Summary of the Evidence Volume-Outcome Relationship in Pediatric Surgery Full Report

Final Version

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Prepared by Gillian Hanley,
BSc, MA, PhD, Postdoctoral Fellow, UBC

Child Health BC
4088 Cambie Street, Suite 305
Vancouver BC, V5Z 2X8
T: (604) 877 6410
F: (604) 874 8702
www.childhealthbc.ca
info@childhealthbc.ca

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Contents

Targeted questions 1
Anesthesia 2
Surgery 3
Trauma 5
Oncology 6
Nursing and other healthcare services 7
Guidelines from the United States 8
Recommendations from England 9
Challenges with respect to setting minimum thresholds 10
Summary 11
References 12

Targeted questions

1. What does the literature tell us about the relationship between pediatric case volumes and outcomes (mortality, morbidity, cardiac arrests, infection rates, pain management, readmission rates, etc.)?
2. Is there anything in the literature to suggest minimum facility and/or provider volumes to maintain competence in pediatric surgery/anesthesia/nursing?

There is a considerable amount of literature on the topic of case volumes both at the level of the health care provider and the institution. While a significant amount of this literature focuses on adults,[1] there is also a wealth of pediatric information. I have focused on reporting and summarizing the information from the pediatric literature. However, it is important to note that this literature is primarily health services research, often uses retrospective administrative data for analyses, and is of varying quality. There is no randomized controlled trial information, and I did not encounter any literature that was able to take advantage of natural experiments. While studies often compare children treated by pediatric anesthetists/surgeons/pediatric trauma centres with those treated by clinicians who primarily practice on adults, there was often a lack of controlling for other possible confounding factors, and a suggestion that there could be some important differences between these two groups of patients. Thus, the evidence is not always of highest quality.

There are several different areas that this literature covers. While there is obviously some overlap (e.g. optimal surgical outcomes rely on good anesthesia outcomes and high quality pediatric nursing care), I have tried to break it down into several different areas of health care. I will briefly review some evidence regarding case volumes and anesthesia, surgery, trauma, oncology, and nursing other ancillary services. I will then report on some of what has been done to address these issues in the United States and England. Finally I will briefly report on what the literature had to say regarding the challenges of setting achievable, meaningful minimum thresholds.

Anesthesia

Reason for concern

There is a substantial amount of evidence indicating that anesthesia is more complex in younger patients—anesthetic complications increase as age decreases.[2-4] Relative to adults, there is a higher incidence of cardiac arrest and death in pediatric patients undergoing anesthesia[2, 5-7]—both bradycardia and pediatric respiratory adverse events (PRAE) are more likely to occur in children. [3, 6] While Morray et al. originally concluded that medical-related problems were the most frequent cause of anesthesia-related cardiac arrests in children between 1994 and 1997,[3] an update of their research suggested that, due to the declining use of halothane (a type of general anesthetic), this was no longer the case in 1998-2003.[8] Instead cardiovascular causes (41% of all arrests) followed by respiratory causes (approx 20%) were the most common cause of cardiac arrests. [8]

The concerns regarding the safety of anesthesia increase, as the age of the child decreases. Morray et al. reported that 55% of all anesthesia-related cardiac arrests occurred in children younger than 1 year of age. The incidence of complications in infants (less than 1 year) has been reported to be nine times greater than children aged less than 15 years.[9] Malpractice claims also suggest that mortality is greater in pediatric claims compared to adult claims and that, in these cases, anesthetic care is more often judged to be less appropriate.[10]

Pediatric specialization of the anesthetist is important for reducing risk

The literature reporting on the relationship between volumes of anesthetics in children and outcomes is old and generally not of very high quality. In 1991, Keenen et al. found a significant increase in major complications for infants who were anesthetized by non-pediatric anesthesiologists.[11] Research has shown that complications, such as bradycardia and PRAEs, are less likely when the anesthesiologist is a member of the pediatric anesthesia service or commonly anesthetizes children.[2, 6, 12, 13] In fact, bradycardia is less likely in the presence of a pediatric anesthesiologist, even if they are not the primary anesthesiologist. [6] This specialization effect appears to be even more important for particularly challenging operations (e.g. ENT surgeries).[2]

Stoddart identified that a major problem of occasional pediatric anesthetic practice is for the anesthetist to remain up to date with their skills.[14] After a national quality assurance study based on voluntary reporting of 20,247 surgical and anesthesia related deaths (417 of which occurred in children under 10 years of age) raised concerns about the absence of skilled pediatric anesthetists in some surgical specialty units, and the questionable clinical competence of locum appointees who provided care for children, investigators in England recommended that surgeons and anesthesiologists not do occasional pediatric cases since "the outcome of surgery and anesthesia in children is related to the experience of the clinicians involved".[15, 16]

Minimum case loads in anesthesia
Auroy et al. reported a relationship between the number of anesthetic complications and the volume of pediatric anesthetics administered per year; however, this was based on a postal survey of anesthetists who were remembering complications in the past year of practice. They recommended a minimum case load of 200 pediatric anesthetics per provider per year to reduce the incidence of complications.[17] While this is a specific numeric recommendation, others have suggested that setting a minimum case load volume is complicated and the exact number is not easy to define and to apply for all pediatric procedures despite the clear inverse relationship between complications of pediatric anesthesia and volume performed.[14] Potentially recognizing the complexity of setting a specific number, it has been suggested that each hospital have jurisdiction over setting their own minimum thresholds. The suggestion is that each hospital that conducts both adult and pediatric anesthesia care produce a policy statement that identifies pediatric operative procedures that require anesthesia on an elective and emergent basis, and then indicate a minimum number of cases required in each category for the facility to maintain its clinical competence in providing anesthesia care. They recommend that the categories include patient age, procedure for which postoperative intensive care is anticipated, and patients with special anesthesia risks on the basis of coexisting medical conditions. [18] England has recommended that anesthetists work with more than 100 children between the ages of 0 and 12 annually. [19]

Surgery

There appears to be little disagreement that all neonatal surgical admission should occur in neonatal surgical centers.[20-25] The research literature consistently reports that operative surgery in children differs in many ways from that in adults, including access and management of the airway, handling of tissue, attention to fluid balance and incision and wound closure.[19] However, there does appear to be some distinction between children over and under the age of 8. Professional recommendations from England state that surgeons with an expertise in adults can undertake common and minor planned surgery on children over the age of 8.[26] Research evidence has also suggested that relationships between volume and outcomes disappear in older children.[27]

Previous studies have documented a relationship between center volume and outcome in children undergoing a variety of surgical procedures including liver transplant, appendectomy, pyloromyotomy, and heart surgery.[28-34] A systematic review of 2 representative conditions, appendicitis (which is a surgery also performed on adults and thus often assumed acceptable for general surgeons to perform on children) and infantile hypertrophic pyloric stenosis (a condition limited to children, thus suggesting that additional training may be required and centralized treatment may be necessary), suggested that specialty of the surgeon and volume matter.[35] Specialist surgeons and high-volume centers were more accurate in diagnosing appendicitis and complication rates for pyloric stenosis differed between specialty, surgeon volume, hospital type and hospital volume. They concluded that surgical volume was the best indicator of operative outcomes for pyloric stenosis.[35] However, again the threshold of minimum numbers of cases was difficult to pinpoint . One study reported that general surgeons with higher operative volumes than 4 cases per year had comparable results to pediatric surgeons.[36]

Surgeon characteristics were more important than hospital type, although access to a children's unit was an important factor; general hospitals had poorer results than specialist children's hospitals, unless the general hospital had a children's unit[37, 38] Pediatric surgeons generally treated more complex cases and were more likely to treat younger and transferred patients who may be likely to be sicker and more complicated to manage. One study that stratified patients by age reported that there was a significant difference in appendectomy outcomes only up to age 13 years. [27]

A Canadian study of inguinal hernia repair, the most common operation performed in children, examined whether there were differences in outcomes when the procedure was performed by subspecialist pediatric surgeons compared with general surgeons. They found that general surgeons performed half of all pediatric inguinal hernia repairs in the province of Ontario between 1993 and 2000. The younger the child, the more likely the surgery was performed by a pediatric surgeon. The rate of recurrent inguinal hernia was higher in the general surgeon group compared with pediatric surgeons. Among pediatric surgeons, the estimated risk of hernia recurrence was independent of surgical volume, but high volume was associated with a lower risk of recurrence among general surgeons. The highest volume general surgeons achieved recurrence rates that were no different than the pediatric surgeons. [39]

A similar relationship has been reported with respect to hospital volume and pediatric cardiac surgery. Jenkins et al. first demonstrated that, for children with a congenital heart defect who underwent surgery, the risk of dying in hospital was much lower if the surgery was performed at an institution performing >300 cases annually.[40] An update of this study revealed that hospitals with annual pediatric cardiac surgery volumes of less than 100 had significantly higher mortality rates (8.26%) than hospital with volumes of 100 or more (5.95%). This updated study was also able to show that this relationship extended to surgeons, demonstrating that 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%). [33] A relationship between institutional volume and specific forms of pediatric cardiac surgery (Norwood procedure) has also been reported. [34]

Exploring the causes of the differences in outcomes

A study that attempted to examine some of the potential mediating factors in the relationship between center volume and outcomes in children undergoing heart surgery reported that the higher mortality at lower volume centers may be related to a higher rate of mortality in those with postoperative complications, rather than a higher rate of complications. [41]

Other work attempting to explain some of the differences in outcomes between high and low-volume centers have shown that patients in specialist centers were more likely to be operated on laparoscopically,[42] and to use different methods of the same surgical technique (e.g. Ramstedt pyloromyotomy).[43] Postoperative antibiotic regimes and other aspects of care pathways could also be explored. A recent article considered the presence of trainees as a possible source of different outcomes. They compared outcomes following appendectomy between teaching and non-teaching hospitals. The authors concluded that outcomes were similar between institutions, and a follow-up study revealed that postoperative morbidity among children with perforated appendices was lower at teaching hospitals. [44, 45]

Minimum case loads in surgery

With respect to neonatal surgery some have recommended that a specialist centre should see about 100 new neonatal surgical cases a year and a minimum of 60 cases to remain a viable centre.[46] However, it's not clear how that number was chosen. Because neonatal surgery makes use of complex and expensive techniques and technologies, these are best concentrated at a single regional site so that expertise and experience can be gathered by both specialist surgeons and intensivists.[46]

It is not clear whether minimum annual caseloads should exist for specific conditions or whether minimum numbers of operations on children is most important. There is some evidence suggesting that operating on children is the most important factor and not minimum numbers of caseloads for a specific condition as some research has showed that pediatric surgeons performing pancreaticoduodenectomies achieved good results despite very low numbers of operations.[47] For appendicitis and pyloromyotomy, Evans et al concluded that general surgeons working in general hospitals who expect to see more than 4 cases per year should achieve the same outcomes as specialists in tertiary centers, as long as appropriate pediatric anesthetic and medical care is available.[35]

In England, they have suggested that a surgeon working in the larger specialties (general, orthopedic, or ear, nose and throat surgery) should complete the equivalent of 100 cases with children each year, in order to maintain their skills to carry out planned work on younger children (children under the age of 8). [48, 49] They go on to state that if a surgeon carrying out planned surgery on children works with fewer than 100 children a year, their trust should find out the age of the children and assure itself that the surgeon is operating within their abilities. [19]

Trauma

Traumatic injuries are the most common cause of death in children aged 1 to 16 years.[50]There are fundamental anatomical and physiological differences that mean that children should not be considered small adults and the management of certain injuries should differ significantly between children and adults. [46] For example, non-operative management of blunt abdominal trauma in children is best practice. Specialist units proved that splenic rupture can be treated either without surgery or with splenic repair rather than removal of the organ.[51-53] Other injuries have also been shown to have different management and outcomes in children, including burns,[54] and pelvic frature. [55]

However, there appears to be some controversy regarding whether childhood trauma can be equally well treated in adult centers. Some researchers have suggested that pediatric trauma centers (PTC) or adult trauma centers (ATC) with additional pediatric qualifications have better outcomes than adult trauma centers.[56, 57] However, others have failed to report such a relationship. [58, 59] While controversy remains, the data suggest that PTCs are more successful in non-operative treatment of blunt abdominal injuries.[56, 60, 61] Research has also shown that pediatric surgeons are more likely to treat splenic trauma appropriately compared to non-pediatric surgeons. [62, 63]

There is also good evidence that severely injured children treated at a PTC have improved outcomes—the mortality rate for children with severe head injuries who required neurosurgical procedures was lower at PTCs and ATCs with additional pediatric qualifications than at ATC I or ATC II. [56] Children treated at a PTC also had improved functional outcomes compared to those treated at an ATC, such as a lower dependency for feeding, locomotion, social interaction and expression categories than those treated at an ATC, even an ATC with additional qualifications. [56]

Overall, two recent reviews of the literature summarize that while there is some conflicting evidence regarding whether injured children treated at PTCs have better outcomes than those treated at ATCs, [64] injured children treated at a PTC do appear to have improved survival and functional outcomes compared with those treated at an ATC. [65] Thus, some have recommended that if adult trauma centers and surgeons are going to treat children, they need to develop a special interest in the management of childhood injuries.[56] There is also a level of impracticality in suggesting that all childhood trauma be managed at pediatric surgical centres.[46]

Oncology

In many adult cancers, for which large numbers of patients can be studied, the relationship between treatment in a high-volume hospital or by a high-case-volume clinician and better outcomes for the patient is clear.[66-68] These analyses are considerably more difficult to undertake in pediatric oncology because all types of childhood cancer are rare, but evidence that centralization of pediatric oncology care improves outcomes does exits.[69] Logically the same volume-to-outcome relation as that reported for adult cancers can be assumed for pediatric cancers since both involve complex processes delivered through multidisciplinary teamwork.[70]

There is a significant amount of research that suggests that survival rates of various cancers greatly improve when treated at centralized specialist centers. In England, the Chief Medical Officer has recommended that all cancer services be centralized and thus coordinated on a regional basis with specified surgeons operating on a required minimum number of cases each year.[71] With respect to children, research has shown that children with non-Hodgkin's lymphoma, Ewing's sarcoma, rhabdomyosarcoma, medulloblastoma, and osteosarcoma treated at pediatric oncology centers had a significantly higher survival rate than those treated elsewhere.[40, 69, 72] Certain childhood cancers with a good prognosis, such as Wilm's tumour, were being overtreated in non-specialist centers.[73]

A recent systematic review lends support to the conclusion that treatment of children with cancer in high-volume hospitals, by high-case-volume clinicians leads to improved outcomes.[74] All included studies of sufficient quality reported either a significant or a non-significant but positive association for the effect of increased volume of patients treated on outcome, and no study showed a negative effect. [74] The evidence is strongest for children with brain tumours,[72, 75, 76] acute lymphoblastic leukemia,[77] bone tumours,[78, 79] and those receiving allogeneic bone marrow transplantation.[80, 81] Thus, some have recommended that the role of the general surgeon in pediatric oncology be limited to arranging referral to a specialist center. [46]

Minimum case loads in oncology

While the evidence does suggest that minimum case-loads would improve care in pediatric oncology, setting them is tricky. No clear threshold can be established for the number of treated cases above which the positive relation plateaus.[70] Also, the rarity of childhood cancers makes setting case numbers difficult. High case numbers per clinician would be very hard to meet. For example, in the population of the Netherlands (17 million people), roughly 550 cases of cancer are new diagnosed in children (0-18 year of age) annually, with patients treated in one of seven childhood cancer centers. [74] With the exception of acute lymphoblastic leukemia, all tumour types occur in fewer than 30 patients per year (the minimum number of cases per year that has been suggested as a threshold for breast cancer treatment).[82] This means not a single provider in a population of 17 million would reach the minimum threshold—making it very unlikely that any provider would meet a 30 case threshold in British Columbia.

Instead, it appears that improvement in highly complex, low-volume treatment will rely on concentration of care services and skilled clinicians to ensure that the best possible care is provided as safely as possible. While concentration of services, in and of itself, does not lead to a substantial increase in survival, it creates the optimum conditions for progress to be made. [70]

Nursing and other healthcare services

Specialist pediatric surgery depends heavily for support on other specialties, such as radiology, pathology, intensive care, physiotherapy, specialist nursing, etc. Better results for diagnosis and treatment of certain high risk or rare disorders can be achieved by concentrating expertise. Research has shown that concentration of expertise results in better outcomes for radiology, [83] pathology,[84] pediatric intensive care,[85, 86] and neonatal intensive care.[87] The argument for centralizing these other services is remarkably similar to those already presented. For pediatric intensive care or surgical care to function well, it must be associated with a full range of on-site pediatric specialties. [88]

While the literature that examines hospital volume and outcomes clearly incorporates nursing, as high-volume centers are also likely to include nurses who see high-volumes of pediatric cases, there was relatively little research that focused specifically on the nurse's role in the pediatric volume-outcomes association. However, the evidence with respect to adults shows an association between nurse staffing and mortality. [89, 90] Higher registered nurse skill mix has also been positively associated with quality of care.[91, 92] A study examining the relationship between nurse staffing skill mix, and Magnet recognition to institutional volume and mortality for congenital heart surgery in children's hospitals, found that none of these nursing characteristics was associated with risk-adjusted mortality. However, they did report that hospital volume was significantly associated with mortality. The authors speculated that the outcome of mortality was insensitive to nursing characteristics in children's hospitals, as long as certain staffing thresholds had been achieved.[93]

Specialist pediatric dialysis has been shown to improve outcomes in children on chronic peritoneal dialysis. Exit site infection rate, risk of peritonitis during the first year and multiple peritonitis attacks were higher in children who were treated in an adult ward and nursed by adult nurses.[94] A relationship between staffing ratio has also been reported. Infant to staff ratios have been shown to affect risk of mortality in very low birthweight infants. Infants exposed to higher infant to staff ratios have an improved adjusted rate of survival to hospital discharge.[95]

Guidelines from the United States

With respect to anesthesia, the American guidelines for the Pediatric Perioperative Anesthesia Environment state the following[96]:

Anesthesiologists providing clinical care to pediatric patients should be graduates of an anesthesiology residency-training program accredited by the Accreditation Council for Graduate Medical Education or its equivalent. In addition, anesthesiologists providing or directly supervising the anesthesia care of patients in the categories designated by the facility's Department of Anesthesia as being at increased anesthesia risk should be graduates of an Accreditation Council for Graduate Medical Education pediatric anesthesiology fellowship training program or its equivalent or have documented demonstrated historical and continuous competence in the care of such patients.

Patient care units should have:

1) Preoperative unit designated to accommodate pediatric patients with age- and size-appropriate equipment
2) A pediatric anesthesiologist responsible for the organization of pediatric anesthesia services
3) Nursing and technical personnel who are trained in pediatric perioperative care
4) Clinical laboratory and radiologic services available at all times
5) Full selection of equipment available for application to the pediatric patient
    a. Resuscitation care with appropriate equipment for pediatric patients
    b. Resuscitation cardiac drugs at appropriate pediatric concentrations
    c. Airway equipment for all ages of pediatric patients
    d. Difficult airway care containing specialized equipment for management of the difficult pediatric airway
    e. Positive-pressure ventilation systems appropriate for infants and children

f. Devices for the maintenance of normothermia
g. Intravenous fluid administration equipment including pediatric volumetric fluid demonstration devices
h. Noninvasive monitoring equipment for the measurement of electrocardiography, blood pressure, pulse oximetry, capnography including anesthetic gas concentrations, temperature and inhaled oxygen concentration; and
i. Equipment for the measurement of arterial and central venous pressure in infants and small children.

Recommendations from England

In England, a nationwide quality assurance study based on voluntary reporting of 20,247 surgical and anesthesia related deaths (417 of which occurred in children under 10 years of age) raised concerns regarding the absence of skilled pediatric anesthetists in some single surgical specialty units, and the questionable clinical competence of locum appointees who provided care for children. The investigators recommended that surgeons and anesthesiologists not do occasional pediatric cases since "the outcome of surgery and anesthesia in children is related to the experience of the clinicians involved". [15, 16] One of the authors of this report went on to publish recommendations that specifically stated that:

1) Surgeons and anesthetists should not undertake occasional pediatric practice. The outcome of surgery and anesthesia in children is related to the experience of the clinicians involved.
2) Consultants who take the responsibility for the care of children (particularly in District General Hospital and in single surgical specialty hospitals) must keep up to date and competent in the management of children.
3) Consultant supervision of trainees needs to be kept under scrutiny. No trainee should undertake any anesthetic or surgical operation on a child of any age without consultation with their consultant.

The report goes on to discuss the provisions of facilities in hospital that are crucial in the management of infants after surgery. These include special skills in the nursing , and a management arrangement ensuring a consultant pediatrician is available to professionally isolated units for advice at least by telephone if not actual attendance. Another committee from England recommended that anesthetics and operations on children should be undertaken only after consultation with pediatric consultants. [16]

As previously mentioned England has suggested that a surgeon working in the larger specialties (general, orthopedic, or ear, nose and throat surgery) should complete the equivalent of 100 cases with children each year, in order to maintain their skills to carry out planned work on younger children (children under the age of 8). [48, 49] They go on to state that if a surgeon carrying out planned surgery on children works with fewer than 100 children a year, their trust should find out the age of the children and assure itself that the surgeon is operating within their abilities. Anesthetists were also expected to have worked with more than 100 children between the ages of 0 and 12 annually. [19]

Challenges with respect to setting minimum thresholds

While the literature supports a positive relationship between increasing volume and improved outcomes in many forms of pediatric care (especially at the level of the center), there are some important challenges to setting specific minimum thresholds for institutions and providers. These include:

1) Research has not been able to show a clear threshold for the number of treated cases above which the positive relation plateaus.[70]
2) The rarity of certain childhood conditions makes hitting a minimum threshold very unlikely in populations the size of BC. [70]
3) It is not clear whether minimum annual caseloads should exist for specific conditions or whether minimum numbers of operations on children is most important.[35, 47]
4) Some suggestion that for certain surgeries, even very low numbers of annual operations (>4) may be enough to ensure competence.[35]
5) Training has been highlighted as a problem when surgical conditions are rare (e.g. congenital diaphragmatic hernia occurs in 1 in 2000 live births) and means that large numbers of cases need to concentrate in one centre or training time needs to be increased to achieve the appropriate case mix. [97]
    a. Training has also been mentioned as a problem in pediatric intensive care[88] and anesthesia.[14]

While England did publish some clear thresholds that it wanted clinicians and institutions to meet, they have not been very successful in meeting those targets. Their initial report examining the success of their trust in meeting the 100 cases per year threshold for both surgeries and anesthetics suggested that:

- 8% of trusts that provided planned surgery to children had no consultant surgical team that completed more than 100 procedures a year
- 21% of trusts that provided planned anesthesia to children said that none of their consultants anesthetized more than 100 children a year.
- Across England, 84% of consultant surgical teams and 77% of consultant anesthetists who carried out planned work with children worked with fewer than 100 children aged 0 to 12 each year. [19]

A follow-up study conducted several years after the first report concluded that poor attention had been given to the recommendation that surgeons and anesthetists working with children need to undertake sufficient work to maintain their skills. While this follow-up report never mentions the specific threshold of >100 pediatric cases annually, they appear to have used these numbers again to assess the trusts. They report that 64% and 74% of trusts carried out procedures by surgeons and anesthetists that have undertaken relatively few of the procedure in that age group, respectively.[98] While this may be a failure on the part of the NHS to provide the best possible care, given other concerns and cautions in the literature about the difficulty in setting attainable and meaningful minimum thresholds, England's lack of success may also be a reflection on the thresholds themselves.

A study done in Northern California suggested that in a majority of hospitals in Northern California, credentialing based on caseload might not be feasible. They suggest that credentialing for pediatric anesthesia based on caseload has a major problem that relates to the distribution of cases: most hospitals care for a few children and most children are cared for in a few hospitals. The results of their study suggest that if credentialing policy requires the minimum number of cases per year per hospital to be greater than 20 (for children under the age of six), then 41% of hospitals in Northern California would have a sufficient number of cases to credential at least one anesthesiologist to provide anesthesia for children. If credentialing requirements involved further age group subdivisions of 0-6 months, 7-24 months, and 25-72 months, and the minimum caseload was increased to 50, then more than 80% of hospitals would not have enough cases to credential one anesthesiologist.[7]

Summary

While the quality of the evidence is not ideal, the finding that increasing institutional and providers volumes/specialty results in improved outcomes for pediatric patients is remarkably consistent. While the relationship was not always statistically significant, it was very rare to find a study that did not at least report a positive association. This consistency of findings (with the exception of the somewhat conflicting literature with respect to trauma) does suggest that concentrating expertise in pediatric care is likely to result in improved outcomes. However, the clinical significance of those improved outcomes seems to depend on the type of surgery performed (e.g. ensuring that every child receives appendectomy from a surgeon who regularly practices on children is unlikely to improve outcomes as much as ensuring that experienced pediatric surgeons are performing cardiac surgery), and patient age (this relationship does seem to disappear once children reach a certain age). However, there are important questions that remain unanswered, such as: Does this relationship plateau? If a surgeon practices regularly on children, do they also need to have a high volume of a specific procedure to improve outcomes? How high does the volume of anesthetics really need to be to ensure good outcomes? Unfortunately current evidence does not inform with respect to these questions.

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