, Nassau, Nassau County Medical Center, and North Shore. Since the Blue Cross announcement, Wyckoff Heights appears to have discontinued its open-heart surgery program, the North Shore Hospital has expanded its program which is now approved, and the other three have maintained services at approximately the same level. Nassau Hospital has also obtained approval from the State and the Nassau County Medical Center has been involved in a fight for approval.

In January, 1974, the Long Island Health and Hospital Planning Council voted overwhelmingly to recommend that the State approve the open-heart surgery program at the Nassau County Medical Center, using the rationale that the Center served the poor of Nassau County who were entitled to care. The one member of the planning Council to vote against approval had suggested that elective cases could be sent to other Nassau hospitals which already had substantial programs. A Blue Cross representative, who had made serious efforts to withhold payments for open-heart surgery from hospitals with marginal programs, was denied permission to appear and give testimony at this meeting.

In March, 1974, in a close vote (11 to 9), the State Hospital Review and Planning Council voted approval of the open-heart surgery program at Nassau County Medical Center. Officials of the Center were allowed to speak at the Council meeting, but no community groups were represented nor was Blue Cross testimony solicited. As a result of this vote Blue Cross is now obligated to include the costs of Nassau County Medical Center's open-heart surgery program in its reimbursement formula.

Final responsibility for approving or disapproving any hospital program in New York lies with the State Department of Health. Blue Cross may not withhold money from any State approved program. Since September, 1973, the strict New York City Hospital Code has been superseded by the State Code; although the New York City Health Department still has the legal authority for inspecting pediatric open-heart surgery programs through its

responsibility for the Title V Crippled Children's Program. Even though the New York City Health Department has been promulgating standards for open-heart surgery programs since 1950, it no longer has the legal authority to inspect or close hospitals in the City.

Although open-heart surgery programs have existed for over fifteen years, the State Department of Health has only promulgated regulations for such programs as of January, 1974. Until that time it granted approval without stating any specifications. In fact, in 1966, the State approved all on-going programs under a so-called "grandfather clause". Since that time it has failed to search out programs opening without approval, has not enjoined any unapproved program from operating, and has not acted upon recommendations for disapproval received from the New York City Health Department.

Amendments to the State Hospital Code, applying to Cardiac Surgical Centers, became effective January 3, 1974. Two subsections are of particular interest.

706.5 (d) State Cardiac Advisory Committee. The State Cardiac Advisory Committee shall, at the request of the commissioner, consider any matter relating to cardiac surgical centers and shall advise the commissioner thereon.

706.5 (e) Approval and review. Project site visits by members of the State Cardiac Advisory Committee shall be made as indicated, as an adjunct to initial approval, and/or for maintaining approval. Cardiac surgical centers seeking to obtain or maintain approval shall demonstrate their capacity to meet minimum workload requirements, as determined by the commissioner. There shall be sufficient utilization of a center to insure both quality and economy of services, as determined by the commissioner.

The State Cardiac Advisory Committee is a technical advisory committee and members are selected by the commissioner on the basis of their proven expertise in the cardiac field. To this date the Cardiac Advisory Committee has not functioned, no minimum workload standards have been developed, and no project site visits have been made for the purposes of approving new open-heart surgery programs or for maintaining approval of existing programs.

WHAT SHOULD BE DONE

It seems obvious that the interest of health consumers lies in the closing of under-utilized open-heart surgical units now in existence, or at the very least in preventing new ones from opening. There is no reason to expect a marked increase in demand for these services. The back-log of cases of congenital heart defects has been eliminated and present facilities are more than adequate to care for the small number of new cases expected each year. In fact, with better pre-natal care, it might be expected that there will be a smaller number of congenital heart defects in the future. A second group of can-

didates for open-heart surgery is also expected to be smaller; as streptococcal disease is brought under control there is less and less rheumatic heart disease with its subsequent valve damage. The third major group is also doubtful, as the usefulness of coronary by-pass operations is currently being questioned. Although the procedure may ultimately prove valuable, it is likely that much more research is needed before it becomes common.

With no need to provide an expansion of facilities for future need, the proliferation of open-heart surgery units is both uneconomical and indefensible at the present time. Even more important is the poorer quality of care provided by an under-utilized unit. Unfortunately, there are no built-in safeguards in our medical care system to protect us. It is impractical to expect doctors and hospitals to control the number of open-heart surgery facilities; medical staffs have historically demanded and received costly equipment for their own use, even though that equipment may be available and under-utilized only a few blocks away. Neither the New York City Health Department nor the third party insurers have any legal clout with which to enforce their convictions that fewer and better units would benefit both the health and pocketbooks of New York City residents. Only the State Health Department has the legal power necessary, and it has shown itself to be dilatory both in setting regulations and standards and in enforcing those standards when they are finally incorporated into the hospital code.

RECOMMENDATIONS

- 1) The State Department of Health should set minimum numerical standards for open-heart surgical units and enforce those standards, both before granting approval to a unit and as a routine matter for maintaining approval of on-going units. Regular hospital inspection visits must be made by the Cardiac Advisory Committee and the State Health Department hospital surveyors. If the State used its power to withdraw approval, the rate-setting procedures of Blue Cross could then operate to control for duplication of facilities.
- 2) Patients can refuse to enter a hospital for open-heart surgery unless they are sure that a minimum number of procedures are done in that institution so that optimal care can be guaranteed.
- 3) Hospital Boards and individual Board members should examine requests for equipment and special staffing with an eye to community need. They should strive for regular self-analysis and evaluation of the hospital and review community needs annually, as they have a great responsibility for quality of care and cost effectiveness of the hospital's operations. They should not allow their pride in the prestige of their home institution to compromise quality and economy.
- 4) The State Insurance Department should examine questions of duplication of facilities and unrec-

essary expenditures when it is approached for rate increases by third party insurers.

- 5) Open-heart units at all hospitals presently performing less than 50 open-heart surgical procedures a year should be closed immediately.
- 6) Open-heart units at all hospitals in table II should be given two years to reach a minimum of 200 procedures per year.

**Selected Sections, State Hospital Code, Part 706,
Special Diagnostic and Therapeutic Services
(Statutory authority: Public Health Law 2803)**

706.5 Cardiac surgical centers. Patients shall not be admitted for cardiac surgery, except in emergencies, unless the facility is an approved cardiac surgical center. Cardiac surgical centers shall provide both diagnostic and surgical services and shall be approved only as such a combined center. The center shall be staffed to provide full integration of all essential professional activities at all times. There shall be specific written policies and procedures for the center, which supplement the basic hospital policies and procedures.

(a) Direction. The center shall be under the direction of a qualified specialist in thoracic surgery with adequate training and concentration of effort in cardiovascular surgery.

(b) Staff. All personnel shall be prepared for their responsibilities through appropriate training and educational programs.

(1) Physicians shall be qualified specialists in their respective specialty, and minimal medical staff shall include:

(i) A pediatric cardiologist to care for patients in the pediatric age group;

(ii) A cardiologist to care for adults;

(iii) In centers doing surgery for coronary artery disease, a cardiac arteriographer, with basic medical training in internal medicine or in radiology. Supplemental qualifications shall include at least two years of training or experience including, but not limited to the areas of cardiac radiology, clinical and laboratory cardiology, basic and/or clinical cardiac physiology and catheter techniques;

(iv) A thoracic surgeon or surgeons whose training emphasized cardiovascular surgery;

(v) A radiologist with additional training in the cardiovascular field;

(vi) An anesthesiologist with experience with cardiovascular surgical patients and open chest anesthesia;

(vii) A pathologist familiar with cardiac abnormalities of all types;

(viii) Residents, full-time in surgery, and medicine and/or pediatrics, or resident fellows, capable of dealing with all problems that arise before, during, and after surgery;

(xi) Consultants, readily available for consultation in additional specialties including hematology, neurology, renal physiology and clinical pharmacology.

(2) Nursing personnel shall include:

(i) A registered nurse supervisor;

(ii) A registered nurse in charge and on the unit at all times;

(iii) Such registered nurses, licensed practical nurses, and nursing aides in such ratios, as the commissioner may require commensurate with the type and amount of nursing needs of the patients.

(3) Heart-lung machine (pump) operators shall have special training and experience in an active program of open heart surgery, including a thorough background in sterile techniques, perfusion physiology, and the use of monitoring equipment. The operator may be a specially trained physician, nurse, or technician, at the discretion of the director of the center.

(4) Medical social workers shall be available to the medical staff of the unit and others to assist with social problems of the patient and the family as they arise, regardless of the economic status of patient and family.

(5) Clerical staff shall be sufficient to insure adequate record keeping and reporting.

(c) Diagnostic and surgical services. All services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organized outpatient services to preclude unnecessary hospitalization and insure continuity of care. Diagnostic and surgical services shall consist of the following:

(1) A full range of diagnostic services.

(2) All essential therapeutic procedures, including but not limited to open and closed heart surgery.

(3) A blood bank, approved by this department, under the direction of qualified specialists in this field.

(4) Intensive care, in specific units, available on a 24 hour basis to provide the special and constant care required by cardiac surgical patients. The unit shall be staffed by personnel trained in the use of monitoring devices, respirators, pacemakers, defibrillators and other necessary equipment for cardiac resuscitation.

(5) Preoperative and postoperative care as indicated.

(6) Patient and family education, pre and postoperative.

(7) A system of adequate follow up.

(d) *State Cardiac Advisory Committee.* The State Cardiac Advisory Committee shall, at the request of the commissioner, consider any matter relating to cardiac surgical centers and shall advise the commissioner thereon.

(e) *Approval and review.* Project site visits by members of the State Cardiac Advisory Committee shall be made as indicated, as an adjunct to initial approval, and/or for maintaining approval. Cardiac surgical centers seeking to obtain or maintain approval shall demonstrate their capacity to meet minimum workload requirements, as determined by the commissioner. There shall be sufficient utilization

of a center to insure both quality and economy of services, as determined by the commissioner.

Historical Note

Sec. filed Jan. 3, 1974 eff. Jan. 3, 1974

706.6 Cardiac diagnostic centers. (a) Cardiac diagnostic centers shall provide coronary arteriography and other invasive diagnostic procedures. Diagnostic services may be provided at hospitals independent of cardiac surgical centers only where the following conditions have been met:

- (1) The local need for service is demonstrated.
- (2) There is written affiliation agreement between the diagnostic center and an approved cardiac surgical center, acceptable to the commissioner, which provides for:
 - (i) The management of cardiac surgical emergencies.
 - (ii) Regular bimonthly conferences, attended by representatives from the surgical center, in which a significant number of pre and postoperative cases are reviewed.
 - (iii) Referral of patients for whom surgery may be indicated.
- (b) *Direction.* The center shall be under the direction of a qualified specialist in internal medicine (cardiovascular disease).
- (c) *Staff.* The staff of such center shall consist of the following:
 - (1) An internist with special training and experience in cardiovascular diseases.
 - (2) A cardiac arteriographer whose basic medical training may be in internal medicine or in radiology. Supplemental qualification shall include at least two years of training or experience including, but not limited to, the areas of cardiac radiology, clinical and laboratory cardiology, basic and/or clinical cardiac physiology and catheter techniques.
 - (3) Residents, fellows or physician's assistants devoting substantial time to service in the center.
 - (4) Anesthesiologists experienced in the manage-

ment of cardiac patients shall be available to the center.

- (5) Nurses or medical technicians with appropriate education and training who shall be regularly assigned to the center.
- (6) A surgeon or surgeons trained and experienced in vascular surgery who should be available to the center for consultation and management of complications.
- (d) *Services.* All services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organized outpatient services to preclude unnecessary hospitalization and insure continuity of care. The following services should be provided at a minimum:
 - (1) A full range of diagnostic services.
 - (2) *Medical social work.* Medical social workers shall be available to the medical staff of the unit to assist with social problems of the patient and the family as they arise, regardless of the economic status of patient and family.
 - (3) Patient and family education.
 - (4) A system of adequate follow up.
- (e) *State Cardiac Advisory Committee.* The State Cardiac Advisory Committee shall, at the request of the commissioner, consider any matter relating to cardiac diagnostic centers and shall advise the commissioner thereon.
- (f) *Approval and review.* Project site visits by members of the State Cardiac Advisory Committee shall be made as indicated as an adjunct to initial approval, and/or for maintaining approval. Cardiac diagnostic centers seeking to obtain or maintain approval shall demonstrate their capacity to meet minimum workload requirements as determined by the commissioner. There shall be sufficient utilization of a center to insure both quality and economy of services, as determined by the commissioner.

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