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CHAPTER TWELVE:
VALIDATION STUDY OF ACUTE MYOCARDIAL INFARCTION, INTRODUCTION AND BACKGROUND

During the first year of the California Hospital Outcomes Project, a number of important questions arose concerning the validity of OSHPD's risk-adjusted outcome rates as a measure of the quality of hospital care. These questions led OSHPD to support two major validation studies in 1994-95, and to suspend the publication of additional outcomes reports until the results of the validation studies became available. Because the validation study for acute myocardial infarction generally supported the validity of OSHPD's analysis, the methods and results of this study are presented in the following four chapters. These results should help the reader to interpret the hospital-specific data presented in the *Results and Study Overview* (Volume One) and in the *Detailed Statistical Tables.*

Quality of care is a complex, multidimensional phenomenon. Researchers and organizations interested in quality of care believe that the variation in risk-adjusted outcomes across hospitals can be partitioned into three components: (1) random error, (2) systematic error, and (3) quality of care. The analytic methods described in the preceding chapters adjust for random error, but cannot identify the systematic error due to unreported and unmeasured risk factors. If the latter error is relatively small, then risk-adjusted mortality rates presumably reflect differences across hospitals in how patients are evaluated and treated.

Given this conceptual framework, risk-adjusted mortality rates should correlate with measures of *process.* Such measures assess the timely and appropriate use of diagnostic tests, the timely and appropriate prescribing of medications, the appropriate use of subspecialty services and invasive therapies, and the prompt recognition of complications. Demonstrating correlations between process and outcome can lead to corrective action by physicians and hospitals - a process known as continuous quality improvement. The absence of such correlations does not mean that risk-adjusted mortality rates are invalid; instead, it suggests the need for further research to understand what low-mortality hospitals are doing differently from high-mortality hospitals.

The AMI validation study was designed primarily to evaluate the impact of systematic error due to unreported and unmeasured risk factors, but it also offers limited opportunities to explore the correlation between outcomes and processes of care. Specifically, the study was designed to answer seven research questions.

QUESTION 1: What propor tion of cases included in the 1993 AMI study should have been excluded because acute myocardial infarction was incorrectly reported or incorrectly diagnosed?

As described in Chapter Three, a set of selection criteria were applied to each discharge abstrac t to determine whether the patient qualified for the AMI outcomes study. Did these selection criteria misclassify some patients who did not actually experience AMIs? In the validation study, cardiac enzyme values, historical data on chest pain, and elect rocardiographic findings were used to confirm the diagnosis of AMI. False positive cases were categorized according to why they were mistakenly included in the original sample.

QUESTION 2: What is the statewide reporting accuracy for important risk fact ors included in the risk -adjustment models?

In response to the 1993 public report and the preliminary draft of this report, many hospitals reviewed the medical records of their AMI patients and acknowledged their failure to code some ICD -9-CM diagnoses us ed as risk factors (e.g., diabetes). To evaluate this problem more systematically, records in the validation sample were carefully reviewed by expert coders who received special training. The reabstracted ICD -9-CM diagnosis and procedure codes were compa red with the codes listed on the original discharge abstract for the same patient. Using the definitions in Chapter Eight, the accuracy of reporting was estimated for each major risk factor (e.g., infarct site, hypertension, congestive heart failure). Th is analysis may lead to changes in the definitions of certain risk factors or elimination of certain risk factors that are unreliably coded.

QUESTION 3: Are important risk factors coded more thoroughly at hospitals with low risk -adjusted mortality than at hospitals with high risk-adjusted mortality? If so, does the variation in risk -adjusted mortality diminish when inter -hospital differences in risk factor coding are removed?

The completeness of risk factor reporting at hospitals with significantly highe r than expected mortality was compared to the completeness of reporting at hospitals with significantly lower than expected mortality and hospitals with not significantly different from expected mortality. Any difference across these three groups may part ially explain the observed variation in risk - adjusted mortality. In other words, hospitals that fail to code important risk factors may have unduly low *expected* mortality rates and unduly high *risk- adjusted* mortality rates.

QUESTION 4: How often do the c linical characteristics used as risk factors in Model B actually represent conditions that developed after admission?

Two different models, labeled A and B, were used to adjust for patient differences across hospitals. Model A was limited to demographic and clinical characteristics that were almost certainly present upon admission, whereas Model B included other factors that may reflect either health at admission or quality of care (e.g., hypotension, shock, pulmonary edema). In the validation study, abstractors recorded the date on which each diagnosis was first established and whether the diagnosis was documented in an emergency room or admission note. This information was used to determine the proportion of patients in whom that risk factor was actually present at admission.

This analysis will enable OSHPD to identify whether specific risk factors properly belong in Model A, or only in Model B. Some risk factors currently assigned to Model B may be present at admission so often that they can be safely included in both models. Conversely, some risk factors currently included in both models may represent hospital-acquired conditions so often that they should be relegated to Model B. In fact, this analysis may lead to the adoption of a single model that incorporates only the risk factors almost certainly present at admission. Finally, this analysis provides a preview of the likely impact of new legislatively established requirements that hospitals report whether each diagnosis was "present at admission."

QUESTION 5: How do the risk-adjustment models change when additional clinical variables are used as risk factors?

One of the most important shortcomings of hospital discharge data is that they do not include physiologic and functional predictors of patient outcomes. As a result, these predictors could not be used in estimating risk-adjusted hospital mortality rates. In response to the 1993 report and the preliminary draft of this report, many hospitals noted that the observed variation in mortality a cross hospitals may be explained by such omitted predictors as pre-hospital cardiac arrest, "do not resuscitate" status, ejection fraction, and initial vital signs. Through literature review and discussion with clinical advisors, OSHPD identified numerous potential predictors of AMI mortality that could not be ascertained from the hospital discharge data. In the validation study, specially trained nurse and physician abstractors reviewed all components of the medical record, including laboratory reports, radiology reports, and electrocardiograms, to collect these data.

OSHPD was then able to explore how the risk-adjustment models described in the *Technical Appendix* (Volume 2) of the 1993 report would be affected by using additional clinical variables as predictors. First, base models were constructed that included the 1993 risk factors. The coefficients for these risk factors were then reestimated using reabstracted ICD-9-CM codes. The resulting models represent the best potential of currently available data. The incremental contribution of additional clinical risk factors was then determined by adding these variables to the base models. The impact of including these clinical factors on other regression coefficients, a measure of confounding, was also examined. This process will help identify the most important

additional data elements that should be collected to improve the validity of OSHPD's AMI mortality reports.

QUESTION 6: Do hospitals with significantly higher or lower than expected mortality, appear closer to average after adjusting for additional clinical variables? How do the risk -adjusted mortality rates and p values for individual hospitals change when additional clinical variables are used as risk factors?

The risk -adjusted mortality r ates for specific hospitals were compared with the corresponding statistics calculated using risk -adjustment models that included additional physiologic predictors. Hospitals were categorized by their risk -adjusted mortality, as described in the next chap ter, so that the aggregate effect of adjusting for additional clinical risk factors on low -mortality and high -mortality hospitals could be estimated.

QUESTION 7: Do hospitals with low risk -adjusted mortality demonstrate better processes of care than hospi tals with high risk -adjusted mortality?

Through literature review and discussion with clinical advisors, numerous process factors that might be associated with mortality among AMI patients were identified. For example, there is ample evidence from random ized controlled trials that thrombolytics, given within 6 -12 hours after the onset of chest pain, reduce mortality among AMI patients. Aspirin, beta blockers, heparin, and emergent percutaneous angioplasty (PTCA) may also reduce mortality among selected p atients. If these therapies are used more frequently at low -mortality hospitals, then high -mortality hospitals might benefit by emulating these "best practices."