EXPERIENCE EXCHANGE

Volume-based credentialing: Practical steps to promote high quality, safe care

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ABSTRACT

All hospitals engage in credentialing to evaluate the qualifications of practitioners who request clinical privileges. Credentialing always includes verifying an applicant's education, training, licensure and board certification, and evaluating information provided by references who have worked with the applicant. Far fewer hospitals consider whether a practitioner's volume of cases is sufficient to demonstrate proficiency in a specialty area. This is surprising, given the well-established relationship in the medical literature between volume and proficiency. The authors identified several reasons for hospitals' reluctance to use volume-based credentialing. These include the fear of lawsuits by physicians and the practical difficulties of satisfying volume requirements in smaller hospitals with fewer patients. The authors conclude that legal challenges to volume-based credentialing are unlikely to be successful and that techniques exist to enable small hospitals to use volume-based credentialing to promote high quality and safe care.

Key Words: Volume, Credentialing, Privileging

1. INTRODUCTION

Hospitals in the United States have a legal duty to ensure that only qualified practitioners treat patients. The rationale for this legal duty is to ensure that patients receive high quality, safe care. Hospitals that fail to use reasonable credentialing procedures can be liable to patients under the legal doctrines of negligent credentialing or corporate negligence.

The use of volume requirements in credentialing can help hospitals satisfy this legal duty and promote high-quality care. Under this approach, practitioners must perform a defined number of procedures, interpret a certain number of images or tests, or treat a certain number of patients with a given condition or in a given specialized setting (e.g., the Intensive Care Unit) to remain eligible for privileges. Volume requirements can be satisfied based on activity at the hospital where the practitioner is applying, at another hospital that is part of the same health system, or at any other hospital.

There are several obstacles to volume-based credentialing. One is the fear of lawsuits by affected practitioners. Another is a lack of widely-accepted volume standards in some specialties, while a third is the lack of cases needed to satisfy volume requirements in small hospitals.

This article begins by discussing legal issues related to the adoption of a volume-based credentialing process. It then describes the benefits of volume-based requirements and the practical steps hospitals may take to implement such an approach.

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2. Legal obligation for hospitals to have an effective credentialing process

2.1 Federal and state regulations governing credentialing

Hospitals in the United States have a duty under federal and state statutes and regulations to evaluate the qualifications of practitioners who seek clinical privileges. This obligation is found in the Medicare Conditions of Participation ("CoPs") for acute care[1] and critical access hospitals ("CAHs"),[2] as well as state hospital licensing regulations. Entities that accredit hospitals (such as the Joint Commission and DNV) also require hospitals to have a robust credentialing process.

2.2 Doctrine of negligent credentialing

In addition to federal and state statutes and regulations, state courts across the United States have ruled that a hospital can be liable to patients for negligent credentialing or corporate negligence if the hospital "fails to abide by the specialized standard of care and industry guidelines, which govern the credentialing process for medical staff".[3] A substantial majority of states recognize negligent credentialing as a viable claim.[4]

Courts have accepted this cause of action on policy grounds, noting that patient harm is foreseeable when hospitals fail to adequately screen physicians' qualifications and that hospitals are in a "superior position to monitor and control physician performance".[5]

The Pennsylvania Supreme Court described the doctrine of negligent credentialing as follows:

[I]f a hospital fails to keep an incompetent doctor from practicing within its walls, and a patient suffers harm as a result, the patient may have a cause of action in corporate liability against the hospital. In that instance, the focus of the action is not the negligence of the doctor, but the negligence of the hospital.[6]

3. Legal support for using volume-based criteria to avoid negligent credentialing

Few judicial opinions specifically address the use of volume requirements in credentialing. However, existing guidance indicates practitioners would be unlikely to succeed in a lawsuit against a hospital that adopted volume requirements as a legitimate part of its credentialing process.

In Yatco v. Nanticoke Mem. Hosp,[7] a hospital opted to stop offering carotid endarterectomies ("CEAs") because the governing board determined that volumes were too low to maintain the competence of staff. Dr. Yatco sued, claiming that the hospital's decision to stop performing CEAs was really a revocation of his privileges and that he had not been afforded due process under the Medical Staff bylaws. The court rejected his claim and stated:

The undisputed record supports [the hospital's] argument that it did not deny surgical privileges to Dr. Yatco but instead made a decision in the exercise of its Board's business judgment to discontinue the performance of CEA procedures at the hospital until such time as the number of procedures to be performed would justify the resources necessary to train staff competently to perform the procedure. Dr. Yatco has no legal basis or standing to challenge this business decision, through a breach of contract claim, bad faith claim or otherwise.

In Kerth v. Hamot Health Foundation,[8] a hospital required cardiac surgeons to perform at least 100 open heart surgeries per year, with 25 as the primary surgeon, to maintain their privileges. As the court noted, "[t]he stated purpose of the volume requirement was to ensure that surgeons participated in enough procedures to maintain their technical proficiency. The rule was supported by contemporary studies linking volume and lower mortality rates."

Two cardiovascular surgeons brought a lawsuit alleging antitrust violations against the hospital and a competing group after the surgeons' privileges were revoked for failure to meet the volume requirements. The surgeons did not attempt to argue that it was improper for the hospital to adopt the volume requirements. Instead, the surgeons argued that the hospital had selectively enforced those volume requirements in a manner adverse to them. The court rejected the surgeons' claims.

Courts have examined volume requirements in other contexts, such as government-imposed minimum volume requirements as a prerequisite for the issuance of certificates of need for hospital programs. For example, in Medstar Health v. Maryland Health Care Commn, the Maryland Health Care Commission decided that "it was generally preferable, as a matter of public policy, to support a small number of high-volume cardiac surgery programs than a large number of lower volume programs."[9] As part of the state's health care regulatory scheme, the Commission adopted a requirement that there should be a minimum of 200 open heart surgery procedures performed annually in any institution in which open heart surgery is performed for adult patients.

The court recognized the "well illustrated" concern about the effect of volume requirements on "accessibility and cost of having only a 'very small number' of programs in a populous area". However, the court nonetheless upheld the Commission's volume requirement on the grounds that the applicable

statute required the Commission to adopt standards that "address the availability, cost, and quality of health care". The Court reasoned as follows:

[The Commission] has determined, based on voluminous medical evidence, that programs consistently performing fewer than 200 open heart procedures a year do not constitute high quality programs, and that, where that deficiency exists, it is empowered to consider whether a new program, capable of performing the minimum number of procedures, should be authorized. As we have indicated, the Commission may not actually authorize a new program unless it is assured from the evidence presented in support of the application that the population in the Region will be benefitted in terms of access, quality, and cost. The regulation is fully consistent with the statutory mandate.

Finally, a Florida regulation offers further support for volume-based credentialing.[10] The regulation states:

The providers of Level I adult cardiovascular services shall develop internal review processes to assess interventional cardiologists performing less than the required annual volume. Low volume operators must be evaluated and confirmed by an independent institutional committee consisting of physicians and other healthcare personnel as selected by the hospital, or an external review organization. Factors that shall be considered in assessing operator competence include operator volume, lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.

4. Examples of hospitals using volume to improve quality

In 2015, three large health systems – Dartmouth Hitchcock Medical Center, the Johns Hopkins Hospital and Health System, and the University of Michigan Health System – adopted the Volume Pledge. Under this program, certain surgical procedures would only be performed if both the surgeon and hospital satisfied certain volume requirements.[11] Through the Volume Pledge, these facilities agreed to direct surgical care to facilities that meet the thresholds. The annual volume thresholds range from 10 per hospital and five per surgeon for carotid stenting to 50 per hospital and 25 per surgeon for hip and knee replacement.[12]

Each health system has taken a different approach to implementing the Volume Pledge.[13] Dartmouth-Hitchcock Medical Center implements the Volume Pledge by internally shifting procedures among facilities and monitoring surgeon volumes as part of the privileging process. If surgeons fall below the minimum thresholds, they either reconfigure their practices to meet the thresholds or participate in further training. Rather than focusing on volume-based credentialing, Johns Hopkins conducts professional practice evaluations with monthly case reviews and morbidity and mortality outbriefs to satisfy the Volume Pledge. The University of Michigan Health System uses surgeon attestation in the privileging process to confirm minimum volume requirements.

Other major U.S. health care institutions, including Kaiser Permanente and Mayo Clinic, declined to take the Volume Pledge. However, these institutions implemented data-driven, volume-conscious policies in an effort to improve quality. In 2018, Kaiser Permanente conducted a study that evaluated surgeon volume and patient outcomes.[14] The results did not identify exact volume thresholds; rather, the data was used as a foundation for developing a more nuanced approach to surgical volume. Kaiser addresses low volume through peer review, simulation, review of surgical techniques using video recordings, and by balancing the distribution of complex cases to low and high-volume hospitals.

The Mayo Clinic developed a surgeon trade program to address lack of volume at smaller facilities.[14] The surgeon trade program involves low-volume surgeons rotating to high-volume facilities to perform surgery and provide pre- and post-operative care for approximately one to two weeks. The program has garnered positive reactions from surgeons, and the Defense Health Board recommended that the Department of Defense implement a similar rotation system to help rural military surgeons maintain their skills.

To summarize, volume-based credentialing and volume-conscious policies are supported by various legal authorities. As noted in the next section, volume-based credentialing is also supported by research in the medical literature.

5. Medical literature and the relationship between volume and quality

Numerous articles in the medical literature have found a correlation between physician and hospital volume and patient outcomes. The Leapfrog Group ("Leapfrog") — a non-profit organization that collects and reports data on inpatient hospital care – observes that:

Three decades of research have consistently demonstrated that patients that have their high-risk surgery at a hospital and by a surgeon that have more experience with the procedure have better outcomes, including lower mortality rates, lower complication rates, and a shorter length of stay than for patients who have their surgery done at a hospital or by a surgeon with less experience.[16]

A recent article described two of these studies:

The nature of the volume-outcomes relationship was demonstrated in 2 seminal studies [from 2002 and 2003] by Birkmeyer and colleagues. In the first report of 2.5 million Medicare beneficiaries, the investigators demonstrated that mortality decreased with increasing hospital volume for all 14 cardiovascular and oncologic procedures studied. For example, operative mortality declined from 16% at hospitals that performed the lowest number of pancreatic resections to 4% at the highest volume centers. In a follow-up study, the investigators demonstrated a similar relationship between higher surgeon volume and reduced mortality. In this study mortality for pancreatic resection was 15% for low volume surgeons compared with 5% for high volume surgeons. The relative importance of surgeon versus hospital volume was found to vary by procedure.[16]

The relationship between volume and quality also exists for non-surgical care. For example, treatment of AIDS was found to have one of the strongest associations between volume and outcome.[17]

Research also suggests that volume in one procedure can promote quality outcomes in related procedures.[18] Thus, hospitals can consider volume for bundles of procedures in assessing a practitioner's qualifications. This is important for small, low-volume hospitals.

Other studies have found that the relationship between volume and quality is affected by other factors. For example, one study found that although a "critical number of admissions" is necessary to maintain skills, the experience level of the entire neonatal team was equally as important in delivering optimal neonatal care.[9] Also, adequate support services and hospital processes affect patient outcomes.[14] Indeed, the Defense Health Board acknowledged these issues in declining to recommend that rural military hospitals adopt rigid volume requirements due to the concerns that minimum thresholds could be arbitrary.[14] The Defense Health Board also criticized the Volume Pledge as neglecting "to acknowledge the team, including a second or third surgeon who may be supporting the procedure" and other quality initiatives that go beyond volume which "have vastly improved since the early 1900s, when volume first emerged as a proxy for quality."[14]

6. Best practices for using volume-based criteria in credentialing

6.1 Adopt volume requirements to the extent feasible

Volume requirements in credentialing can help to promote quality care. They can also be part of a larger effort to transform hospitals into high reliability organizations ("HROs"). As noted in one article, "toughen[ing] up credentialing and re-credentialing processes" is a key step for hospitals wishing to become HROs.[20]

Accordingly, the authors recommend that volume requirements be incorporated into the credentialing process to the extent feasible. While volume requirements are more common for surgical and other invasive procedures, they can also be used for the care of non-surgical patients. Volume requirements can also be used for the interpretation of radiology, cardiology, and other images and tests, as well as for the care of patients in the Emergency Department, Intensive Care Unit, and other clinical settings.

6.2 Process for adopting volume requirements

Volume recommendations are available from various sources. These include specialty society publications, organizations such as Leapfrog, articles in the medical literature, and private organizations that publish Clinical Privilege White Papers and similar documents.

A careful, transparent process should be used to evaluate recommendations from such sources and determine which are feasible for a hospital or health system. Practitioners should be informed that volume requirements are being considered and should be given an opportunity to provide input prior to their adoption. In particular, specialists should be asked to comment on proposed volume requirements affecting their specialty. Volume requirements would then be approved by the Medical Executive Committee and Board of Directors as part of the Clinical Privilege Request Forms ("CPRF") (otherwise known as a Delineation of Privileges ("DOP")) at the hospital.

Hospitals that are part of a health system could pool their resources and develop joint working groups for specialties to study volume requirements in that specialty. This collaborative approach would help to ensure consistency among the DOPs/CPRFs that are approved at each system hospital. The system should also adopt a process by which proposed changes to the DOP/CPRF at any system hospital are reviewed by a joint working group and presented to each hospital. This approach will help to ensure that a single standard of care applies across the system.

6.3 Options for low volume hospitals

In some instances, it may not be practical for all practitioners to satisfy volume requirements that are recommended in the literature because there are not enough cases at the hospital. Hospitals have several options to address this common problem.

First, the physician might be able to obtain the necessary volume at another facility. For example, if the hospital is part

of a health system it might be able to adopt a surgeon trade program similar to the Mayo Clinic program described above. Alternatively, a physician might perform per diem or locum tenens work periodically at a higher-volume, higher-acuity hospital to achieve the same outcome.

Second, the hospital could choose to not adopt volume requirements recommended in the literature and not require any privilege-specific alternative means to ensure competence. Instead, the hospital would rely on traditional credentialing to evaluate a practitioner's competence (e.g., by considering a practitioner's general training and experience). This approach requires the hospital to consider the risk of allowing practitioners to exercise privileges for which they may lack direct experience and for which no other special efforts to assure competence have been made.

Another option is for the hospital to no longer offer a certain procedure if it is not performed frequently enough to ensure that practitioners remain proficient. While access to care is important, for certain activities the risk of permitting a practitioner to perform the activity infrequently is too great. Promoting access to care can never be an excuse to grant privileges to an unqualified practitioner.

Finally, the hospital could adopt volume requirements but use alternative means of ensuring competence for practitioners who are unable to obtain sufficient volume. For example, it may be possible to identify bundles of privileges for which volume in one privilege counts toward the volume requirements for all privileges in the bundle. Or practitioners could be required to complete periodic training as a substitute for engaging in a certain clinical activity. The goal would be for the sum of the practitioner's activities – whatever the combinations may be – to demonstrate competence. The next two subsections describe these alternative means of ensuring competence in more detail.

6.3.1 *Identifying bundles of procedures with similar characteristics may help to make volume requirements feasible for low volume hospitals*

A recent article found that higher surgical volume of pancreaticoduodenectomies was associated with better outcomes.[21] However, the article also noted that "[f]or groups of moderate volume surgeons (3-5 and 6-11 cases per year), higher [volumes of related procedures] was associated with better outcomes for pancreaticoduodenectomy." This finding further suggests that skills in one procedure are transferable to other, similar procedures.

Importantly, for surgeons who performed two or fewer procedures per year, higher volume of related procedures was not enough to overcome the lack of experience with pancreaticoduodenectomies. This finding supports the common-sense notion that volume in related procedures can be useful but is not enough on its own for a practitioner to maintain competence in the target procedure.

Another study "confirmed prior studies demonstrating that a high-volume experience with esophagectomy improves mortality rates for that operation, compared with surgeons with a low-volume experience."[18] However, the study also found that experience with related or surrogate procedures could help to overcome low volume with esophagectomies. The authors concluded that "a high-volume experience with related upper gastrointestinal operations is an adequate surrogate for surgeons with a low-volume experience with esophagectomy."

These studies are particularly important for small hospitals. While a lack of patients may make it impossible for small hospitals to satisfy standard volume requirements, it may be possible to identify bundles of privileges in which any procedure in the bundle goes toward satisfying the volume requirement and confirming competence.

The use of bundles is similar to the idea of identifying core privileges in a specialty and stating that activity in one area of the core satisfies volume requirements for the core generally.[22] The thought is that privileges in the core share a common denominator of skills, so activity in one area contributes to proficiency in other areas.

Privileges that require unique skills can be moved out of the core and deemed special privileges with separate volume requirements. However, the concept of bundling can still apply. For example, a set of three procedures may be so different from the core that they require separate volume requirements, but they may be similar enough to one another so that activity in any one of these three special privileges will satisfy volume requirements for the other special privileges.

A related point is that when privileges are performed by practitioners from multiple specialties, volume requirements should be considered in the context of the practitioner's specialty. For example, a specialist with significant experience in procedures that are very similar to a certain privilege may need less volume than another specialist who has no experience with such related procedures.

6.3.2 *If volume requirements are adopted, hospitals can identify alternative means of demonstrating and maintaining competence and improving outcomes for low volume practitioners*

If hospitals adopt a volume requirement for a privilege and a practitioner is unable to meet that requirement, one option is for the hospital to view the practitioner as ineligible for the

requested privileges. A determination of ineligibility would not require a Medical Staff hearing. It would also not require a report to the National Practitioner Data Bank ("NPDB") or to any state government agency.[23]

Another option would be for the hospital to adopt alternative means to ensure the practitioner is competent despite not satisfying the volume requirement. Essentially, the practitioner would be granted a waiver of some or all of the volume requirement conditioned upon the practitioner taking other actions to ensure competence.

For example, hospitals could use simulation, video recordings, and other forms of additional training to help practitioners demonstrate and maintain competence for privileges for which they do not meet volume requirements. If a hospital is too small to have its own simulation lab, practitioners could participate in simulation lab training at larger hospitals or academic medical centers. Also, vendors offer various products that could be used on the hospital premises. As technology advances more training options are available online. Rural hospitals should consider whether simulation and other virtual training options could help maintain the skill set of low-volume surgeons. Hospitals could also develop their own training programs where practitioners maintain competence through case reviews, grand rounds and similar learning opportunities.

The Clinical Privilege Request Form or Delineation of Privileges form (which should outline any volume requirements) could also include a catch-all exception that would allow the Credentials Committee and MEC to recommend a waiver of the volume requirement based on some other unique experience.

The rationale for granting an exception for a particular practitioner should be carefully explained in the minutes of the Credentials Committee. The practitioner's file should also include documentation related to the exception. This may include the practitioner's request and explanation as to why an exception is merited along with correspondence from the hospital notifying the practitioner of the results. Such documentation would be essential in defending against claims of favoritism or discrimination, and in showing regulators there was a sound reason for departing from volume requirements in a given case.

Also, any grant of a waiver should include the monitoring that will be used to evaluate the practitioner's performance of the privilege. Second opinions, concurrent proctoring, and focused prospective monitoring may be used to confirm competence in such situations.

Finally, waivers of volume requirements should also include the number of cases for which the monitoring will occur. If a privilege is exercised very infrequently, the monitoring may be for every case and may last indefinitely.

The goal of these recommendations for the CPRF/DOP is to establish a binding requirement for those seeking privileges while also giving the hospital flexibility through a waiver process to promote access to high quality, safe care. Such language would also help protect the hospital and the practitioner if there is ever a lawsuit questioning why volume based standards were not required for or applied to a certain practitioner.

Another way to improve outcomes for low volume procedures is to improve all other aspects of patient care. While these issues are beyond the scope of this article, outcomes for certain procedures may be improved by increasing nurse ratios, obtaining telemedicine support, designing immediate feedback loops, offering additional training to nurses and other staff, or by acquiring equipment or other technology that helps staff do their jobs.

6.4 Adopting lower volume standards than recommended in the literature

Smaller hospitals with low patient volume may choose to adopt volume requirements for a procedure that are lower than what is recommended by specialty societies or in the medical literature. This approach would still provide some benefit in terms of ensuring competence, but may lead a plaintiff's attorney to question why the recommendation of the specialty society or in the medical literature wasn't followed. As discussed in the prior subsection, hospitals could mitigate their risk in such situations by carefully documenting the alternative means they will use to ensure practitioner competence and improve outcomes.

Of course, hospitals must ensure that the alternative means of ensuring competence are effectively implemented. For example, hospitals may wish to require practitioners to submit proof of completion of training programs to the Credentials Committee for review during the reappointment process.

Also, while ongoing peer review is important for all practitioners, it is particularly important if a hospital uses lower volume requirements than recommended in the medical literature or used at other similar hospitals. Hospitals should closely monitor the outcomes of such cases to demonstrate the effectiveness of the lower volume requirements. Hospitals should also carefully document the process that is used to confirm competence in such situations, such as second opinions, concurrent proctoring, and focused prospective monitoring. This monitoring should be tied to the number of cases performed rather than a defined time period, so the

duration of the monitoring will vary based on how frequently the privilege is exercised.

7. Conclusion

Numerous articles in the medical literature have found a link between a practitioner's volume and patient outcomes. Recent research also suggests that volume in bundles of related procedures is associated with better outcomes. Adding volume requirements to the credentialing process can help hospitals to provide safe, high-quality care. Smaller hospitals with low patient volumes may still benefit from volume based credentialing for at least certain procedures. Alternative approaches to ensuring competence (such as simulation or other forms of training) may be used to supplement volume requirements.

Conflicts of Interest Disclosure

The authors declare they have no conflicts of interest.

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