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The Impact Of Managed Care On Clinical Research: A Preliminary Investigation

Managed care is changing the research agenda and resources of academic medical centers. This raises new opportunities and new conflicts.

by Robert E. Mechanic and Allen Dobson

PROLOGUE: Clinical research at academic medical centers is supported by a variety of public, private, and institutional sources. However, as the health care world is overturned by the rapid emergence of a system driven by market principles, the sources of support for clinical research seem destined to change, too. In this paper Robert Mechanic and Allen Dobson discuss the impact of managed care on clinical research. Mechanic and Dobson have worked together on graduate medical education and hospital financing issues over the past seven years.

Mechanic, who holds a master's degree in business from the Wharton School at the University of Pennsylvania, is a senior manager with The Lewin Group, where he specializes in health care financing and reimbursement. Mechanic has analyzed the impact of public and private health care reform and managed care on physicians, hospitals, and academic medical centers. He also has assisted in the design and analysis of health care reform proposals at the national level and in many states.

Dobson is a vice-president of The Lewin Group and was formerly director of research at the Health Care Financing Administration. Dobson, who holds a doctorate in economics from Washington University in St. Louis, is leading an extensive analysis of physician practice expenses for a variety of physician groups. He also led the analysis of the potential future impact of managed care on the demand for inpatient hospital services for several major hospital groups.
ABSTRACT: Rapid growth in managed care enrollment is likely to affect clinical research at the nation's academic medical centers (AMCs). Our site visit interviews indicate that managed care has not markedly reduced coverage for research-related care. However, market competition in some areas has limited AMCs' ability to subsidize research activities with clinical revenues. As they gain market share, managed care organizations will have a growing influence on research priorities. Therefore, it is important for the academic community to work with managed care leaders to identify areas for collaboration and an agenda for moving forward in the future.

ACADEMIC MEDICAL CENTERS (AMCs), where a large portion of the nation's clinical research is conducted, combine a university basic-science research infrastructure with a clinical care enterprise. The resulting organizations are well equipped to investigate the practical applications of new medical knowledge on human subjects. However, the AMC-based research model faces serious challenges as markets for health services undergo rapid, fundamental change. These changes are being driven by employers and other purchasers, who are taking steps to control health spending growth, and by managed care plans, which are steadily gaining market share.

The study presented here was designed to explore three major issues. First, as more patients are enrolled in "closed" provider networks, AMC-based investigators may have reduced access to research subjects. Second, managed care plans may scrutinize patient care services more carefully than fee-for-service plans do and thereby identify more research-related services that are not eligible for payment. Finally, the general financial impact of price-competitive managed care markets may adversely affect the cross-subsidies that AMCs use to support education and research activities.

Few data exist to provide nationally representative insight about the impact of managed care on clinical research. It is questionable whether such a database could be developed, given the speed of market change, the unique geographic and institutional characteristics affecting AMCs' finances, and the lack of appropriate public information. Therefore, this analysis draws on seven case studies that included site visits to AMCs and interviews with clinical researchers, hospital administrators, managed care executives, and health maintenance organization (HMO) medical directors. Although the site visits represent a "snapshot" of emerging market forces, they provide fairly consistent findings and identify implications for the future of clinical research.

Defining Clinical Research

Our interviews revealed a range of views about how clinical research should be financed. Confusion about terminology, however,
frequently obscured key points. Therefore, we incorporated the following definitions in our study.

Clinical research is medical research involving human subjects, including studies to understand the mechanisms of disease, develop treatment algorithms (including clinical trials), and assess outcomes. Clinical research often involves diagnosis and treatment of an underlying disease by physician-investigators in a hospital or clinic setting. Clinical research involves a broad spectrum of activities that may involve both standard and experimental treatments.

Experimental therapies are treatments that generally are not considered “standard” care in the medical community. For purposes of third-party payer coverage, new treatments are categorized as experimental if there is not sufficient scientific evidence about their safety or efficacy in the treatment of a specific disease. Food and Drug Administration (FDA) approval of a drug or device for a given indication often is used as a criterion for determining whether a treatment is considered standard or experimental and therefore whether it will be covered. In some cases, experimental therapies may differ from standard therapies in relatively minor ways. For example, in cancer treatment, changes in the dosage, frequency, or combinations of drugs often are classified as experimental.

Clinical trials are formal investigations of the effects of an intervention (usually involving new or experimental therapies) on human subjects. Clinical trials follow carefully designed treatment protocols and are designed to answer specific research questions. Phase I clinical trials are intended primarily to test drug safety and toxicity and often use healthy volunteers who do not receive any clinical care. Phase II trials focus on demonstrating the efficacy of a drug or intervention and on identifying side effects. Phase III trials are used to clarify benefits and risks as well as to establish optimum dosage rates. Phase III trials also may compare the efficacy of new therapies with that of standard treatments.

The phase of a clinical trial was commonly mentioned in our interviews as a consideration in payment decisions. There is less ambiguity about Phase I trials, which generally are considered “pure research” and are not covered by insurance (with the exception of Phase I cancer and acquired immunodeficiency syndrome [AIDS] trials, which involve highly experimental and very expensive treatments for gravely ill patients). Phase I trials generally are financed with grants or other AMC funds. There is much more ambiguity in determining payment responsibility for insured patients enrolled in Phase II and Phase III trials in which patient care and research take place simultaneously.

Outcomes research refers to studies that compare alternative thera-
pies to determine which are most effective in terms of subsequent mortality, functional status, and other such measures. Outcomes studies generally focus on standard therapies.

**Study Methodology**

Our study goals included assessing current perceptions about managed care’s impact on clinical research, identifying emerging AMC market trends, and exploring HMOs’ and AMCs’ perspectives about collaborative efforts to support clinical research. The seven case studies were structured around two-day site visits to each market. In addition to interviewing senior AMC and managed care plan staff, we reviewed internal documents, analyzed publicly available hospital and HMO market data, and conducted follow-up telephone interviews.

Case study institutions were drawn from the 121 Association of American Medical Colleges (AAMC) member hospitals that have particularly close relationships with their medical schools. We selected institutions with large research programs; the seven AMCs account for nearly 20 percent of the National Institutes of Healths [NIH’s] clinical research funding. All were drawn from metropolitan statistical areas (MSAs) with high HMO penetration or rapidly growing HMO enrollment (Exhibit 1). In addition, we sought to include institutions that varied by geographic location, ownership, predominant HMO model, and single versus multiple AMC markets. Although there is great diversity in market conditions across the sites, the sample overrepresents AMCs with strong NIH support that are located in rapidly evolving markets.

All of the study markets have high HMO or preferred provider organization (PPO) penetration, but the dynamics of managed care and market evolution vary greatly. One model for measuring market evolution, developed by the University HealthSystem Consortium, classifies markets into five stages based on managed care penetration and concentration, hospital consolidation, and physician organization. None of the study markets has yet reached Stage 5, in which integrated systems manage patient populations (Exhibit 1).

In each institution we identified informants with diverse perspectives on the intersection between managed care and clinical research. Because quantitative data were limited, the diversity of interviews provided a more complete picture of current conditions. Researchers were likely to have different views depending on their specialty; for example, oncologists were more likely than most other specialists were to have experience with coverage disputes. In contrast to the researcher perspective, our interviews with utilization review (UR) and billing personnel provided a broader picture of the
EXHIBIT 1
Market Characteristics Of Academic Medical Center (AMC) Case Study Sites, 1994

<table>
<thead>
<tr>
<th>Market</th>
<th>AMC visited</th>
<th>HMO penetration a</th>
<th>PPO penetration b</th>
<th>Market evolution stage c</th>
<th>Inpatient days per 1,000 d</th>
<th>Number of AMCs e</th>
<th>Physician prepayment scale f</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baltimore</td>
<td>Johns Hopkins</td>
<td>29.7%</td>
<td>39.0%</td>
<td>2</td>
<td>854</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Minneapolis</td>
<td>University of Minnesota</td>
<td>38.5</td>
<td>40.0</td>
<td>4</td>
<td>572</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Philadelphia</td>
<td>University of Pennsylvania</td>
<td>29.4</td>
<td>20.0</td>
<td>2</td>
<td>883</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Portland</td>
<td>Oregon Health Sciences</td>
<td>63.6</td>
<td>37.0</td>
<td>3</td>
<td>430</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>San Francisco</td>
<td>University of California, San Francisco, and Stanford University</td>
<td>39.2</td>
<td>44.0</td>
<td>3</td>
<td>731</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Seattle</td>
<td>University of Washington</td>
<td>21.8</td>
<td>39.0</td>
<td>3</td>
<td>460</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

SOURCES: See below.
NOTES: HMO is health maintenance organization. PPO is preferred provider organization.

a InterStudy, 1994.
b Charles Singer Managed Care Market Reports, 1995. (HMO and PPO date are from different sources and may overlap.)
c APM, Inc., and the University HealthSystem Consortium, as reported in Hospitals and Health Networks, 5 March 1995. Stage 2 is "loose framework;" Stage 3 is "consolidation;" and Stage 4 is "managed competition."
d The Lewin Group calculations using American Hospital Association (AHA) statistics from 1995-1996. Community hospitals only, including days provided in long-term care units.
e AMC designation based on 121 Association of American Medical Colleges (AAMC) member hospitals as defined in this paper. Does not include osteopathic institutions. Philadelphia figure reflects recent MCP/Hahnemann merger.
f APM, Inc., and the University HealthSystem Consortium. Markets ranked on a scale of 1 to 4, with highest number indicating most prepayment.

magnitude of denials and the direction of trends over time. We also interviewed HMO representatives from each market (and several national plans), including administrators, medical directors, and HMO-based researchers.

AMC interviews were structured to assess the impact of managed care growth on the overall volume of patients, the availability of research subjects, and the role of reimbursement denials for patients enrolled in clinical studies. We also asked about general financial pressures—whether these were affecting research and which managed care activities were thought to have the greatest impact on research. Interviewers at the managed care plans inquired about contracting relationships with AMCs, whether plans had concerns about enrolling patients in clinical studies, and each plan’s clinical research interests and activities. In all of the interviews we asked about the potential for managed care organizations and
AMCs to develop collaborative clinical research arrangements.

Because of the limited sample, the findings presented here may not be fully representative of the universe of AMCs or of prevailing market conditions. However, there was great consistency in our findings across sites, which suggests that the direction of the trends we identified is accurate. The robustness of these findings could be strengthened through analysis of a larger number of markets or through monitoring specific institutions over time.

The Changing Context For Clinical Research

The future outlook for AMC-based clinical research in local markets is influenced heavily by the interaction of three factors: (1) the structure of clinical research financing; (2) managed care activities; and (3) AMCs' strategies and competitive position.

Clinical research financing. There are several major sources of AMC-based clinical research financing. Direct sources such as federal and industry-sponsored research grants are supplemented by internal cross-subsidies (such as surplus clinical income, tuition, and endowments). In addition, the clinical research enterprise relies on third-party insurance payments to reimburse the cost of standard care provided to patients in research protocols.

Direct research support. Health research and development (R&D) funding has increased steadily over the past decade. Overall, R&D funding increased by 10.5 percent annually between 1984 and 1994, compared with 4.8 percent annual growth in the NIH biomedical R&D index. NIH funding, of which about 60 percent goes to institutions of higher education, grew by 9.3 percent annually over the same period. Despite the current budget-cutting climate in Washington, NIH has received strong support from Congress and a 5.7 percent increase in its fiscal year 1996 appropriation. Industry-sponsored health R&D also has grown 13.6 percent annually over the past decade. Medical schools received about $6.5 billion in research-related grants and contracts in 1993-1994.

The ability to attract direct research support may buffer the impact of market pressures on clinical cross-subsidies. Some administrators claimed that their research programs were supported predominantly by grants with few subsidies from the medical school or teaching hospital. Although market conditions affect research at these institutions, their success in competing for research grants may be equally important as their success in the clinical care market. However, competition for research grants has intensified. The percentage of NIH grant applications receiving awards fell from 31.4 percent in 1988 to 24.5 percent in 1993. In addition, AMCs face increasing competition from private contract research organizations.
“The future of clinical research is linked closely to AMCs' ability to compete effectively in markets for health services.”

for management of industry-sponsored studies.\textsuperscript{7}

\textit{Internal} AMC cross-subsidies. Under standard university accounting practices, 22.4 percent of medical school expenditures were classified as research in 1993-1994.\textsuperscript{8} It is difficult to accurately identify the specific sources of clinical research financing. However, it is clear that the sources of medical school funding have changed dramatically over the past decade. Perhaps most significant is the growing reliance on clinical service revenue to finance medical school operations. Clinical revenues rose from about 22 percent of medical school budgets in 1980-1981 to nearly 47 percent in 1993-1994 (Exhibit 2). According to one recent study, more than $800 million in faculty practice plan revenues was used to support research in 1992-1993.\textsuperscript{9} Therefore, the future of clinical research is linked closely to AMCs’ ability to compete effectively in markets for health services. Because the financing structure varies across institutions and across clinical departments, however, the impact of managed care on research varies widely.

In addition to common cross-subsidies—such as the so-called dean’s tax, in which faculty practice plans provide funding to specific clinical departments and faculty—many AMCs give productive

\begin{table}
\centering
\caption{Medical School Funding Sources, Millions Of Dollars, 1980-1981 And 1993-1994}
\begin{tabular}{lcc|cc}
\hline
\textbf{} & \multicolumn{2}{c|}{\textbf{1980-1981}} & \multicolumn{2}{c}{\textbf{1993-1994}} \\
\textbf{} & \textbf{Amount} & \textbf{Percent of total} & \textbf{Amount} & \textbf{Percent of total} \\
\hline
Clinical revenues & $1,424 & 21.9\% & $12,779 & 46.5\% \\
Practice plans & 1,020 & 15.7 & 9,120 & 33.2 \\
Payments from hospitals & 404 & 6.2 & 3,659 & 13.3 \\
Other operating revenues & 2,197 & 33.9 & 6,319 & 23.0 \\
Federal appropriations & 57 & 0.9 & 110 & 0.4 \\
State appropriations & 1,351 & 20.8 & 2,781 & 10.1 \\
Tuition and fees & 348 & 5.4 & 1,130 & 4.1 \\
Other & 441 & 6.8 & 2,298 & 8.4 \\
Grants and contracts\textsuperscript{a} & 2,861 & 44.1 & 8,411 & 30.6 \\
\hline
Total & 66,482 & 100.0\% & $27,509 & 100.0\% \\
\hline
\end{tabular}
\end{table}

\textsuperscript{a} Including indirect cost recovery
investigators more time for research and do not hold them to the same clinical productivity standards to which other faculty are held.

Third-party financing. Because of the "joint-product" nature of care provided in AMCs, determining third-party payers' responsibility is a major issue in financing clinical research. Any particular course of treatment may include costs related to patient care, research, and medical education. The cost mix varies across disease categories, medical specialties, institutions, and specific patients.

There was a general consensus in our interviews that research costs such as those for experimental drugs, extra tests, and data management should not be the responsibility of third-party payers. Most interviewees also agreed that payers have a responsibility to cover appropriate (nonexperimental) patient care services. However, for payment purposes, there often is uncertainty and disagreement about where routine care ends and research begins. These situations occur, for example, when an experimental therapy replaces a standard therapy (and the patient would have to be treated anyway), when a patient has an adverse reaction to an experimental drug and thus requires additional treatment, or when there is no effective standard therapy for a patient's condition.

Third-party payers can respond to this "zone of uncertainty" in a variety of ways. One response is to pay for the care. One reason insurers pay is that they may be unaware that research is taking place. Many payers we interviewed acknowledged that they implicitly finance research costs even though they have an explicit policy not to do so. Insurers also make explicit decisions to pay for experimental therapies in support of specific types of research or particular institutions. Finally, insurers' payment decisions are affected by the potential for litigation and the negative press coverage that accompanies reimbursement denials. HMO representatives made numerous references to the impact of the multimillion-dollar judgment against the Health Net HMO in California regarding coverage decisions for bone marrow transplantation.

A second response is to narrow the zone of uncertainty by accounting for research and nonresearch costs more carefully. This requires close cooperation between payers and AMCs. Of particular importance is the question of what patient care costs would have been in the absence of research. To the extent that insurers pay for care on a fixed-price basis (an all-inclusive per case rate or capitation), accounting for research costs is less relevant. As markets become price-competitive and capitation becomes more common, the key issue for AMCs is whether payment rates are adequate to support research activities.

Finally, third-party payers may choose to deny payment for cases
involving research protocols. Decisions to deny coverage typically are based on a perceived lack of evidence on the safety or effectiveness of a specific therapy. Researchers have charged that some insurers deny payment for a case if they learn that any research is taking place; we did not encounter any payers that admitted to having such a policy. Most large insurers have an explicit process for reviewing coverage decisions that includes assessment of the published literature and consultation with outside experts. Both the insurers and the AMCs that we interviewed expressed frustration with this time-consuming process, which typically occurs case by case.

The third-party payment environment varies greatly across geographic markets. Managed care organizations' support for research is affected by market dynamics such as the degree of consolidation among plans, the level of price competition, and the personal relationships and philosophies of key players. We do not have enough information in this study to rigorously relate market maturity to the level of support for research. Our general impression, however, is that in loosely structured markets, the lack of pressure on prices means that managed care plans pay less attention to research than they do in more competitive markets. Plans in such markets are extremely focused on costs and are unlikely to give institutions the "benefit of the doubt" that higher costs are justified by value created by teaching or research activities. Managed care plans in more consolidated markets are likely to express more support for "community resources" but still may be unwilling to subsidize AMCs' activities through higher payments if their competitors do not.

- **Managed care activities.** Four managed care activities are likely to affect AMC-based clinical research: utilization review, selective contracting, gatekeeping, and payment rate negotiation.

  **Utilization review.** Utilization review may curtail the flow of patients into clinical trials by prospectively denying coverage for experimental therapies not covered by third-party payer contracts. It also may result in retrospective payment denials, which reduce the number of patients that can be studied with a fixed pool of research dollars. UR programs create pressure for hospitals to be "efficient" by encouraging more rapid discharges and the elimination of unnecessary or marginally useful tests and procedures. This affects both the process of care and the amount of time that researchers have to spend with patients.

  Researchers reported that UR denials have been concentrated in easily identifiable, high-cost services such as bone marrow transplantation or expensive diagnostic tests such as magnetic resonance imaging (MRI) scans. However, a number of the AMC staff we interviewed noted that managed care organizations, particularly
those with a large local presence, increasingly have reviewers on site and can scrutinize treatments in greater detail.

Selective provider networks. Provider networks that offer discounted prices and potentially better control over specialty referrals are a major component of managed care plans' cost containment efforts. AMCs that are excluded from these networks receive fewer referrals, a trend that would exacerbate the 20 percent decline in hospital inpatient volume over the past decade. Several HMO managers whom we interviewed had made explicit decisions not to include local AMCs in their networks. Although these arrangements do not preclude the use of AMC services, they tend to direct patients to other community hospitals. Data from 1994 indicate that AMC inpatient volume fell more rapidly than overall market volume in three of the institutions we visited; however, market share increased in the other four AMCs (Exhibit 3). Given the speed of change, these data may not fully reflect current market conditions.

### EXHIBIT 3
Change in Hospital Inpatient Days in Selected Geographic Markets and Academic Medical Centers (AMCs), 1984-1994

<table>
<thead>
<tr>
<th>Market/AMC</th>
<th>Inpatient days</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Areas where AMC has gained market share</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baltimore</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Johns Hopkins Hospital</td>
<td>2,755,718</td>
<td>2,098,856</td>
</tr>
<tr>
<td></td>
<td>323,390</td>
<td>276,670</td>
</tr>
<tr>
<td>Philadelphia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital of the University of Pennsylvania&lt;sup&gt;a&lt;/sup&gt;</td>
<td>5,369,010</td>
<td>4,371,853</td>
</tr>
<tr>
<td></td>
<td>298,935</td>
<td>311,345</td>
</tr>
<tr>
<td>Portland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University Hospital</td>
<td>942,302</td>
<td>720,434</td>
</tr>
<tr>
<td></td>
<td>94,535</td>
<td>100,010</td>
</tr>
<tr>
<td>Seattle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University of Washington Medical Center</td>
<td>1,357,326</td>
<td>1,003,309</td>
</tr>
<tr>
<td></td>
<td>108,040</td>
<td>94,170</td>
</tr>
<tr>
<td><strong>Areas where AMC volume has declined faster than overall</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minneapolis/St. Paul</td>
<td>2,508,716</td>
<td>1,747,818</td>
</tr>
<tr>
<td>University of Minnesota Hospital and Clinic&lt;sup&gt;b&lt;/sup&gt;</td>
<td>196,370</td>
<td>131,400</td>
</tr>
<tr>
<td>San Francisco</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Center at UCSF&lt;sup&gt;c&lt;/sup&gt;</td>
<td>1,575,873</td>
<td>1,203,003</td>
</tr>
<tr>
<td></td>
<td>245,645</td>
<td>170,820</td>
</tr>
<tr>
<td>San Jose, San Francisco</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stanford University Hospital</td>
<td>2,436,419</td>
<td>2,003,739</td>
</tr>
<tr>
<td></td>
<td>160,965</td>
<td>125,560</td>
</tr>
</tbody>
</table>


<sup>a</sup> Includes Presbyterian Medical Center of Philadelphia.
<sup>b</sup> Minneapolis and UMHC figures are based on 1993 and 1983 because 1994 and 1984 data were not available.
<sup>c</sup> UCSF figures include Moffit-Long Hospitals, Mount Zion Medical Center, and Langley Porter Psychiatric Hospital in both years.
Primary care gatekeepers. Most HMOs require that patients receive a referral from a primary care gatekeeper before they can receive nonemergency specialty or hospital services. Even if AMCs are included in provider networks, they may receive fewer patients if gatekeepers control referrals aggressively. Financial incentives influence the degree to which gatekeepers control referrals. Some are expected to act as care coordinators but have no direct financial incentives to control referrals. At the other end of the spectrum, the principal model used in California is capitation of prepaid medical groups for primary and specialty physician services. In addition, prepaid medical groups often have a hospital expenditure target for enrolled members. HMOs share savings below the target with the medical groups, which creates strong incentives to control hospital use. AMC-based researchers in markets such as Portland, Oregon, report that increased use of capitation has led primary care physicians to treat more patients themselves, with fewer referrals.

Aggressive payment rate negotiation. As health care markets become more price-competitive, AMCs face increasing pressure to bring their rates in line with those of community hospitals. AMC representatives in the markets we visited reported that the premiums they command over community hospitals for comparable services are shrinking. In West Coast markets it was estimated that the differential had fallen to between 0 and 10 percent. In contrast, as of 1993 major U.S. teaching hospitals had average costs per discharge that were about 35 percent above those of nonteaching institutions after adjusting for case-mix and local wages.

AMCs may be able to negotiate more effectively to provide tertiary services when they are the “only game in town.” However, our AMC interviewees estimated that only about 10 to 20 percent of their volume represents services that are unavailable elsewhere in the community. Furthermore, regional competition for tertiary and quaternary services is growing more intense. The fact that many AMCs and faculty practice plans are reporting shrinking clinical surpluses indicates that payments are declining faster than costs.

AMCs’ strategies and competitive position. The AMCs we visited were involved in a wide variety of activities to become more competitive in their local health care markets; nearly all of our interviewees described intensive cost reduction efforts. These efforts are reflected in recent industrywide hospital cost growth data. Between 1983 and 1991 the Medicare hospital prospective payment system (PPS) cost per discharge rose at an average annual rate in excess of 8 percent. This rate declined to 4.9 percent in 1992, 1.3 percent in 1993, and -1.3 percent in 1994. Some AMCs are actively pursuing managed care contracts and
"Managed care has had little impact on the rate of payment denials for research activities but has increased the 'hassle factor'.”

developing internal systems to coordinate and monitor managed care patients. One AMC leader told us that AMCs were trying to become “managed care-friendly” to attract new contracts and hold on to existing ones. However, some AMCs were viewed by managed care plans as distinctly “unfriendly” in their systems, processes, and willingness to cooperate. Although contracting efforts are driven primarily by economic forces, they also have the potential to yield closer working relationships on research issues.

Many AMCs are deciding whether to develop integrated delivery systems, join local systems, or position themselves as regional specialty providers. In Philadelphia, the University of Pennsylvania Health System is aggressively purchasing primary care physician practices to develop a large regional health care system that will support the university’s teaching and research activities. Another Philadelphia research institution, the Fox Chase Cancer Center, is developing a “loose” regional network of affiliated hospitals and community physicians that is designed to ensure that appropriate cases are referred to Fox Chase research protocols. In contrast, the University of Minnesota Hospital and Clinics (UMHC) has not joined any of the local Minneapolis integrated delivery systems and is concentrating instead on being a specialty referral center. Some of our interviewees were concerned, however, that this decision ultimately could lead to substantial declines in UMHC’s patient base, given the competitive Minneapolis environment.

Finally, some AMCs attempt to buffer reductions in clinical cross-subsidies by aggressively pursuing direct research support from government and industry. For example, researchers at the University of California, San Francisco, described the Center for Creative Therapies, which was designed to attract industry-sponsored Phase I trials from local biotechnology companies. This project demonstrates that AMCs’ efforts to compete more effectively in the research market can be implemented parallel to strategies to remain competitive in patient care services.

AMCs, in general, continue to enjoy strong financial performance. On average, the net income earned by 120 of the nations premier teaching hospitals remained stable at about 4 percent in 1994, according to an AAMC survey. Anecdotal evidence suggests, however, that some institutions, particularly those in markets with high HMO penetration, have experienced recent declines. These institu-
tions vary widely in their reputation, financial strength, capability to adapt and compete in a changing market, and local community support. It remains to be seen whether strategies now being developed will stabilize AMCs’ competitive position effectively.

**Has Managed Care Affected Clinical Research?**

Our site visits suggested that managed care has had a limited impact on clinical research to date, but that economic forces affecting AMCs may dramatically alter the future research environment.

- **Payment denials.** Most investigators we interviewed reported that managed care had had little impact on the rate of payment denials for their own research activities but noted an increased “hassle factor” surrounding coverage decisions. One concern at the outset of this study was that managed care organizations would refuse to pay for care associated with research. Our interviews indicate that third-party payer reimbursement denials for experimental care are relatively infrequent and generally have not disrupted clinical research. Researchers acknowledge that denials often are reversed on appeal. We heard a number of anecdotes about insurance companies’ refusal to pay for patients enrolled in clinical studies, most often for expensive treatments such as bone marrow transplantation. Investigators also mentioned that research resources were being used to pay for extra hospital days or expensive diagnostic tests not covered by insurance.

In practice, many insurers indicated flexibility about paying for the care of patients enrolled in clinical trials. A number of insurers told us that they commonly pay for care not authorized in their standard contracts; one medical director said that although his plans policy is not to cover any experimental treatment, payments for patients in Phase II and Phase III clinical trials were routinely approved.

In addition to a desire for more explicit decision making, plan representatives expressed concern about authorizing services without being aware that patients are enrolled in research protocols. There is widespread fear among investigators that if insurers know about research involvement, coverage will be denied. AMCs address this issue in different ways. Some are direct with managed care executives and on-site review personnel; one investigator said that it is the AMCs’ responsibility to educate managed care organizations about the research, “so if it is justifiable to have them cover it, we get agreement up front.” Other investigators do not promote awareness of research activities among insurers. This creates distrust among insurers.

We have no way to directly assess how much research-related
clinical care would be denied reimbursement if insurers had full knowledge of all research activities. However, some responses suggest that AMCs’ concerns about full disclosure are justified. One managed care executive, who expressed support for research but a desire for a more explicit process of coverage determination, told us that “if there are 100 experimental protocols going on today, we probably deny coverage for about 30 percent explicitly, pay for 65 percent implicitly because we don’t know about them, and pay for another 5 percent explicitly. With a better review process, we might be willing to pay for about 15 percent explicitly.”

Competitive market pressures. Pressures created by competitive managed care markets have a much more important financial impact on AMC-based research than reimbursement denials do. Managed care organizations are negotiating reduced prices and directing patients to lower-cost sites of care. In addition, the 1996 congressional budget resolution proposes substantial reductions in Medicare payments, which would affect teaching hospitals adversely. Most AMC representatives we met described “reengineering” efforts to reduce patient care costs. These efforts also affect support staff and other resources available for research, although some institutions are attempting to counter this by improving the efficiency of research operations. Nevertheless, reductions in clinical revenues, which historically have been used to subsidize the academic mission, are of concern to institutions that do not receive substantial government or industry research support.

AMCs in competitive markets report that faculty face increasing pressure to bring in clinical revenue and have less time for research. AMC representatives in several markets told us that they are revising faculty compensation formulas and considering reductions in faculty size. Some administrators predicted that faculty who cannot support their salaries through grants will have to curtail their involvement in research. They also noted that the changing economic climate will have the greatest impact on young investigators who lack established track records with grant-making organizations. This may affect the future pool of researchers.

Access to research subjects. There is also much concern that managed care limits access to research subjects but little evidence that this actually occurs. With only a few exceptions, most investigators said that they had been able to enroll adequate numbers of patients in their clinical studies. Researchers in more competitive managed care markets whose work is focused on understanding the mechanisms and processes of emerging diseases expressed the greatest concern. Because these diseases often are not well known or understood in the mainstream medical community,
research subjects are more difficult to identify. Network arrangements that limit patient flow to AMCs or specialist physicians who study these diseases could impede this type of research, particularly if network physicians have difficulty identifying these conditions.

**Different research priorities.** Managed care plans' clinical research priorities differ from traditional AMC activities. As plans become major players in specific markets, there is a growing need for research partnerships. Many of the managed care plans we interviewed already are involved in a range of research activities, including clinical trials, outcomes research, and health services research, although their basic research and clinical trial activities are smaller than those of AMCs. Managed care plans are most interested in applied research that is focused on measuring the cost-effectiveness of treatments for conditions that are common among their enrollees. In contrast, medical school faculty historically have concentrated on basic research and clinical trials, some with substantial focus on rare diseases. Much of the research conducted at AMCs is not perceived as addressing the immediate clinical needs of managed care plans or as devoting adequate attention to economic reality.

Many insurers we met expressed an interest in clinical research and support for institutions with a research mission. They expressed concern, however, about major participation in research funding. Many voiced reservations about paying higher rates to support research if investigators are not held accountable for ensuring that questions are appropriate, studies are well-designed, and research results are relevant to clinical practice. They also expressed concern that some researchers are not open about what is experimental and have not made efforts to cooperate with the managed care community. Finally, to the extent that they are called upon to help support research costs, managed care plans would like to participate in the setting of research priorities.

Ultimately, managed care plans may not recapture their investments in clinical research. It is difficult to quantify the long-term benefit of clinical investigation, and research conducted in the public domain is unlikely to provide a competitive advantage to sponsoring plans. Although some managed care plans express a commitment to research, many see large financial contributions as impractical, given the realities of the competitive market. This suggests that research programs will be scaled back if AMC-based activities cannot be supported by current financial structures or if the federal government does not maintain its commitment to research.
Implications

Our preliminary investigation indicates that although managed care has not deterred AMC-based clinical research significantly, intense competition is placing financial pressure on some institutions. Over time, market pressures will affect the volume and nature of research. Increased enrollment in plans with closed provider networks will relocate more clinical research outside of AMC settings, although much of it still may be managed by university researchers. The general shift from inpatient to outpatient care also will affect the organization of research; the number of outpatient visits in NIH-funded general clinical research centers has virtually doubled over the past decade, while the number of inpatient days has declined. By following trends in health care delivery, these shifts may improve the value and applicability of clinical research but may reduce the dominance of AMC-based research models. One potential benefit of more decentralized approaches, such as the Fox Chase network model mentioned earlier, is the potential to improve the quality of research conducted in community-based settings.

As managed care organizations control a greater share of health care expenditures, they will exert more influence over research priorities. Continued growth in NIH- and industry-sponsored research grants will allow AMCs to continue many of their current activities. However, some medical schools are beginning to think seriously about how to make their clinical, educational, and research programs more attractive to managed care. This includes closer ties with schools of public health and greater focus on cost-effectiveness and outcomes research. Some medical schools believe that growing managed care market power may lead to less research in the short run and perhaps a different mix of research activities in the long run. Like Willie Sutton, researchers will “go where the money is,” to keep funds flowing. Some new funding sources may include foundations that are established as a result of insurance company conversions to for-profit status, as has recently occurred in California. But these funds may include certain sponsor-imposed conditions that will affect the direction of research.

Finally, it is clear from our site visits that the communication between researchers and managed care organizations is inadequate. Potentially beneficial collaborative efforts are hindered by poor communication and mutual distrust. We heard multiple references to “academic arrogance” and to “managed care organizations that only care about cutting costs.” Interactions between researchers and managed care plans historically have revolved around the adversarial process of reimbursement decision making, rather than exp-
Explicit discussions about research and education. Although payment issues will remain in the forefront, we believe that new interactions are called for that focus on other topics of mutual interest.

Many promising opportunities exist. As managed care enrollment increases, having access to these patients will become more important for AMC-based researchers. Managed care plans have highly sophisticated patient information systems that can identify patients with specific conditions for research studies and track outcomes over time. At the same time, AMCs offer an “unbiased research environment, access to trained investigators, and well-equipped research infrastructures. These powerful capabilities can be used to address questions that are important to managed care plans. Affiliation with leading research institutions also may prove beneficial in attracting enrollees to managed care plans.

There is bound to be some contentiousness as these two large economic forces collide. Academic health system leaders should not view managed care solely as a barrier to clinical research but should explore the potential for productive collaboration. We believe that it would be helpful for a neutral third party to bring together AMC and managed care leaders to develop an agenda for moving forward and create a better understanding of each party’s operational goals and research priorities. It also should begin to address key issues such as developing a framework for reimbursement and coverage decisions for patients in research protocols, a process for expediting coverage for high-priority clinical studies, parameters for sharing information, and training needs of clinical researchers and physicians. As health care markets surge ahead, it is important that the key players shaping health care delivery have a seat at the table as the future course of clinical research is charted.

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NOTES

3. This definition includes all teaching hospitals under common ownership with a medical school and those in which the majority of the chiefs of service also serve as department chairs at the medical school.
8. Ganem et al., ‘Review of U.S. Medical School Finances.” This figure excludes some departmental research that is not budgeted separately.
16. Linda Fishman, associate vice-president, Division of Health Care Affairs, Association of American Medical Colleges, personal communication, spring 1996.
18. Ibid.