

# **Virtual Mentor**

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## **Policy forum**

### **Is it ethical to send patients to low-volume hospitals for cancer surgery?**

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Over the last decade, multiple studies have concluded that cancer patients may have better outcomes if their surgery is performed in high-volume rather than low-volume hospitals [1-6]. These findings have generated great interest in volume-outcome studies, not only in the medical literature but in the lay press. Specifically, patients frequently seek practical medical advice about how they should interpret volume-related data and whether they should seek care in high-volume centers. Appealing to hospital-based volume data, physicians sometimes think they have an ethical obligation to refer cancer patients to high-volume centers. In discerning whether such an obligation exists, one must understand both the hospital volume data and the related ethical issues.

#### **Understanding volume data**

Volume-outcome relationships constitute one measure by which an institution may be judged, but statistics generated by aggregating data from numerous centers are not informative about a specific institution. Outcomes measured for specific institutions are superior in value and appropriateness of application. Thus if a low-volume center demonstrates excellent outcomes, these data clearly trump simple volume data pertaining to the center. A large caseload is not necessarily indicative of optimal treatments or outcomes [7]; individual high-volume centers may have worse outcomes because they treat higher risk cases and, if they are teaching hospitals, more indigent patients. Small-volume hospitals may still provide excellent care and achieve excellent outcomes [8].

Most volume-related data are not surgeon-specific. This is a critical shortcoming, since the predicted outcomes for some procedures (e.g., hernia repair) are highly surgeon-dependent while predicted outcomes for others (e.g., renal transplantation) are highly hospital-dependent. Furthermore, most current data include outcome information only on patients who underwent surgery. Judgment, clinical expertise, experience and wisdom go into deciding which patients should and should not have surgery; this critical aspect of clinical decision making is not captured in surgery-based volume-outcome studies. Finally, the majority of volume-outcome data with the notable exception of cardiac surgery is not risk-adjusted, so volume-related data may reflect a select patient population—rather than true improved quality—at high volume centers.

Volume-related studies also have inherent statistical problems that can result in misleading conclusions and overly strong suggestions of association. For example, the standard deviation applicable to a single center's outcome data is dependent on its patient volume. Hence, the predicted outcome of a single low-volume center based on its own data will be associated with a greater standard deviation (e.g., variability) than that of a single higher-volume center. This higher standard deviation is often misinterpreted as "less certainty" or "more unpredictable"—terms with negative connotations.

A second statistical problem involves the potential clustering of patients within physician practices [9]. In other words, a few unusually outstanding physicians might achieve higher-than-mode-predicted outcomes that exaggerate the estimated difference in performance between "typical" high-volume and low-volume hospitals [9].

### **Ethical considerations**

Information on volume and outcome specifically following cancer surgery are derived from large administrative data sets designed to answer policy questions—not provide individual patient recommendations. In fact, it is estimated that the average gain from being treated at a high-volume versus low-volume hospital is actually quite small for the individual patient; rather, most volume-related benefits are realized at the population level [5]. Therefore, the ethical duty of physicians to refer a *specific* patient to a high-volume center for fear of a worse outcome at a low-volume center cannot be directly derived from the data. When a physician is balancing benefits and burdens, the relative improvement in outcome at a high-volume center must be weighed against the additional burdens of having to obtain care in that facility.

The term "outcome" should be carefully scrutinized and defined by the physician and, more importantly, by the patient. One person may decide that surviving the surgery is the most important outcome on which to base a decision, while another may reasonably conclude that cancer-free survival is most important. Others may consider results of satisfaction surveys or long-standing relationships with community medical personnel in their decision making.

Every individual will bring a different set of values to bear on the decision and will weigh pieces of data differently. The calculus of benefit versus burden therefore needs to be interpreted within the context of a specific clinical situation. We know, for example, that the benefits of high-volume centers are more pronounced with some operations (hepatectomy, pancreatectomy and esophagectomy) [1, 5, 6] and less clear in others (pneumonectomy, gastrectomy or ovarian cancer resection) [3, 5]. When discussing therapeutic options, it is appropriate to highlight the relative benefits of a higher-volume center for certain operations only. This may assist the patient in judging, on balance, the best decision in light of other personal considerations.

At times, the definition of a high-volume center is prohibitively restrictive, leaving most hospitals categorized as low volume. In one study, only 10 to 12 centers in the entire nation were defined as high volume for pancreatic or liver surgery [6]. In contrast, more than 1,000 centers were categorized as low volume. Such definitions of high-volume centers can be logically untenable and ethically problematic. Most patients do not have the resources (personal, travel or financial) to be treated in one of 10 or 15 high-volume centers in the entire country.

It would not be feasible, even if it were desirable, to refer all patients to high-volume institutions. The centralization of all cancer patients and resources in a handful of hospitals does not serve to improve quality of care for the entire population, nor does it help improve the outcomes at low-volume hospitals. A downward spiral of fewer and fewer cases at low-volume centers would ostensibly result in worse care for the few patients who, by choice or lack of choice, are treated at these institutions. Further, surgeons at low-volume hospitals would lose proficiency in related procedures. Rather than automatically referring all cancer patients to high-volume centers, physicians have an opportunity to focus on more than just volume and outcome data. We must strive to identify the specific elements of patient care in large-volume hospitals that lead to better outcome and then implement these elements in lower-volume centers.

### **Conclusion**

The ability to predict outcomes is limited to statements of probabilities. In contrast, the ethical responsibility of the physician is more contextual and grounded in the process of informed consent. Physicians should provide patients with knowledge—including the interpretation of aggregate volume-outcome and institution-specific data—that will help them make educated, well-informed decisions. Physicians should be able to discuss relative volume and outcome data that pertain to local, regional and national centers.

Ultimately referrals and recommendations should be based less on volume data and more on the physician's familiarity with a particular institution and confidence that it will deliver the best possible care for the specific patient. It is then the patient's responsibility to integrate these data with his or her own values, priorities, fears, anxieties and philosophy of life in reaching a decision about where to be treated. For example, it may not be unreasonable for a patient to select a doctor he knows and likes over another he dislikes, even if the latter doctor has a better outcomes record. This tradeoff is a balance that the physician needs to discuss with each patient to ensure that he or she understands how care may be affected. Physicians perform their ethical duty when they fully disclose all of the foreseeable risks, benefits and alternatives to proposed treatments so that whatever patients finally consent to or reject, their decision is truly informed. Finally, physicians should take the lead in measuring and providing relevant outcome data for their own practices.

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