Executive Summary
Cardiovascular Services Demand Needs Study

for the

Maine Department of Human Services

by

Public Health Resource Group, Inc.

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Public Health Resource Group, Portland, Maine

I. Study Overview

A. Background

The need for cardiovascular services has been widely debated and hotly contested throughout the State of Maine. This debate has centered on Certificate of Need (CON) applications by several hospitals seeking to expand their service delivery capabilities.

At present, five hospitals provide cardiac catheterization services: Maine Medical Center (MMC), Eastern Maine Medical Center (EMMC), York Hospital, St. Mary's Hospital and Central Maine Medical Center (CMMC). Maine Medical Center and Eastern Maine Medical Center have open-heart surgery and full spectrums of interventional cardiology capabilities. York Hospital also performs angioplasty procedures relying on an agreement with Portsmouth Hospital in Portsmouth, NH to provide surgical backup.

Seven hospitals have submitted CON applications or letters of intent to develop cardiac catheterization laboratories: Southern Maine Medical Center (SMMC), Maine General Medical Center (MGMC), Mid Coast Hospital, Inland Hospital, Mercy Hospital, St. Joseph's Hospital, and The Aroostook Medical Center (TAMC). Maine Medical Center has filed an application for an additional (5th) cardiac catheterization laboratory. In addition, Central Maine Medical Center has submitted an application for an open-heart surgery and interventional cardiology program. Other hospitals may well decide to submit CON applications to develop invasive cardiovascular services in the future.

These filings have created a dynamic of competing interests and uncertainty as to the most appropriate way to address the delivery of cardiovascular services within Maine. The Maine Department of Human Services (DHS), which has the responsibility and authority to approve these applications as well as to establish public health policy on the deployment of health resources within the State, has recognized a need to evaluate the need/demand for cardiovascular services within a broader health policy context. These responsibilities mandate fairness to affected hospitals and, more importantly, effective deployment of specialized health services to the people of Maine.

Accordingly, the DHS issued a request for proposal to study the need and demand for cardiovascular services, and selected Public Health Resource Group (PHRG), Portland, Maine to undertake an independent study.

B. Study Objectives

The need and demand study has been framed around a series of interrelated tasks spelled out in the charge to the consultants. These include a requirement to:

1. Examine provider perspectives on the current adequacy of invasive diagnostic and therapeutic cardiovascular services in the State and the need for additional services;
2. Analyze past trends in utilization rates for invasive diagnostic and therapeutic cardiovascular procedures and compare these with regional and national rates;
3. Forecast future needs for invasive diagnostic and therapeutic services and the optimal distribution of these within the State;
4. Examine changes in medical technology that may influence future need and demand for invasive cardiovascular services;
5. Examine the implications of current standards of care and potential changes in these for the delivery of cardiovascular services;
6. Evaluate current policies, rules, and regulations governing CON applications for cardiovascular services in Maine and other states; and to
7. Make recommendations for:
    - The future development of invasive diagnostic and therapeutic cardiovascular services
    - Changes to CON processes and criteria for evaluating future applications for invasive cardiovascular services

C. Approach and Methodology

The work plan included four distinct, yet interrelated, processes:

1. Interviews with Provider Organizations: A series of interviews were conducted with representatives from existing providers and applicant hospitals in order to learn of their perceptions on a wide-ranging set of cardiovascular service topics.
2. Document Review: Voluminous documents were reviewed and analyzed in the conduct of this study. These study resources included:
    - Maine DHS documents on the CON process
    - CON applications submitted to the DHS
    - Supplemental information provided by the hospitals
    - Literature review on a host of topics relating to clinical, technological, and organizational delivery of cardiovascular services.

3. Data Analysis: A multi-year cardiovascular database has been constructed containing population, demographic and risk factor characteristics, and utilization of cardiovascular health services. These data have been used to evaluate trends over time and to compare hospital utilization patterns.

4. Forecasting: The above data, coupled with information on hospital service areas, form the basis for projecting future need and demand for cardiovascular services for geographic regions and for the State as a whole.

Cardiology Service Areas

In determining service areas we applied a consistent methodology for the respective hospital CON applicants. We used inpatient cardiology admissions to determine a primary cardiology service area (CSA) and a secondary cardiology service area (CSSA). Combined hospital market share of CSA and CSSA admissions ranged 25% to 38% while hospital dependency on combined CSA and CSSA ranged 89% to 96% with one hospital at 82%. The definition of CSA and CSSA are as follows:

Cardiovascular Primary Service Area (CSA) for each hospital:

- hospital has a market share of 50% or more of town[1] **or**
- hospital relies on the town for 4% or more of its admissions, **or**
- hospital relies on the town for 3% or more of its admissions and the town has a market share of 30% or more, and town is contiguous with CSA towns **or**
- town does not meet criteria for market share or % hospital admissions **but** is surrounded on 3 or more of its borders by CSA towns

Cardiology Secondary Service Areas (CSSA) for each hospital:

- hospital has a market share of 15% or more of town, **or**
- hospital relies on the town for more than 1% of its admissions

D. Framework for Decision-Making -- Access, Quality, and Costs

Health policy makers and health care providers alike must continually confront the conflicting priorities of various stakeholders. This is certainly true for the further development of cardiovascular services in Maine. Our study documents these tensions and attempts to consider them in arriving at its recommendations for cardiovascular services that will best serve the interests of the people in Maine, while they also meet the legitimate objectives of the hospitals.

Healthcare planning requires the evaluation of each of the three key dimensions: access, quality, and costs. These dimensions speak to the public's rights and expectations to have access to needed services that are of high quality, and at a reasonable cost. The dynamic tension between these elements is often referred to as the "elusive triangle" of health care planning. Various environmental forces are involved including market competition, population demographics, health status, emerging technology, changing clinical practices, payment pressures, and consumer expectations. The challenge for policy makers is to strike the best possible balance among these elements.

[1] towns were identified by Geocodes

This study reveals that these tensions are evident in the realm of cardiovascular services. Clearly there are conflicting viewpoints, competing interests, and differing opinions about what will best serve the cardiac care interests of the people in Maine while also meeting the organizational objectives of the various hospitals.

The affected hospitals have asserted their ability to balance desirable care attributes by adhering to and building upon their existing programs. However, it is also clear that each of the access, quality, and cost attributes have different meaning to the affected parties and perhaps to the public as a whole. Each attribute is subject to differing definitions, standards of measurement, and interpretations of relative importance.

Definitions are important. Access includes not only the dimensions of time and distance but also includes the very important consideration of timely scheduling of needed health care. Issues of medical access predicated on patient need for prompt treatment must be distinguished from consumer convenience. The latter, while important, is of secondary importance from a health planning perspective.

The definition of high quality care, and its measurement and improvement, is receiving ever more attention. While there is no universal consensus, most would agree that quality should ultimately be measured in terms of outcomes - symptoms relieved, productive lives prolonged, and complications avoided. Measures of health care processes often provide useful proxies when their links to outcomes have been well established. From a health policy perspective, two components are essential. One is to use best available knowledge to set standards for new programs in terms of structure, staffing, processes, and volumes. These standards are usually derived from the experiences of other like programs or "benchmarks." The other component is to establish a process for continuous monitoring of the quality performance linked to initiatives for improvement.

Finally, costs are always important - to the taxpayer who must ultimately pay for Medicare and Medicaid; to the employer who offers health insurance as a benefit; and to the individual who must pay a portion of the bill out of his or her own pocket. Costs, in turn, depend on many factors; the foremost of which are rates of use of services and the efficiency by which services are produced. Two points are particularly germane to cardiovascular services: (1) Roemer's Law reminds us that use of a given service tends to expand to fill the capacity available. There is extensive research showing a strong correlation between high system capacity and increased utilization. For example, the number of invasive cardiac programs and physicians directly influences service utilization. (2) Efficiencies of scale are important for cardiovascular services because of the high capital costs involved and the high fixed costs of skilled staffing. Smaller programs are typically more costly per unit of service than larger programs.

In addressing and resolving these matters, we have attempted to frame the issues so as to recognize key decisions facing policy makers and affected providers in ways that:

- Build upon the strengths of existing providers;

- Evaluate the extent to which competition among providers should be encouraged versus relying on a regulated "franchise" system;
- Address whether or how cooperative arrangements among hospitals will facilitate deployment of high quality care;
- Determine whether there is need for another open heart surgery and interventional cardiac services provider(s) such as proposed by Central Maine Medical; and
- Delineate the benefits of additional cardiac catheterization laboratories and priorities for their location(s) within Maine.

E. Findings and Conclusions

- **Health Status and Utilization**

Behavioral risk factors in populations (smoking, obesity and sedentary life style) along with age are important drivers of cardiovascular disease medical risk factors (hypercholesterol and high blood pressure) and morbidity (heart attacks [AMI], unstable angina, strokes, etc.). These in turn, drive the need both for invasive and non-invasive cardiovascular care. Maine's population, which is older than the US population, aged significantly over the past decade and projections suggest that this trend is continuing. The middle age (age 45-64) and older (age 75+) adult age groups are estimated to increase between 20% to 80% respectively from 1998 to 2003. A summary of population trend data, by age, is presented as Exhibit I-1 and I-2.

Behavioral risks for cardiovascular disease remained fairly constant over the decade with the exception of obesity that rose by 16%. Despite some improvements in behavioral risks in the last two years, modest increases were observed in levels of medical risks and morbidity (see Exhibit I-3). For example, the prevalence of diagnosed hypercholesterol increased by 50% and rates of heart attack (AMI) hospitalizations increased by 20%. (See Exhibits I-4 through I-7 for a summary of this data).

Although there were more people who developed cardiovascular disease, death rates from heart disease, AMI, and stroke remained the same or declined from 1991 to 1997. Patients have more access to care, including sophisticated medical (non-surgical) treatment, which is the likely reason for the lower mortality rates. Statewide, the frequency of invasive (surgical) procedures also increased dramatically over the past 10 years: cardiac catheterizations went up 35%, angioplasty, 75%, and open heart surgery, 42%.

This pattern was observed most keenly among the age group 75+. This group has been one of the fastest growing (but still small) sectors of the state's population. Heart attack incidence (morbidity) increased more dramatically (26%) in this group, as did utilization rates for diagnostic cardiac catheterizations, angioplasty procedures and open heart surgery (64%, 235%, and 67% respectively). Heart attack deaths (AMI mortality) in this age group decreased by more than 15% from 1991 (mortality rate of 840/100,000) to 1997 (716/100,000) (see Exhibits I-8 through I-11).

We examined the same set of indicators in the cardiology service areas (CSAs) of each CON applicant hospital (See Exhibit I-12 through I-14). Patterns of health status and service utilization

varied substantially among those communities. Those variations provided important information about the relative need for additional preventive, medical and invasive cardiovascular services for sub-populations within Maine.

The CON applicant hospital CSA communities represented by Maine Medical Center (MMC), Mercy and Mid Coast hospitals experienced the most dramatic increases in their middle and older adult populations. Despite these demographic changes, risk for cardiovascular disease stayed the same or increased only slightly, except for a significant increase in the prevalence of hypercholesterol. Morbidity and mortality for heart disease decreased in the 1990s to levels that are generally lower than those in state and in all other CSAs examined. However the rates of invasive diagnostic and therapeutic cardiovascular services in the MMC and Mercy Hospital CSAs increased dramatically over the same period. Diagnostic catheterizations rates increased by approximately 60%, angioplasty utilization nearly doubled and open heart surgery increased 30% to 40%. Indeed, during the last two years of this decade, utilization rates in the same two communities substantially exceeded rates in the state as well as in most other CSAs, particularly among adults age 75+.

Despite having the same demographic and risk trend as MMC, Mercy and Mid Coast CSAs, SMMC saw cardiovascular disease morbidity increase over the past decade. SMMC's CSA morbidity is elevated over the state and neighboring CSAs, especially among adults age 75 and over. Mortality from heart disease and AMI also increased while rates of diagnostic catheterizations, angioplasty procedures and open heart surgery also increased significantly. Among the 75+ age group the increase was approximately 400% between 1994 and 1999. Access to invasive cardiovascular services did not appear to effect morbidity and mortality patterns in this population. More analysis might uncover the reasons for this unexpected result.

In the TAMC CSA communities, there were substantial reductions in behavioral risk factors over the past decade, and the prevalence of cardiovascular disease also increased substantially. However, cardiovascular disease morbidity and mortality increased and exceed those in the state and in most other CSAs examined. Levels and trends in the rates of invasive cardiovascular services mirrored those for disease morbidity and mortality. Utilization rates for each type of service were higher than rates in the state (by 50%-80%) and rates in all other CSAs examined. Moreover, crude and age-adjusted rates of diagnostic catheterizations increased two- to three-fold in the TAMC community between 1993 and 1999. Rates of inpatient angioplasty procedures and open heart surgeries showed even more dramatic increases during the same time period. Thus, from an access/availability perspective the TAMC hospital community appears to have sufficient access to cardiovascular services. But its effectiveness on reducing morbidity and mortality is not yet apparent.

AMI hospitalization and death rates in MGMC and Inland Hospital CSAs are significantly higher than expected given levels of behavioral risk factors and prevalence of disease. Rates of heart attacks and heart attack deaths increased over the past decade in spite of reductions in risk factors and high levels of diagnosed conditions. Utilization rates for invasive cardiovascular services showed corresponding increases throughout the 1990s and, in the Inland Hospital CSA, use rates for diagnostic catheterizations and open heart surgery exceeded corresponding use rates in the

state at the end of the decade. These findings suggest that while access to invasive diagnostic services is not lacking in these communities, the availability and/or adequacy of primary and secondary prevention services for cardiovascular disease might need to be enhanced, along with emergency services for people who suffer an acute heart attack.

AMI hospitalizations and deaths occur at higher rates in the CMMC CSA than what would be expected based on levels of behavioral risk and prevalence of diagnosed cardiovascular disease in this community. Heart attack hospitalizations increased fairly dramatically over the past decade, especially among the oldest adults, while heart disease mortality declined slightly. Behavioral risk factors, especially smoking rates, showed some improvement although they are still high. Rates of diagnostic catheterizations declined over the past 10 years to levels that are similar to the state. These reductions occurred even though both CMMC and St. Mary's Hospital have had fully operational cardiac catheterization laboratories for more than 15 years. Rates of angioplasty procedures and open heart surgery increased over the past decade, particularly among older adults; while the increase was smaller than other CSAs studied, they are still higher than the state. These patterns suggest that access to invasive procedures is not an issue for this population and that primary and secondary prevention services, in particular medical services for cardiovascular disease, while still needed, have improved over the decade.

The St Joseph Hospital CSA exhibited low levels of cardiovascular disease risk as well as low disease prevalence during the latter part of the decade, although both have been on the rise. Recent data also showed that the St. Joseph Hospital CSA population is no more likely than their state counterparts to be admitted for a heart attack. Although heart attack rates among the oldest members of the St. Joseph CSA increased by 50% over the past decade, while rates of diagnostic cardiac catheterizations doubled in that cohort, angioplasty use rates quadrupled and rates of open heart surgery increased by 60%. Heart attack mortality rates stayed constant and the most recent rates are moderately elevated over the state. Thus, the use of invasive cardiovascular services among the older population of the St. Joseph Hospital CSA increased at a faster rate than did disease morbidity—suggesting that needs for invasive diagnostic or therapeutic services are being met.

- **Procedure Volume**

Current Provider Volumes Over Time:

Trends in procedure volumes were analyzed for those facilities in Maine that currently offer diagnostic catheterizations, angioplasty and open heart surgery services (see Exhibit I-15 through I-17). The annual average number of procedures performed at each facility (inpatient) over consecutive two-year periods, beginning in 1991-1992 and going through 1999 revealed dramatic increase of invasive procedures in the State. However the increases were not consistent for each facility.

Overall, the total number of diagnostic cardiac catheterizations performed in Maine increased by 40% from the 1991-1992 period to 1999. Only two of the five facilities that offer this procedure - EMMC and MMC - saw increases in the number of diagnostic services performed, however.

EMMC performed nearly 80% more diagnostic catheterizations in 1999 than they did during the 1991-1992 period and MMC performed nearly 70% more. The number of inpatient diagnostic catheterizations performed at the remaining three hospitals decreased over the same time period, by 50% at CMMC, by 35% at St. Mary's Hospital and by 65% at York Hospital.

The number of angioplasty procedures performed by Maine hospitals nearly doubled throughout the 1990s. Of the two hospitals that have offered angioplasty over the past decade[2], the most precipitous increases occurred at EMMC where three times as many angioplasty procedures were performed in 1999 as were performed during the 1991-1992 period. The number of angioplasty procedures performed at MMC also increased by 65%.

Finally, Maine facilities performed 50% more open heart surgeries at the end of the decade compared to the beginning. EMMC was performing 60% more surgeries in 1999 than they were during the 1991-1992 period and MMC was performing 40% more.

Estimates of Procedure Volume:

A key component of the CON process is the development of the estimates of the volume of services to be provided. Estimating procedure volume is especially critical for cardiovascular services due to the volume/quality relationship for these services. The estimates also are essential in analyzing geographic access and cost considerations in striking a balance among the cost, quality and access dimensions of this challenging health policy issue.

By their very nature, volume estimates must be based upon a variety of assumptions regarding how a proposed new service will affect the delivery of health care services. In planning for cardiovascular services in the community hospital setting, assumptions play an even greater than usual role in estimating volume. The increased reliance on assumptions is due to 1) the potential for the community hospital to serve patients from communities in addition to the communities it has historically served, and ii) the uncertainty regarding the degree to which patients will continue to go to the established regional and/or statewide providers. This latter issue reflects many factors, including the nature of the specific cardiovascular service, the perceived quality of the community hospital and regional/statewide providers, the referral patterns of the physicians in the community, travel distance and travel time.

Certain aspects of the CON process also have a significant effect on the assumptions that underlie the volume estimates:

- Volume estimates are a particularly important component of CON applications where minimum volume standards must be met for an application to be approved. These circumstances call for a more rigorous review of the reasonableness of the volume estimation method and assumptions.
- Applications for CONs and the volume estimates that support them are prepared assuming that there are no other CON applications for the same service affecting all or part of the applicant's proposed service area. In those circumstances where there are applications from

[2] Trends in angioplasty procedure volume were not be analyzed for York Hospital because the program was established too recently.

two providers for the same service with overlapping service areas, the independently prepared hospital volume estimates have diminished utility. This effect is greater in those rare circumstance when there are multiple competing applications, as currently exists for cardiac catheterization services.

To address the many issues with volume estimates for cardiovascular services, PHRG concluded that it should develop volume estimates for these services in Maine that would:

- Apply a consistent set of assumptions to all proposed applicants,
- Assess the reasonableness of its assumptions by developing and comparing a minimum of three different volume estimation methods for each of the three cardiovascular services.

The results of these analyses are as follows:

- Diagnostic Cardiac Catheterization Labs (see Exhibit I-18)
  - If all eight new providers were approved or if there were no CON process and all were fully operational this year:
    - MaineGeneral Medical Center would have the highest volume of the proposed new providers, with approximately 600 caths per year.
    - Mercy Hospital and Southern Maine Medical Center would exceed the minimum volume threshold with procedure volume in the mid to upper 300 caths per year.
    - St. Joseph Hospital's volume would be very close to the volume standard for new providers of 300 cases per year.
    - Inland Hospital, Mid Coast Hospital and TAMC would not meet the current CON standard.

- If only one additional catheterization program were approved, we recommend approving one in the Augusta area since it yields the highest volumes, significantly improves access for the largest population without ready access to this service, and significantly improves local resources for cardiovascular care. If only the MGMC application were approved our estimate is that the hospital would perform between 650 and 700 catheterizations per year (see Exhibit I-19).

- If only two additional catheterization programs were approved and the choice was MGMC and Southern Maine Medical Center, our estimate is that MGMC would perform approximately 650 catheterizations per year and SMMC would perform approximately 375 per year. Based on these estimates MMC could experience a reduction in its catheterization volumes by as much as 13% —or 580 based on its current volume (see Exhibit 1-20.)

- If two additional cardiac catheterization programs were approved and the choice was MGMC and SMMC, our estimates are that MGMC would continue at around 650 and SMMC would perform approximately 375 cases. An option of MGMC and Mercy produces the same result for MGMC and approximately 400 cases for Mercy. (see Exhibit I-21)

- If three additional cardiac catheterization programs were approved, the option of MGMC, SMMC and Mercy would result in estimates of approximately 650, 360 and 380 cases, respectively. (see Exhibit 1-22)

Angioplasty

- Approval of the open heart surgery program in the central Maine area or approving a central Maine area provider for primary angioplasty results in increased access to a local service . PHRG estimates that angioplasty volumes as a result of this would range in the mid-to-upper 200s. This volume would exceed the current ACC/AHA guideline of 200 cases. (See Exhibit I – 23)

Open Heart Surgery

- Approval of an open heart surgery program in the central Maine community served by CMMC will result in increased local access to open heart procedures. PHRG used several models to estimate 1999 volumes of open heart surgery procedures for CMMC. Findings from all estimation methods suggested that if a program were approved in the CMMC community, volumes would be low, either under the current CON threshold of 200 cases or slightly over the threshold. (See Exhibit I – 24.)
- Using the 'Cardiac Catheterization Market Share Method,' we estimated that CMMC would have performed between 188 and 206 surgeries if they had had a fully operational open heart program in 1999. This method uses CMMC's share of the cardiac catheterization market when compared to the two existing open heart surgery hospitals and an adjustment for the larger service areas associated with open heart surgery compared to cardiac catheterization. (See Chapter IV of the PHRG report for a complete description of this and other methods of estimating volumes). The two ends of the range reflect different assumptions regarding the percentage of patients from St. Mary's Hospital who would elect to have open heart surgery at CMMC.
- The 'Surgery to Cardiac Cath Ratio Method,' which assumed that 26.5% of CMMC's inpatient and outpatient diagnostic catheterizations would result in open heart surgery, estimated that CMMC would perform between 187 and 203 open heart surgeries in 1999. Again the range in the estimates reflects differing assumptions regarding St. Mary's patients. The higher end of this range used the number of inpatient and outpatient cardiac catheterizations performed at both CMMC and St. Mary's hospitals as the denominator.
- Finally, the service area method reflects the product of i) CMMC's primary secondary, and tertiary CSA population, ii) the rate of open heart surgery in its service area, and iii) CMMC's market share for cardiac catheterization, adjusted for the larger open heart surgery service area. This method estimated that the 1999 volume of open heart surgery at the CMMC facility would be 208.

The estimates of changes in the service areas due to the implementation of a new cardiac surgery program necessarily depend on a number of factors. In addition, the health care environment in Maine is extremely dynamic and may likely include new providers of cardiac catheterization services. For example, if an Augusta based cardiac catheterization program is approved it is

unlikely that a central Maine cardiac surgery program will capture very much additional Kennebec County market share. CMMC will have to improve its market share to the west, in particular in Oxford and Franklin Counties.

- **Tradeoffs Between Thrombolysis and Primary Angioplasty in the Treatment of Patients with AMI**

Thrombolytic (platelet busting drugs) therapy and primary angioplasty (emergency angioplasty performed on patients who have just experienced an acute heart attack) each have advantages and disadvantages. Neither is clearly superior given current evidence. Selective use of the combination may ultimately prove to be the approach of choice, but further research is needed to define indications. Moreover, technological advances such as the use of stents and the use of long-acting platelet glycoprotein inhibitors may change the balance as they improve outcomes.

The most important advantages of thrombolysis are speed, ease of administration, and universal availability. The treatment can even be administered before the patient arrives in the hospital assuming the diagnosis of AMI has been established and eligibility determined. Disadvantages are lower reperfusion rates in the culprit vessel causing the AMI and an increased risk of bleeding.

Advantages of primary angioplasty are higher initial reperfusion rates and absence of the risk of intracranial bleeding. Disadvantages are delays in treatment, high levels of technical expertise required by the operator and laboratory staff, and significant rates of procedure complications leading to death, reinfarction, or need for emergency CABG surgery.

Available evidence indicates that the prudent approach for community hospitals is to develop and implement protocols that will ensure prompt and expert administration of thrombolytic agents in eligible patients. Urgent transfer to tertiary centers should be arranged for patients with contraindications to thrombolysis or cardiogenic shock that are otherwise eligible for primary angioplasty. Primary angioplasty should be performed only in high volume programs staffed by skilled and experienced operators. The decision-to-procedure time should be no more than 60 minutes - 24 hours a day. Cardiac surgical backup should be readily available either on-site or in a nearby facility. (See section C 5 for a discussion of surgical backup for angioplasty programs.)

Conclusions on the Need for Onsite Surgical Backup for Angioplasty Programs:

Vigorous debate ensues over whether or not on-site cardiac surgical backup should be an absolute requirement for an angioplasty program. Increasing numbers of hospitals with diagnostic cardiac catheterization programs are performing angioplasty without on-site surgical backup. Anecdotal reports indicate good results. Critical conditions are that angioplasty programs have experienced, skillful operators and laboratory support team, reasonably high volumes of both elective and primary angioplasty, and have a formalized arrangement for surgical backup with a nearby tertiary center. This arrangement should ensure that a patient who has suffered a complication and needs emergency surgery be in the operating room within 90 minutes. This requires that: (1) an ambulance with cardiac support capability be readily available; (2) transport takes no more than 30 minutes door-to-door; (3) communication is

excellent between the angioplasty laboratory and surgical program; and (4) the surgical program can have the patient into a fully staffed OR within 30 minutes after arrival.

- **Certificate of Need**

The certificate of need program in Maine has been operative in Maine since 1978. It is generally well understood by providers who are accustomed to submitting applications using DHS documents that explain the intent of the legislation. Providers are also given information about the procedures for filing and review. However, the guidelines used to evaluate special clinical programs are brief, and lack the robustness to handle rapidly changing services such as cardiovascular care. Reviews of cardiovascular applications have thus been subject to delay and intense political debate throughout the State. Part of the problem is rooted in the fact that the process is essentially reactive in nature, and there are no materials for providers and the public that address the complexities and rapidly changing aspects of cardiac care delivery.

Providers indicate a spectrum of regard for the value of CON regulation. Some see it as a function that has served the State well over the years instilling a sense of discipline and public disclosure in the deployment of expensive health care resources. Others favor a deregulated approach relying more on free market forces. Still others believe that the concept should be preserved but with major modifications. Our analysis tends to support the latter view.

Certificate of need issues, particularly with respect to cardiovascular services, have been addressed differently among the various states. Some states have completely eliminated CON while others have commissioned specific studies to form policy directives governing the regulation of these services. Maine is among the more (CON) regulated states and joins about half the states that specifically require certificate of need approval for establishing cardiac catheterization laboratories or cardiac surgery programs.

The issues of cardiovascular care are complex. They deal with diverse environmental forces involving market competition, demographics, health status and behavior, standards of care, technology, and economics. It is therefore incumbent on the state to revitalize a planning initiative using the findings, conclusions, and recommendations from this study as a point of departure.

F. Recommendations for the Development of Cardiovascular Services in the State of Maine

1 Diagnostic Cardiac Catheterization Services

Goals: Goals should be to establish an optimal balance between medically needed access to catheterization laboratories and the quality of services provided, while controlling medical care costs. Standards should include:

Adequate Access:

A laboratory should be within one hour's travel time for 90 percent of the population, 90 percent of the time (day or night and time of year). Laboratory capacity and staffing within a program should permit an elective procedure to be performed within one week, an urgent procedure within 4 hours, and an emergent procedure (such as for patients with acute myocardial infarctions) within one hour, 24 hours a day. For laboratories that are not adequately staffed to perform catheterizations in high risk patients or which choose not to provide 24 hour per day services, formalized agreements should be established with tertiary centers that will ensure that patients will receive needed services within 90 minutes of reaching the first hospital.

High Quality Services:

The ability to deliver high quality cardiac catheterization services depend both on the technical quality of laboratory equipment and on the judgment and skills of the cardiologist and laboratory staff. These criteria have been well defined by the ACC/AHA. Commitment to monitoring and improving the quality of services is essential. This is best done when all laboratories in the state adhere to standardized procedures for monitoring the process and outcomes of care and engage in meaningful consultation and sharing of data. Work done by the Northern New England Cardiovascular Disease Study Group is an outstanding example. Maine cardiologists currently participate in this activity. The Maine Cardiovascular Health Council should be considered for the role of defining standards of care, and coordinating local quality monitoring. Currently the Council plans and promotes cardiovascular risk prevention programs in Maine.

Cost of Services:

The cost of cardiac catheterization services to the people of Maine depends on the number of services provided, unit costs per service, and any uncompensated capital or fixed costs passed on to the cost of other services. Of particular importance to CON decisions are the well known relationship between excess capacity and increased utilization of services (Roemer's Law). This is particularly true for cardiac catheterization where decisions to perform the procedure are often discretionary. Efficiencies of scale are particularly applicable to services such as cardiac catheterization laboratories with their relatively high capital costs and fixed costs of skilled staff.

Translation of Goals into CON Decisions

Observations

Access: Our study finds that both geographic access and scheduling access within the State are generally adequate. Possible exceptions are:

- Aroostook County where travel time to EMMC is more than one hour under good weather conditions and may be considerably longer in bad weather.
- The Waterville/Augusta area which is at least one hour from Portland and Bangor and somewhat less than an hour from Lewiston. Current referral patterns, however, suggest that the travel time to Portland is the more relevant.
- Existing catheterization laboratories seem to have adequate or excess capacity, with the possible exception of MMC that has applied for a fifth laboratory. Complaints about access to MMC by referring physicians appear to relate less to patient need and more to convenience for the patient and for the physician, subjective measures at best.

Quality of Services: No data were available on the appropriateness or quality of existing catheterization programs. Only treatment programs are currently monitored by the NNECD Study Group. Anecdotes about problems with the quality of radiographs for patients referred to MMC from smaller catheterization laboratories, suggest that mentoring of new programs, including real time electronic transmission and review of digital radiographs, would facilitate quality control.

Costs: At present, unit costs of cardiac catheterization procedures appear to be higher, on average, in small volume programs in Maine. Prudence suggests avoiding excess capacity in an effort to reduce incentives for overuse.

General Recommendations

Regionalization of Services:

New programs should be linked to and mentored by a tertiary program that would provide angioplasty and surgical backup. Advantages will be improved quality of catheterization services, ready availability of consultations when needed, and improved continuity of care when coronary interventions or surgery are indicated.

Volume Standards:

New programs should achieve volumes of at least 300 catheterization procedures per year within 3 years. Each cardiologist should perform at least 100 total cases per year at all hospitals at which he/she has privileges.

New Laboratories Should be Restricted to Low Risk Patients:

New programs should be limited to providing catheterizations to low risk patients. Catheterizations would not be permitted during the acute phase of admissions for AMI or unstable angina that might be candidates for primary angioplasty or in patients with cardiogenic shock or other high risk conditions.

Fixed Laboratories:

Any new catheterization program should be in a fixed laboratory that is an integral part of the hospital.

Dual Purpose Laboratories:

Multiple function laboratories are acceptable provided they meet the radiographic and physiologic monitoring equipment and staffing standards required for state-of-the-art cardiac catheterization laboratories.

Priorities for New Cardiac Catheterization Programs

Stepwise Development of New Programs: New programs should be added incrementally over a 3 year period, and no more than two new programs should approved in Year 1. This stepwise approach will permit the effects of initially approved programs on the need/demand and referral patterns to be evaluated before decisions are made to add others. In our view, the risk of creating excess capacity and resultant over-utilization of cardiac catheterization services outweighs any benefits of easier access to the citizens of Maine.

Highest Priority: A new program should be implemented in the Waterville/Augusta area. This recommendation is supported by size of the population; the distance from existing catheterization laboratories and difficulties hospitals in this area have encountered in attracting and retaining geographic full-time, highly qualified, cardiologists. The MGMC proposal is substantially stronger than the Inland Hospital proposal both because of the strengths of its component hospitals, the size of its service area, and its historical close linkage to an existing tertiary provider.

Other Proposed Program Areas:

- Proposals from Mid Coast Hospital and SMMC fit the regionalization model with their linkages to MMC but represent lower priorities because of shorter travel times to catheterization services, smaller services areas, and, except for SMMC, the likelihood of relatively lower volume program. At the same time health status of populations served by these hospitals have improved, outcomes (especially in the Mid Coast region) tend to be improving and utilization rates are low (Mid-Coast). A program at SMMC would, in all likelihood, reduce case volumes in York Hospital substantially, creating a potential conflict with current CON guidelines.
- A proposal from Aroostook County should be evaluated carefully. Utilization data indicate the population is getting access to invasive services and risk for disease has declined. However, outcomes are worsening indicating either need is greater and/or access to current

services is not sufficient. Tradeoffs are reduced access due to distance versus the downsides of creating a very small program. A close relationship with EMMC would be essential.

- Proposals from Mercy Hospital in Portland and St. Joseph Hospital in Bangor raise different issues. Both hospitals are staffed by cardiologists from local group practices and, hence, do not have the same coverage problems as MGMC or Inland Hospital in Waterville/Augusta. Significant numbers of these cardiologists are interventionalists with privileges at MMC or EMMC, respectively. At the same time, each hospital, justifiably, argues that the monopoly held by the tertiary center compromises its ability to compete for cardiac patients and may unfairly affect hospital finances. Mercy Hospital has the stronger case because of Portland's larger service area. In either case, approval should be conditional on establishing a mutually satisfactory collaborative relationship with the corresponding tertiary center. Even if both proposals are denied, steps should be taken to ensure that these two hospitals receive equitable treatment with respect to charges for invasive procedures for patients of these hospitals. The cost to the sending hospital should be closer to actual payments from third party payers than full charges.
- Maine Medical Center's proposal for a fifth laboratory needs to be considered by different criteria than applications for first laboratories by other hospitals. There is no question that MMC's existing laboratories are fully used and that little leeway exists for the downtime required for maintenance and upgrading. At the same time, demand for diagnostic catheterizations is likely to fall to the extent that new affiliated programs are approved and are successful. Demand may fall further if the on-site surgical backup requirement for angioplasty services is liberalized (see below). A prudent course might be to delay a decision on MMC's application until information is available on these matters.

2. Coronary Interventional (Angioplasty) Programs

- **Program and Provider Volumes:** Statistically significant relationships exist between higher program and operator volumes and better clinical outcomes despite overall improvement in outcomes in recent years. The ACC/AHA continues to recommend minimum provider volumes at least of 75 cases per year and program volumes of at least 200 cases per year. Data from NY State indicate improvements in risk-adjusted outcomes up to program volumes of 600 cases per year.

Recommendation: PHRG recommends that all angioplasty programs in Maine adhere to these volume standards. Primary angioplasty, in particular, should be staffed by very experienced cardiologists who are supported by experienced and highly trained laboratory teams. Programs that do primary angioplasty should commit to 24 hour coverage, 365 days a year, with a response time of less than 60 minutes from the time the cardiologist is notified until the procedure begins.

- **Primary Angioplasty Versus Thrombolysis for AMI:** Vigorous competition has developed between pharmacological and mechanical methods of reperfusion. Thrombolysis has the advantages of rapid administration as soon as eligibility is established in the ER or even in the ambulance. Special procedural skills are not required. Actual reperfusion doesn't occur until 60-90 minutes after the agent is given, however. Moreover, thrombolysis is accompanied by up to a one percent risk of intracerebral hemorrhage, especially in elderly

patients. Primary angioplasty has more stringent procedural requirements and an obligatory delay between the diagnosis and the procedure. Moreover, it is available only to patients who present initially to a hospital that has the ability to perform primary angioplasty rapidly and skillfully - optimally 24 hours per day. Major advantages are a higher likelihood of achieving acceptable reperfusion and angiographic information that is valuable for guiding further treatment. The advent of stents has further increased the success of primary angioplasty. At the same time, improvement in thrombolysis regimens by adding long-acting platelet inhibitors and low dose heparin has been shown to significantly increase reperfusion rates from pharmacological treatments. We conclude that the debate over the relative efficacy of the two approaches, used singly or in combination, is not yet settled. Further research is needed.

Under these circumstances, what should hospitals do? We recommend the following:

Recommendation: Hospitals with high volume angioplasty programs should individualize treatment, offering thrombolysis to patients who meet the eligibility criteria defined by the ACC/AHA and primary angioplasty to patients who have relative or absolute contraindications to thrombolysis, are in cardiogenic shock, or have evidence of continued ischemia after thrombolysis.

Hospitals with a 24 hour per day, fully staffed Emergency Department but no angioplasty programs should implement a thrombolysis program that takes full advantages of latest procedures and pharmacological advances. Protocols should be developed to facilitate the rapid transfer of patients who are not eligible for thrombolysis to the closest hospital with primary angioplasty capacity.

Whenever possible, patients with symptoms consistent with an AMI should not be transported to hospitals without fully staffed Emergency Departments.

- **Surgical Backup for Angioplasty:** The tradition has been to require on-site surgical backup for angioplasty programs. More recently, this requirement has been the subject of debate. In fact, ACC/AHA guidelines for the treatment of myocardial infarction and PTCA appear to differ on this subject. The conservative view is to maintain “transfer to surgery by gurney” as the standard. Others argue that well developed protocols with nearby surgical programs that permit the patient to be on cardiopulmonary bypass within 90 minutes are satisfactory. The British Cardiac Society and British Cardiovascular Intervention Society have recently adopted guidelines that allow both elective and emergent angioplasty to be performed at hospitals without on-site surgery, provided systems are in place to enable patients to be on cardiopulmonary bypass within 90 minutes of calling the cardiac surgeon.

Recommendation: We recommend that a more flexible surgical backup policy be carefully explored for the State of Maine. This policy might include either on-site surgical backup or carefully developed referral agreements between the hospital performing the angioplasty and the hospital having surgical capability. The central goal is to ensure that the patient will have access to cardiac surgery within 90 minutes when it is needed day or night.

One implication of a decision to liberalize the requirement for on-site surgical backup will be that it will encourage hospitals with diagnostic cardiac catheterization laboratories to begin doing PTCA. In Maine, angioplasties are performed in two tertiary centers (MMC and EMMC) and York Hospital. The latter relies on Portsmouth Hospital in New Hampshire for surgical backup. Hence, the model is already in place.

Recommendation: A decision to permit off-site surgical backup should be linked to efforts to restrict low volume programs and to require all programs to systematically monitor processes and outcomes of care, share these results with other programs, and participate in joint discussions at quality improvement.

3. Open Heart Surgery Programs

- **Program and Surgeon Volumes:** Minimum annual volumes for open heart surgery programs range from 200 to 500 cases per year in different states. The highest figure is for New York that also has published the most convincing evidence of an association between volume and risk-adjusted surgical outcomes. Massachusetts uses 250-300 cases as the program minimum. The ACC recommends 200-300 cases annually for a program and 100-150 cases for the surgeon. These limits represent "average" relationships between volume and quality. Low volume programs are not necessarily of low quality, however.

Recommendation: We recommend adoption of the ACC volume limits at the outset of a new open heart program and ongoing emphasis on actual measurement of risk-adjusted outcomes, data sharing, and regular discussions aimed at quality improvement by all surgical programs.

- **A central Maine Program for Open Heart Surgery and Angioplasty:** Analyses of the best available data indicate that volume projections for an open heart surgery program in central Maine are low. In addition, some of the effects of the changes in technology in recent years, such as the use and refinement of stents and improvements in non-invasive treatment options, have reduced the need for some open heart surgery. A new cardiac surgery program in the central Maine area would, almost certainly, be a low volume one that would face difficult challenges to achieving high quality outcomes. Furthermore, it is clear from data presented in Chapter 3 that the heart health of the central Maine population is improving, mortality rates are declining and utilization of invasive procedures are leveling off. This is strong evidence of both sufficient access to care and reduced need for additional invasive cardiac services.

Recommendation: We conclude that a new open heart surgery program in the central Maine area is not needed at this time. We recommend continued evaluation of the merits of an angioplasty service in the central Maine region consistent with the recommendations set forth above.

G. CON Processes and Policies

The Certificate of Need program has been an integral part of the healthcare delivery system in Maine for over twenty years and has contributed substantially to the development of

cardiovascular services that have established a solid balance between care access, quality, and costs. Service delivery patterns in Maine compare favorably to those elsewhere in New England and in the Nation as a whole. Thresholds for triggering Certificate of Need reviews for invasive cardiology or cardiac surgery programs are not unduly restrictive.

Recommendations: Maine's CON program should continue its oversight of cardiovascular services, but the process should be improved in a number of respects.

1. CON reviews should be made more explicit. In its mandate to "support effective health planning", the State should initiate planning processes that deal directly with critical services such as cardiovascular care. This would include developing a strategic plan for cardiovascular service delivery that would build upon the findings, conclusions, and recommendations of this Need and Demand study. Ultimately, practice standards, clinical access criteria, quality measures, and prudent cost management should be addressed proactively by clinical and health professionals within the State. We recommend convening a technical advisory group composed of up to 15 persons to advise and assist DHS in formulating this strategic plan that would include consideration of changes that are occurring in cardiovascular services. One option should extend the mandate of an existing body such as the Maine Cardiovascular Health Council.

2. The salient findings of this cardiovascular plan should be distributed for public comment and ultimately embodied in official Certificate of Need documents such as revised Health Care Facility/ Agency (Space and Needs) Guidelines. The plan should provide guidance on issues that have emerged in the current review of pending CON applications, including, but not limited to, service area definitions, use rate protocols, market share indicators, volume thresholds, access standards, and specific economic impact analyses of plans and proposals. Future applicants for new cardiovascular services should be required to submit their filings with specific reference to these guidelines as well as adhering to protocols governing all applications.

3. The State should modify its CON review process in ways that will provide strict adherence to time for review and decision. Applicants and other affected parties have a need to understand and have a right to expect definitive and timely reviews. Ways to achieve this will come from issuance of more definitive guidelines. Additional investment in staffing resources in CON planning and review will almost certainly be required.

4. Within cardiovascular services, greater emphasis should be given to prevention, education, rehabilitation and non-invasive services. Planning guidelines must clearly recognize that invasive services, while the most technically sophisticated and expensive elements of the care continuum, are but a component of the total spectrum of care for cardiovascular diseases. One policy option to explore is for the state to establish conditions on approvals of applications for invasive cardiovascular services that would require successful applicants to enhance these services in the communities they serve.

5. Within cardiovascular services, greater emphasis should be given to prevention, education, rehabilitation and non-invasive services. Planning guidelines must clearly recognize that invasive services, while the most technically sophisticated and expensive elements of the care continuum, are but a component of the total spectrum of care for cardiovascular diseases.

6. Quality criteria should be explicitly addressed in DHS-initiated plans and reviews governing cardiovascular services. Our study has revealed diverse viewpoints on practice standards and care protocols among existing and proposed providers of invasive cardiovascular services. Quality initiatives should:
   - Develop explicit measures of clinical quality
   - Promote the sharing of relevant data among providers through sponsorship and funding of quality reporting of utilization and outcomes. Alternatively, DHS might sanction sharing of information and peer review through bodies such as the Northern New England Cardiovascular Disease Study Group.
   - Require new providers of invasive services to participate in detailed monitoring of all aspects of their program.
   - Hold new and existing providers accountable for meeting quality objectives and taking steps to rectify deficiencies. The monitoring of the quality of cardiovascular services would be significantly enhanced if the state were to require hospitals to obtain a license for these services. Program closure should be considered if deficiencies go uncorrected.

7. DHS should encourage the concept of regional coordination of cardiovascular services among providers in its plans and CON reviews. Affiliations with tertiary centers have already been formed in the submission of some pending applications. These affiliations extend to program administration, clinical support, education, information services, and quality monitoring. The goal should be for tertiary centers and specialty providers to contribute their expertise to community hospitals and, hence, bring the benefits as close to as many patients as possible. It should not be to control local health care centrally.

Cardiovascular Services Demand/Needs Study

Community Population Trends

Age Group Population and Change: 1990, 1998, 2003

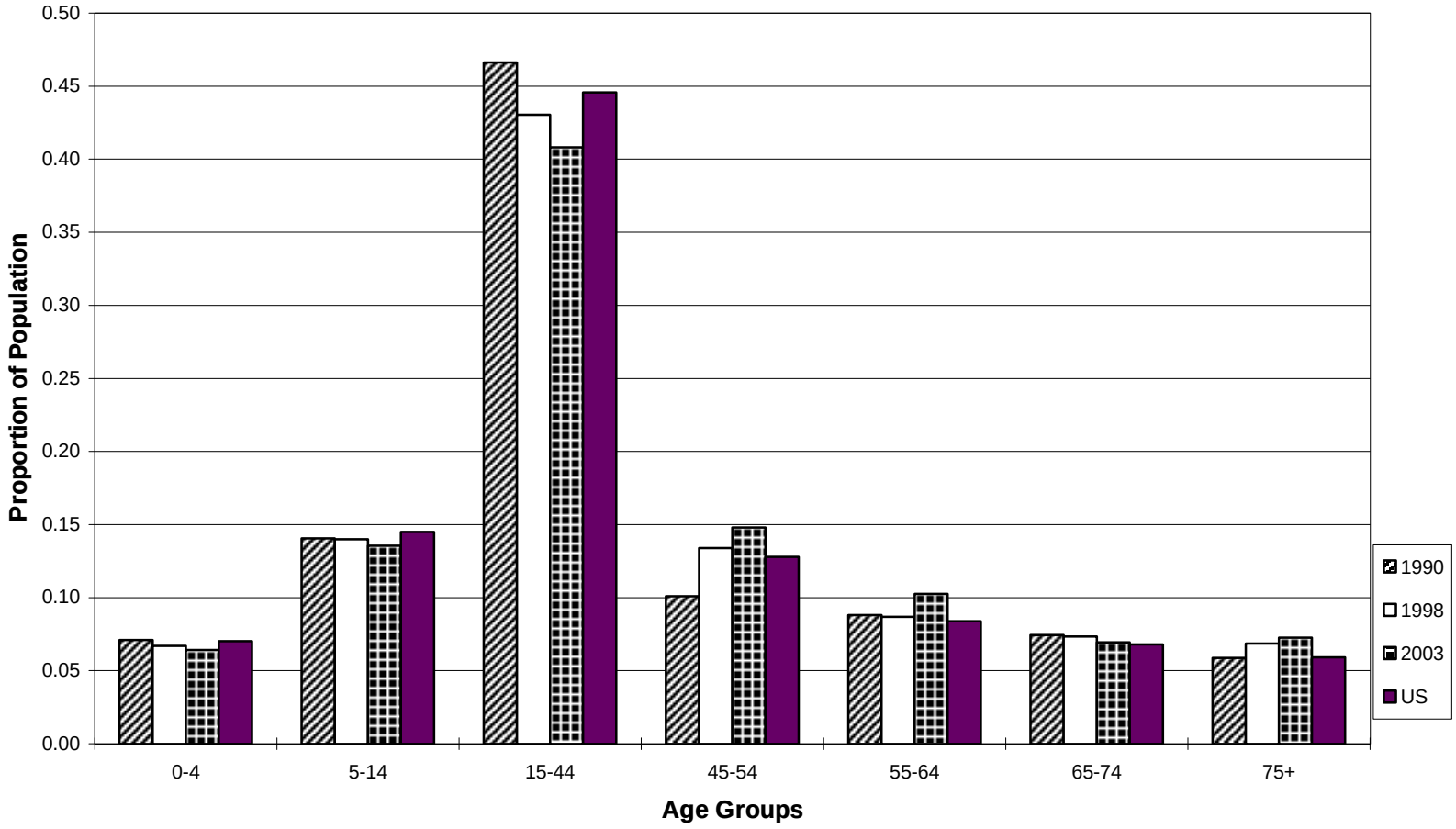
MAINE TOTAL

Age Groups	Population									
	1990		1998		2003		1990-1998		1998-2003	
	N	%	N	%	N	%	N	%	N	%
0-4	87,201	7.1%	83,131	6.7%	81,190	6.4%	-4,070	-4.7%	-1,941	-2.3%
5-14	172,489	14.0%	173,967	14.0%	171,620	13.5%	1,478	0.9%	-2,347	-1.3%
15-44	575,507	46.9%	535,012	43.0%	516,982	40.8%	-40,495	-7.0%	-18,030	-3.4%
45-54	123,990	10.1%	166,527	13.4%	187,389	14.8%	42,537	34.3%	20,862	12.5%
55-64	108,136	8.8%	107,832	8.7%	129,788	10.2%	-304	-0.3%	21,956	20.4%
65-74	91,443	7.4%	91,273	7.3%	87,910	6.9%	-170	-0.2%	-3,363	-3.7%
75+	72,162	5.9%	85,227	6.9%	92,022	7.3%	13,065	18.1%	6,795	8.0%
Total	**1,227,928**	**100.0%**	**1,242,969**	**100.0%**	**1,266,901**	**100.0%**	**15,041**	**1.2%**	**23,932**	**1.9%**

SOURCE: 1990 U.S. Census
POPULATION ESTIMATES & PROJECTIONS: Strategic Mapping

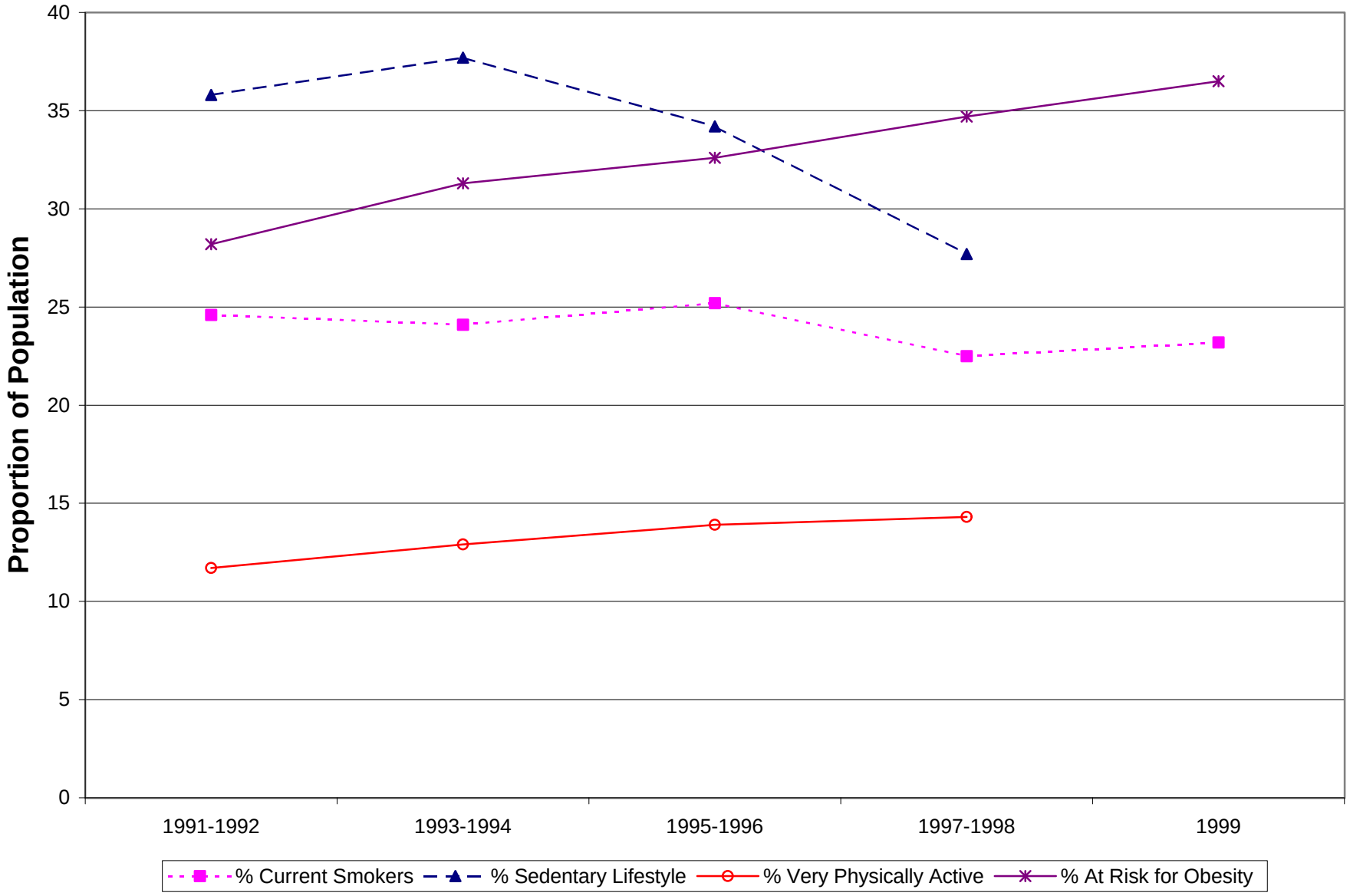
Cardiovascular Services Demand/Needs Study

ME Population Characteristics



SOURCE: 1990 U.S. Census
PROJECTIONS: Strategic Mapping

Cardiovascular Health Status Indicators: Maine



Source: BRFSS 1991-1998
Based on available data.

PHRG
9/15/00

Cardiovascular Health Status Profile for the Cardiology Primary Service Areas of the CON Applicant Hospitals (1991-1994/1996-1999)

HEALTH STATUS INDICATOR	St. Jos	MGMC	Inland	MidCst	Mercy	MMC	SMMC	CMMC	TAMC	ME	US[a]
CSA Population	60,964	112,560	27,945	55,266	153,232	230,486	65,206	81,371	21,764	1,242,969	
% Current Smokers 1991-1994	20.6	26.7	24	19.2	21.1	20.7	23.7	27.9	30.4	24.4	22.7
% Current Smokers 1996-1999	24.1	24.1	22.0	26.3	23.6	23.8	21.2	22.7	22.2	23.4	22.9
% change 1991-1994 to 1996-1999	17%	-9.7%	-8.3%	37%	12%	15%	-11%	-19%	-27%	-4.1%	0.9%
% Lead a Sedentary Lifestyle 1991-1994	31.5	38.9	42.7	32.2	29.3	31.1	38.5	38	48.8	36.8	29.4[b]
% Lead a Sedentary Lifestyle 1996-1999	29.0	29.0	33.7	24.4	25.2	26.7	25.6	35.2	36.5	30.9	28.0[d]
% change 1991-1994 to 1996-1999	-7.9%	-25%	-21%	-24%	-14%	-14%	-34%	-7.4%	-25%	-16%	-4.8%
% Engage in Regular Exercise 1991-1994	11.5	11.9	10.3	10	19.5	18	8	12.2	2.3	12.3	14.0[b]
% Engage in Regular Exercise 1996-1999	15.3	12.0	21.1	18.6	18.7	16.9	18.8	11.2	9.2	14.1	13.3[d]
% change 1991-1994 to 1996-1999	33%	0.8%	105%	86%	-4.1%	-6.1%	135%	-8.2%	300%	14.6%	-5.0%
% At Risk for Obesity 1991-1994	27.2	35.1	38.6	23.3	25	27	23.4	31.6	41.6	29.8	30.7
% At Risk for Obesity 1996-1999	35.5	34.6	32.6	28.8	30.9	32.2	33.6	32.2	35.1	34.7	34.9
% change 1991-1994 to 1996-1999	31%	-1.4%	-16%	24%	24%	19%	44%	1.9%	-16%	16%	14%
% Diagnosed with High Cholesterol 1991-1994	15.6	25.8	29.3	16.9	16.9	17.2	16.5	18.3	14.5	18.1	19.4[c]
% Diagnosed with High Cholesterol 1996-1999	26.4	24.4	25.9	21.2	23.0	22.6	27.3	26.9	28.3	23.4	19.9[e]
% change 1991-1994 to 1996-1999	69%	-5.4%	-12%	25%	36%	31%	65%	47%	95%	29%	2.6%
% Cholesterol Checked (past yr) 1991-1994	45.1	55.1	56.6	52.6	49.5	49.7	55.3	54.2	42.3	48.7	47.4
% Cholesterol Checked (past yr) 1996-1999	47.1	51.5	56.2	51.1	48.1	48.0	54.1	48.7	49.1	47.5	47.5
% change 1991-1994 to 1996-1999	4.4%	-6.5%	-0.7%	-2.9%	-2.8%	-3.4%	-2.2%	-10%	16%	-2.5%	0.2%
% Diagnosed with High Blood Pressure 1991-1994	19.1	22.6	30.7	18.7	19.8	20.6	23.6	22.4	25.3	21.4	21.6
% Diagnosed with High Blood Pressure 1996-1999	25.6	26.8	26.3	26.6	22.5	22.8	22.6	25.3	27.9	24.1	22.6[e]
% change 1991-1994 to 1996-1999	34%	19%	14%	42%	14%	11%	-4.2%	13%	10%	13%	4.6%
% Diagnosed with Diabetes 1991-1994	4.3	5.1	4.8	3.9	3.1	2.6	3.4	3.8	4.7	3.6	5.0
% Diagnosed with Diabetes 1996-1999	5.5	4.8	3.6	4.0	4.1	4.7	5.3	4.4	4.2	5.2	6.2
% change 1991-1994 to 1996-1999	28%	-6.1%	-24%	2.6%	32.3%	81%	56%	16%	-11%	44%	24%

Source: BRFSS data

a US data are for the period 1993-1994 and the period 1997-1998.

b 1994 only. c 1993 only. d. 1998 only. e. 1997 only.

Cardiovascular Health Status Profile of the Cardiology Primary Services Areas of the CON Applicant Hospitals
(1991-1994 to 1996-1999)

Exhibit I-5

HEALTH STATUS INDICATOR	St. Jos	MGMC	Inland	MidCst	Mercy	MMC	SMMC	CMMC	TAMC	ME
Total Heart Disease Mortality Rate 1991-1994	294	290	301	254	283	264	304	317	287	282
Total Heart Disease Mortality Rate 1996-1997	291	307	370	236	269	248	301	297	335	281
% change 1991-1994 to 1996-1999	-0.9%	6.0%	23%	-7.3%	-5.0%	-6.2%	-1.1%	-6.2%	17%	-0.5%
AMI, Hospital Admissions 1993-1994	271	399	545	269	264	256	386	293	386	312
AMI, Hospital Admissions 1998-1999	390	446	567	261	237	227	439	451	524	376
% change 1993-1994 to 1996-1999	44%	12%	4.1%	-3.0%	-10%	-12%	14%	54%	36%	21%
AMI, Mortality Rate 1991-1994	91	101	92	68	73	69	89	85	105	89
AMI, Mortality Rate 1996-1997	94	92	115	64	65	62	100	79	159	85
% change 1991-1994 to 1996-1999	3.7%	-8.8%	25%	-6.6%	-11%	-9.3%	12%	-7.3%	51%	-4.8%
CVD, Hospital Admission Rate 1993-1994	280	233	319	293	320	279	410	304	277	291
CVD, Hospital Admission Rate 1998-1999	319	321	335	301	319	305	379	331	437	319
% change 1993-1994 to 1996-1999	14%	37%	5.0%	2.8%	-0.2%	9.3%	-7.5%	8.8%	57%	9.7%
CVD, Mortality Rate 1991-1994	56	60	70	57	62	55	59	58	70	58
CVD, Mortality Rate 1996-1997	67	60	71	61	61	56	62	61	52	60
% change 1991-1994 to 1996-1999	21%	-0.5%	0.2%	6.9%	-2.4%	1.8%	4.5%	4.3%	-26%	3.8%
Diag Cath, Hospital Admission Rate 1993-1994	488	306	408	280	424	410	402	712	454	436
Diag Cath, Hospital Admission Rate 1998-1999	612	582	741	330	611	598	520	555	889	588
% change 1991-1994 to 1996-1999	25%	91%	82%	18%	44%	46%	29%	-22%	96%	35%
Diag Cath,Outpatient Procedure Rate 1994	33	1	0	43	0	1	0	67	0	13
Diag Cath,Outpatient Procedure Rate 1998	185	53	47	40	54	66	351	172	83	111
% change 1994 to 1998	463%	5230%	from 0	-8.5%	from 0	7358%	from 0	156%	from 0	786%
PTCA, Hospital Admission Rate 1993-1994	140	102	125	89	131	126	148	195	111	128
PTCA, Hospital Admission Rate 1998-1999	269	222	259	182	230	231	258	262	322	235
% change 1991-1994 to 1996-1999	92%	117%	107%	104%	76%	84%	74%	34%	191%	84%
OHS, Hospital Admission Rate 1993-1994	151	132	165	103	154	153	157	187	146	143
OHS Hospital Admission Rate 1996-1999	180	186	234	131	206	202	216	218	278	195
% change 1991-1994 to 1996-1999	19%	40%	42%	27%	34%	32%	37%	17%	91%	37%

Sources: ME Inpatient 91-99; ME AmSurg 94 98; ME Mortality 91-97
Based on first listed diagnosis and all listed procedures.

All rates expressed are per 100,000 Population.
Rates do not include ME residents who had procedures performed out of state.

Cardiovascular Health Status Profile of the Cardiology Primary Service Areas of the CON Applicant Hospitals (1994-1998-1999)

HEALTH STATUS INDICATOR	St. Jos (n=369)	MGMC (n=596)	Inland (n=147)	MidCst (n=307)	Mercy (n=866)	MMC (n=1250)	SMMC (n=356)	CMMC (n=409)	TAMC (n=124)	ME (n=6687)
Diag Cath, Hospital Admission Rate 1994	530	330	456	282	383	384	329	668	485	433
Diag Cath, Hospital Admission Rate 1998-1999	612	582	741	330	611	598	520	555	889	588
% change 1994 to 1998-99	15%	76%	63%	17%	60%	56%	58%	-17%	83%	36%
Diag Cath,Outpatient Procedure Rate 1994	33	1	0	43	0	1	0	67	0	13
Diag Cath,Outpatient Procedure Rate 1998	185	53	47	40	54	66	351	172	83	111
% change 1994 to 1998	463%	5957%		-8%		7358%		156%		786%
PTCA, Hospital Admission Rate 1994	165	116	151	96	128	126	137	203	113	135
PTCA, Hospital Admission Rate 1998-1999	269	222	259	182	230	231	258	262	322	235
% change 1994 to 1996-1999	63%	91%	72%	88%	79%	83%	88%	29%	186%	74%
OHS, Hospital Admission Rate 1994	144	126	165	100	146	146	153	177	144	137
OHS, Hospital Admission Rate 1998-1999	180	186	234	131	206	202	216	218	278	195
% change 1994 to 1998-1999	25.0%	47.8%	42.5%	30.9%	41.4%	38.4%	40.9%	23.1%	93.6%	42.9%

Sources: ME Inpatient 94-99
ME AmSurg 94, 98
ME Mortality 91-97
Based on first listed diagnosis and all listed procedures.

Does not include ME residents who had procedures performed out of state.

Cardiovascular Health Status Profile for the Cardiology Primary Service Areas of the CON Applicant Hospitals (1991-1994/1996-1999)

HEALTH STATUS INDICATOR	St. Jos	MGMC	Inland	MidCst	Mercy	SMMC	CMMC	TAMC	ME	US
Change in Current Smokers										
% change 1991-1994 to 1996-1999	17%	-9.7%	-8.3%	37%	12%	-11%	-19%	-27%	-4.1%	0.9%
Change in Those Leading a Sedentary Lifestyle										
% change 1991-1994 to 1996-1999	-7.9%	-25%	-21%	-24%	-14%	-34%	-7.4%	-25%	-16%	0.0
Change in Those who Exercise Regularly										
% change 1991-1994 to 1996-1999	33%	84%	105%	86%	-4.1%	135%	-8.2%	300%	15%	-0.1
Change in Those At Risk for Obesity										
% change 1991-1994 to 1996-1999	31%	-1.4%	-16%	24%	24%	44%	1.9%	-16%	16%	14%
Change in Those Diagnosed with High Cholesterol										
% change 1991-1994 to 1996-1999	69%	-5.4%	-12%	25%	36%	65%	47%	95%	29%	2.6%
Change in Those who had their Cholesterol Checked										
% change 1991-1994 to 1996-1999	4.4%	-6.5%	-0.7%	-2.9%	-2.8%	-2.2%	-10%	16%	-2.46%	0.00%
Change in Those Diagnosed with High Blood Pressure										
% change 1991-1994 to 1996-1999	34%	19%	-14%	42%	14%	-4.2%	13%	10%	13%	4.6%
Change in Those Diagnosed with Diabetes										
% change 1991-1994 to 1996-1999	28%	-6.1%	-24%	2.6%	32%	56%	16%	-11%	44%	24%

 denotes an increase greater than or equal to 10%

 denotes a decrease greater than or equal to 10%

 denotes no change greater than or equal to 10%

Source: BRFSS Data
Based on available data.

Cardiovascular Health Status Profile of the Cardiology Primary Services Areas of the CON Applicant Hospitals
(1991-1994 to 1996-1999)

HEALTH STATUS INDICATOR	St. Jos	MGMC	Inland	MidCst	Mercy	MMC	SMMC	CMMC	TAMC	ME
Change in Heart Disease Mortality Rate										
% change 1991-1994 to 1996-1999	-0.9%	6.0%	23%	-7.3%	-5.0%	-6.2%	-1.1%	-6.2%	17%	-0.5%
Change in AMI Admission Rate										
% change 1991-1994 to 1996-1999	44%	12%	4.1%	-3.0%	-10%	-12%	14%	54%	36%	21%
Change in AMI Mortality Rate										
% change 1991-1994 to 1996-1999	3.7%	-8.8%	25%	-6.6%	-11%	-9.3%	12%	-7.3%	51%	-4.8%
Change in CVD Admission Rate										
% change 1991-1994 to 1996-1999	14%	37%	5.0%	2.8%	-0.2%	9.3%	-7.5%	8.8%	57%	9.7%
Change in CVD Mortality Rate										
% change 1991-1994 to 1996-1999	21%	-0.5%	20%	6.9%	-2.4%	1.8%	4.5%	4.3%	-26%	3.8%
Change in DxCath Admission Rate										
% change 1991-1994 to 1996-1999	25%	91%	82%	18%	44%	46%	29%	-22%	96%	35%
Change in DxCath Outpatient Rate										
% change 1991-1994 to 1996-1999	463%	5957%	from 0	-8.5%	from 0	7358%	from 0	156%	from 0	786%
Change in PTCA Admission Rate										
% change 1991-1994 to 1996-1999	92%	117%	107%	104%	76%	84%	74%	34%	191%	84%
Change in OHS Admission Rate										
% change 1991-1994 to 1996-1999	19%	40%	42%	27%	34%	32%	37%	17%	91%	37%

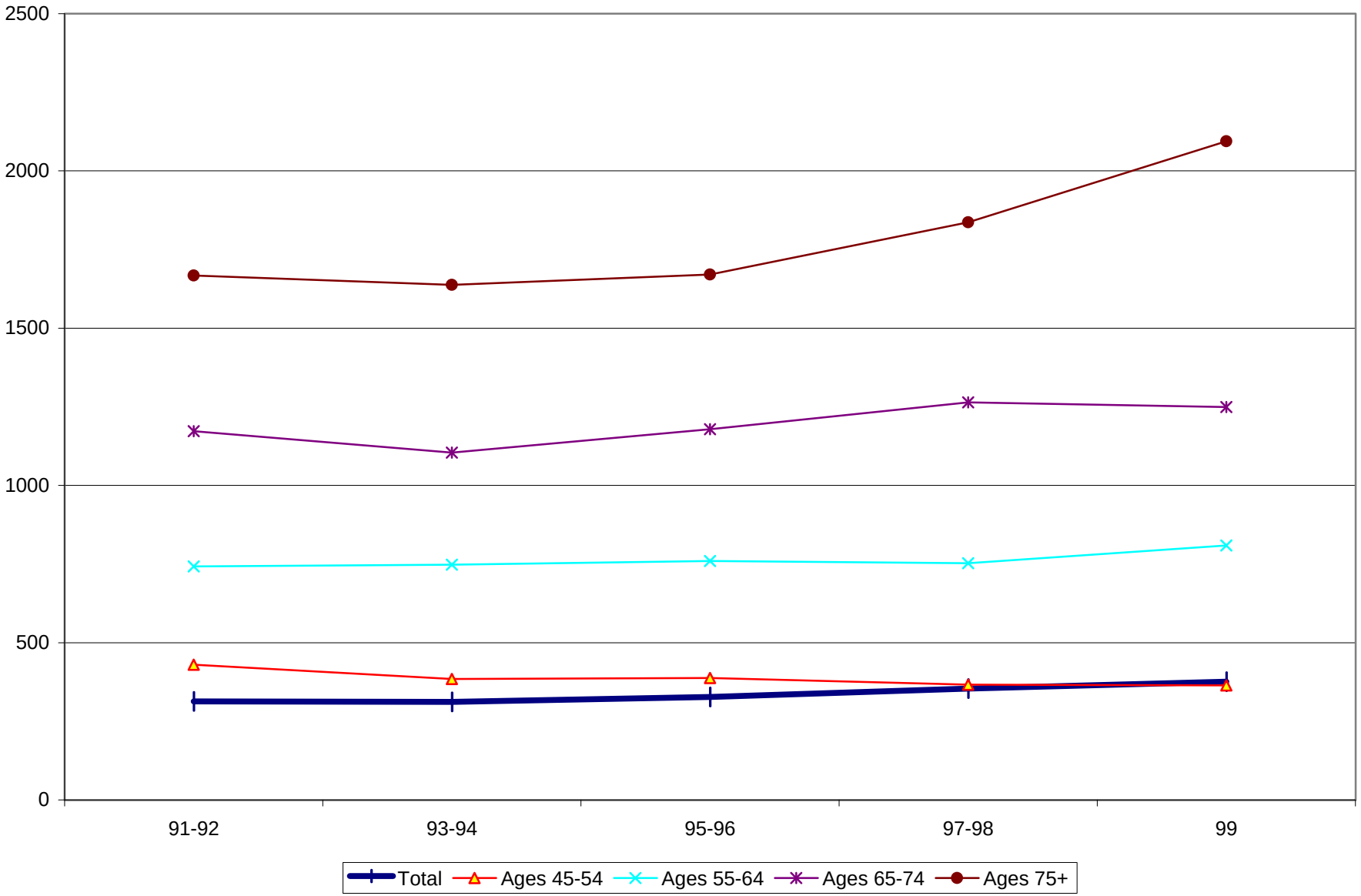
 denotes an increase greater than or equal to 10%   denotes a decrease greater than or equal to 10%   denotes no change greater than 10%

Sources: ME Inpatient 91-99; ME AmSurg 94 98; ME Mortality 91-97.
Based on first listed diagnosis and all listed procedures.

All rates are per 100,000 Population.
Rates do not include ME residents who had procedures performed out of state.

Trends in AMI Hospital Admission Rate: Maine

Exhibit I-8



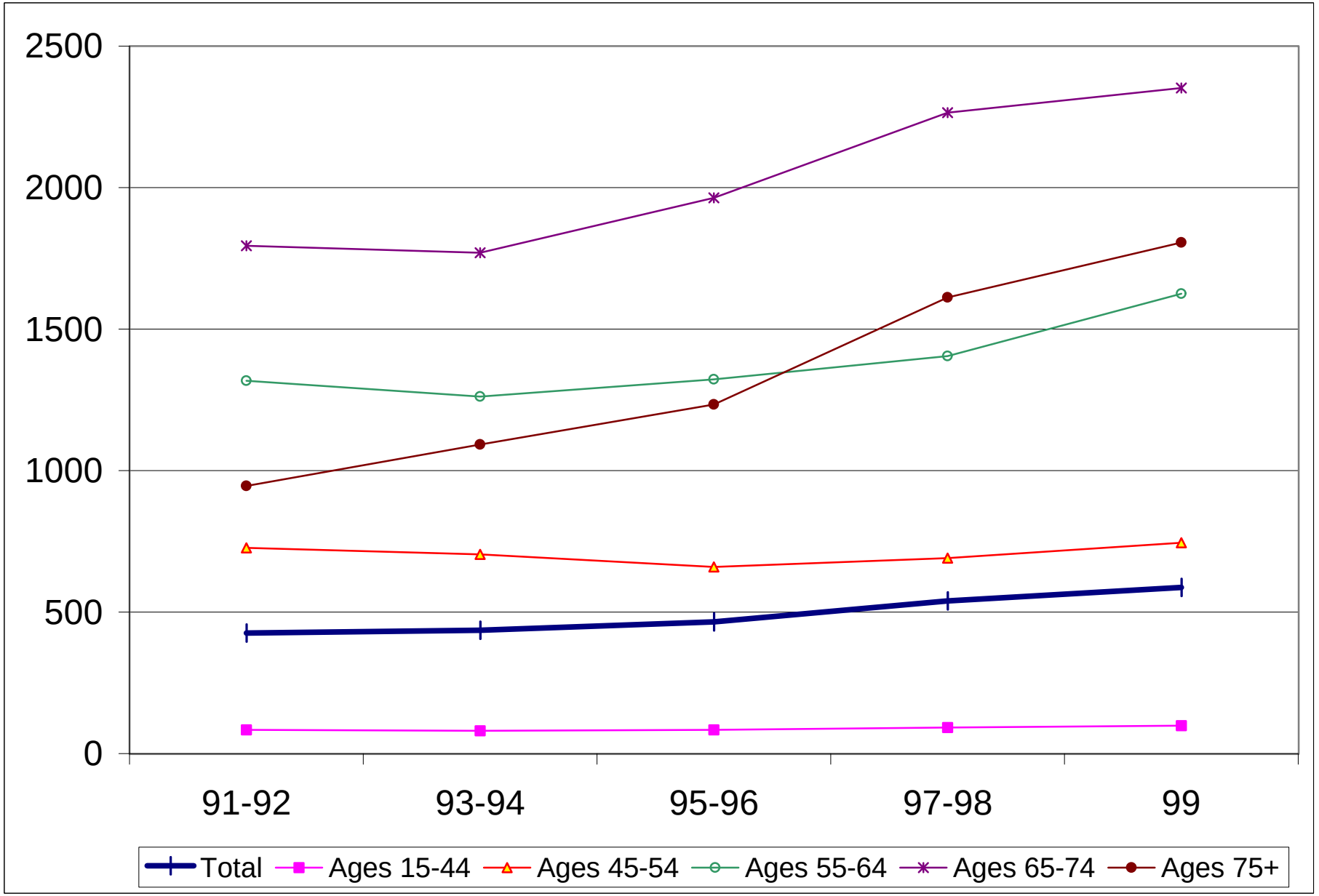
All Rates expressed are per 100.000 Population.
Rates do not include ME residents
who had procedures performed out of state.

Source: ME Inpatient 1991-1999.
Rates based on first listed diagnosis and all listed procedures.

PHRG
9/15/00

Trends in Cardiac Catheterization Admission Rates: Maine

Exhibit I-9



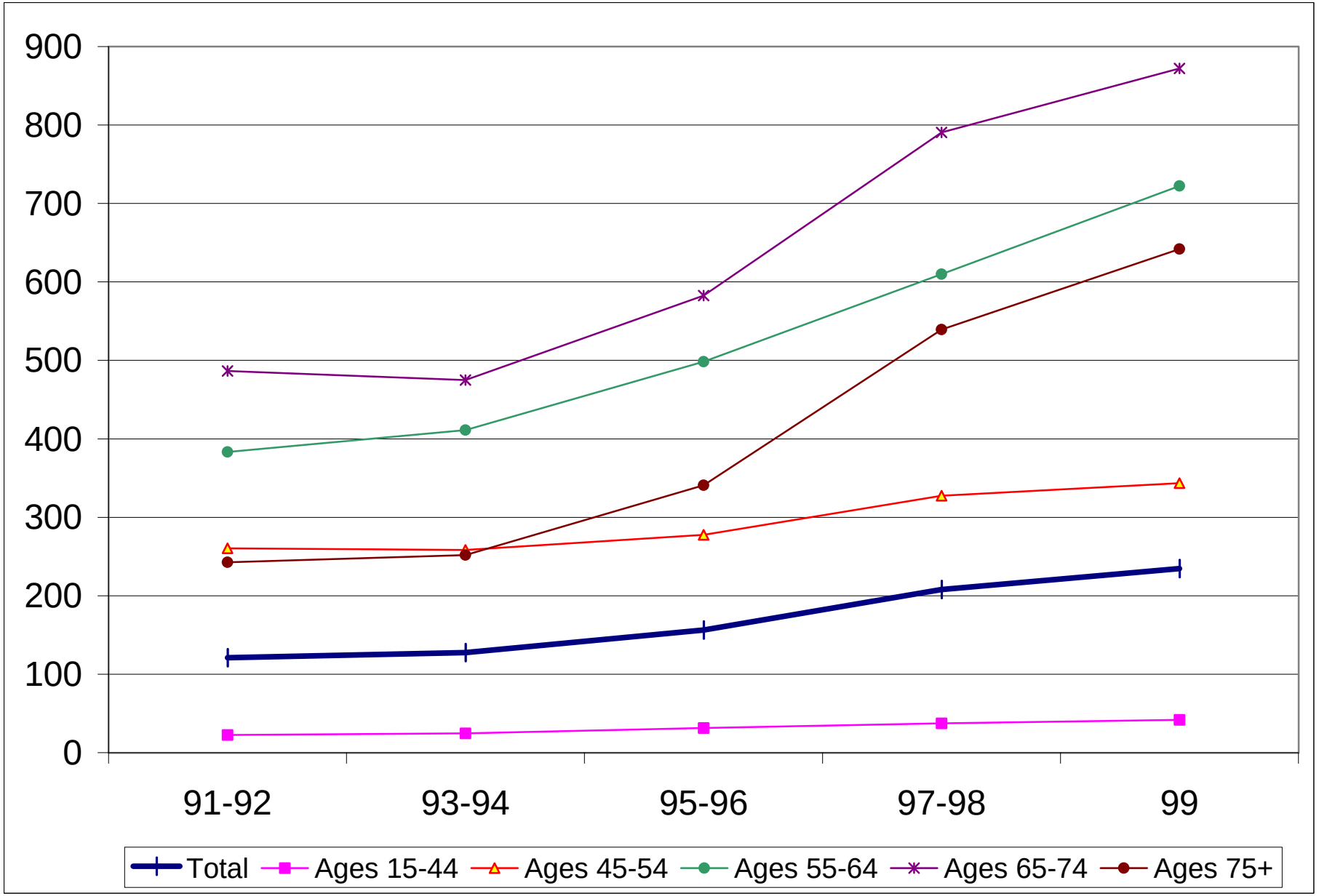
Source: ME Inpatient 1991-1999
Rates based on all listed procedures.

All rates expressed are per 100,000 population.
Does not include ME residents who had procedure performed out of state.

PHRG
9/15/00

Trends in Angioplasty Admission Rates: Maine

Exhibit I-10



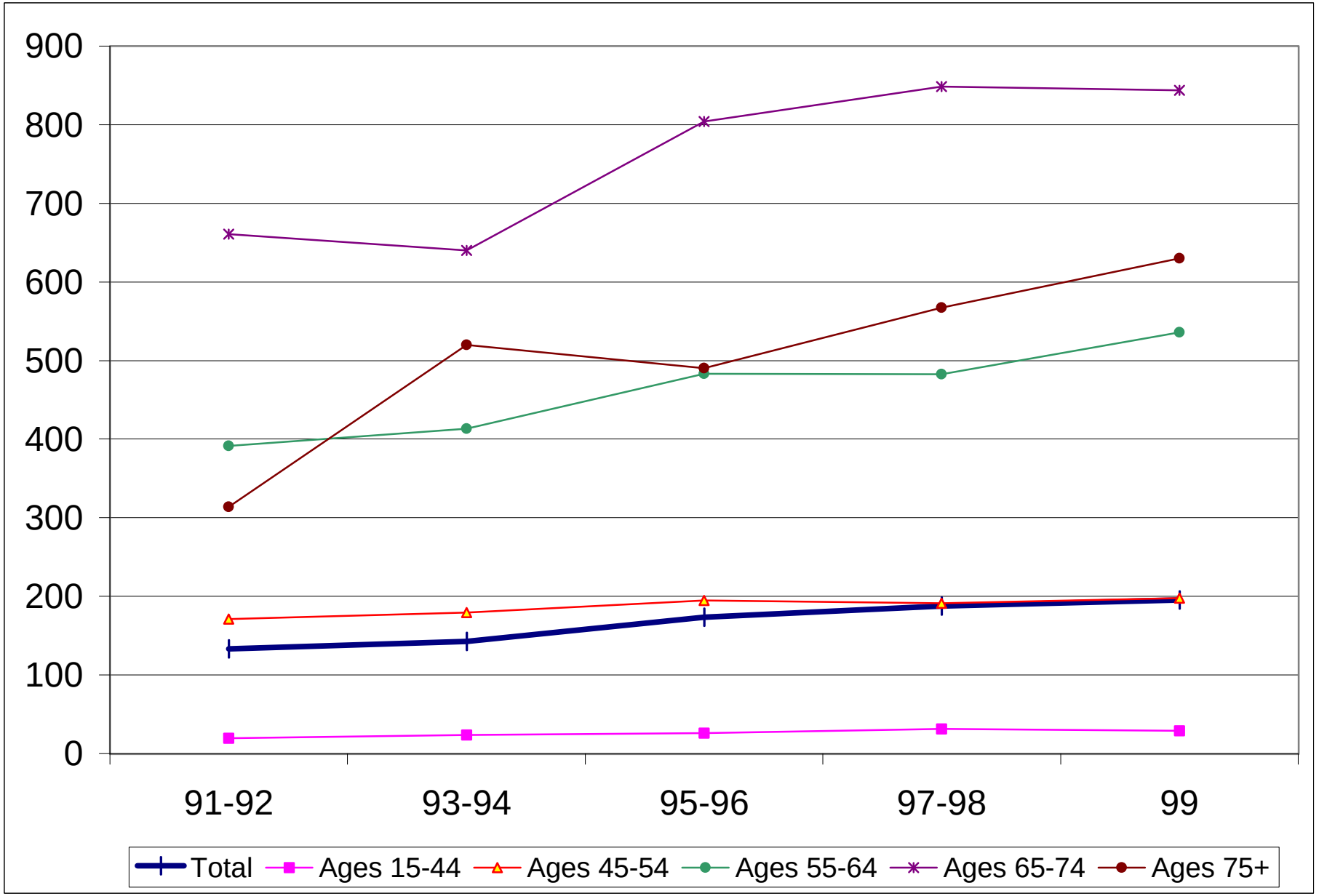
Source: ME Inpatient 1991-1999
Rates based on all listed procedures.

All rates expressed are per 100,000 population.
Does not include ME residents who had procedure performed out of state.

PHRG
9/15/00

Trends in Open Heart Admission Rates: Maine

Exhibit I-11



Source: ME Inpatient 199-1999
rates based on all listed procedures

All rates expressed are per 100,000 population.
Does not include ME residents who had procedure performed out of state.

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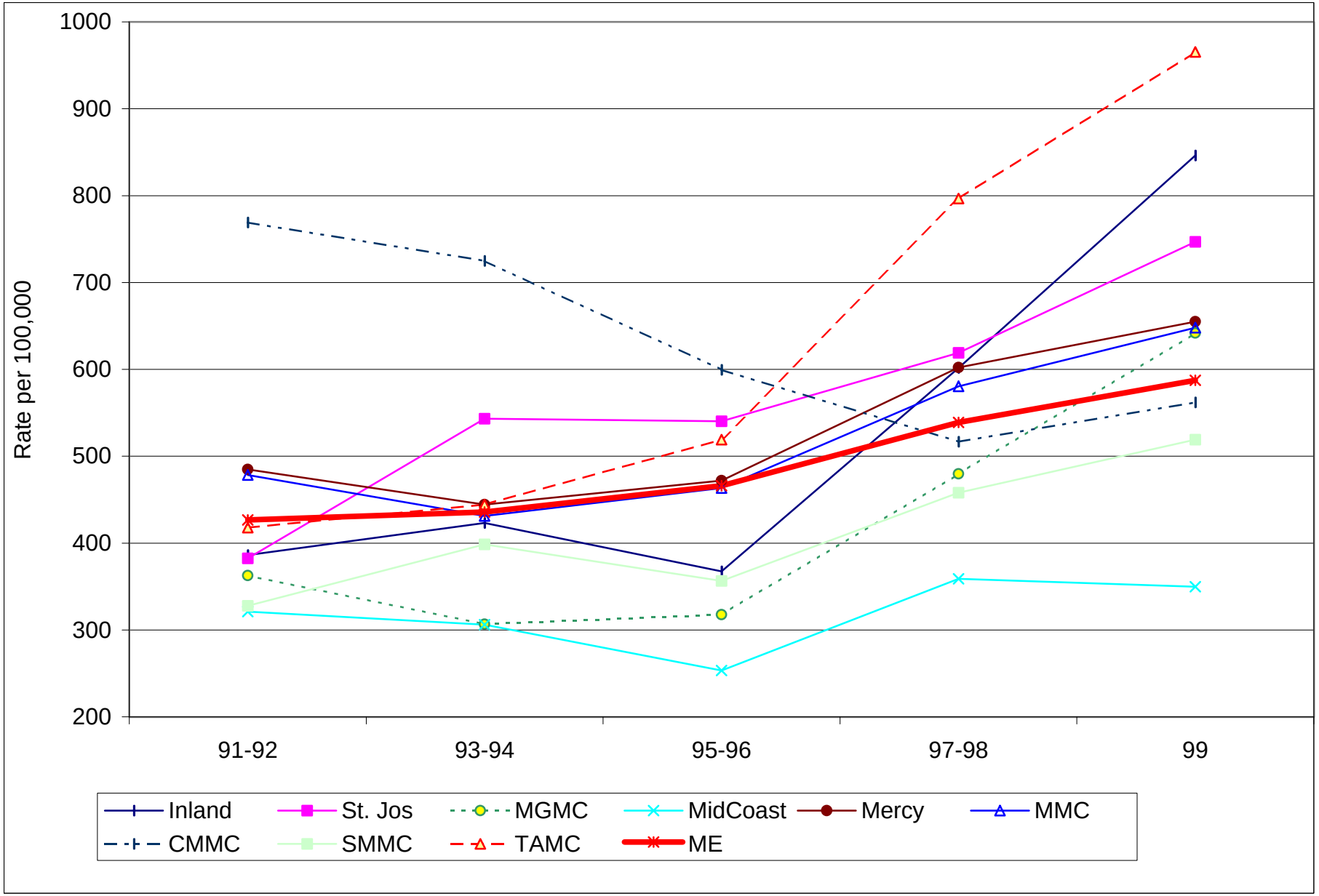
9/15/00

Exhibit I-12

Trends in Cardiac Catheterization Procedures in Maine and by CSA
(CSA Rates Age and Sex Adjusted to ME)



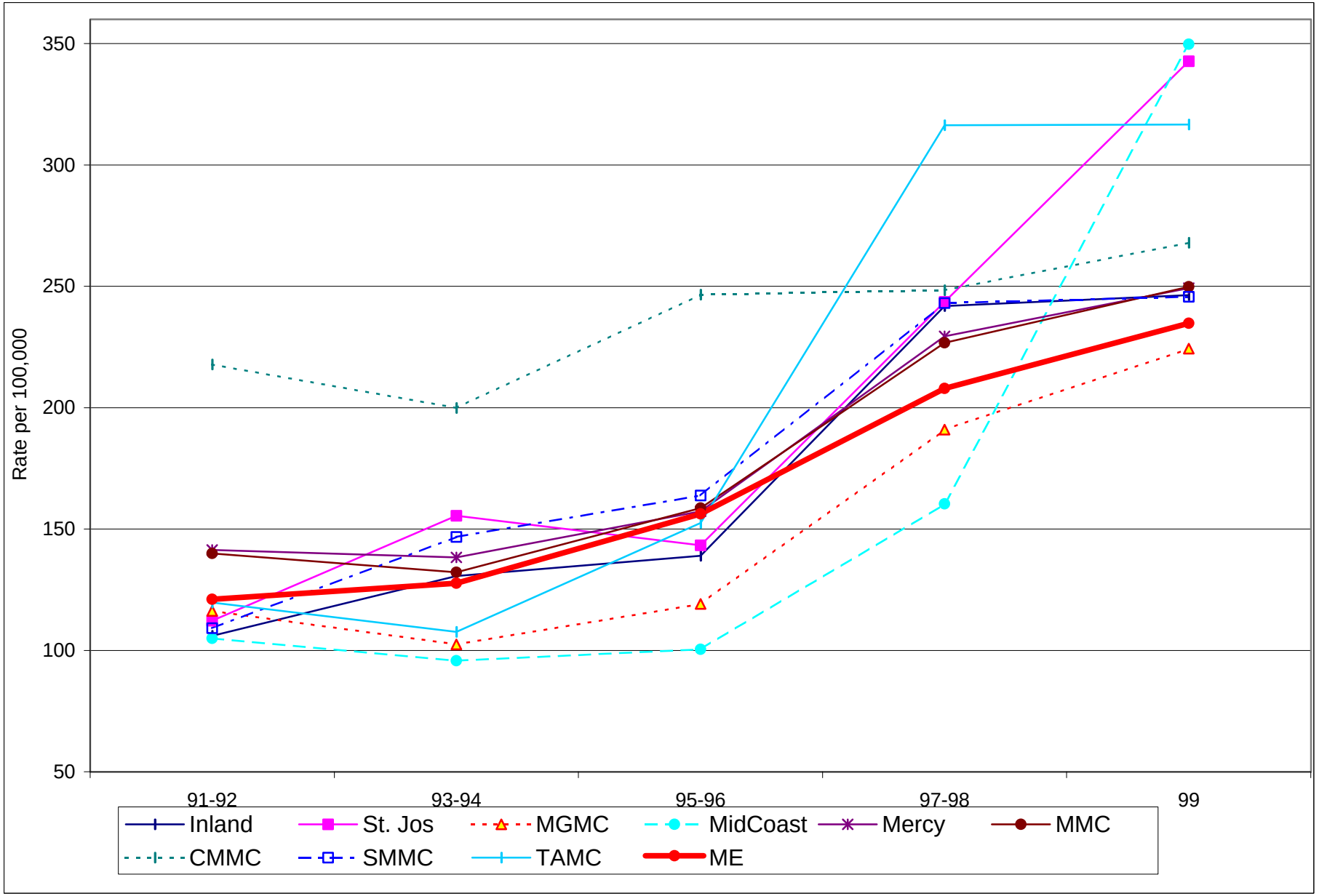
Source: ME Inpatient 1991-1999
Based on all listed procedures

All rates expressed are per 100,000 population.
Does not include ME residents who had procedure performed out of state.

PHRG
9/15/00

Trends in Angioplasty Procedures in Maine and by CSA
(CSA Rates Age and Sex Adjusted to ME)

Exhibit I-13



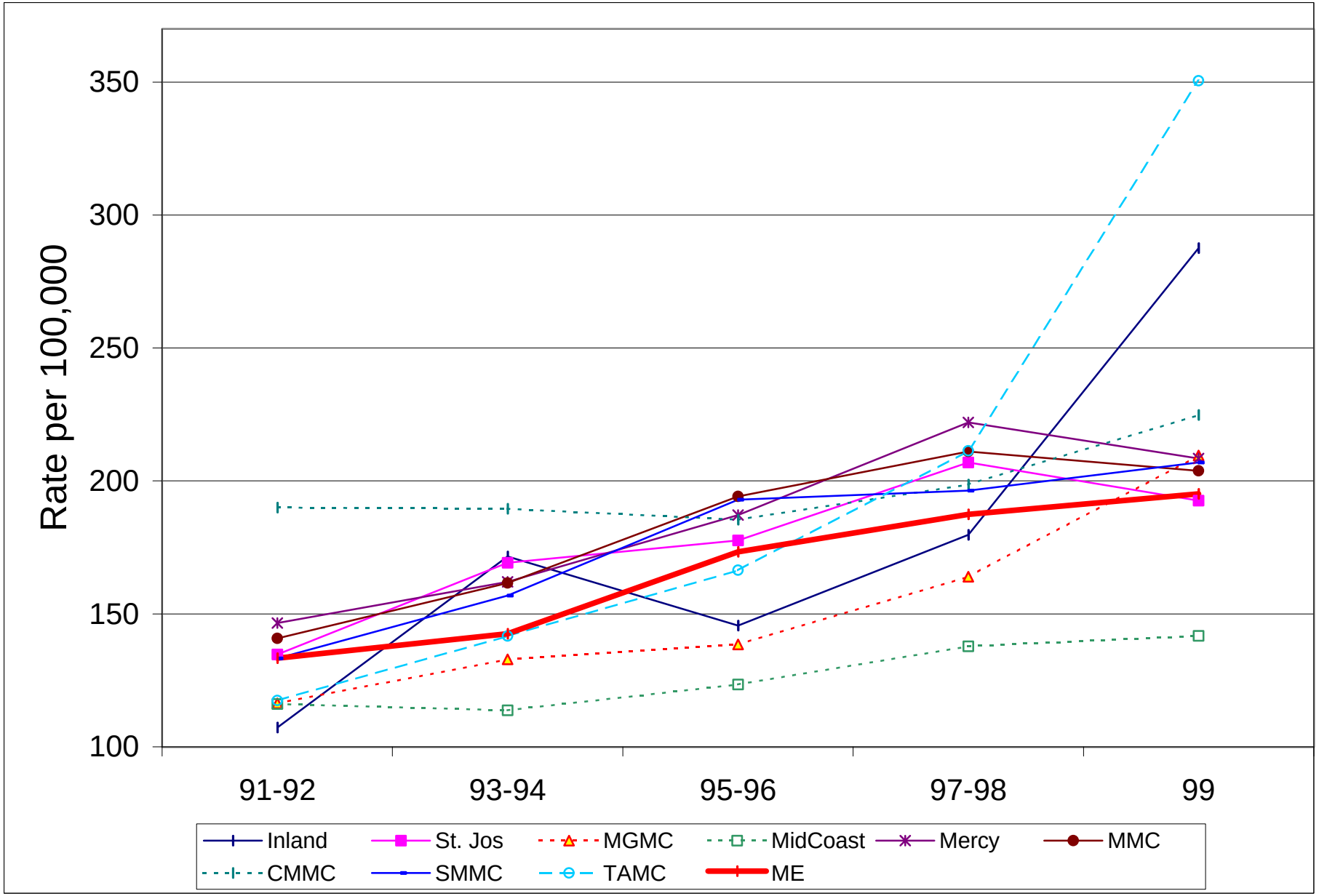
Source: ME Inpatient 1991-1999
Based on all listed procedures

All rates expressed are per 100,000 population.
Does not include ME residents who had procedure performed out of state.

PHRG
9/15/00

Trends in Open Heart Sugery in Maine and by CSA
(CSA Rates Age and Sex Adjusted to ME)

Exhibit I-14



Source: ME Inpatient 1991-1999
Based on all listed procedures

All rates expressed are per 100,000 population.
Does not include ME residents who had procedure performed out of state.

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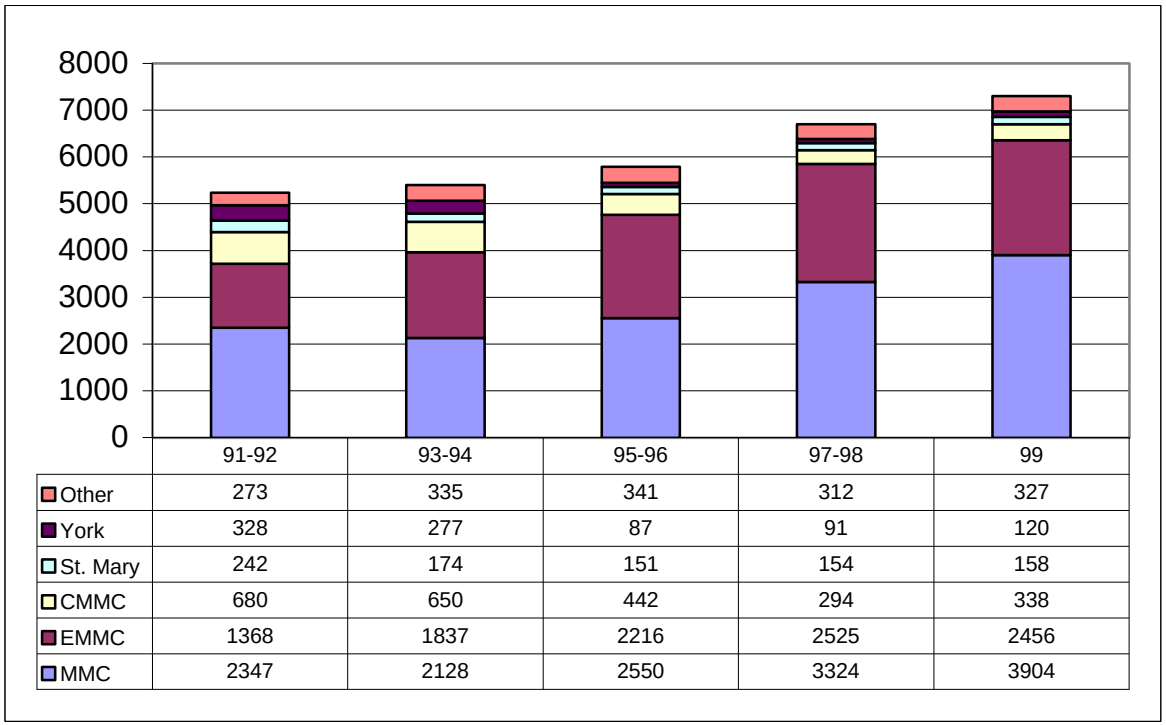
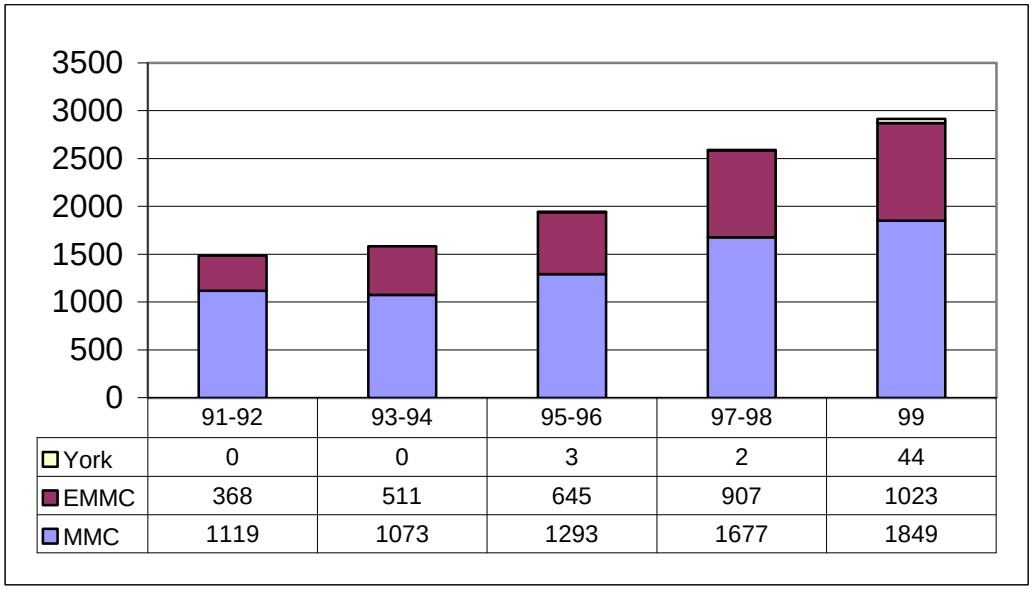


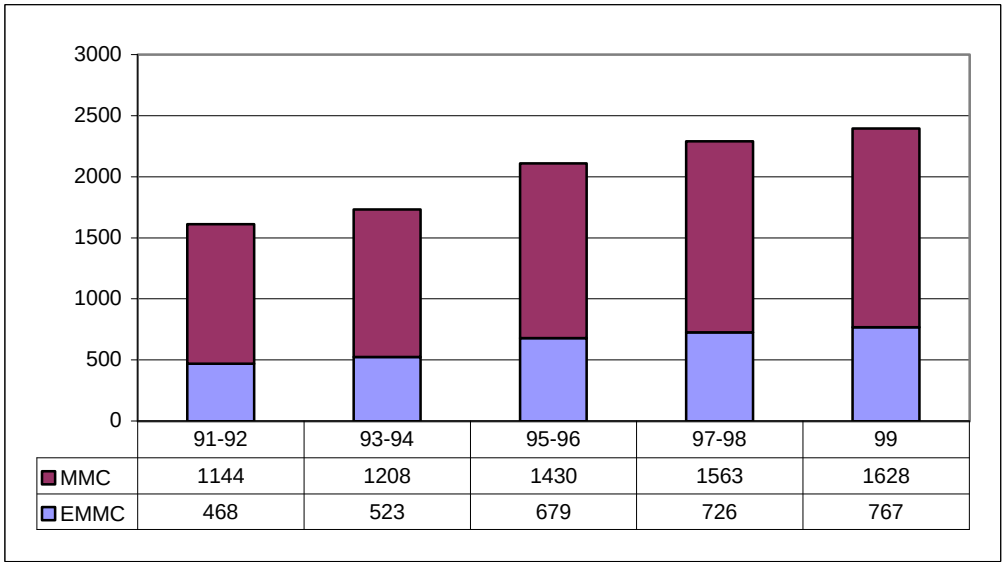
	91-92	93-94	95-96	97-98	99
Other	273	335	341	312	327
York	328	277	87	91	120
St. Mary	242	174	151	154	158
CMMC	680	650	442	294	338
EMMC	1368	1837	2216	2525	2456
MMC	2347	2128	2550	3324	3904

Trends in Volume by Facility: Angioplasty



	91-92	93-94	95-96	97-98	99
York	0	0	3	2	44
EMMC	368	511	645	907	1023
MMC	1119	1073	1293	1677	1849

Trends in Volume by Facility: Open Heart Surgery



	91-92	93-94	95-96	97-98	99
MMC	1144	1208	1430	1563	1628
EMMC	468	523	679	726	767

1999 Cardiac Catheterization Estimates:
If All Existing and Proposed Programs Were Fully Operational in 1999

HOSPITAL	1999 INPATIENT & OUTPATIENT CARDIAC CATH PATIENTS	1999 CARDIOLOGY MARKET SHARE METHOD	1999 CARDIAC CATH PERCENTAGE OF CARDIOLOGY METHOD	1999 CARDIAC CATH ADMISSION RATE METHOD
CENTRAL MAINE MEDICAL CENTER	521	443	521	475
EASTERN MAINE MEDICAL CENTER	2,978	2,172	2,139	2,266
INLAND HOSPITAL		158	164	134
MERCY HOSPITAL		453	495	379
MAINE GENERAL MEDICAL CENTER		696	825	573
MID-COAST HOSPITAL		213	277	196
MAINE MEDICAL CENTER	4,462	3,116	2,746	3,305
SOUTHERN MAINE MEDICAL CENTER		430	488	365
ST. JOSEPH HOSPITAL		347	327	296
ST MARY'S HOSPITAL	239	195	239	235
THE AROOSTOOK MEDICAL CENTER		198	224	187
YORK HOSPITAL	454	230	210	243
TOTAL	8,654	8,652	8,654	8,654

2003 Cardiac Catheterization Estimates:
If All Existing and Proposed Programs Would Be Fully Operational in 2003

HOSPITAL	2003 CARDIOLOGY MARKET SHARE METHOD	2003 CARDIAC CATH PERCENTAGE OF CARDIOLOGY METHOD	2003 CARDIAC CATH ADMISSION RATE METHOD
CENTRAL MAINE MEDICAL CENTER	536	630	575
EASTERN MAINE MEDICAL CENTER	2,644	2,605	2,758
INLAND HOSPITAL	190	197	161
MERCY HOSPITAL	548	598	458
MAINE GENERAL MEDICAL CENTER	842	999	694
MID-COAST HOSPITAL	259	337	238
MAINE MEDICAL CENTER	3,771	3,324	4,001
SOUTHERN MAINE MEDICAL CENTER	520	590	441
ST. JOSEPH HOSPITAL	424	399	362
ST MARY'S HOSPITAL	237	290	285
THE AROOSTOOK MEDICAL CENTER	251	283	236
YORK HOSPITAL	278	253	293
TOTAL	10,499	10,503	10,502

Sources: ME Inpatient:98-99; ME AmSurg: 98;
Population Estimates and Projections: Strategic mapping

1999 Cardiac Catheterization Estimates:
If All Existing Programs and MGMC Were Fully Operational in 1999

	EXISTING PROVIDERS (excluding York)	EXISTING PROVIDERS (excluding York) + MGMC	CHANGE	PERCENT CHANGE
Central Maine Medical Center	521	485	-36	-6.90%
Eastern Maine Medical Center	2,978	2,801	-177	-5.93%
Maine Medical Center	4,462	4,042	-420	-9.41%
St. Mary's Hospital	239	214	-25	-10.58%
Maine General Medical Center	N/A	654	654	N/A
TOTAL (excluding York)	8,200	8,196	-4	

Sources: ME Inpatient: 98-99; ME AmSurg: 98;
Population Estimates and Projections: Strategic mapping

1999 Cardiac Catheterization Estimates:

If All Existing Programs, MGMC and SMMC Were Fully Operational in 1999

	EXISTING PROVIDERS	EXISTING PROVIDERS + MGMC +SMMC	CHANGE	PERCENT CHANGE
Central Maine Medical Center	521	484	-37	-7.04%
Eastern Maine Medical Center	2,978	2,794	-184	-6.17%
Maine Medical Center	4,462	3,882	-580	-12.99%
St. Mary's Hospital	239	213	-26	-10.79%
York Hospital	454	250	-204	-44.87%
Maine General Medical Center	N/A	651	651	N/A
Southern Maine Medical Center	N/A	376	376	N/A
TOTAL	8,654	8,651	-3	

Sources: ME Inpatient: 98-99; ME AmSurg: 98 only;
Population Estimates and Projections: Strategic mapping

1999 Cardiac Catheterization Estimates:
If All Existing Programs, MGMC and Mercy Were Fully Operational in 1999

	EXISTING PROVIDERS	EXISTING PROVIDERS + MGMC + MERCY	CHANGE	PERCENT CHANGE
CMMC	521	482	-39	-7.57%
EMMC	2,978	2,792	-186	-6.26%
MMC	4,462	3,840	-622	-13.95%
ST MARY'S	239	213	-26	-10.96%
YORK	454	270	-184	-40.52%
MGMC	N/A	650	650	N/A
MERCY	N/A	404	404	N/A
TOTAL	8,654	8,650	-4	

Sources: ME Inpatient: 98-99, ME Outpatient: 98 only,
Population Estimates and Projections: Strategic Mapping

1999 Cardiac Catheterization Estimates:
If All Existing Programs, MGMC, SMMC and Mercy Were Fully Operational in 1999

	EXISTING PROVIDERS	EXISTING PROVIDERS + MGMC + SMMC + MERCY	CHANGE	PERCENT CHANGE
CMMC	521	481	-40	-7.75%
EMMC	2,978	2,787	-191	-6.41%
MMC	4,462	3,528	-934	-20.93%
ST MARY'S	239	212	-27	-11.20%
YORK	454	247	-207	-45.55%
MGMC		649	649	N/A
SMMC		364	364	N/A
MERCY		383	383	N/A
TOTAL	8,654	8,651	-3	

Sources: ME Inpatient: 98-99, ME Outpatient: 98 only,
Population Estimates and Projections: Strategic Mapping

1999 Angioplasty Estimates:
If All Existing and Proposed Programs Were Fully Operational in 1999

	1999 ACTUAL PTCAs	1999 CARDIAC CATH MARKET SHARE METHOD	1999 PTCA PERCENTAGE OF CARDIAC CATH METHOD	1999 PTCA ADMISSION RATE METHOD
CENTRAL MAINE MEDICAL CENTER	N/A	251 - 275	249 - 275	296
MAINE MEDICAL CENTER	1947	1707 - 1683	1689 - 1663	1640
EASTERN MAINE MEDICAL CENTER	1052	1041	1061	1063
TOTAL	2,999	2,999	2,999	2,999

2003 Angioplasty Estimates:
If All Existing and Proposed Programs Would Be Fully Operational in 2003

	2003 CARDIAC CATH MARKET SHARE METHOD	2003 PTCA PERCENTAGE OF CARDIAC CATH METHOD	2003 PTCA ADMISSION RATE METHOD
CENTRAL MAINE MEDICAL CENTER	330 - 362	328 - 362	390
MAINE MEDICAL CENTER	2,295 - 2,263	2,271 - 2,236	2,205
EASTERN MAINE MEDICAL CENTER	1,374	1,401	1,404
TOTAL	3,999	4,000	3,999

NOTE: YORK HOSPITAL WAS EXCLUDED FROM THIS ANALYSIS

1999 and 2003 Open heart Surgery Volume Estimates:
If All Existing Programs and CMMC were Fully Operational in 1999 and 2003

	ACTUAL OPEN HEART SURGERY	CARDIAC CATH MARKET SHARE METHOD	OPEN HEART PERCENTAGE OF CARDIAC CATH METHOD	OPEN HEART SURGERY ADMISSION RATE METHOD
CENTRAL MAINE MEDICAL CENTER	N/A	188 - 206	187 - 203	208
MAINE MEDICAL CENTER	1,649	1,443 - 1,425	1,473 - 1,457	1,455
EASTERN MAINE MEDICAL CENTER	783	802	789	769
TOTAL	2,432	2,432	2,432	2,432

Sources: ME Inpatient: 98-99, ME Outpatient: 98 only,
Population Estimates and Projections: Strategic Mapping