Variations in Medical Care for HIV-Related Pneumocystis carinii Pneumonia*

A Comparison of Process and Outcome at Two Hospitals

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**Background:** Institutional variation in the quality of medical care may be evaluated by examining process measures, such as use of diagnostic procedures or treatment modalities, or outcome measures, such as mortality. We undertook this study to examine variations in both process and outcome of care for patients with HIV-related Pneumocystis carinii pneumonia (PCP) at two geographically diverse, HIV-experienced, public municipal hospitals.

**Design:** Retrospective review of hospitalized patients diagnosed as having PCP cared for at two municipal hospitals from 1988 to 1990. At hospital A, charts of all patients diagnosed as having PCP were abstracted (n=209); at hospital B, a random sample of 15% were abstracted (n=136).

**Results:** Among all hospitalized patients diagnosed as having PCP, the frequency of making a definitive diagnosis of PCP (as opposed to treating empirically) differed markedly at the two hospitals (85% in hospital A vs 26% in hospital B; p<0.001), as did the use of intensive care (18% vs 3%; p<0.001) and “do-not-resuscitate” orders (39% vs 14%; p<0.001), although the timing of starting anti-Pneumocystis medications (89% vs 88% within the first 2 hospital days) and the use of corticosteroids (21% vs 23%) were similar. Despite differences in the process of care, survival rates were similar at the two institutions (75% vs 76%; p=0.8) and remained similar when logistic regression was used to control for demographic variables and severity of illness (odds ratio for survival, hospital B vs A, 1.2 [95% confidence interval, 0.7, 2.0]). The 95% confidence intervals (0.7, 2.0), however, were consistent with a considerable (and clinically significant) disparity in survival (from 30% lower to a twofold higher odds of survival). Sample size calculations showed that a sample of 10 cases in each hospital would be required to detect the observed difference in definitive diagnosis rates (85% vs 26%), but 722 cases in each hospital would be required to detect a relevant difference in mortality.

**Conclusions:** The process of care for hospitalized patients with PCP in these two institutions differed considerably, but the survival rates were not significantly different, even after adjusting for confounding factors. While sample sizes available at the individual institutions were sufficient for evaluation of the process of care, they did not provide the power necessary to evaluate outcomes. Comparisons of outcomes such as mortality between individual hospitals may not have the statistical power to exclude important differences.

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**Key words:** AIDS; intensive care; outcome; Pneumocystis carinii pneumonia; process; quality of care

**Abbreviations:** CI=confidence interval; DNR=do not resuscitate; OR=odds ratio; PCP=Pneumocystis carinii pneumonia

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Measures assessing individual hospitals’ outcomes (“report cards”) have been recommended to evaluate hospitals’ quality of care for AIDS-related conditions. These report cards use outcomes such as mortality adjusted for demographic and severity of illness differences or “case mix” as a marker of quality of care. The underlying assumption is that, after adjusting for variations in case mix, differences in hospital mortality rates are attributable to either random variation or differences in quality of care. Case mix-adjusted mortality rates have been used by the Health Care Financing Administration to compr-
pare hospitals and are widely used in state programs to evaluate hospital performance for surgical procedures such as coronary artery bypass.\textsuperscript{3,4} Mortality-based report cards for cardiac surgery have been credited with shifting patients to providers with better ratings.\textsuperscript{5,6} However, the impact of cardiac surgery report card programs on patient outcomes is unclear,\textsuperscript{7} and providers are increasingly concerned about the reliability, validity, and utility of outcome-based rankings. Comparing providers by risk-adjusted mortality rates is problematic because of difficulties identifying a distinct episode of care,\textsuperscript{8,9} adjusting for case mix,\textsuperscript{10-14} and distinguishing true outcome differences from random variation.\textsuperscript{2,15-17} Additionally, these mortality-based reports are of minimal value in identifying the specific factors that can be changed to improve outcomes.\textsuperscript{18-20}

In response to the difficulties of using mortality-based outcomes to assess quality of care, several authors have suggested that quality of care assessment should focus on measuring the process of care rather than its outcome.\textsuperscript{2,21,22} High-quality care is defined as performing diagnostic tests or treatments that are linked, by empirical studies, to good outcomes. Mant and Hicks\textsuperscript{23} used hypothetical data to demonstrate that they could detect differences between two institutions in quality of care for patients with acute myocardial infarction using process measures with attainable sample sizes; in contrast, outcome measures, in the form of hospital-specific mortality rates, required much larger, unattainable, sample sizes. The assessment of outcome vs process-of-care measures for evaluating quality of care for AIDS-related diseases has not yet been well studied.

In this study, we examine data on process and outcome measures and assess the relative sensitivity of these measures to detect differences in quality of care for hospitalized patients with HIV-related \textit{Pneumocystis carinii} pneumonia (PCP). We chose to examine two public hospitals because such hospitals provide more than half of the medical care for HIV-infected individuals in the United States even though they account for only 5\% of US hospitals.\textsuperscript{24} Despite advances in prevention of PCP, it remains the most frequent AIDS-defining opportunistic infection in the United States\textsuperscript{25} and the most common life-threatening infection in HIV-infected individuals.\textsuperscript{26-28} Appropriate prophylactic therapy, antibiotic treatment, and adjunctive corticosteroid therapy have been well defined.\textsuperscript{29} In contrast, some controversy remains about appropriate strategies for diagnosis, in particular the role of empiric treatment of PCP and the use of intensive care resources for patients with HIV-related PCP.\textsuperscript{30-32}

In this analysis, we employ a working hypothesis that a definitive diagnosis of PCP represents better quality of care for hospitalized patients than empiric therapy without a definitive diagnosis. This assumption is controversial because to our knowledge, no randomized, controlled trial has compared empiric therapy to definitive diagnosis, and two decision analyses comparing empiric therapy with early definitive diagnosis estimated that these two approaches were equally effective.\textsuperscript{33,34} Nevertheless, recent evidence supports early definitive diagnosis. First, two studies have documented that bronchoscopy will identify a treatable condition other than PCP or bacterial pneumonia in 10 to 20\% of patients evaluated for PCP.\textsuperscript{35,36} Second, Bennett and colleagues\textsuperscript{37} demonstrated that the risk of death was greater among hospitalized patients treated empirically than among those with a definitive diagnosis, controlling for severity of illness. Although this observational study does not prove that treatment of PCP without a definitive diagnosis causes an increase in mortality, it suggests that outcomes may be improved with definitive diagnosis. Finally, some experts have recommended definitive diagnosis in the management of hospitalized patients with PCP.\textsuperscript{38}

The purpose of this article is not to evaluate whether early definitive diagnosis of PCP constitutes better quality of care for hospitalized patients, but to use this working hypothesis to compare the utility of process and outcome measures in assessing quality of hospital care for patients with HIV-related PCP.

\section*{Materials and Methods}

\subsection*{Patient Identification and Data Collection}

The two hospitals used in this report represent the hospital studied in a previous report of ICU utilization patterns for patients with PCP\textsuperscript{30} and the largest county hospital in a five-city study of the quality of care for PCP.\textsuperscript{37,39} As part of these previously reported, independent studies, we identified all HIV-positive inpatients with PCP at two university-affiliated, public, municipal hospitals from January 1, 1988 to December 31, 1990.\textsuperscript{31,37,39} Inpatients with a diagnosis of PCP were identified through a computer search of all ICD-9-coded hospital discharge diagnoses for the study period. All records from patients were abstracted at hospital A, while a random sample (using a computerized random number generator) of 15\% of records was abstracted for hospital B. Information on each episode of PCP was collected by medical record review using standardized data collection forms. Trained registered nurses or physicians who had experience with AIDS were recruited and trained as medical record abstractors. Interrater reliability was assessed through reabstraction of a 5\% sample of charts by a different abstractor. Complete agreement was observed for the major variables of this report. Thirty percent of the records contained one or two disagreements; most disagreements concerned documentation of a prior episode PCP and this variable was excluded from the database.
Diagnosis and Severity of Illness

Patients were classified as having either definitive or empirically treated (presumptive) PCP. PCP was definitively diagnosed by cytologic or histologic identification of P carinii from specimens obtained by sputum induction, BAL, or transbronchial biopsy. To qualify for a presumptive diagnosis of PCP, patients had to be diagnosed as having presumptive PCP by the treating physicians and, either treated with anti-Pneumocystis therapy for at least 14 days or died within 14 days with a clinical diagnosis of PCP.

Severity of illness stages used in this analysis are a modification of a rapid staging system for PCP. Patients with mild disease were defined by an alveolar-arterial oxygen difference \( \leq 48.5 \) mm Hg and patients with severe disease were defined by an alveolar-arterial oxygen difference \( >48.5 \) mm Hg (96% of patients at hospital A and 94% at hospital B had arterial blood gas analysis within 24 h of admission).

Statistical Analysis

\( \chi^2 \) and \( t \) tests were used to compare groups on discrete and continuous variables, respectively. Logistic regression was used to compare survival at the two hospitals while adjusting for demographic and severity-of-illness variables. Logistic regression was performed with hospital survival as the outcome variable using the change-in-estimate procedure. All demographic and severity-of-illness variables listed in Table 1 were placed in the model and kept in the final model only if their inclusion changed the odds ratio (OR) associated with the hospital by 5% or if they were significantly associated with survival at \( p<0.05 \). Process-of-care variables were not considered in this model because the objective of the model was to assess survival as the sole measure of the quality of care provided at the two hospitals.

Results

Between January 1, 1988 and December 31, 1990, 209 patients at hospital A and more than 1,000 patients at hospital B were hospitalized because of PCP. Table 1 shows the demographic and clinical characteristics of all 209 individuals with PCP at hospital A and a random sample of 136 individuals at hospital B. At hospital A, patients with PCP were predominantly male, non-Hispanic white, and gay or bisexual. In contrast, patients at hospital B were more likely to be female, African-American or Hispanic, and injection drug users (Table 1). Despite these differences, patients at the two hospitals had a similar mean age (36 years at hospital A; 37 years at hospital B; \( p=0.2 \)), a similar likelihood of having a prior AIDS-defining opportunistic infection or neoplasm, and a similar likelihood of having received PCP prophylaxis before PCP was diagnosed.

Table 1—Demographic and Clinical Characteristics at Hospital Admission of Patients Discharged With a Diagnosis of PCP at Two Municipal, Public Hospitals*

<table>
<thead>
<tr>
<th></th>
<th>Hospital A (n=209)</th>
<th>Hospital B (n=136)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>202 (96.7)</td>
<td>103 (75.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>6 (2.9)</td>
<td>33 (24.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>174 (83.3)</td>
<td>39 (28.7)</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>10 (4.8)</td>
<td>54 (39.7)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>13 (6.2)</td>
<td>32 (23.5)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (2.4)</td>
<td>11 (8.1)</td>
<td></td>
</tr>
<tr>
<td><strong>HIV risk group</strong></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gay or bisexual male</td>
<td>156 (74.4)</td>
<td>50 (36.8)</td>
<td></td>
</tr>
<tr>
<td>IDU</td>
<td>11 (5.3)</td>
<td>37 (27.2)</td>
<td></td>
</tr>
<tr>
<td>Gay/bisexual male and IDU</td>
<td>28 (13.4)</td>
<td>3 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>13 (6.2)</td>
<td>46 (33.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Prior AIDS defining condition</strong> (1987 US CDC criteria)</td>
<td>68 (33.5)</td>
<td>37 (27.2)</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Prior AZT use</strong></td>
<td>56 (26.8)</td>
<td>14 (10.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Prior PCP prophylaxis</strong></td>
<td>37 (17.7)</td>
<td>33 (24.3)</td>
<td>0.6</td>
</tr>
<tr>
<td><strong>Severity stage on admission</strong></td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td>( P(A-a)O_2 ) difference ( \leq 48.5 )</td>
<td>97 (46.4)</td>
<td>62 (45.4)</td>
<td></td>
</tr>
<tr>
<td>( P(A-a)O_2 ) difference ( &gt;48.5 )</td>
<td>103 (49.3)</td>
<td>66 (51.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Survival to discharge</strong></td>
<td>156 (74.7)</td>
<td>103 (75.7)</td>
<td>0.8</td>
</tr>
</tbody>
</table>

*IDU=injecting drug user; CDC=Centers for Disease Control and Prevention; AZT=zidovudine; \( P(A-a)O_2 \)=alveolar-arterial oxygen pressure difference.

1Severity stage based on reference 39.
(Table 1). Patients at the two hospitals also had similar severity of PCP, as defined by a PCP severity staging system based on the alveolar-arterial oxygen difference.37

Process of Care for PCP

The two hospitals differed markedly in their diagnostic strategy for PCP (Table 2). At hospital A, 85% of patients had the diagnosis definitively confirmed by induced sputum or bronchoscopy. In contrast, at hospital B, only 26% of patients had a confirmed diagnosis. In addition, among patients who underwent bronchoscopy, 19% of those at hospital A had bronchoscopy on hospital day 7 or later, compared to 58% at hospital B. These results reflect two different diagnostic approaches to PCP: early definitive diagnosis vs empiric therapy with definitive diagnosis only for those patients who do not respond to treatment.

Despite differences in diagnostic strategies, there were no important differences in the drug treatment of patients with PCP. Hospitals A and B initiated antibiotic treatment effective against PCP within the first 48 h of hospitalization for 89% and 88% of patients, respectively. In addition, adjunctive corticosteroid therapy was used in 21% and 23% of patients, respectively. There were also no significant differences between the two hospitals in the number of hospital days for survivors and for nonsurvivors (Table 2).

The utilization of intensive care for patients with PCP differed significantly at the two hospitals: 18% of patients at hospital A but only 3% of patients at hospital B were cared for in the ICU (p<0.001). Among patients with a PCP severity classification of 3 or 4, 32% at hospital A received intensive care, compared with 5% at hospital B (p<0.001). These differences in intensive care utilization remained significant when patients were stratified by history of a prior clinical AIDS-defining illness.

The hospitals also differed in their utilization of do not resuscitate (DNR) orders: 39% of patients at hospital A had DNR orders written during their hospitalization, compared with 14% at hospital B (p<0.001). There was no significant difference in the proportion of DNR orders that were written in the first 72 h of hospitalization (35% at hospital A vs 50% at hospital B; p=0.3). We examined the proportion of patients who died in the hospital with a DNR order and without spending time in the ICU as a marker of a deliberate decision to forego intensive care; this occurred for 10% of patients at hospital A and 11% at hospital B (p=0.8).

Outcomes of PCP

The unadjusted proportion of patients with PCP surviving to hospital discharge was essentially the same at the two institutions: 75% at hospital A and 76% at hospital B (OR, 1.06 for hospital A compared with hospital B; 95% confidence interval [CI], 0.63,
of death of 1.64 compared with those with a definitive diagnosis of PCP. \(^{37}\) If this relative risk is true, the difference in rates of definitive diagnosis that we found at hospital A and hospital B would correspond to a 25% reduction in mortality at hospital A (OR for survival of 0.75). As shown in Table 4, the sample size necessary to demonstrate a 25% reduction in mortality would be 722 patients per hospital. In contrast, the sample size needed to demonstrate this difference in rate of definitive diagnosis would be <20 patients per hospital.

**Discussion**

**Variations in the Care of HIV-Infected Patients With PCP**

At two municipal, public hospitals that have substantial HIV experience, we found large differences in the medical care, particularly in diagnostic strategies, for hospitalized patients with HIV-related PCP: rates of confirmation of PCP varied from 85% in hospital A to 26% in hospital B. Despite these differences, we found no significant difference in hospital survival at the two institutions. There are several possible explanations for these results. First, the anticipated improvement in survival as a result of higher rates of definitive diagnosis may have been confounded by other factors, such as unmeasured differences in severity of illness, comorbidity, or quality of care between the two hospitals. Although patients in these geographically diverse hospitals had very different demographic characteristics and HIV risk behaviors, these sociodemographic variables were not associated with survival, and the patients did not differ in severity of illness. A second explanation for our results could be confounded by the HIV experience of the institutions or physicians. Bennett and colleagues\(^{41}\) have shown decreased mortality among patients with HIV-related PCP at institutions with more HIV experience, although it is not known what processes of care accounted for the differences in outcome. HIV experience increases a physician’s likelihood of identifying and initiating treatment for HIV-related PCP,\(^{42}\) and HIV experience of physicians or institutions has been associated with better outcomes for patients with HIV.\(^{43,44}\) Although both institutions in our study are highly experienced providers of care for HIV-infected patients, hospital B cared for five times as many patients with PCP in the 3-year period. A third explanation for our findings could be that diagnostic strategy does not affect survival. However, examination of statistical precision of the comparison suggests a fourth explanation for the failure to detect differences in survival between the two hospitals.

### Table 3—Results of the Logistic Regression Model for Survival to Hospital Discharge for Patients With HIV-Related PCP

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Hospital B</td>
<td>1.2</td>
<td>0.7, 2.0</td>
</tr>
<tr>
<td>Initial alveolar-arterial oxygen difference, mm Hg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤48.5</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>&gt;48.5</td>
<td>0.3</td>
<td>0.2, 0.6</td>
</tr>
</tbody>
</table>

Detecting a Difference in Quality of Care: Sample Size Estimates

Because the CIs around the relative odds of survival at the two institutions include clinically significant differences, we estimated the number of patients needed to detect significant differences in quality of care for HIV-related PCP. We calculated the number of patients needed to detect differences in quality of care using hospital survival and compared it with the number needed to detect differences using a process variable (definitive diagnosis). Table 4 shows the sample size estimates needed to (1) show a difference in survival (outcome) between two hospitals and (2) show a difference in rate of definitive diagnosis (process) that would result in the same mortality difference, assuming that those treated empirically for PCP have an estimated rela-
The study’s statistical power to demonstrate a difference in rate of definitive diagnosis far exceeded its power to demonstrate a difference in mortality. Comparison of the crude and risk-adjusted survival rates in the two hospitals did not exclude the 25% reduction in mortality that we would have expected based on the different rates of definitive diagnosis, assuming the effect of definitive diagnosis on survival reported in a previous study.37

We also found variations in the utilization of intensive care for HIV-infected patients with PCP. Previous research has shown substantial fluctuations between 1985 and the early 1990s in an individual hospital’s utilization of intensive care for patients with PCP.31,32 This variation is probably the result of publications showing changing survival rates for patients with PCP and respiratory failure.32 Although data in our study were collected at both hospitals during the same time, temporal trends in practice patterns may have been different in these two hospitals. However, these differences are more likely to represent true practice variation between the two hospitals. The fact that outcomes were the same at the two hospitals despite different rates of intensive care utilization does not argue that intensive care is ineffective for patients with PCP, because of the inadequate statistical power in this study to demonstrate a difference in survival.

The hospital that used intensive care for patients with PCP more frequently was also the hospital that used DNR orders more often. Patients at the two hospitals were equally likely to die in the hospital with a DNR order and without intensive care, suggesting that there was not a large difference in the proportion of patients who died after a decision to withhold aggressive care. The difference in the use of DNR orders may represent variation in the physician’s threshold for discussing the issue of resuscitation with patients and families and for writing these orders. In this study, we cannot distinguish the role of physicians from that of patients and families in decisions about intensive care utilization or DNR orders.

Previous research has suggested that geographic variation in patterns of care is most pronounced in situations in which the medical profession lacks consensus on the “correct” practice.45,46 Our data are consistent with this conclusion. Variation was large in the rate of definitive diagnosis and intensive care utilization for PCP (areas with little consensus) and small in time to initiation of antimicrobial therapy (an area with general consensus). Complete consensus on process of care is rare because of the limitations of available data. While evidence-based care determined by randomized trials remains the gold standard, arriving at practice consensus based on other types of information (such as outcomes research or consensus panels) is often necessary because of a limited number of relevant randomized, controlled trials.47

### Assessing and Improving Quality of Care

Quality of care assessment is a highly sensitive issue because the findings may have profound implications for providers.48 To be fair, valid, and useful, a reporting system that rates providers by quality of care must limit the comparison to a statistically meaningful sample of observations of appropriate and accurately measured quality indicators. This requirement creates a number of difficult challenges. The system must identify and adjust for those confounding factors not under the provider’s control. Further, it must provide enough observations within
a reasonable time period for the measurement to reflect, to a suitable degree of confidence, the provider’s true performance rather than random variation or temporal trends.\textsuperscript{2,15-17} Because of these requirements, comparing quality of care among providers by using disease-specific mortality rates is fraught with problems.

As our data show, a sample of 722 cases would be needed to demonstrate the reduction in mortality expected from increasing the definitive diagnosis of PCP from the rate of 26\% we found at hospital B to the 85\% rate at hospital A. A sample this large would require data collection for 15 years at hospital A. Mant and Hicks\textsuperscript{23} reported similar power limitations in a hypothetical analysis of care for patients with acute myocardial infarction. Even extremely large quality-of-care studies may be limited in this way. For example, in a study of 9,932 Medicare patients, Kahn and colleagues\textsuperscript{49} were unable to demonstrate a difference in severity-adjusted mortality rates between a group of hospitalized poor or African-American patients and a group of nonpoor control patients, despite significant differences between the two groups in scores for validated process-of-care measures.

Assessing quality of care by focusing on process of care is less vulnerable to many of these methodologic problems. Important process variables can be identified through consensus obtained from empiric studies and expert opinion. Confounding factors that might interfere with the process of care are fewer in number and more easily identified. As shown in Table 4 and previously demonstrated by Mant and Hicks,\textsuperscript{23} the sample sizes necessary to detect differences in quality of care are much smaller for process variables than for survival. Using process variables would allow assessment of quality of care over shorter periods of time, with more rapid feedback. However, process measures are useless if there is not clinical evidence that the process under examination is associated with improved outcomes or a clear consensus on the value of the process. It is critical that a quality assessment system selects clinically relevant and meaningful quality indicators that have achieved general consensus regardless of whether the system uses process or outcome variables.\textsuperscript{8,9}

The different implications of using mortality-based outcome indicators and process-of-care measures for quality improvement are profound. If differences in process are found, these can be directly linked to quality of care improvement by targeting the specific process identified. Detecting differences in outcomes, however, does not necessarily identify methods to improve those outcomes, because it is rarely apparent which of multiple care processes may be responsible for the worst outcomes.\textsuperscript{9} Consequently, quality of care assessment that focuses, at least in part, on processes of care is important for quality improvement efforts.\textsuperscript{19,20,50}

We found marked differences in the process of care for hospitalized patients with HIV-related PCP in two municipal public hospitals. In contrast, a valid comparison of quality of care based on risk-adjusted mortality could not be made between these two institutions because of sample-size constraints. Consequently, demonstrating no difference in risk-adjusted mortality does not exclude important differences in quality of care as measured by process variables. Institutional quality of care may be more easily and effectively assessed by process measures than outcomes, provided assessments are made using multiple, well-validated process variables.

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