

CARDIAC SERVICES
Issues and Recommendations

REPORT OF THE
NEW JERSEY CARDIAC SERVICES TASK FORCE

January 1987

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Molly Joel Coye, M.D., M.P.H.
Commissioner

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The Robert Wood Johnson Foundation

P.O. Box 2316
Princeton, New Jersey 08540
(609) 452-8701

December 24, 1986

Molly Joel Coye, M.D.
Commissioner of Health
State of New Jersey
CN-360
Trenton, New Jersey 08625

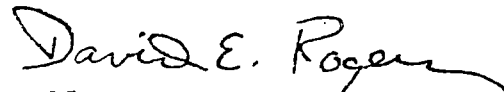
Dear Dr. Coye:

The Cardiac Services Task Force is pleased to submit its final report containing recommendations for the provision of invasive cardiac diagnostic and surgical services in the State of New Jersey.

The final report of the Task Force represents the culmination of an eight-month-long process of inquiry, analysis, and deliberation by the Task Force and its staff. From its inception, the Task Force faithfully maintained a course consistent with its charge to address issues of quality, cost, and access in the provision of cardiac services. The final report reflects the commitment, cooperation, and full involvement of Task Force members and staff. The twenty-nine recommendations contained in the report cover a broad range of concerns, including institutional volume standards and professional criteria for seven invasive cardiac modalities, quality audit systems and data requirements, the establishment of a state-wide cardiac services registry, measures to make cardiac care more affordable and more accessible to New Jersey residents, and mechanisms for the periodic review and reassessment of the state-of-the-art in cardiac services.

It is the hope of the Task Force that this report will prove useful to you and to your staff. I wish to thank you for this opportunity to serve the State of New Jersey and its residents, and I wish to thank all members of the Task Force and its staff for their time, effort, and valued contributions to this endeavor.

Respectfully submitted,



David E. Rogers, M.D.
Chairman, Cardiac Services
Task Force

Table of Contents

	<u>Page</u>
Task Force Members	i
Background and Charge	1
Cardiac Task Force Objectives, Organization and Process	2
Volume Standards and Staffing Criteria	3
Cardiac Catheterization	6
Percutaneous Transluminal Coronary Angioplasty.	7
Electrophysiology Studies.	8
Adult Open Heart Surgery	9
Pacemaker Implants	10
Pediatric Cardiac Surgery	11
Cardiac Transplant Services	11
Cardiac Assist Devices	12
Sites of Cardiac Invasive Procedures	12
Education and Research	13
Quality Audit Systems and Data Requirements.	13
Cardiac Services Registry	14
Costs	15
Access	16
Conclusions.	18
Appendices and Charts	19
Chart 1. Cardiac Surgery - U.S.A.	20
Appendix 1. New Jersey Cardiac Services Task Force - Committees	21
Table 1. Classification of Invasive Cardiac Modalities.	22
Appendix 2. Acute Myocardial Infarction Registry in the State of New Jersey	24
Appendix 3. Cost Estimates	26
Appendix 4. Access to Care	33

i

New Jersey
Cardiac Services Task Force

David E. Rogers, M.D. (Chairman)
The Robert Wood Johnson Foundation

Bernard Rabinowitz (Vice-Chairman)
Atlantic Industries, Inc.

Diane C. Adler, RN, MA, FAAN
The University of Pennsylvania

John Banas, M.D.
Morristown Memorial Hospital

Leo Brach
Elberon, New Jersey

Enrique D. Carter, M.D.
Public Health Service, Department
of Health and Human Services

Charles Cuniff, M.D.
Blue Cross & Blue Shield of
New Jersey, Inc.

Harvey V. Fineberg, M.D., Ph.D.
Harvard School of Public Health

John Gregory, M.D.
Overlook Hospital

Jacob Haft, M.D.
St. Michael's Medical Center

Kevin G. Halpern
Cooper Hospital/University
Medical Center

Roger Herdman, M.D.
Office of Technology Assessment,
U.S. Congress

John E. Hutchinson, III, M.D.
Hackensack Medical Center

John Kostis, M.D.
UMDNJ - Rutgers Medical

Dryden Morse, M.D.
Deborah Heart and Lung Center

Victor Parsonnet, M.D.
Newark Beth Israel Hospital

Richard Pitman
Shore Memorial Hospital

J. Sanford Schwartz, M.D.
The University of Pennsylvania

Nolan B. Sommer, Ph.D.
Franklin Lakes, New Jersey

William A. Tansey, III, M.D., F.A.A.C.
Short Hills, New Jersey

Edward H. Tetelman, Esquire
Office of the Public Advocate

Arthur Wood
Prudential Group & Finance
Services Office

Staff to Task Force

John Calabria, M.P.H., M.P.A. - New Jersey Department of Health

Alan B. Cohen, Sc.D. - The Robert Wood Johnson Foundation

John Gontarski, M.C.R.P. - New Jersey Department of Health

Ruth S. Hanft, M.A. - Consultant, Washington, D.C.

Theodore C. Seamans, M.P.A. - New Jersey Department of Health

Background and Charge

During the past 30 years and particularly during the last decade, great advances have been made in the diagnosis and treatment of cardiovascular disease. Although all the reasons for this decrease are not known, most observers feel there is a relationship between development of new methods of diagnosis and treatment, and disease prevention through risk modification. These methods range from new drugs for the management of hypertension, arrhythmias, and heart failure, to new acute interventions for myocardial infarction, such as angioplasty, thrombolysis, and coronary bypass surgery. Although heart attacks still claim 10,000 lives a year in New Jersey, further advances in surgery and medical therapy should continue to improve prognosis. Because these new procedures can be and are being used increasingly on our rapidly growing older population with favorable outcomes, further reductions in mortality will increase the number of elderly with cardiac disease.

Thus National and State estimates of trends predict a substantial increase in the use of cardiac services during the next decade (Chart I). Costs of a number of these procedures are high, and with increased volume of services, systemwide costs can be expected to rise substantially. This is a subject of particular concern in New Jersey where costs already exceed those in many states, including our neighbors, New York and Pennsylvania.

Most current cardiac catheterization and cardiac surgery services in New Jersey were established prior to the Certificate of Need (CON) regulatory process. During the decade after the CON standards were established, only two new cardiac catheterization laboratories and two new cardiac surgery services were developed in the State. Initial utilization requirements were developed to ensure quality and efficiency, but these standards preceded many improvements in cardiac diagnostic and surgical techniques, the use of percutaneous transluminal coronary angioplasty (PTCA), and the development of electrophysiologic studies. Because other areas adjacent to New Jersey (i.e., New York City and Philadelphia) and areas elsewhere in the country have developed high quality, cost-effective services, the fact that substantial numbers of New Jersey residents either seek or are referred to services elsewhere, and to enhance the possibilities for integration of services, the following step was taken. In May 1986, the State of New Jersey Department of Health, established a Task Force to review the state-of-the-art of invasive cardiac procedures, existing standards, and with the goals of assuring equitable access to high quality, cost-effective services for all New Jersey citizens, to recommend standards for the delivery of these services. The Chairman of the Task Force was David Rogers, M.D., President of The Robert Wood Johnson Foundation. The specific charge to the Task Force was:

The Cardiac Services Task Force will examine New Jersey's planning requirements for the provision of the invasive cardiac diagnostic and catheterization services and cardiac surgery services in view of technological innovations taking place in the treatment of cardiovascular disease. The Task Force will also consider how the Department of Health might best address issues of quality, cost and access in the provision of cardiac care services as a whole in the State, and how the Department could further the development of academic research in this area.

With regard to a range of clinical cardiac conditions and interventions, the Task Force will be asked to examine the following questions:

- staffing standards
- professional credentialing requirements
- volume standards for facility and physician/team performance
- quality audit systems
- systemwide and case costs
- access issues and transport issues.

The Task Force was also asked to consider the desirability of establishing a cardiac disease registry for the State of New Jersey, which would provide a public health and clinical research base for the evaluation of preventive and therapeutic interventions in cardiac disease.

Cardiac Task Force Objectives, Organization and Process

From the initial meeting of the Task Force and its charge from the Commissioner of Health, there was agreement that the primary focus of deliberations and recommendations would be the establishment and maintenance of high quality services for all the citizens of New Jersey. Cost and access were also carefully considered, but because of considerable evidence that the use of inadequate facilities or the conduct of invasive procedures by professionals with insufficient training and skills to perform them could result in excess mortality, morbidity and disability, the Task Force used the quality of services as its major yardstick for its recommendations.

Based on the charge from the Department of Health, the Task Force established four committees:

1. Quality Audit Systems and Volume Standards:

- To consider recommendations on volume standards for specific cardiac services;
- To design a blueprint and consider data needs for the development of a quality audit system to monitor the quality of cardiac services provided;
- To develop plans for a cardiac services registry for the State;

2. Staffing Standards and Professional Credentials:

- To develop criteria for institutional staffing and physician credentialing requirements for specific cardiac services;
- To develop training criteria for other personnel (e.g., nurses, technicians) as appropriate;

3. Cost:

- To develop costs per case and systemwide cost data and to indicate the bases for estimates;
- To consider whether large regional centers are preferable to numerous smaller centers;

4. Access:

- To evaluate the adequacy of existing patient access to state-of-the-art cardiac care in New Jersey, including transportation systems;
- To consider the need for patient education by the primary physician and cardiologist;

- To consider the concept of regionalization as it pertains to accessibility.

(See Appendix 1 for listing of committee members).

The committees and the Task Force reviewed numerous reports and studies on cardiac services including the Report of the 17th Bethesda Conference, a draft Office of Technology Assessment (OTA) report on the potential impact of new drugs, articles in peer reviewed journals, access data from the State, and cost data from the State and from other third-party payers.

A public hearing was conducted in July to assure all interested groups and individuals an opportunity to express their views on the issues. In addition, throughout the Task Force deliberations, written communications were received by the Task Force from a number of groups and individuals. The Task Force and committees met throughout the summer and early fall of 1986 to develop their findings and recommendations.

During its deliberations, the Task Force found that there were two opposing philosophic views on the best way to achieve optimal cardiac services for New Jersey, one regulatory, one free market in approach. In its final work, the Task Force concluded that neither a fully regulatory nor a fully market-oriented approach would assure optimal quality of care that was cost-effective and accessible to all New Jersey citizens. Thus, the recommendations represent a blend of both approaches. Hence, the Task Force sought to set high performance volume standards for institutions, permitting more flexibility in its recommendations regarding the qualifications of the individuals performing invasive cardiac procedures. Numerical standards were considered essential because of the many studies showing strong inverse correlations between volume of procedure performed and morbidity and mortality. Clearly, to improve quality and to maintain flexibility, an ongoing quality assurance and data collection system is required, as well as periodic review of the recommended standards and criteria. Thus, the standards and quality audit indicators recommended in this report are guidelines that must be supplemented by the consideration of other criteria when individual applications for CON are reviewed.

Volume Standards and Staffing Criteria

Institutional and professional volume affect both the quality and the cost-effectiveness of the delivery of invasive cardiac services. In developing institutional volume standards and professional staffing criteria, the Task Force has attempted to strike a balance which will assure quality while maintaining a competitive environment to enable new facilities and professionals to enter the field.

A classification system that categorized cardiac procedures in terms of their relative acceptance into clinical practice was developed. Invasive modalities were defined as those involving the introduction of a surgical instrument or device into a heart chamber or artery. The degree of acceptance into clinical practice was defined in terms of three levels of risk/efficacy:*

* This terminology is not the same as that used by third party payers and the FDA and is not suggested as a basis for payment decisions.

- 1) established modalities (class I): where risks are known, efficacy has been established, and the modality has been widely accepted into practice;
- 2) investigational modalities (class II): where uncertainty regarding risks and efficacy remains, but the modality is gaining acceptance in practice; and
- 3) experimental modalities (class III): where risks are uncertain, efficacy has not been established, and the modality has not gained widespread acceptance.

Table I contains a listing of invasive cardiac modalities by level of risk/efficacy. While the Task Force has addressed only invasive modalities within its mandate, it has also recommended that non-invasive modalities be included in later examinations undertaken by the Department of Health and subsequent task forces.

Based on the classification system, the Task Force identified seven major cardiac services for which volume standards, staffing criteria, and quality audit indicators are proposed.

In developing these standards and criteria for cardiac services, the Task Force employed the following principles:

- Institutional volume standards should reflect the minimal numbers of procedures needed to assure both quality of service and reasonable cost. Economies of scale should be taken into account.
- Individual/professional volume criteria should reflect the numbers of procedures needed to build and to maintain professional competence in providing a given service.
- The medical literature should be examined and, wherever feasible, data used as evidence to support specific proposed standards. Particular attention should be paid to the quality of evidence on efficacy and on the nature of observed relationships between institutional/individual performance and patient outcomes.

Since there were many difficulties in defining "optimal" quality standards, the Task Force focused its attention on the development of minimum volume requirements. Three types of minimum standards or criteria were considered: (1) institutional volume standards - that annual volume necessary to assure institutional quality and to obtain reasonable unit cost for services; (2) training and individual volume criteria - the training of physicians and other personnel and that annual volume necessary to assure individual clinician quality; and (3) institutional saturation volume criteria - that annual volume above which an operating room or catheterization laboratory might be considered "overloaded" and, thus, subject to possible compromise in quality.

The notion of institutional saturation volume was further defined by the Committee as a threshold: (a) below which, an institution cannot reasonably argue for additional capacity or expansion of the service, and (b) above which, the institution might have a basis for arguing for expanded capacity. Other factors pertinent to the specific case would bear on the latter decision. In order that the definition of saturation volume for services performed in the same unit or laboratory could be translated into operational criteria, a measure of

"catheterization-equivalents" (CEs)* was adopted that could be used to weight a procedure as a function of time and degree of difficulty. CEs were developed for percutaneous transluminal coronary angioplasty (PTCA) and for initial and repeat electrophysiology studies (EPS), all of which may be performed in the cardiac catheterization laboratory.

Obviously, in addition to simple volume requirements, advanced and invasive cardiac technologies all require appropriate institutional infrastructure, including specialized nursing services, sophisticated laboratory technology, and in some cases well-developed non-cardiac specialty expertise. Nursing care units such as coronary care, progressive care, and open heart recovery should be well-equipped to provide a full range of pre- and post-procedure clinical cardiac support. Nurse staffing procedures must be calibrated to the degrees of medical and psychological acuity of the patients in the respective units at any time. A clearly visible pyramid of organization helps insure ongoing quality of care surveillance. These parameters are difficult to quantify but they are important considerations in evaluating institutional abilities to assure quality of care.

Quality of care in critical care units also relates directly to the ease of communication between nurses and physician staff. An in-house director appears not to be essential, but this role might well facilitate the communication. The climate of interaction should be fully assessed at any institution prior to the selection of that institution as a site for expanded cardiac services.

The proposed volume standards and the corresponding staffing criteria are presented along with the rationale behind each. It was the intention of the Task Force that these volume standards were to be used for general guidance of the Department of Health, and not as fixed specific parameters on which to judge the merits of an individual CON application alone. The provisional standards and reporting requirements described must be supplemented by the consideration of other criteria when reviewing individual CON applications. These criteria should include, but are not necessarily limited to:

- demonstration of institutional and provider competence in delivering the proposed service
- capacity to perform the proposed service at the recommended minimum level within the stated period of time
- commitment from the hospital's Board to establish the proposed service program
- examination of the capacity of existing facilities in the referral area
- evidence that the new or expanded service will capture referrals currently made to out-of-state facilities
- evidence that essential support services in the hospital (e.g., renal and pulmonary) are capable of coping with an increase in caseload
- evidence that the project would be financially feasible

	CEs
* Catheterization	1.0
PTCA	2.5
Initial EP studies	3.0
Repeat EP studies	1.5

- evidence that demographic statistics support service growth
- evidence that the proposed service is compatible with overall health planning goals for the State and for the service area
- evidence that access to care will either remain constant or improve for individuals in the service area.

The Task Force wishes to emphasize that the field of invasive cardiology is undergoing rapid change. The proposed standards and provisional guidelines are based on the best information available at this time. The State, therefore, must exercise discretion in applying them, and should periodically reassess and refine them. Rather specific volume standards are recommended for institutions. The recommendations on criteria for professionals which follow are less firm and are intended:

- to serve as guidelines for hospitals to use in developing their own criteria, and
- to permit the State to determine whether a hospital has the appropriate resources when it petitions for CON permission to provide a specific cardiac service.

As is apparent from the statement, the Task Force believes that the hospital professional infrastructure has the best mechanisms of which to judge the qualifications of individual professionals and their competence in carrying out such complex cardiac procedures.

Cardiac Catheterization*

Institutional Standards

The current New Jersey institutional volume standard for cardiac catheterization services is more stringent than the national health planning guidelines (minimum of 500 per year for a dedicated laboratory versus 300 per year). The existing New Jersey standard also makes an allowance for shared laboratories to perform fewer catheterizations (250 per year) than full-time dedicated laboratories.

Recommendation 1. 500 catheterizations per year are the minimum necessary to assure institutional quality and efficacy. New services must attain this level within the first three years of operation. A fully utilized catheterization laboratory may be defined as one performing not fewer than 1,000 "catheterization-equivalents" (CEs) per year. Shared laboratories must meet the same standards.

While other procedures, such as angiography and angioplasty, may be performed in the catheterization laboratory, the total number of catheterizations should not fall below 500 per year. Attaining the 1,000 CE threshold is a necessary, but insufficient, condition for service expansion (i.e., adding a second laboratory).

* Catheterization means entering the systemic circulation and catheterization of the left heart or angiography of the cardiac structure

As described earlier, other factors specific to the institution and its application must also be considered. Laboratories with service volumes below this threshold clearly are not operating at full capacity.

Recommendation 2. Catheterization services should be performed in a hospital setting.

This recommendation is consonant with recommendations of the American College of Cardiology and the American Heart Association.

Recommendation 3. Cardiac surgery services should be accessible promptly, either in-house or by immediate transfer, in the event of an emergency or complication. Therefore, outpatient catheterization is recommended only when the unit is physically part of a facility offering inpatient support services.

Professional Criteria

In reviewing applications for CON for cardiac catheterization laboratories, the following criteria for professional training, credentials and practice should serve as guidelines in evaluating the merit of proposals.

Criteria

1. The physician performing a cardiac catheterization procedure must be a board certified* cardiologist with a minimum of 12 months in a cardiac catheterization training program and who has performed a minimum of 200 cardiac catheterization procedures, including 100 procedures in which the physician served as the primary operator.
2. Physicians seeking to continue to perform cardiac catheterization should perform 50 a year with a minimum of 100 cases over a two-year period.
3. A registered nurse, trained and experienced in cardiac catheterization procedures and competent in advanced life support (ALS) and a technician trained and experienced in cardiac catheterization procedures shall be present during all procedures.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

Institutional Standards

No standards currently exist in New Jersey for PTCA, since this procedure was developed and dispersed after initial standards were established.

Recommendation 4. The Committee recommends that a minimum of 200 angioplasties per year be performed in order to assure acceptable institutional quality. New services should attain this minimum level within three years of service implementation. Cardiac surgical services must be available on site.

* While board certification represents a desirable standard for those performing invasive cardiac services, an exception may be appropriate for selected graduates of accredited training programs who have demonstrated exceptional skill and experience and have not yet been certified, and for some senior physicians who by experience and performance have demonstrated their competence. This definition applies to the term board-certified throughout the document.

Professional Criteria

In order to insure the performance of high quality PTCA procedures, the Committee recommends:

1. The physician directing the performance of a PTCA procedure must be a board certified cardiologist with well-recognized excellence in the management of routine cardiac catheterization and who has participated in a minimum of 100 PTCA procedures, including at least 50 PTCA procedures in which the physician was the primary operator.
2. A physician seeking to continue to perform PTCA procedures as the primary operator should perform a minimum of 75 procedures a year, 150 procedures over a two-year period (excluding the physician's first year of clinical practice following completion of training), with 50 per year as primary physician.
3. An assisting physician may be a board eligible cardiologist or a cardiology fellow.
4. A registered nurse trained and experienced in advanced life support, cardiac drugs, and cardiac catheterization/PTCA and a technician trained and experienced in cardiac catheterization/PTCA shall be available to assist with PTCA procedures.

Electrophysiology Studies (EPS)

The Task Force believes that there is a particular merit in restricting the availability of EPS services to a limited number of medical centers at this time. EPS remains basically an elective procedure, therefore patients may safely be transferred reasonable distances to a facility providing this service without being subjected to increased health risks. EPS is a relatively new field. Indicators for EPS are still being defined and techniques are still developing. There may be particular benefit in limiting the performance of EPS to those institutions and groups which may be able to contribute further to our understanding of the indications, technique, and efficacy of the procedure.

Standards for electrophysiology studies currently do not exist in New Jersey. In proposing volume standards for this modality, the committee defines EPS to include the more complex variety (either tachystimulation or catheter mapping), and not the His bundle study variety.

Institutional Standards

Recommendation 5. The Task Force recommends that an institution perform a minimum of 100 studies per year, with at least 50 representing initial studies of patients. New services should attain the recommended minimum within three years of service implementation.

An initial study refers to the first diagnostic EPS performed during a given patient's hospitalization.

For purposes of determining institutional saturation volume, the Task Force has assigned a weight of 3.0 to "catheterization-equivalents" to initial EP studies and a weight of 1.5 CEs to repeat EP studies. A repeat study refers to all subsequent

EPs performed during the same hospitalization in which an initial diagnostic study was conducted.

Recommendation 6. Electrophysiology services should be performed in a hospital setting in which cardiac surgery is available.

Professional Criteria

In order to insure the performance of high quality electrophysiology studies (EPS), the Committee recommends:

1. EPS shall be performed under the direction of a board certified cardiologist, who has training and experience in cardiac catheterization (as defined above), and who has obtained at least one additional year of specialized training in EPS and cardiac arrhythmias.
2. The physician responsible for performing EPS studies must have participated in 100 EPS procedures.
3. Physicians seeking to continue to perform EPS procedures should participate in 50 EPS procedures per year as primary operator, at least 25 of which are initial studies.
4. A physician performing EPS should be assisted by another physician who may be a board certified cardiologist.
5. A registered nurse trained and experienced in advanced life support, cardiac drugs, and cardiac catheterization/EPS and a technician trained and experienced in cardiac catheterization/EPS shall be present during the procedure.

Adult Open Heart Surgery

The current New Jersey institutional volume standard for cardiac surgery services is 200 open heart procedures per operating room per year. The Task Force believes these standards are not adequate.

Institutional Standard

Recommendation 7. A minimum of 250 procedures per operating room per year is necessary to assure institutional quality. New services should achieve this level within the first three years of operation. In order to be considered for possible service expansion (i.e., adding a second operating room), a hospital must perform at least 350 procedures per year in its existing operating room. Hospitals performing adult open heart surgery may utilize a separate operating room for PTCA backup -- that room should not be used for routine cardiac surgery and should not be considered as a cardiac surgery suite.

Institutions not meeting the threshold may not be fully utilizing their existing capacity. In making this determination, however, the Department of Health should give special consideration to several other factors, including the number of PTCAs performed in the surgical suite, the numbers of emergency surgical procedures performed, the need for reoperation (as reflected in severity of illness in surgical cases treated), and the number of existing operating rooms serving the population within a defined geographic area. A hospital offering PTCA services must also be

capable of performing cardiac surgery, and vice versa, making the institution a "full service" cardiac center.

Recommendation 8. Expansion of existing facilities with high volume of procedures often is more cost-effective than the creation of new cardiac surgical centers. Such cost-effectiveness data should be considered along with data on access and quality when adding capacity. No new service should be approved unless the applicant hospital can project that two surgical suites will be needed within a three-year period (i.e., 350 cases within three years).

Cost estimates indicated that both capital and operating costs are more efficient with economies of scale.

Professional Criteria

In order to insure the performance of high quality cardiac surgery services:

1. All cardiac surgery shall be directed by a surgeon who is certified in cardiothoracic surgery. In order for this surgeon to assume primary responsibility for coronary artery bypass surgery cases, it is recommended that the supervising surgeon perform at least 100 procedures annually.
2. The surgeon in charge is to be assisted by a board qualified surgeon or surgical assistants or other appropriately trained non-physicians who practice under the supervision of a qualified surgeon in the operating room. A cardiothoracic surgery resident or fellow may serve as an assistant. There should be two surgeons in the operating room.
3. A board certified anesthesiologist with additional training and experience in cardiac surgery problems shall be responsible for the anesthetic management of cardiac surgery patients. This anesthesiologist may be assisted by another board certified or board eligible anesthesiologist, an anesthesia resident, an anesthesia technician, or a nurse anesthetist with special training and experience with cardiac surgery patients.
4. A board certified cardiologist should be available to assist in the management of problems relating to unstable hemodynamic status and complex arrhythmias, if necessary.
5. In most cases, two operating room nurses (at least one of whom must be a registered nurse) trained and experienced in cardiac surgery and advanced cardiac life support should be in each operating room.
6. One certified* perfusionist shall operate the perfusion pump. A second qualified perfusionist should be available to assist this perfusionist as the need arises.

Pacemaker Implants

Institutional Standards

New Jersey has no current standards for pacemaker implants. Standards should be imposed to assure quality care.

* A trained and qualified perfusionist who is currently part of a cardiac surgical team may be included.

Recommendation 9. In order to assure institutional quality in the provision of this service, a hospital should perform a minimum of 35 primary implants and/or total replacements per year. As with other cardiac services, hospitals offering this service for the first time will be expected to reach the minimum level within three years of service introduction.

In all instances, pacemaker implants should be performed using operating room sterility techniques and not in non-sterile treatment rooms. Provisions for pacemaker followup should be made.

Professional Criteria

In order to insure the performance of high quality cardiac pacemaker implant services, the Task Force recommends:

1. Permanent pacemakers should be implanted by a board-certified cardiologist or a surgeon who has implanted at least 25 permanent pacemakers under supervision, and 10 replacements in patients who had received previous pacemakers.
2. While a single physician should be sufficient for most cases, some of the newer, more complex pacemakers may, on occasion, require the services of two physicians.
3. A registered nurse trained and experienced in cardiac catheterization or cardiac surgery, and a biomedical technician with training and experience with pacemaker insertions also shall be present to assist with pacemaker implantation, threshold measurements and programming.

Pediatric Cardiac Surgery

Institutional Standards

The present New Jersey volume standards for cardiac surgery services do not distinguish between adult and pediatric cases. For the purposes of this report, the Committee defines pediatric cases as those below the age of 16.

Recommendation 10. Recognizing that a substantial number of closed heart procedures may also be performed in a pediatric population, each hospital should be required to perform a minimum total of 150 procedures (open and closed heart) per operating room per year in order to maintain the skills of the surgical team. New services should achieve the overall target level by the end of the third year of operation. A neonatology staff, and neonatal and pediatric intensive care units should be required before a hospital is approved for pediatric cardiac surgery.

It is assumed that approximately half of the procedures will be of the open heart variety.

Cardiac Transplant Services

Even more so than for the other cardiac services discussed by the Task Force, a successful program in cardiac transplantation requires a closely coordinated, integrated, and highly skilled interdisciplinary medical and surgical team at a medical center. Federal guidelines for cardiac transplant centers address all the requirements of such procedures in great detail. The Task Force recommends they be adopted by New Jersey.

Institutional Standards

Recommendation 11. The State of New Jersey should adopt the Medicare standards and criteria for heart transplants.

These standards and criteria include detailed specifications proposed in the Federal Register Vol. 51, No. 201, October 17, 1986, which include the following:

1. Patient selection
2. Patient management
3. Commitment
4. Facility plans
5. Experience and survival rates
6. Maintenance of data
7. Organ procurement
8. Laboratory services.

The final Federal regulations should be adopted.

Cardiac Assist Devices

New cardiac assist devices are rapidly emerging, such as intraaortic balloon pumps and left ventricular assist devices. The Task Force did not have sufficient information on safety, efficacy and use to make recommendations. The future committee, as recommended later in this report, should assess these developments and recommend appropriate standards and criteria for the establishment and maintenance of services.

Sites of Cardiac Invasive Procedures

The Task Force feels strongly that the invasive cardiac procedures addressed in this report should be performed only in hospital-based settings with appropriate technical support. The recent emergency of free-standing ambulatory surgical centers and catheterization laboratories poses serious concerns about the quality of cardiac services offered in these facilities. At present, such facilities are not subject to New Jersey's Certificate of Need (CON) law and, thus, are not regulated by the Department of Health. In order to assure both institutional and individual clinician quality in the performance of cardiac procedures at these facilities, the Task Force recommends that the Department seek appropriate amendment to the State CON law that would extend coverage to free-standing cardiac service centers. This may warrant change in the current State definition of a "health care facility" covered under the CON program. The Task Force believes that such legislative change is necessary to improve health planning within the State and to assure New Jersey residents of receiving quality cardiac services at reasonable cost.

Recommendation 12. All PTCA and cardiac catheterization procedures must be performed in a licensed health care facility.

In order to accomplish this recommendation, the Department of Health should seek an amendment to the New Jersey Health Care Facilities Planning Act (Chapters 136 and 138, Laws of New Jersey 1971) to require that the provision of any health care service for which there is a Department of Health planning regulation adopted pursuant to N.J.S.A. 26:2H-5 obtain Certificate of Need approval regardless of the kind of organization, corporation, association, partnership, group, or individual practice which offers, proposes to offer, adds, or replaces (or "holds" any of the aforementioned entities) such a regional health care service.

To assure the continuation of high quality services, to reinforce the volume standard recommendations, and to assure that underutilized facilities do not serve as a barrier to the entry of facilities which can provide high quality services, the Task Force recommends:

Recommendation 13. Institutions that do not achieve the volume standards within a two-year period should be notified of intention of the State to withdraw CON. If standards are not met within one additional year steps should be taken to withdraw the CON.

As with the other recommendations, other criteria should be weighed in making the decision, but the burden should be placed on the hospital to provide substantive reasons for continuation of the CON.

Education and Research

While not part of the charge of the Task Force, the importance of education, continuing education, and research in cardiovascular disease and in invasive and non-invasive procedures should not be ignored. Practitioners whose skills are developed and enhanced through high quality education programs contribute to and insure high standards of cardiac services. Advancement of knowledge through research activities will further enhance the scope and quality of these services.

The State, therefore, should actively encourage cooperative relationships for education and research between its medical schools and the hospitals that provide comprehensive cardiac services. Over time, it is of critical importance that the State's Academic Health Centers be intimately involved in advancing our knowledge and skills in invasive cardiac services.

Quality Audit Systems and Data Requirements

The primary goal of a statewide audit system for cardiac services should be to inform the State, individual institutions, and citizens of the quality of cardiac services provided both in absolute and relative terms.

Recommendation 14. At minimum, the State should require each hospital offering cardiac services to submit a plan, given its individual circumstances, that outlines its current and projected quality assurance activities for each of the cardiac services identified in this report.

The Task Force adopted the following principles regarding a quality audit system:

- The information needed for quality audit purposes should be objective, quantitative, and adjusted for risk factors. Information obtained from hospitals, thus, should have face validity.
- The State should mandate minimum service-specific data collection and reporting requirements for the seven categories of cardiac modalities identified. These data should not impose undue costs but should be adequate to monitor quality.
- Existing State data collection forms for cardiac surgical centers and for cardiac diagnostic facilities will need to be modified and expanded. New

reporting forms should be designed with the elements of uniformity, convenience, and ease of use kept in mind.

- The data gathered for quality audit should be a subset of the data required for a proposed cardiac services registry. At a minimum, the data collected should include the volume of each service provided, the incidence of mortality, morbidity and other adverse occurrences, and patient risk factors.
- To the extent possible, the State should explore with hospitals the joint development of a common computerized information system for all hospitals offering cardiac services. The system should include standardized computer software for reporting service-specific data.
- Institutions should report data to the State on a periodic basis to be determined by the State.

Recommendation 15. With an ongoing commission as recommended later and with experts in coronary care services, epidemiology, and statistics, the State Department of Health should design reporting systems that include:

1. Case mix/risk factors;
2. Quality and outcome measures;
3. Access for different population groups including emergency room and outpatient services; and
4. Other factors including referrals and success rates and costs.

Since these data will become public information, raw data should not be used to avoid misinterpretation. Data should be stratified and sufficient explanation should be attached to assure appropriate interpretation.

Recommendation 16. The Department of Health should undertake an evaluation of the predictive value of these indicators, and should establish a dynamic quality audit system that can be refined as new information becomes available.

The Task Force was not charged with an examination of non-invasive cardiac modalities. However, the Task Force believes that these modalities warrant future attention.

Recommendation 17. The Department of Health should include non-invasive cardiac modalities in future assessments of cardiac services in the State.

Where feasible, volume standards and quality audit indicators should be developed to aid both the State and individual hospitals in monitoring and assuring the quality of all cardiac services delivered in New Jersey. A list of non-invasive modalities stratified by level of risk/efficacy appears in Table 1.

Cardiac Services Registry

The establishment of a cardiac services registry in New Jersey is viewed by the Task Force as essential to supporting both clinical research and State study of evolving cardiac modalities. More specifically, cardiac services registry data could be expected to serve four major purposes: (1) epidemiologic studies of the incidence and determinants of various cardiac disease, (2) demographic analyses of the patient populations served within New Jersey, (3) clinical assessments of alternative diagnostic and therapeutic modalities, and (4) quality assurance efforts intended to

improve the delivery of cardiac services in the State. In addition, the registry is likely to offer two additional benefits in the form of: improved capacity to predict the risk of patients about to undergo certain procedures; and more accurate identification of the case mix of populations served so that performance standards may be adjusted accordingly.

The design of a full cardiac services registry was deemed by the Task Force to be beyond the scope of its mandate. The Task Force, therefore, does not have a specific configuration in mind, but instead offers the following recommendation:

Recommendation 18. The State Department of Health should establish a Statewide cardiac care registry.

- We propose the formation of a state-wide registry of patients who suffer acute myocardial infarction. The basic design of a registry is described in Appendix 2.
- The need for obtaining informed patient consent and for maintaining patient confidentiality in the registry is clear, particularly in light of experience with other registries, including the New Jersey Cancer Registry.
- The State may wish to employ a strategy of establishing "pilot registries" in defined geographic sub-regions and/or in defined patient subsets (e.g., AMI, sudden death, etc.) in order to test plans and alternative data systems for a statewide registry.
- The Department of Health should appoint an advisory committee to assist its staff in the design, development, and implementation of a cardiac services registry.

Costs

All evidence indicates that both quality of care, as reflected in mortality, and cost, as reflected in length-of-stay and physicians' fees, are influenced by the volume of procedures done by and the skill of the physician. Since most of these procedures are performed on a non-emergency basis, the Task Force believes networking of services will enhance quality and reduce long-term costs. The Task Force also believes that surgical volume performed by a specific physician is correlated with quality and cost.

Should emergency PTCA prove to be effective in reducing mortality in a selective subset of acute myocardial infarction, around-the-clock cardiac catheterization and angioplasty services, appropriately dispersed throughout the State, will be required. Provision of these services at the majority of community hospitals where most patients with acute myocardial infarction are first seen is neither desirable nor feasible, based on quality standards and the costs of establishing and maintaining high quality services.

Recommendation 19. The State, through Certificate of Need and other planning mechanisms, should encourage networking of New Jersey's hospitals for purposes of acute critical cardiac care.

Total costs for cardiac services, and particularly physician prices in New Jersey, are higher than those of surrounding areas. Projections of increases in volume, as shown in Appendix 3, will lead to very high systemwide costs for the State and its citizens, unless costs and prices are reduced. New Jersey's providers should also be

aware of the continued growth of a competitive market, where the financial feasibility of providing certain services will require careful review. Efficiencies in the delivery of services such as appropriate use of manpower and volume of services that enhance economies of scale are important in a competitive environment. Payment levels and methods are beginning to change and price will play a larger role in attracting and retaining patients.

Costs in New Jersey were of deep concern to the Task Force and may be a significant factor, although not the only one, in out-of-state referrals of New Jersey residents. The Task Force believes that several steps should be taken to influence more competitive costs and prices.

New Jersey is the only State that does not permit the licensing of surgical assistants/physicians' assistants. These professionals are used in high quality cardiac services programs elsewhere as a substitute for a physician on the team.

Recommendation 20. New Jersey law should be changed to permit the use of surgical assistants/physicians' assistants.

The growth and development of HMOs, and the encouragement of enrollment of Medicare beneficiaries in comprehensive health systems are changing pricing and payment mechanisms. Medicare is considering the downward recalibration of cardiac service DRGs.

Recommendation 21. To assure that New Jersey maintains a competitive role in providing quality cardiac services, a careful study of hospital resource costs for cardiac services should be undertaken. In addition, the Commissioner and other interested parties should undertake a study of comprehensive payment structures to include both hospital costs and physician services.

Several of the existing approved surgical and catheterization programs have volumes at the present low recommended levels. With the new standards recommended by the Task Force these institutions may fall below the standards.

Recommendation 22. Existing surgical and catheterization programs that fail to meet the new standards should be put on notice. If volume standards are not met within one year, denial of reimbursement and conditioning of licensing should be instituted.

Access

While New Jersey's all-payer system, with its built-in provision for uncompensated care, has generally eliminated economic access barriers to inpatient and hospital outpatient care, some economic and other barriers to non-hospital care remain, particularly with respect to the elderly and minorities. See Appendix 4 for a description of use of these services. These barriers include:

1. A relatively low proportion of New Jersey physicians accepting Medicare assignment (40 percent) - both primary care and specialist physicians;
2. A lack of primary care physicians in some inner-city and rural areas of the State;
3. Cultural perceptions regarding when and how to enter and use the health care system;
4. Language problems; and
5. Lack of an adequate payment source.

These barriers, of course, are not limited to cardiac services. But since such barriers tend to encourage the postponement or non-use of preventive and primary care services, the end result may increase the magnitude of the cardiac problem in those groups confronted by these access barriers.

As noted above, the poor and the minorities are more likely to enter the health care system through the hospital clinic or emergency room. This episodic care while necessary is more costly and fails to provide ongoing comprehensive preventive and primary services that would identify coronary heart disease problems and indicators at an early stage. In addition, many persons who enter a facility as an emergency or clinic patient and receive treatment often do not receive or seek follow-up services. While there are little data available at the present time to fully document the extent of the problem, the Task Force believes that these factors are in part a result of the previously noted access barriers.

Recommendation 23. Hospitals and other institutions should be encouraged through adjusting the rate-setting mechanisms to develop cardiology outreach mechanisms and referral services.

Recommendation 24. Department of Health hospital licensing standards should be amended to mandate that hospitals offering cardiac services should assure that appropriate care be made available by the institution and its physicians to all Medicare, Medicaid, indigent, and uninsured patients regardless of ability to pay.

Recommendation 25. Hospitals and other health care providers should, to the extent possible, have native speaking clinical personnel available who can overcome language barriers and know and understand cultural differences among patients.

There is a wide range of preventive activities that can reduce the incidence and severity of cardiac disease and the need for invasive intervention. Among these are a variety of risk reduction approaches such as smoking cessation, lipid control, etc.

Recommendation 26. Special efforts must be made to provide information concerning heart disease for all New Jersey citizens, particularly Hispanics and other non-English speaking groups in New Jersey. In addition, the State should consider enrolling Medicaid recipients and uninsured people into comprehensive care systems.

Medicaid payment is substantially below Medicare or private insurance payments, particularly for cardiac services

Recommendation 27. Medicaid rates should be revised upward to increase physician incentives to provide services.

Transportation, or the lack thereof, is also often perceived as an access barrier. In New Jersey all areas of the State are covered by local ambulance squads and all but the four rural counties of Cumberland, Salem, Warren, and Sussex are served by Mobile Intensive Care Units (MICUs). Each MICU is an emergency room and intensive care unit on wheels, staffed by paramedics and/or nurses who are specially trained to deal with life-threatening emergencies. All MICU personnel operate under direct communication with qualified physician supervision and treat and stabilize the victims of an emergency. They also accompany the victim to the hospital in the local rescue squad vehicle since in New Jersey, for a variety of reasons, only rescue squad vehicles transport patients from the site of an emergency to the hospital. The training of rescue squad personnel, however, can vary widely. Thus transportation for inpatient care after an emergency is generally available

throughout the State, though the quality of care received in transit is not consistent. There are little data regarding transportation for outpatient primary and specialty services. While major urban areas have well-established public transportation networks, many rural and suburban poor and elderly may lack the means for transportation to these services. Fortunately, New Jersey's cardiac care services are primarily located in the more populous urban and suburban areas of the State. New Jersey's ten adult and pediatric cardiac surgery centers, for example, are located in six of the State's 21 counties (28.6 percent) but these counties (Bergen, Burlington, Camden, Essex, Middlesex and Passaic) contain one-half of the State's population.

Recommendation 28. MICU services should be extended into those counties (Warren, Sussex, Cumberland, and Salem) currently without them. MICU vehicles should be allowed to transport patients who are critically ill. MICU and paramedic personnel should be trained in the use of appropriate state-of-the-art cardiac procedures (e.g., thrombolytic agents). There should be prompt access to surgery centers using helipads.

Conclusions

Throughout the deliberations of the Task Force, it was clear that rapid changes continued to occur in the state-of-the-art of cardiac invasive and non-invasive procedures. Good data are lacking in a number of areas. Thus, the Task Force was obliged to rely on professional consensus judgment in recommending certain standards and criteria. The Task Force believes that its recommendations will require periodic review, reassessment and revision as more information develops.

Recommendation 29. The State should develop a mechanism for periodic review and reassessment of the state-of-the-art in cardiac services.

The Department of Health should establish a mechanism/process by which the state-of-the-art in cardiac services could be reevaluated periodically and the guidelines/standards for these services revised accordingly. Coupled with this is the need for the Department to identify new cardiac technologies as they emerge and develop through the three classes of risk/efficacy (see Table 1). Equally important is the need to identify existing modalities that appear to be obsolete.

The Department should also develop a communications link with third-party payers in the State so that as soon as a cardiac procedure reaches Class I status, an appropriate reimbursement policy may be implemented.

Respectfully submitted,

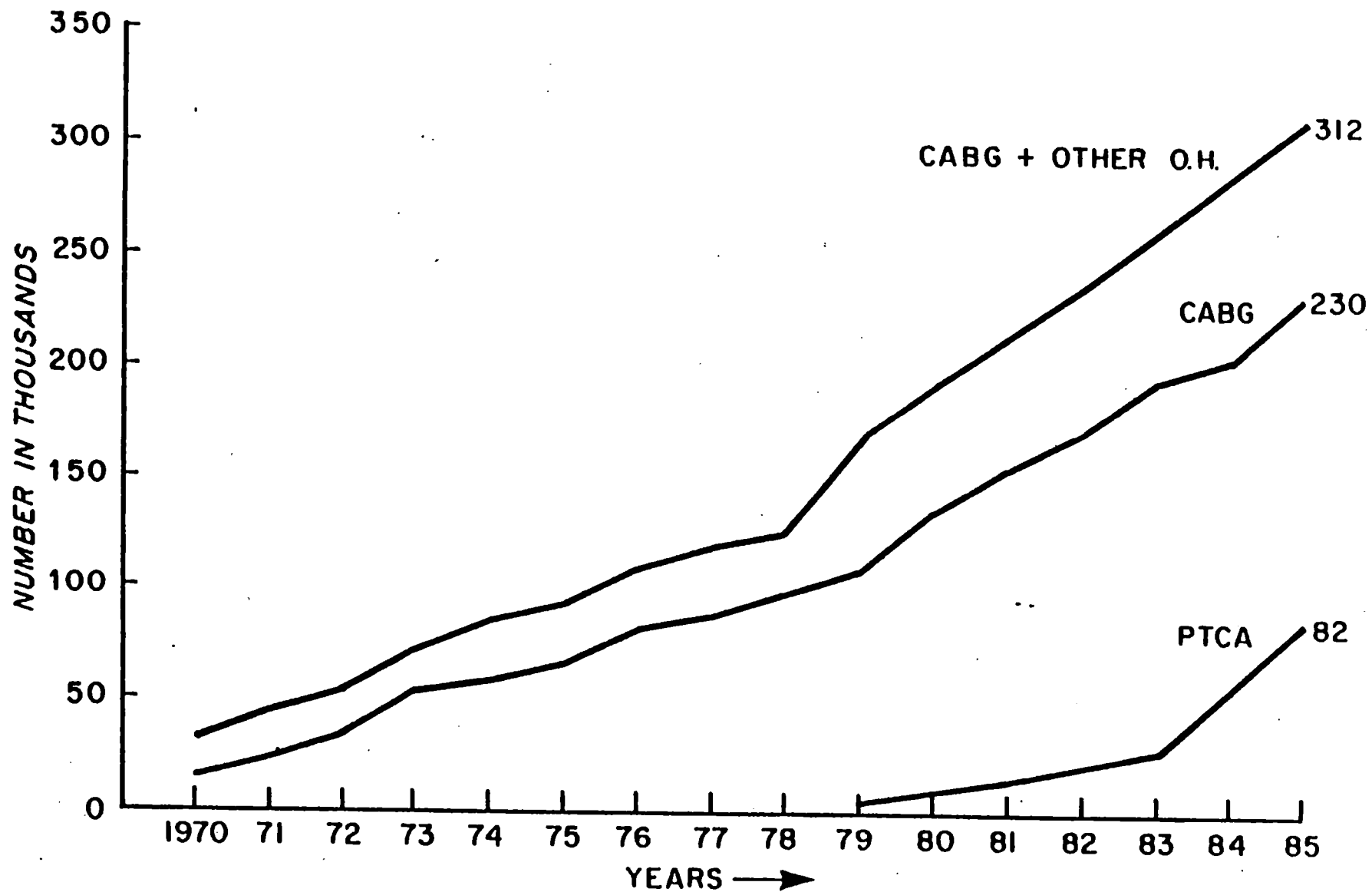
David E. Rogers, M.D.
Bernard Rabinowitz
Diane C. Adler, RN, MA, FAAN
John Banas, M.D.
Leo Brach
Enrique D. Carter, M.D.
Charles Cunniff, M.D., Ph.D.
Harvey V. Fineberg, M.D., Ph.D.
John Gregory, M.D.
Jacob Haft, M.D.
Kevin G. Halpern

Roger Herdman, M.D.
John E. Hutchinson, III, M.D.
John Kostis, M.D.
Dryden Morse, M.D.
Victor Parsonnet, M.D.
Richard Pitman
J. Sanford Schwartz, M.D.
Nolan B. Sommer, Ph.D.
William A. Tansey, III, M.D., F.A.C.C.
Edward H. Tetelman, Esq.
Arthur Wood

APPENDICES

Chart I

CARDIAC SURGERY - U.S.A. 1970-85



APPENDIX 1

NEW JERSEY CARDIAC SERVICES TASK FORCE

Chairman: David E. Rogers, M.D.
Vice-Chairman: Bernard Rabinowitz

COMMITTEES

1. Staffing Standards and Professional Credentials

Chairman: J. Sanford Schwartz, M.D.
Members: Enrique D. Carter, M.D.
Charles Cuniff, M.D.
Jacob Haft, M.D.
William A. Tansey, III, M.D., F.A.C.C.
Staff: John Gontarski, M.C.R.P.

2. Quality Audit Systems and Volume Standards

Chairman: Harvey V. Fineberg, M.D.
Members: John Gregory, M.D.
John Kostis, M.D.
Victor Parsonnet, M.D.
Nolan Sommer, Ph.D.
Diane Adler, R.N.
Staff: Alan B. Cohen, Sc.D.
John Gontarski, M.C.R.P.

3. Costs: Per Case and Systemwide

Chairman: Bernard Rabinowitz
Members: Kevin G. Halpern
Roger Herdman, M.D.
John E. Hutchinson, III, M.D.
Arthur Wood
Staff: Ruth Hanft, M.A.

4. Access to Cardiac Services

Chairman: Edward H. Tetelman, Esq.
Members: John Banas, M.D.
Leo Brach
Dryden Morse, M.D.
Richard Pitman
Staff: John Calabria, M.P.H., M.P.A.
John Gontarski, M.C.R.P.

Staff Facilitator: Theodore C. Seamans, M.P.A.

TABLE 1

Classification of Invasive Cardiac Modalities

<u>Level of Risk/Efficacy</u>	<u>Modality</u>
Established (Class I)	• Cardiac catheterization/angiography • Electrophysiology studies • Adult open heart surgery—includes CABG and valve repair • Pediatric cardiac surgery • PTCA (elective) • Intraaortic balloon pump insertions • Cardiac transplants • Pacemaker implants • Automatic implantable cardioverters/defibrillators
Investigational (Class II)	• PTCA (emergency) • Thrombolysis—includes streptokinase infusion (SI) and tissue-type Plasminogen activator (TPA) • Transvenous cardioversion • Left ventricular assist devices • Tachyarrhythmia surgery • Antitachyarrhythmia devices
Experimental (Class III)	• Laser angioplasty • Artificial heart implants

TABLE 1 (Continued)
Classification of Non-Invasive Cardiac Modalities

<u>Level of Risk/Efficacy</u>	<u>Modality</u>
Established (Class I)	● Stress tests – treadmill, thallium ● Standard CT scan ● Echocardiogram ● Radionuclide (thallium) imaging ● Dynamic cardiac monitoring (“Holter”) ● Rehabilitation programs for post-operative and post-myocardial infarction patients ● Clinical follow-up of pacemaker function – waveform plus transtelephone monitoring; transtelephone monitoring alone
Investigational (Class II)	● Stress tests – dipyridamole ● Cine CT scan ● Magnetic resonance imaging (MRI) of chest ● Rehabilitation programs for long-term maintenance ● Preventive maintenance – dietary, wellness programs ● Clinical follow-up of pacemaker function – private office systems
Experimental (Class III)	● Magnetic resonance spectroscopy for cellular function

APPENDIX 2

ACUTE MYOCARDIAL INFARCTION REGISTRY IN THE STATE OF NEW JERSEY

Although cardiovascular disease mortality has declined in the last 20 years, diseases of the cardiovascular system remain the number one killer in the industrialized world. Acute myocardial infarction claims at least 10,000 lives yearly in the state of New Jersey. In recent years, great strides have been made in the understanding and management of this condition. These developments include the realization that plaque disruption, intracoronary thrombosis, coronary spasm, and biochemical factors play a role in transforming asymptomatic coronary artery disease to potentially lethal acute coronary syndromes; and the development of pharmacological (thrombolysis) and mechanical (PTCA, coronary artery bypass surgery) reperfusion techniques. Further improvements are expected in the understanding of biochemistry and pathophysiology of myocardial ischemia and reperfusion. The ultimate usefulness of new therapeutic approaches and the importance of environmental factors in causing acute myocardial infarction can be ascertained only if data on large numbers of patients are collected.

We propose the formation of a statewide Registry of patients who suffer acute myocardial infarction. The system envisioned would have data collected from hospitals and paramedic units across the state in order to provide improved opportunities for evaluation of efficacy of the different therapeutic approaches now employed in the state and eventually provide more information about prevention, rehabilitation and determinant of long- and short-term outcomes.

The therapy for acute treatment of myocardial infarction is in a period of rapid change with an emphasis on preserving myocardial viability. It has become clear that one of the most important determinants of myocardial salvage is time from onset of infarction to definitive treatment. The information gathered via a Myocardial Infarction Registry may then provide information that could be used to better understand and improve the management of this condition.

I. Scientific Benefits

- a. Study of the efficacy of different treatment modalities now employed in the state (Coronary Care Units, Thrombolysis, PTCA, Mobile Intensive Care Units).
- b. Determination of the risk factors and precipitants of acute myocardial infarction.
- b. Determination of correlates of favorable and unfavorable short- and long-term outcomes
- d. Determination of factors that favor long-term survival by longitudinal follow-up.
- e. Creation of a pool of potential volunteers for interventional research studies sponsored by the State of New Jersey, the federal government including the National Institutes of Health and other agencies.

II. Operations Benefits

- a. Response time evaluation of mobile intensive care units and other methods of entry into the health care system in different geographical areas and socio-economic subsets.
- b. Survival rates for population subsets in various categories of myocardial infarction will be available for further study.
- c. Community involvement can be assessed in each area.
- d. Data provided could be helpful for development and deployment of resources throughout the state.

III. Publicity

- a. Local level: The Registry will generate interest in acute myocardial infarction and will improve compliance with health care measures.
- b. Statewide level: The Registry will enhance the image and reputation of the Department of Health, hence favoring the success of its programs and point the way towards improvement of its services.
- c. National level: Publicity generated by the Registry for Acute Myocardial Infarction will enhance both the public and medical image of the state of New Jersey. The potential numbers of patients that could be followed via this Registry will make it the most comprehensive program of this nature in the world. This would undoubtedly facilitate the acquisition of additional grants from federal and other sources.

APPENDIX 3

COST ESTIMATES

Introduction

Current costs for cardiac services in New Jersey are approximately \$227 million. These costs, according to our projections, are expected to increase to \$633 million by 1990. This latter estimate is very conservative, probably underestimating the growth of PTCA and the effects of streptokinase and TPA, and inflation in costs.

The following summarizes early estimates of the use of clot-dissolving drugs in the treatment of heart attacks, based on the OTA study.

Effect on Mortality

Only one large study has been conducted to date (11,000 + persons). This showed an 18 percent reduction in mortality at 21 days for the treated group (10.7 percent for treated versus 13 percent for controls). A pooled analysis of 33 smaller, randomized controlled trials supports this finding (22 percent reduction $\pm$ 5 percent) in short-term mortality (6 to 12 weeks after hospital discharge). Effects on long-term mortality have not yet been reported.

Cost Effects

The drugs are costly and would be used in conjunction with other treatment modalities. Therefore

- a. the DRG rate for medical treatment of acute heart attack would be expected to rise;
- b. the number of cardiac catheterizations would increase;
- c. the number of angioplasties might increase;
- d. the number of CABG procedures may rise as "increased cardiac catheterization will uncover more candidates for this surgical procedure," and if PTCA, as anticipated, will result ultimately in CABG.

Estimates and Assumptions

The assumptions for the cost estimates appear in each table.

Table 1 shows the estimates of volume.

Table 2 shows 1986 actual average costs per case and projected costs to 1990.

Table 3 shows the results of combining volume and costs, weighting the basic data by type of payor.

Table 4 shows population by age in the State. The volume of cases has not been adjusted for the growth in the older population since the population change from 1980 to 1986 is reflected in actual data.

State of New Jersey
Cardiac Services - Selected DRGs

Table 1. Volume of Cases, 1984, 1986, and 1990

<u>Procedure</u>	<u>DRG</u>	<u>1984 Actual</u>	<u>1986 Estimated</u>	<u>1990 Estimated</u>	<u>Estimated^{1/} Annual % Increase to 1986</u>	<u>Estimated^{2/} Annual % Increase to 1990</u>
Valve w/catheter	104	322	377	739	8.3	18.3
Valve w/o catheter	105	553	650	1,274	8.3	18.3
Bypass w/catheter	106	1,137	1,333	2,854 ^{3/}	8.3	18.3
Bypass w/o catheter	107	1,823	2,138	4,430	8.3	18.3
PTCA	112	2,085	2,445	4,789	8.3	18.3
Myocardial infarction-complex	124	3,249	4,290	10,440	14.9	24.9
Myocardial infarction-simple	125	8,596	11,353	27,629	14.9	24.9

^{1/} It was assumed that the percentage increase in numbers of surgical procedures would remain flat during the next few years. There are conflicting data on the numbers of PTCA procedures performed during the years 1983 to 1985. To be conservative, the same factor was used as for DRGs 106 to 107. If indeed the number of PTCAs is continuing a steep upward climb, then these figures will tend to underestimate the actual number of cases and, therefore costs.

^{2/} It has been assumed that volume will increase an additional 10 percent per year from 1986 to 1990 due to recapture of patients who now go to New York and Pennsylvania for care.

^{3/} Approximately 12 percent of PTCA cases later receive a CABG. It is assumed that these cases would be evenly divided between DRGs 106 and 107 and would represent an addition to CABG cases in the following year.

State of New Jersey
Cardiac Services - Selected DRGs

Table 2. Average Hospital Cost per Case by DRG, 1986 and Projected 1990

<u>Procedure</u>	<u>DRG</u>	<u>1986</u>		<u>1990</u>	
		<u>Actual^{1/} Average Rate</u>	<u>Mark-up (= X1.85)</u>	<u>Estimated^{2/} Average Rate</u>	<u>Mark-up (= X1.85)</u>
Valve w/catheter	104	\$14,091	\$26,068	\$17,128	\$31,687
Valve w/o catheter	105	12,021	22,239	14,611	27,030
Bypass w/catheter	106	11,588	21,438	14,085	26,057
Bypass w/o catheter	107	9,185	16,992	11,164	20,653
PTCA	112	4,445	8,242	5,403	9,996
Myocardial infarction-complex	124	2,346	4,340	2,852	5,276
Myocardial infarction-simple	125	1,113	2,059	1,352	2,501

^{1/} Average cost is the average 1986 DRG rate by hospital weighted by the actual 1984 number of cases by hospital.

^{2/} 1990 average cost assumes an annual 5 percent rate of inflation.

**State of New Jersey
Cardiac Services - Selected DRGs**

Table 3. Aggregate Hospital and Physician Costs, 1986 and Projected 1990

<u>Procedure</u>	<u>DRG</u>	<u>1986 Costs</u>		
		<u>Hospital^{1/}</u>	<u>Physician^{2/}</u>	<u>Total</u>
Valve w/catheter	104	\$9,788,403	\$3,354,169	\$13,142,572
Valve w/o catheter	105	14,447,277	5,133,700	19,580,977
Bypass w/catheter	106	28,619,343	13,583,270	42,202,613
Bypass w/o catheter	107	36,409,540	21,786,220	58,195,760
PTCA	112	20,073,662	8,354,565	28,428,227
Myocardial infraction-complex	124	18,623,383	6,435,000 ^{a/}	25,058,383
Myocardial infraction-simple	125	<u>23,447,124</u>	<u>17,029,500^{a/}</u>	<u>40,476,624</u>
Total		\$151,408,732	\$75,676,424	\$227,085,156
<u>Procedure</u>	<u>DRG</u>	<u>1990 Costs</u>		
		<u>Hospital^{3/}</u>	<u>Physician^{4/}</u>	<u>Total</u>
Valve w/catheter	104	\$23,205,943	\$7,991,546	\$31,197,489
Valve w/o catheter	105	34,126,294	12,230,400	46,356,694
Bypass w/catheter	106	73,697,378	35,349,644	109,047,022
Bypass w/o catheter	107	90,669,355	54,869,980	145,539,335
PTCA	112	47,440,006	19,888,717	67,328,723
Myocardial infraction-complex	124	54,585,707	19,032,120	73,617,827
Myocardial infraction-simple	125	<u>68,478,228</u>	<u>50,367,667</u>	<u>118,845,895</u>
Total		\$392,202,911	\$199,730,074	\$591,932,985
Percent Change 1986 to 1990		+ 159	+ 163	+ 161

See notes on attached pages.

State of New Jersey
Cardiac Services - Selected DRGs

Table 3 notes.

1/ 1986 Costs - Notes

Total hospital costs equal the sum of hospital costs by payer. Costs for each payer were derived by:

- a. Estimating 1986 volume of cases using 1984 DRG actuals as the base and applying an annual percentage increase.

For example, for DRG 104 the annual percentage increase was assumed to be 8.3 percent. Medicare volume for DRG 104 in 1984 was 176 cases.

1986 cases = $176 \times 1.083 \times 1.083 = 206$ cases.

- b. Deriving average payer payment for the DRG, this equals:

Average DRG payment per case $\times 1.85 \times$ payer factor.

- c. Multiplying average payer payment by volume of cases by payer factor. For example, for Medicare for DRG 104

Average DRG payment	=	\$14,091
Mark-up	=	1.85
Medicare Factor	=	.991
# of Medicare cases	=	206

Thus: $\$14,091 \times 1.85 \times .991 \times 206 = \$5,321,749$

- d. Sum across all payers for total costs.

2/ 1986 Physician Costs

Uses average professional charges by procedure multiplied by total estimated 1986 volume for the DRG.

3/ 1990 Costs

A 5 percent annual inflation rate was applied to the 1986 DRG average cost per case. The 1.85 mark-up was applied to the result which was then multiplied by the total projected volume of cases for the DRG. The result was then multiplied by .991 (the payer factor for Medicare and Blue Cross which account for more than 70 percent of payments).

4/ 1990 Physician Costs

An annual 5 percent rate of inflation was applied to the 1986 average physician charges. The result was then multiplied by the estimated total 1990 volume for the DRG.

- a/ No actual physician charges were available. An average of \$1,500 was assumed for both DRGs 124 and 125.

State of New Jersey

Table 4. Population by Age 1980 to 1990

<u>Age Group</u>	<u>1980</u>	<u>1990 (Projected)</u>	<u>Percent Change Increase (Decrease)</u>
0	115,822	126,363	9.1
1-14	1,461,755	1,245,917	(7.9)
15-29	1,859,628	1,805,340	(2.9)
30-64	3,067,847	3,499,290	14.0
65 +	859,771	1,065,340	23.9
Total	7,364,823	7,842,250	6.5

Table 4 notes.

During the ten-year period from 1980 to 1990, the age group 30-64 is expected to increase by 14 percent and those 65 and over by 24 percent. Overall, 30 + population (which accounts for the majority of cardiac procedures performed, see attached) will increase at an average rate of 1.62 percent per year, far below the annual percentage increase in cardiac procedures experienced from 1979 to 1985. More information is needed to determine the reasons for the continuing rise in the numbers of procedures since population increases explain very little.

State of New Jersey
Attachment to Table 4.

1984 Statewide Totals of Age-Specific Cardiac DRGs

<u>DRG</u>	<u>Number of Patients</u>	<u>Age</u>	
104	322	0	= 6
		1-15	= 5
		16-30	= 9
		31-64	= 144
		65 +	= 158
105	553	0	= 3
		1-15	= 5
		16-30	= 25
		31-64	= 293
		65 +	= 215
106	1,137	0	= 1
		1-15	= 0
		16-30	= 3
		31-64	= 678
		65 +	= 455
107	1,823	0	= 0
		1-15	= 0
		16-30	= 1
		31-64	= 1,276
		65 +	= 546
112	2,085	Not available by age	
124	3,274 ^{1/}	0	= 18
		1-15	= 20
		16-30	= 35
		31-64	= 2,082
		65 +	= 1,119
125	8,616 ^{1/}	0	= 79
		1-15	= 327
		16-30	= 149
		31-64	= 6,066
		65 +	= 1,995

^{1/} These numbers are slightly higher than those used in Tables 1, 2, and 3.

APPENDIX 4

ACCESS TO CARE

In order to ascertain the degree of access of the residents of NJ to existing inpatient cardiac services, DRG data were analyzed from the Department of Health on all appropriate discharge diagnoses (DRGs 104 - 143) for each hospital by age, race, sex, source of payment and County of origin. These data elements for 1984 were then tabulated by the number of admissions (Table 1A) and the percentage of patients represented by these admissions (Table 1B).

The following DRGs were considered clinically appropriate for study:

DRG 104	-	Valve OR Procedure with Pump with Cardiac Catheterization
105	-	Valve OR Procedure with Pump, without Cardiac Catheterization
106	-	Coronary Bypass with Cardiac Catheterization
107	-	Coronary Bypass without Cardiac Catheterization
108	-	Other Cardio-Thoracic OR Procedure with Pump
121	-	Circulatory Disorder with Acute MI, Discharged Alive, with Cardiovascular Complication, Medical
122	-	Circulatory Disorder with Acute MI, Discharged Alive, without Cardiovascular Complication, Medical
123	-	Circulatory Disorder with Acute MI, Discharged Dead, Medical
124	-	Circulatory Disorder without Acute MI, with Cardiac Catheterization, with Complex diagnosis, Medical
125	-	Circulatory Disorder without Acute MI, with Cardiac Catheterization, without Complex Diagnoses, Medical
127	-	Heart Failure and/or Shock Medical
134	-	Hypertension, Medical
135	-	Congenital and/or Valvular Disorder, with age 18 +, with age 70cc, Medical
136	-	Congenital and/or Valvular Disorder, with age 18 +, without age 70cc, Medical
137	-	Congenital and/or Valvular Disorder, with age 0 - 17, Medical
140	-	Angina, Medical

The data for cardiac diagnostic and cardiac surgery services in New Jersey is as follows:

TABLE 1A

STATEWIDE TOTALS

		Actual # Patients							
# Patients		Medicare	Medicaid	White	Black	Hisp.	Other	Male	
DRG	104	322	176	7	283	28	4	7	157
	105	553	238	27	461	48	6	38	273
	106	1,137	500	17	1,052	45	3	37	801
	107	1,823	607	30	1,676	62	7	78	1,400
	108	683	113	45	546	42	29	66	437
	121	6,147	4,088	73	5,573	385	6	183	3,590
	122	9,830	4,504	154	8,615	772	28	415	6,591
	123	3,276	2,648	32	2,995	177	6	98	1,651
	124	3,274	1,271	95	2,787	307	12	168	2,157
	125	8,616	2,348	316	7,376	693	66	481	5,515
	127	23,740	19,838	602	19,909	2,933	33	845	10,795
	134	5,319	2,377	313	3,460	1,491	25	343	2,051
	135	794	449	35	656	83	4	41	314
	136	509	57	37	362	98	3	46	173
	137	216	0	68	109	6	1	45	100
	140	22,578	13,360	788	18,850	2,549	75	1,104	10,732

TABLE 1B

STATEWIDE TOTALS

		# Patients	Percent					Male	
			Medicare	Medicaid	White	Black	Hisp.		Other
DRG	104	322	54.7	2.2	87.9	8.7	1.2	2.2	48.8
	105	553	43.0	4.9	83.4	8.7	1.1	6.9	49.4
	106	1,137	44.0	1.5	92.5	4.0	0.3	3.3	70.4
	107	1,823	33.3	1.6	91.9	3.4	0.4	4.3	76.8
	108	683	16.5	6.6	79.9	6.1	4.2	9.7	64.0
	121	6,147	66.5	1.2	90.7	6.3	0.1	3.0	58.4
	122	9,830	45.8	1.6	87.6	7.9	0.3	5.1	66.4
	123	3,276	80.8	1.0	91.4	5.4	0.2	5.6	50.4
	124	3,274	38.8	2.9	85.1	9.4	0.4	3.6	65.9
	125	8,616	27.3	3.7	85.6	8.0	0.8	6.4	64.0
	127	23,740	83.6	2.5	83.9	12.4	0.1	5.2	45.5
	134	5,319	44.7	5.9	65.0	28.0	0.5	9.0	38.6
	135	794	57.3	4.5	83.7	10.6	0.5	20.8	40.1
	136	509	11.2	7.3	71.1	19.3	0.6	0.1	34.0
137	216	0	31.5	50.5	28.2	0.5	0	46.3	
140	22,578	59.2	3.5	83.5	11.3	0.3	0	47.5	

Table 2
Statewide Cardiac Catheterization Patients
[DRGs 124 & 125]

	<u>1982</u>	<u>1983</u>	<u>1984</u>	<u>1980 Census Data Population on Sex/Race</u>
Total Patients	10,132	11,907	11,890	7,364,823
Total Males	6,886	7,952	7,672	3,533,012
Percent Males	68.0%	66.8%	64.5%	48.0%
Total Females	3,246	3,955	4,218	3,831,811
Percent Females	32.0%	33.2%	35.5%	52.0%
Total Blacks	783	950	1,000	924,786
Percent Blacks	7.7%	8.0%	8.4%	12.6%
Total Hispanics	31	57	78	491,867
Percent Hispanics	0.31%	0.48%	0.66%	6.7%
Total Non-Whites	1,361	1,570	1,727	1,728,935
Percent Non-Whites	13.4%	13.2%	14.5%	23.5%
Total Whites	8,771	10,337	10,163	6,127,090
Percent Whites	86.6%	86.8%	85.5%	83.2%

Table 3
Statewide Cardiac Surgery Patients
[DRGs 104-107]

	<u>1982</u>	<u>1983</u>	<u>1984</u>	<u>1980 Census Data Population on Sex/Race</u>
Total Patients	2,871	3,723	3,835	7,364,823
Total Males	2,125	2,717	2,631	3,533,012
Percent Males	74.0%	73.0%	68.6%	48.0%
Total Females	746	1,006	1,204	3,831,811
Percent Females	26.0%	27.0%	31.4%	52.0%
Total Blacks	145	163	183	924,786
Percent Blacks	5.1%	4.4%	4.77%	12.6%
Total Hispanics	7	20	20	491,867
Percent Hispanics	0.24%	0.54%	0.52%	6.7%
Total Non-Whites	229	308	363	1,728,935
Percent Non-Whites	8.0%	8.27%	9.46%	23.5%
Total Whites	2,642	3,415	3,472	6,127,090
Percent Whites	93.0%	91.7%	90.5%	83.2%

TABLE 4
1984 New Jersey Mortality Data
Major Causes of Death-Cardiac Related

Cause of Death	Total Deaths	Whites		Blacks		Other	
		No.	(%)	No.	(%)	No.	(%)
Arterial Disease	725	654	90.2	68	9.4	3	0.4
Arteriosclerosis	765	721	94.3	42	5.5	2	0.3
CVD	4,609	4046	87.8	539	11.7	29	0.6
Hypertension	224	177	79.0	46	20.5	1	0.5
Heart Disease	27,460	25209	91.8	2169	7.9	72	0.3
Nephritis/Nephrosis	818	653	79.8	161	19.7	4	0.5

