

Regionalization for Quality: Certificate of Need and Licensure Standards by John Steen

"The pursuit of quality is, in essence, the moral dimension of professional life."

- Avedis Donabedian, MD

"The future belongs to whoever best measures quality of care and then markets it the best. Whoever does will absolutely control the market, and everyone who doesn't will disappear."

- Richard L. Scott, CEO, Columbia/HCA Healthcare Corp.

The pursuit of quality in health care begins with physicians and nurses, but encompasses also the social workers and other ancillary caregivers, planners, administrators, and regulators who play key roles in the pursuit. Institutional missions express commitments to providing health care of the highest quality to communities through the competence and dedication of the professionals serving them. Clearly, it is in the public interest to ensure that the health care delivered is of the highest quality.

While caregivers pursue quality to advance professional practice, and institutions pursue it to fulfill their missions, to compete with other institutions, and to survive, it is regulators who pursue it in the public interest. State health regulatory agencies which perform planning and licensing functions, judge the value of the state's health care services to state residents in terms of access, quality, and cost. In order to ensure the highest access and quality at the lowest cost, states establish standards for licensure and, where available, for certificate of need (CON) review of services.

Since CON was invented by New York State through legislation enacted in 1964 and 1965, state reviewers have always employed criteria addressing access, quality, and cost. The most effective way of doing so is through a State Health Plan which is developed through a public process which brings with it a consensus of public support for its goals and standards, and is continually updated to reflect the state-of-the-art in health care delivery. A State Health Plan is designed to be proactive in shaping its health care industry.

Most state health planning agencies regulate under a legislative mandate to ensure the orderly development of health care in their state. Furthermore, health care providers' revenues are the earnings of state residents, and should be intelligently used to best meet the health care needs of the state. Only a fully accountable public agency can be trusted to ensure equity in the use of those resources optimally to meet the needs of all state residents.

Utilization Volume and Outcomes

Regionalization of services has long been recognized as a uniquely cost-effective strategy for achieving better outcomes and lower costs. National Guidelines for Health Planning issued by the Federal government in 1985 specified minimum volumes necessary to maintain quality of care for four services: open heart surgery, cardiac catheterization, neonatal special care units,

and radiation therapy. Recent research has clearly demonstrated the value of high volumes for at least the following six services:

Coronary Artery Bypass Grafting

Coronary artery bypass grafting (CABG), or open-heart surgery in general, is regionalized in some, but not all states. For example, in New York, New Jersey, and Massachusetts, CON has limited the number of hospitals licensed for CABG. Ratios of one CABG facility per 600,000 residents are found in New York and New Jersey, and about one per 500,000 in Massachusetts (31, 13, and 12 facilities, respectively). In New York, a facility volume of 500 per year is the minimum for a new CON, and New York's CABG outcomes are the best in the nation. By contrast, California is without CON, and only about 26% of CABG operations in 1987-1989 took place in hospitals performing 500 or more per year. The mortality rate for California hospitals performing fewer than 100 was twice that of high volume California hospitals.(1) In Iowa, where CABG is not regionalized, one study determined that if optimal volume standards were applied, the 12 hospitals performing CABG in 1990 could be reduced to two.(2)

Cardiac Catheterization and Angioplasty

A study covering percutaneous coronary transluminal angioplasty (PTCA) in New York State for the years 1991-1994 demonstrates that patients in hospitals with annual volumes of less than 600 experienced a significantly higher risk-adjusted mortality rate. It found that both hospital volume and cardiologist volume are significantly inversely related to mortality and complications for PTCA.(3)

In March 1999, HCIA released its study entitled 100 Cardiovascular Hospitals which identifies the best performing hospitals in the nation for CABG and PTCA. It found that the 100 best hospitals for PTCA did twice the volume of PTCAs as their peers and cost 20% less. They were 50% less likely to escalate patients to a CABG, the major complication for a failed PTCA. There are many other peer-reviewed research studies documenting the relation between high volumes and lower (risk-adjusted) mortality, lower rates of complications, and lower costs for PTCA.(4) New York State considers an adequate procedure volume for cardiac catheterization laboratories to be 1,200 per year (1993), and will not grant a CON for a new lab unless all existing labs are performing a minimum of 1,200 procedures and the proposed lab can document its ability to achieve that minimum level in its third year of operation. The Iowa study found that optimal volume for catheterization would be realized if the 22 hospital facilities were reduced to two.

Pediatric Cardiac Surgery

A recent study examined clinical data related to all the children who underwent congenital heart surgery in New York State from 1992 to 1995 (7,169 cases). After adjusting for risk, it found that hospitals with annual pediatric cardiac surgery volumes of fewer than 100 had significantly higher mortality rates (8.26%) than hospitals with volumes of 100 or more (5.95%), and surgeons with annual volumes of fewer than 75 had significantly higher mortality rates (8.77%) than surgeons with annual volumes of 75 or more (5.90%).(5)

Neonatal Intensive Care Units (NICU)

After elimination of CON in California in 1987, there was a rapid, competition-driven increase in the number of intermediate level (II and II+) NICUs. One study examined all of the single births in non-federal hospitals in California in 1990 (473,209 births). It found that risk-adjusted neonatal mortality is much lower for births that occur in hospitals with large (average census, >15 patients per day) level III NICUs, and that those births even cost less. It concluded that the proliferation of NICUs has probably prevented neonatal mortality from being as low as it could be if births in urban areas were concentrated at a smaller number of hospitals that provided level III NICU care. Very provocatively, it also noted large differences in mortality across types of insurance, thus raising a new set of concerns about the effects of competition on outcomes.(6)

Trauma Care

A Pennsylvania study supports the regionalization of trauma care by affirming that greater volume per surgeon in the treatment of seriously injured patients is associated with improved outcomes.(7)

Organ Transplantation

One study looked at liver transplantation in the U.S. over a two-year period (1987-89; over 4,000 liver transplants in 68 facilities) to determine if greater experience in liver transplants decreases the probability of graft failure. It found evidence of a learning process resulting in improved outcomes, and concluded that CON regulation of liver transplants is appropriate.(8) A review of the literature on organ transplantation suggests that a relationship between volumes and outcomes exists.(9)

If there is a cautionary note regarding the multiple benefits of regionalizing such services as these six, it is to be found by considering patient preferences. One study shows that many patients prefer to undergo surgery locally even when travel to a regional center would result in lower operative mortality risk. This is true even with local risk of over twice the regional risk.(10)

Conclusion

These studies demonstrate the learning curve effect in medicine, particularly as it relates to surgery and intensive care. With greater volume comes greater experience and greater proficiency, resulting in better outcomes and lower costs. This effect is better observed in longitudinal studies of the same hospital over time than in cross-sectional studies of many different hospitals at one time.(11)

In most states, for most of these services, the conditions necessary to realize these benefits will exist only if the services are regionalized by state regulation. Classic market competition does not exist in health care. Indeed, hospitals compete with each other by acquiring the fullest set of services possible so as to appear more attractive to insurance companies and patients. Physicians too establish facilities to enhance their professional practice and their incomes. Where there is

capacity beyond need, there is also utilization beyond need. With regard to hospital beds, this is known as the "Roemer Effect:" the proposition that "a bed built is a bed filled."(12) Physician practice patterns still reflect this phenomenon of overutilization. It is not by accident that New York State has one of the lowest utilization rates in the nation for cardiac surgery, and the lowest rate of inappropriate cardiac surgery.

The public interest here requires that states seize the opportunity afforded by their regulatory authority to shape utilization of these key services. Licensure is a normative, not a descriptive process. It must establish the quality levels to be achieved by providers in order to assure that all services are state-of-art and best serve the public interest. It is thus that in 1998, New Jersey adopted regulations requiring each CABG hospital to assure that each of its surgeons perform a minimum of 100 bypass surgeries at the hospital by the year 2001. Licensure sanctions quality to the public, and professional practice to physicians. Physicians need volume to excel. In an initiative to market the quality of their services, a national network of cardiologists and cardiovascular surgeons has formed the National Cardiovascular Network (NCN). To become an NCN member, cardiac surgeons must be affiliated with a hospital or group practice that performs at least 500 CABG surgeries per year, and the surgeons must themselves perform at least 150 per year, each demonstrating a mortality rate of less than 5%. Interventional cardiologists must be affiliated with a catheterization laboratory which performs at least 500 angioplasties per year, and must themselves perform at least 150, each with a mortality rate of less than 1.5%. Where a state produces a State Health Plan, its Plan can be an instrument for educating its public about quality in health care. New York State took the further step of producing an annual "report card" for CABG surgery.

The state collects and analyzes clinical data from all 31 of its hospitals and reports its findings back to those hospitals in order to stimulate continuous quality improvement efforts. The state also publishes the risk-adjusted operative mortality data by hospital and surgeon, motivating performance improvement through peer pressure. This quality improvement program is now in its 11th year, and has resulted in many hospitals restricting the operating privileges of low-volume surgeons, some triaging high-risk patients to surgeons with greater skill for those circumstances, and some finding specific processes of care that need improvement. In the first five years of the program, the state's CABG mortality rate declined by almost 50%, and New York State has the lowest mortality rate for CABG surgery in the nation.

Today, New York State is the only state in which it has been demonstrated that there is no longer a correlation between hospital CABG volume and in-hospital mortality. This is a consequence of the strict CON-regulated regionalization which maintains a high volume in all hospitals, and the quality improvement program which fine-tunes all surgical programs and assigns patients to the most appropriate surgical teams.(13)

However, another study demonstrates that Massachusetts, without statewide outcome reporting, nevertheless experienced reductions in risk-adjusted mortality for CABG during the same period of time which are comparable to New York's, without, however, achieving quite so low a level. This suggests that the progress of the state-of-the-art among cardiac surgeons is chiefly responsible for improvements, and that the high volumes achieved through regionalization are more essential.(14)

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