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REVIEW

A systematic review of the power of standardization in pediatric neurosurgery

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Abstract
In the current neurosurgical field, there is a constant emphasis on providing the best care with the most value. Such work requires the constant optimization of not only surgical but also perioperative services. Recent work has demonstrated the power of standardized techniques in limiting complication while promoting optimal outcomes. In this review article, protocols addressing operative and perioperative care for common pediatric neurosurgical procedures are discussed. These articles address how various institutions have optimized procedures through standardization. Our objective is to improve patient outcomes through the optimization of protocols.

Keywords Standardization · Protocol · Pediatric neurosurgery · Operative care · Perioperative care

Introduction

Largely popularized by Henry Ford, the assembly line — an innovation promoting consistency in manufacturing — increased production while improving quality. Likewise, the aviation and nuclear energy industries have a long history of regulations, incorporating an element of predictability, to promote safety, reduce costs, and facilitate international collaboration [1–3]. More recently, process standardization emerged in healthcare, initially targeting the excessive number of preventable iatrogenic injuries [4–7]. The World Health Organization (WHO) defines standardization as “the process of developing, agreeing upon, and implementing uniform technical specifications, criteria, methods, processes, designs, or practices that can increase compatibility, interoperability, safety, repeatability and quality” [8]. Lack of standardization contributes to medical errors, compromising patient safety [9–11]. Clinical practice variation abounds at multiple levels including national, hospital, and individual practitioners [12]. This variation extends to many surgical techniques, despite, in certain cases, high quality evidence demonstrating the superiority of one technique [13]. Standardization can reduce unnecessary clinical variation and improve patient outcomes via reduction of technical errors, operative times, and blood loss, among others [6, 14–16].

Quality improvement initiatives in various surgical disciplines revolve around integration of consistent practice, and pediatric neurosurgeons have recently embraced this concept [14, 15, 17–19]. While standardized protocols were introduced into pediatric neurosurgery as early as 1992, the landmark Hydrocephalus Research Network (HCRN) shunt infection protocol in 2011 increased interest [20]. Since then, a flurry of standardized protocols have been proposed targeting obstacles posed to the common operations including Chiari decompression, intrathecal baclofen pump placement, and spinal surgeries. From 1981 to 2023, there has been a great increase in the number of PubMed-indexed standardized neurosurgery protocols (Fig. 1). In this article, we review published standardized protocols, provide a broad analysis of their aggregate findings, and highlight the benefits of uniformity in surgery. Our objective is to provide a framework with which physicians can improve outcomes through standardization.

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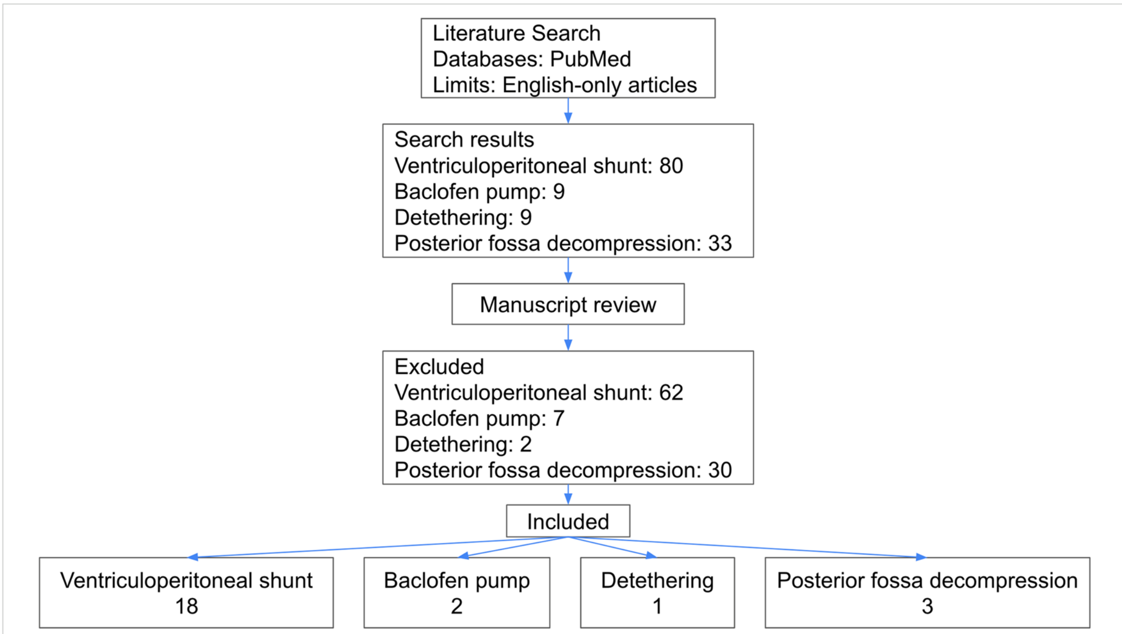

Fig. 1 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for the literature search

Materials and methods

All articles in PubMed were searched for inclusion criteria of "Pediatric neurosurgery," "standardization" or "protocol," and "ventriculoperitoneal shunt," "baclofen pump," "Chiari decompression," or "spinal fusion" in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for all PubMed articles up to January 2022. Results were then reviewed by the authors cooperatively for inclusion. Articles were included if a comprehensive protocol with data-driven outcomes was presented. Subjects in articles had to be < 18 years of age, and articles had to be written in English (Fig. 2). Data obtained from each paper was restricted to reported outcomes which varied widely based upon study. No data was interpolated. No effect measures or synthesis of data was performed. No studies were excluded that met inclusion criteria. An independent review protocol was not submitted to an outside database.

Articles were assessed for level of quality according to the Newcastle–Ottawa Scale (Tables 5, 6, 7, and, 8), which grades articles based on the following criteria: selection of proper cohort, comparability to other studies, and proper assessment of outcome; each category can award a number of stars depending on the subcategories present, with 9 stars being the highest score a work can achieve. Scores were converted to the Agency for Healthcare Research and Quality (AHRQ) standards, which designated each work as "good," "fair," or "poor" quality. The thresholds for converting the Newcastle–Ottawa scales to AHRQ standards are as follows:

a. Good quality: 3 or 4 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain.
b. Fair quality: 2 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in outcome/exposure domain.
c. Poor quality: 0 or 1 star in selection domain OR 0 stars in comparability domain OR 0 or 1 stars in outcome/exposure domain.

Of note, the Newcastle–Ottawa Scale only applies to cohort studies, and as such, the works of Janjua et al. [21] and Mallucci et al. [22] were excluded from the quality assessment, as these publications were a review article and randomized control trial, respectively.

Results

Ventriculoperitoneal shunt

Infection is a common complication in ventriculoperitoneal shunt placement (VPS) in children with several groups developing standardized methods to combat this complication (Table 1). In 1992, the first such protocol reported certain peri-operative steps which substantially decreased infection rates from 7.75 to 0.17% [23]. Pirotte et al. believed that

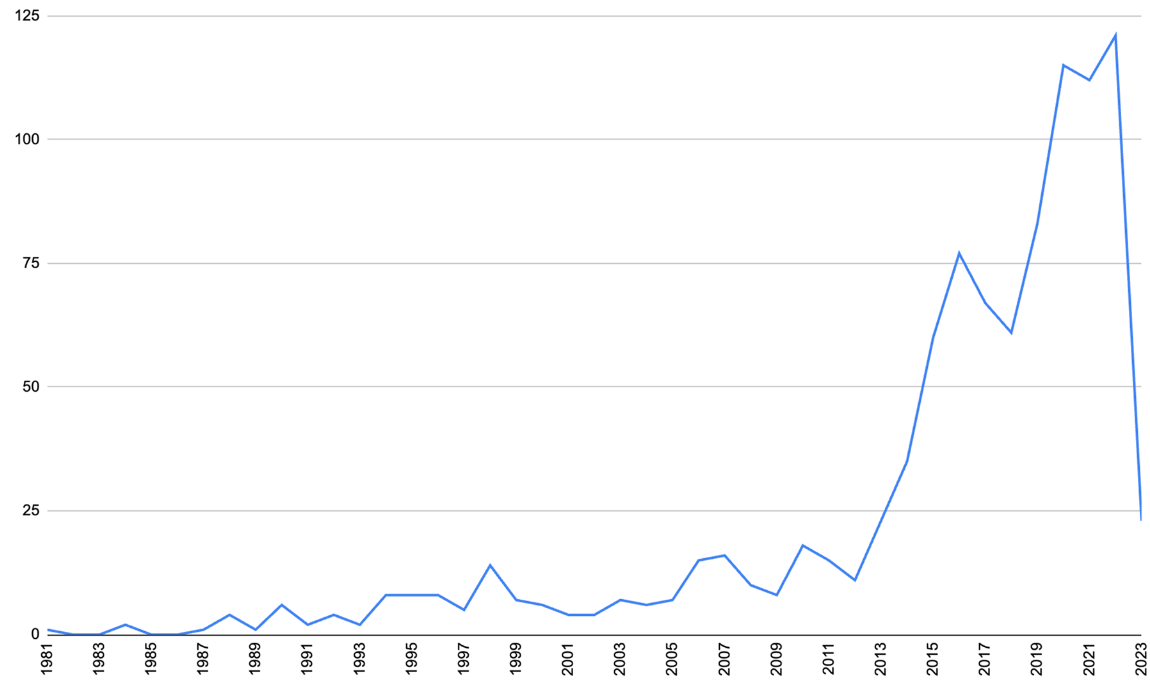

Fig. 2 Graphic representation of the pediatric neurosurgery protocols published in PubMed based upon year demonstrating an increased number of standardized protocols

the simple act of protocol implementation — which included minimal implant and skin-edge manipulation, minimal staff in operating room, systemic antibiotic prophylaxis for 24 h, double gloving, among others — resulted in 0 infections in 115 shunt operations [24] (Tables 2, 3, 4).

In 2011, the first multi-center standardized protocol geared towards reduction of shunt infections was published by the Hydrocephalus Research Network (HCRN) [20]. In this study across four institutions, an 11-step protocol led to a reduction in infections from 8.8 to 5.7% ($p=0.0028$). As part of a Plan-Do-Study-Act (PDSA) cycle, the protocol evolved to the following 5-steps [25, 26]:

1) Pre-incision IV antibiotics.
2) Chlorhexidine as final prep.
3) Hand scrubbing (not Avagard).
4) Double-gloving.
5) Use of iodine-impregnated drape.
6) Everything else optional.

Optional steps included use of antibiotic-impregnated catheters (AICs), intraventricular vancomycin and gentamicin, outer gloves changed after draping, no-touch catheter technique, and bacitracin or vancomycin irrigation of wounds. In 4913 procedures across 13 centers, the overall infection rate was 5.1%, with the use of AICs and vancomycin irrigation as the only protective factors in multivariate analysis [25]. A randomized, controlled trial in UK and Ireland corroborated these findings, with dramatically reduced infections from about 6.0% with standard or silver-impregnated catheters to 2.2% with AICs [22].

These early protocols inspired a multitude of institutional infection prevention bundles. Raygor et al. evaluated a single-institution experience with intraventricular vancomycin as well as topical vancomycin, reducing their infection rate from 6.9 to 3.2% ($p=0.03$) [27]. A 9-step Calgary Shunt protocol reduced infection rates from 12.7 to 2.7% ($p=0.004$). The authors concluded that implementation of the protocol alone was significant in reducing infections, while chlorhexidine as the skin prep agent and waiting ≥ 20 min between IV antibiotic administration and skin incision may also have improved outcomes [28]. A UK group reduced infections from 5.4 to 3.3% ($p=0.138$) via inclusion of many HCRN steps in addition to povidone-iodine soaked patties over incisions and catheters perioperatively [29]. Similarly, a group in Zimbabwe, Namibia and Democratic Republic of Congo instituted periodic povidone-iodine application to the skin during the operation among various other steps inherited from Choux et al. and Birotte et al. and reduced infections from 3.5 to 1.9% per procedure [30].

The benefits of standardization not only included improved patient outcomes, but also, included financial benefits. Berns et al. demonstrated the cost-savings reaped from standardization, limiting their valve selection to one nonprogrammable and one programmable type. This reaped

Table 1 List of protocols for ventriculoperitoneal shunt surgery

Authors	Title	Journal	Type of study	Summary of findings
Berns et al. (2021) [31]	Standardization of cerebrospinal fluid shunt valves in pediatric hydrocephalus: an analysis of cost, operative time, length of stay, and shunt failure	*J Neurosurg Pediatr*	Retrospective cohort	Surgeons at a single institution were encouraged to standardize shunt valves to either one fixed pressure valve or one programmable valve. The savings and the outcomes for patients were compared at 12 months demonstrating significant savings with similar outcomes demonstrating the change was cost-effective and safe
Chu et al. (2022) [25]	The Hydrocephalus Clinical Research Network quality improvement initiative: the role of antibiotic-impregnated catheters and vancomycin wound irrigation	*J Neurosurg Pediatr*	Prospective cohort	Surgeons performed 4913 procedures at 13 HCRN centers while tracking whether the HCRN protocol was followed. Infection rates dropped with antibiotic-impregnated catheters were used (8.4 to 4.9%). Multivariate analysis identified a prior, recent shunt surgery and have chronic conditions as risk factors. Antibiotic-impregnated catheters and vancomycin irrigation were identified as independent protective factors
Faillace (1995) [91]	A no-touch technique protocol to diminish cerebrospinal fluid shunt infection	*Surg Neurol*	Prospective cohort	The authors of this study used a touch method and a no-touch method for insertion of VPS. They noted a decrease in shunt infection rates using the no touch method (9.1 to 2.9%, $p=0.058$) and a threefold decrease in the infection rate per patient (11.3 to 3.9%, $p=0.032$)
Janjua et al. (2017) [21]	Contemporary management and surveillance strategy after shunt or endoscopic third ventriculostomy procedures for hydrocephalus	*J Clin Neurosci*	Review	This article is a review of the management of hydrocephalus. They propose a management and follow-up algorithm
Kalangu et al. (2020) [30]	Towards zero infection for ventriculoperitoneal shunt insertion in resource-limited settings: a multicenter prospective cohort study	*Childs Nerv Syst*	Prospective cohort	A total of 209, under 5 years of age children requiring a VPS were evaluated following a protocol. Interestingly, intermittent applications of povidone-iodine were performed. The children were followed for 3 months. This cohort had a 1.9% shunt infection rate despite being part of a health-system with limited resources

Table 1 (continued)

Authors	Title	Journal	Type of study	Summary of findings
Kestle et al. (2011) [20]	A standardized protocol to reduce cerebrospinal fluid shunt infection: the Hydrocephalus Clinical Research Network Quality Improvement Initiative	*J Neurosurg Pediatr*	Prospective cohort	After applying a standardized protocol at 4 centers, the authors were able to demonstrate a decrease in infection from 8.8 to 5.7% with an absolute risk reduction of 3.15% ($p=0.0028$). Additionally, use of BioGlide catheters or antiseptic cream instead of a formal scrub was demonstrated to increase infection risk by logistic regression analysis ($p=0.01$)
Kestle et al. (2016) [26]	A new Hydrocephalus Clinical Research Network protocol to reduce cerebrospinal fluid shunt infection	*J Neurosurg Pediatr*	Prospective cohort	Previous work has demonstrated an 11-step protocol reduced shunt infections; However, antibiotic-impregnated catheters were not included
Mallucci et al. (2020) [22]	Silver-impregnated, antibiotic-impregnated or non-impregnated ventriculoperitoneal shunts to prevent shunt infection: the BASICS three-arm RCT	*Health Technol Assess*	Randomized control trial	Patients aged neonate to 91 year old were randomized in a 1:1:1 ratio for shunt catheters (non-impregnated, silver-impregnated, and antibiotic-impregnated). VPS failure was evaluated as was time to failure, cause of failure, types of VPS infection, rate of infection after clean revision. Evaluation was by intention-to-treat. Infection was 6% in the non-impregnated group, 2.2% in the antibiotic-impregnated group, and 5.9% in the silver-impregnated group. Antibiotic-impregnated catheters led to a lower infection rate and decrease probability of infection. Antibiotic-impregnated shunts lead to a substantial savings in cost per infection
Omrani et al. (2018) [29]	Effect of introduction of a standardized peri-operative protocol on CSF shunt infection rate: a single-center cohort study of 809 procedures	*Childs Nerv Syst*	Retrospective cohort	This study was performed at a single center in the UK. A control population was obtained from 2009 to 2012. A protocol was implemented, and the study population was gathered from 2012 to 2015. The overall infectious rate decreased but not significantly (5.43 to 3.27%, $p=0.138$). Multivariate analysis identified surgeon experience as a significant predictor of infection

Table 1 (continued)

Authors	Title	Journal	Type of study	Summary of findings
Pirotte et al. (2007) [24]	Sterile surgical technique for shunt placement reduces the shunt infection rate in children: preliminary analysis of a prospective protocol in 115 consecutive procedures	*Childs Nerv Syst*	Retrospective cohort	Surgeons investigated compliance with standardized shunt protocol in 115 children. The authors found the ability to decrease shunt infection rate with standardization despite not using antibiotic impregnated catheters
Raygor et al. (2020) [27]	Ventriculoperitoneal shunt infection rates using a standard surgical technique, including topical and intraventricular vancomycin: the Children's Hospital Oakland experience	*J Neurosurg Pediatr*	Prospective cohort	In this study, 593 pediatric patients with hydrocephalus had a VPS placed utilizing a protocol including intrathecal antibiotics and topical vancomycin. The results demonstrated people who adhered to the protocol had fewer infections (3.2% vs 6.9%, $p=0.03$). Additionally, multivariate analysis demonstrated a CSF leak or age <6 months as factors associated with VPS infections with most infections occurring 2-months post-operatively and the causative organisms being *S. epidermidis*
Yang et al. (2019) [28]	Calgary Shunt Protocol, an adaptation of the Hydrocephalus Clinical Research Network shunt protocol, reduces shunt infections in children	*J Neurosurg Pediatr*	Prospective cohort	The researchers attempted to validate whether the 9-step Calgary shunt protocol reduced infection in children. The protocol was applied to all patients after May 2013. The control was the children undergoing surgery before May 2013. The primary outcome was shunt infection. There was an absolute risk reduction of 10% after implementing the shunt protocol (12.7 to 2.7%, $p=0.004$). Chlorhexidine was associated with fewer infections than iodine-based solutions (4.1 to 12.3%, $p=0.02$). A 20-min delay between pre-operative antibiotics and skin incision led to decreased infection (4.5% vs 14.2%, $p=0.007$). In multivariate analysis, only the overall protocol led to infections

Table 2 List of protocols for baclofen pump surgery

Authors	Title	Journal	Type of study	Summary of findings
Desai et al. (2018) [35]	A standardized protocol to reduce pediatric baclofen pump infections: a quality improvement initiative	*J Neurosurg Pediatric*	Retrospective/prospective	Due to the high risk of complications, a baclofen pump protocol was initiated at a center. After reviewing patients from 2012 to 2014, a protocol was developed and implemented in 2014. Data was collected prospectively from 2014 to 2016. A total of 128-baclofen pump surgeries were performed. After implementation of the protocol, infections dropped (12.5 to 6.3%, p=0.225), and complications decreased (23.4 to 9.4%, p=0.032)
Patel et al. (2021) [37]	Characterization of standard work tools for intrathecal baclofen therapy	*Childs Nerv Syst*	Retrospective cohort	The goal of this study was to identify a comprehensive workflow for managing intrathecal baclofen. From July 2017 to November 2020, 60 procedures were identified following this workflow. At 6 months, the overall complication rate was 14.5%. This study demonstrates that workflow optimization can help lower complication rates

savings of approximately $488/procedure with no difference in shunt survival rate pre- and post-standardization [31].

While most VPS protocols demonstrate improved infection control rates, the significance of each individual intervention is often indeterminable despite the overall protocol's success. This reinforces the notion that the act of standardization itself can generate quality improvement.

Each work reviewed in this section was categorized as "good" by the AHRQ standards, and most works received 8 or 9 stars (out of 9 possible) according to the Newcastle–Ottawa Scale. Works by Pirotte et al. [24] and Raygor et al. [27], scored slightly lower with 7 stars, although this did not impact their AHRQ Standards designation (Table 5). Works by Janjua et al. [21] and Mallucci et al. [22] were excluded from the quality assessment as these publications were not cohort studies.

Baclofen pump

While intrathecal baclofen (ITB) pumps effectively treat spasticity and dystonia, surgical placement has been fraught with complications with rates ranging from 3 to 41% [32, 33]. Infection remains the most common complication spurring multiple institutions to standardize peri-operative measures to reduce these rates (Table 2).

Best practices for pump placement were initially discussed at the ITB Therapy Best Practice forum in Minnesota in 2004 [34]. While this paper did not provide a comprehensive protocol, it provided a consensus of providers at the time on best practices. This established the foundation for standardization in ITB pumps.

In the first formal protocol for ITB pump placement, a total of 128 (64 pre-protocol and 64 post-protocol) cases were evaluated using the Clavien-Dindo classification for surgical complications [35, 36]. The authors demonstrated decreased complications (23.4 to 9.4%, $p = 0.032$) and infections (12.5 to 6.3%, $p = 0.225$). Yet, it had insufficient power to draw conclusions on individual steps.

Patel et al. devised a standardized approach to extra-operative care for patients undergoing baclofen pump placement [37]. Their pre-operative workflow hinged upon a comprehensive approach, with physiatry, neurosurgery, and developmental pediatrics, in concert with intimate patient involvement involving a clinical care coordinator. The authors also provided a post-operative troubleshooting algorithm, with paradigms for both suspected infections and pump failures [37]. Using this workflow, 60 procedures were performed in 46 patients, with a 14.5% total complication rate, 3.6% infection rate, and 1.7% CSF leak rate at 6 months. While no pre-protocol data was provided, the authors cite reduced complication rates relative to the literature, attributing this to their standardized algorithm.

Table 3 List of protocol for Chiari malformation surgery

Authors	Title	Journal	Type of study	Summary of findings
Mazur-Hart et al. (2021) [48]	Standardizing postoperative care for pediatric intradural Chiari decompressions to decrease length of stay	*J Neurosurg Pediatr*	Retrospective study	To determine if a standardized protocol would decrease the length of stay and cost, 132 patients with a Chiari decompression with expansile duraplasty were studied. Enacting a protocol decreased length of stay and costs
Shao et al., 2020 [49]	Multimodal Analgesia After Posterior Fossa Decompression With and Without Duraplasty for Children With Chiari Type I	*Hosp Pediatr*	Retrospective study	The goal was to determine if using multimodal anesthesia decrease opioid usage after a posterior fossa decompression with or without duraplasty. Patients without a duraplasty required less opioids. Patients with a duraplasty following a standardized protocol had lower mean opioid requirements. The multimodal protocol was the only significant variable for opioid usage in patients on regression analysis

Each work in this section received a designation of "good" according to the AHRQ Standards, in which the works of Desai et al. [35] scored 8 stars and Patel et al. [37] scored 7 stars according to the Newcastle–Ottawa Scale (Table 6).

Chiari protocols

Chiari malformation is one of the most common pathologies encountered by pediatric neurosurgeons with a prevalence of 0.6–1% [38, 39]. Multiple surgical interventions are employed for this pathology ranging from posterior fossa decompression only (PFD), to posterior fossa decompression with duraplasty (PFDD) and even O-C fusion [40–43]. The complication profile is relatively low with overall complication rates of 12–15%, mostly comprised of CSF-related issues (10–12%) and infection (0.3–1.2%) [44]. While long-term quality of life assessments show significant overall improvement in symptoms and quality of life, the requisite muscle dissection, bony and ligamentous decompression, and duraplasty often inflict significant short-term postoperative pain that leads to extended hospitalization [45–47]. Towards the goal of reducing postoperative pain, nausea, length of stay, and costs, two protocols have been developed (Table 3).

Mazur-Hart et al. instituted a protocol for pediatric patients undergoing PFDD that included scheduled medications (diazepam and ketorolac), dexamethasone taper, and PRN medications for breakthrough pain and early urinary catheter removal and ambulation [48]. The authors compared their results pre-protocol (97 patients) to post-protocol (35 patients). Length of stay significantly decreased from 55 to 46 h post-protocol ($p=0.014$), and post-operative day 1 discharge increased from 22 to 40% ($p=0.045$). There was no change in 30-day readmission rate. This amounted to about $194,000 in savings per 100 cases in hospital bed use alone. The authors conclude that implementation of a standardized protocol, especially if targeted towards pain and nausea control as well as early mobilization, can decrease length of stay and, thereby, healthcare costs [48]. The authors note several limitations of this study including variability in each patient's surgical requirement, such as need for more aggressive decompression or tonsillectomies, social situations beyond medical care, and Hawthorne bias, with greater inclination for rapid discharge post-protocol implementation.

Shao B et al. instituted a multi-modal analgesia (MMA) protocol in Chiari decompression patients, administering scheduled ketorolac alternating with scheduled acetaminophen and diazepam, PRN oxycodone, patient-controlled analgesia as the discretion of the pain team, and no epidural or neuropathic analgesics [49]. In their analysis, while no difference in opioid use was seen in patients undergoing PFD only, those undergoing PFDD required 40% less opioids ($p=0.006$), with no difference in anti-emetic requirements, discharge opioid prescriptions, costs, or length of stay [49]. Limitations noted by the authors included single institution, retrospective nature, only 59% protocol adherence, and lack of pain score analysis.

Table 4 List of protocols for spinal fusion surgeries

Authors	Title	Journal	Type of study	Summary of findings
Ballard et al. (2012) [50]	A multidisciplinary approach improves infection rates in pediatric spine surgery	*J Pediatr Orthop*	Retrospective study	394 patients were retrospectively review and divided into high risk and low risk cohorts before and after protocol initiation. They were followed for 1 year for surgical site infections. Infection risks were nonsignificantly reduced from 7.8 to 4.5%
Stephan et al. (2021) [53]	Surgical Site Infection Following Neuromuscular Posterior Spinal Fusion Fell 72% After Adopting the 2013 Best Practice Guidelines	*Spine*	Retrospective study	A retrospective study of neuromuscular scoliosis patient was performed investigating surgical site infections within 1 year. A cohort was performed before and after initiation of the guidelines in Vitale et al. 2013 [51]. Surgical site infections were decreased from 16.1 to 4.4% with a shift in microbe identified
Ryan et al. (2014) [54]	A standardized protocol to reduce pediatric spine surgery infection: a quality improvement initiative	*J Neurosurg Pediatr*	Prospective study with retrospective control	Children undergoing spine surgery were prospectively followed after implementing an infection protocol. The infection rate dropped from 5.8% to 2.2% ($p = 0.0362$). Non-compliance was found to be a source of infection in 4/6 infections
Poe-Kochert et al. (2020) [55]	Surgical site infection prevention protocol for pediatric spinal deformity surgery: does it make a difference?	*Spine Deform*	Retrospective study	Following patients from 1999 to 2017 with implementation of an infection protocol in 2008, the goal was to identify the efficacy of the infectious protocol in complex pediatric spine surgery. In 2008, an infectious bundle was introduced. In 2011, intraoperative wound vancomycin was initiated. Surgical site infections dropped from 7.2 to 2.5% ($p = 0.01$)
Vandenberg et al. (2018) [56]	Compliance With a Comprehensive Antibiotic Protocol Improves Infection Incidence in Pediatric Spine Surgery	*J Pediatr Orthop*	Retrospective study	The goal of this study was to assess the efficacy of implementation of an antibiotic protocol in reducing spinal surgical site infections. Three criteria were required to follow the protocol: antibiotics within 1 h of the incision, antibiotics appropriately redosed intraoperatively, and antibiotics discontinued within 24 h of the surgery. With a compliance rate of 85%, the likelihood of infection was nonsignficantly increased in the noncompliant group ($p = 0.0587$)

Table 5 Quality assessment of ventriculoperitoneal shunt surgery literature using the Newcastle–Ottawa Scale

Study ID	Selection				Comparability* (★★)	Outcome			Total (9★)	Conversion to AHRQ Standards (good, fair, poor)
	Representativeness of exposed cohort (★)	Selection of non-exposed cohort (★)	Ascertainment of exposure (★)	Demonstration that outcome of interest was not present at start of study (★)		Assessment of outcome (★)	Was follow-up long enough for outcomes to occur (★)	Adequacy of follow-up of cohorts (★)		
Berns et al. (2021) [31]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good
Chu et al. (2022) [25]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good
Faillace (1995) [91]	★	★	★	★	-★	★	★	★	★★★★★★★★ (8)	Good
Kalangu et al. (2020) [30]	★	-	★	★	★★	★	★	★	★★★★★★★★ (8)	Good
Kestle et al. (2011) [20]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good
Kestle et al. (2016) [26]	★	-	★	★	★★	★	★	★	★★★★★★★★ (8)	Good
Omrani et al. (2018) [29]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good
Pirotte et al. (2007) [24]	★	-	★	★	-★	★	★	★	★★★★★★★ (7)	Good
Raygor et al. (2020) [27]	★	-	★	★	-★	★	★	★	★★★★★★★ (7)	Good
Yang et al. (2019) [28]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good

*Comparability assessed at the following: one star rewarded if study accounted for varying outcomes depending on operating surgeon/shunt preference, another star rewarded if study contained large enough sample size to limit confounding bias

Abbreviations: *AHRQ* Agency for Healthcare Research and Quality

Table 6 Quality assessment of baclofen pump surgery literature using the Newcastle–Ottawa Scale

Study ID	Selection				Comparability*	Outcome			Total (9★)	Conversion to AHRQ Standards (good, fair, poor)
	Representativeness of exposed cohort (★)	Selection of non-exposed cohort (★)	Ascertainment of exposure (★)	Demonstration that outcome of interest was not present at start of study (★)	(★★)	Assessment of outcome (★)	Was follow-up long enough for outcomes to occur (★)	Adequacy of follow-up of cohorts (★)		
Desai et al. (2018) [35]	★	★	★	★	★-	★	★	★	★★★★★★★★ (8)	Good
Patel et al. (2021) [37]	★	-	★	★	★-	★	★	★	★★★★★★★ (7)	Good

*Comparability assessed at the following: one star rewarded if study accounted for varying outcomes depending on operating surgeon/pump type, another star rewarded if study contained large enough sample size to limit confounding bias

Abbreviations: *AHRQ* Agency for Healthcare Research and Quality

Each work in this section received a designation of "good" according to the AHRQ Standards, with both works scoring 8 stars according to the Newcastle–Ottawa Scale [48, 49] (Table 7).

Spinal fusion surgeries

Similar to VPS and baclofen pump implantation, pediatric spinal fusions suffer high infection rates, ranging from 0.5 to 1.6% in low-risk cases to 8 to 42% in high-risk ones [50, 51]. Additionally, significant clinical variability exists, as seen in a 2013 survey among Pediatric Orthopedic Society of North America/Scoliosis Research Society, prompting the development of several infection reduction protocols (Table 4) [52]. Ballard et al. organized a multidisciplinary task force to standardize a set of peri-operative measures, resulting in a nearly 50% relative reduction in infection rates. While no compliance data is offered, the authors mention monthly meetings and empowering all staff to enforce the protocol ensured a high compliance rate [50].

Vitale et al. [51] used the Delphi method to reach a consensus of fourteen infection reduction measures, also consisting of pre-, intra-, and post-op steps. This article focuses on proof of concept demonstrating the process and feasibility of implementing a standardized practice across multiple institutions and surgeons with a follow-up article noting a dramatic 72% reduction in spinal infection rates [51, 53].

Ryan et al. devised a similar protocol based on the literature and prior institutional experience, with bimonthly meetings until a consensus was reached [54]. The authors noted a 2.2% infection rate after protocol adoption compared to 5.8% before implementation. While no multivariate analysis of each step's significance could be performed, the authors identified a higher infection rate inversely correlating with compliance [54].

Several other antibiotic bundle protocols have been published, with each demonstrating significant reductions in infection rates [55, 56]. While a portion of these reductions are attributable to Hawthorne bias, one group specifically analyzed correlation between protocol compliance and infection rates, finding that non-compliance led to a nearly threefold increased risk of surgical site infection [56].

Each work in this section received a designation of "good" according to the AHRQ Standards, with all works scoring either 8 or 9 stars according to the Newcastle–Ottawa Scale [50, 53–56] (Table 8).

Other protocols

A growing interest in standardization has steadily emerged in many pediatric neurosurgical pathologies. The 2003 Brain Trauma Foundation guidelines for traumatic brain injury management sparked a series of similar institutional algorithms for pediatric patients, demonstrating a stark improvement in survival and discharge disposition [57–59]. Numerous hospital systems have incorporated standardized pathways for pediatric cervical spine clearance, achieving marked reductions in radiation exposure, costs, and time to clearance while maintaining the number of missed injuries at zero [60–62]. Hypothermia is an often neglected yet important variable in optimizing patient outcomes with pediatric patients at particularly high risk. Several authors have proposed warming protocols to counteract this with encouraging results [63–65].

Lastly, Schaffzin et al. applied a standardized surgical site infection prevention protocol to all pediatric neurosurgical operations. The protocol included skin integrity assessment, *S. aureus* screening/decolonization, CHG baths, CHG wipes, and the patient warmer with each step subdivided into a family task and a healthcare team task. The authors identified a 79% risk reduction in surgical site infection [66].

Discussion

Clinical practice variation encompasses two basic categories: necessary, related to patient characteristics, and unexplained or unwarranted [67, 68]. The latter has complex contributions from practitioner level to hospital and systemic levels and is simply defined as identical patients receiving different levels of care depending on their location, timing, and provider at times despite established "best evidence" [68–71]. Minimizing unexplained variation via checklists and protocols has substantially improved outcomes in many disciplines by limiting human variability especially during periods of fatigue and high stress [6, 14–19, 67]. The WHO Surgical Safety Checklist, a mandatory pre-, intra-, and post-operative pause for verbal discussion of anesthetic, surgical, and nursing considerations — nowadays simply referred to as "time out" — reduced postoperative complications and deaths by over 30% [72]. Additionally, the Clinical Excellence Commission's Blood Watch program regulated transfusion practices resulting in $890,000 in savings over 1 year [73]. A Health Research and Education Trust study identified that a key commonality of 45 high-performing health systems was greater standardization of training and care processes emphasizing adherence to best practice guidelines while employing various strategies to maintain autonomy [74]. Standardization promotes conformity in healthcare to enable consistent implementation of widely agreed upon standards by different users, at different times, and in different settings [8]. Presently, many surgical steps are subconsciously "standardized." Once considered revolutionary, antiseptic hand-washing, gloving, sterile draping, and pre-incision IV antibiotics now represent universal

Table 7 Quality assessment of Chiari malformation surgery literature using the Newcastle–Ottawa Scale

Study ID	Selection				Comparability*	Outcome			Total (9★)	Conversion to AHRQ Standards (good, fair, poor)
	Representativeness of exposed cohort (★)	Selection of non-exposed cohort (★)	Ascertainment of exposure (★)	Demonstration that outcome of interest was not present at start of study (★)	(★★)	Assessment of outcome (★)	Was follow-up long enough for outcomes to occur (★)	Adequacy of follow-up of cohorts (★)		
Mazur -Hart et al. (2021) [48]	★	★	★	★	★-	★	★	★	★★★★★★★★ (8)	Good
Shao et al. (2020) [49]	★	★	★	★	★-	★	★	★	★★★★★★★★ (8)	Good

*Comparability assessed at the following: one star rewarded if study accounted for varying outcomes depending on operating surgeon, another star rewarded if study contained large enough sample size to limit confounding bias

Abbreviations: *AHRQ* Agency for Healthcare Research and Quality

Table 8 Quality assessment of spinal fusion surgery literature using the Newcastle–Ottawa Scale

Study ID	Selection				Comparability*	Outcome			Total (9★)	Conversion to AHRQ Standards (good, fair, poor)
	Representativeness of exposed cohort (★)	Selection of non-exposed cohort (★)	Ascertainment of exposure (★)	Demonstration that outcome of interest was not present at start of study (★)	(★★)	Assessment of outcome (★)	Was follow-up long enough for outcomes to occur (★)	Adequacy of follow-up of cohorts (★)		
Ballard et al. (2012) [50]	★	★	★	★	-★	★	★	★	★★★★★★★★ (8)	Good
Stephan et al. (2021) [53]	★	★	★	★	★-	★	★	★	★★★★★★★★ (8)	Good
Ryan et al. (2014) [54]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good
Poe-Kochert et al. (2020) [55]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good
Vandenberg et al. (2018) [56]	★	★	★	★	★★	★	★	★	★★★★★★★★★ (9)	Good

*Comparability assessed at the following: one star rewarded if study accounted for varying outcomes depending on operating surgeon, another star rewarded if study contained large enough sample size to limit confounding bias

Abbreviations: *AHRQ* Agency for Healthcare Research and Quality

Table 9 Risk of bias in the ventriculoperitoneal shunt surgery literature using the Cochrane risk of bias in cohort studies tool

Study ID	Cohorts drawn from the same population*	Assessment of exposure	Outcome of interest was not present at the start of the study	Study matched cohorts for all variables or adjust for prognostic variable	Assessment of prognostic factors†	Assessment of outcome	Adequate follow-up	Co-interventions similar between groups
Berns et al. (2021) [31]	–	–	–	–	–	–	–	–
Chu et al. (2022) [25]	–	–	–	–	–	–	–	–
Faillace (1995) [91]	–	–	–	?	–	–	–	–
Kalangu et al. (2020) [30]	+	–	–	+	–	–	–	+
Kestle et al. (2011) [20]	–	–	–	–	–	–	–	–
Kestle et al. (2016) [26]	+	–	–	+	–	–	–	+
Omrani et al. (2018) [29]	–	–	–	–	–	–	–	–
Pirotte et al. (2007) [24]	+	–	–	+	–	–	–	+
Raygor et al. (2020) [27]	+	–	–	+	–	–	–	+
Yang et al. (2019) [28]	–	–	–	–	–	–	–	–

Grading system: + high risk of bias; **?** unclear risk of bias; **–** low risk of bias

*Studies without a formal control group were graded as high risk of bias in this category, which affected the level of bias in other categories depending on the presence of a control

†Defined as the assessment of factors that may affect risk of VPS complication

standards [75]. Present-day protocols in essence attempt to grow these universal standards.

Though nascent, the impact of standardization in pediatric neurosurgery is evident, with significant reductions in shunt and baclofen pump infection rates, decreased lengths of stay and faster recoveries post-Chiari decompression, decreased costs, reduced radiation, faster time to cervical spine clearance, and more. Standardization streamlines patient management, increasing knowledge and efficiency while optimizing care provided by all healthcare members in the pre-, intra-, and post-op settings. Protocolization minimizes uncertainty — and arguably operative errors as a result — especially during off-peak hours, when "general" staff cover highly specialized operations while hindered by

Table 10 Risk of bias in baclofen pump surgery literature using the Cochrane risk of bias in cohort studies tool

Study ID	Cohorts drawn from the same population*	Assessment of exposure	Outcome of interest was not present at the start of the study	Study matched cohorts for all variables or adjust for prognostic variable	Assessment of prognostic factors†	Assessment of outcome	Adequate follow-up	Co-interventions similar between groups
Desai et al. (2018) [35]	–	–	–	–	–	–	–	–
Patel et al. (2021) [37]	+	–	–	+	–	–	–	+

Grading system: + high risk of bias; **?** unclear risk of bias; **–** low risk of bias

*Studies without a formal control group were graded as high risk of bias in this category, which affected the level of bias in other categories depending on the presence of a control

†Defined as the assessment of factors that may affect risk of baclofen pump complication

Table 11 Risk of bias in Chiari malformation surgery literature using the Cochrane risk of bias in cohort studies tool

Study ID	Cohorts drawn from the same population*	Assessment of exposure	Outcome of interest was not present at the start of the study	Study matched cohorts for all variables or adjust for prognostic variable	Assessment of prognostic factors†	Assessment of outcome	Adequate follow-up	Co-interventions similar between groups
Mazur-Hart et al. (2021) [48]	–	–	–	–	?	–	–	–
Shao et al. (2020) [49]	–	–	–	–	–	–	–	–

Grading system: + high risk of bias; **?** unclear risk of bias; **–** low risk of bias

*Studies without a formal control group were graded as high risk of bias in this category, which affected the level of bias in other categories depending on the presence of a control

†Defined as the assessment of factors that may affect risk of Chiari malformation surgery complication

unfamiliarity with each surgeon's varied preferences [76, 77]. Consistency reinforces critical surgical steps and promotes teamwork in all operative stakeholders, including nursing and surgical technicians, and high-functioning teams experience significantly fewer adverse events [72].

While standardized protocols have proven efficacy, resistance to their widespread adoption exists, stemming from lack of awareness, familiarity, or agreement, as well as feelings of insecurity or curtailed physician autonomy and creative decision-making [78–82]. Opponents also argue that it debases individual-, patient-centered care [83]. Oftentimes however, clinical variability stems from provider or practice preferences as opposed to varying patient characteristics. While certain factors — such as age, comorbidities, and others — engender variability in care, identical patients treated by two different physicians should logically receive the same optimal, evidence-based care. However, up to 30–40% of patients receive care inconsistent with current evidence, often reflecting clinician or institutional preference as opposed to patient needs [71]. Difficulty often derives from the sparsity of best evidence, especially in surgical disciplines — purportedly, only 40% of current surgical interventions are amenable to randomized, controlled studies; in many cases, lack of surgical equipoise presents a critical obstacle [84]. In such cases, surgeons often rely on personal experience, training, and lower quality evidence [85]. Given that the act of standardization alone improves outcomes — as opposed to the finite elements contained

Table 12 Risk of bias in the spinal fusion surgery literature using the Cochrane risk of bias in cohort studies tool

Study ID	Cohorts drawn from the same population*	Assessment of exposure	Outcome of interest was not present at the start of the study	Study matched cohorts for all variables or adjust for prognostic variable	Assessment of prognostic factors†	Assessment of outcome	Adequate follow-up	Co-interventions similar between groups
Ballard et al. (2012) [50]	–	–	–	–	?	–	–	–
Stephan et al. (2021) [53]	–	–	–	–	–	–	–	–
Ryan et al. (2014) [54]	–	–	–	–	–	–	–	–
Poe-Kochert et al. (2020) [55]	–	–	–	–	–	–	–	–
Vandenberg et al. (2018) [56]	–	–	–	–	–	–	–	–

Grading system: + high risk of bias; **?** unclear risk of bias; **–** low risk of bias

*Studies without a formal control group were graded as high risk of bias in this category, which affected the level of bias in other categories depending on the presence of a control

†Defined as the assessment of factors that may affect risk of spinal fusion complication

within the protocol — quality improvement efforts undertaken by patient-centric teams driving uniform techniques may partially offset the shortcomings of low quality evidence to maintain optimal care [24].

As such, the Delphi method, with inclusion of all stakeholders, may present an opportunity for common pathway or protocol development that preserves physician autonomy [86–88]. Providers value local protocols developed via interdisciplinary consensus — as opposed to blindly following another institution's guidelines, and an institutional culture that encourages respectful, collaborative inter-departmental decision-making plays a vital role in protocol adherence [76]. In this view, promoting team practice over individual practice encourages intra-team learning while respecting individual autonomy [68]. Kriznik et al. proposed four key steps in successful protocol development, based on their experience devising a line-labeling policy: defining the problem and solution, inclusion of all stakeholders from the start, prototyping/piloting of the protocol, and planning for implementation [89].

Successful implementation and enduring compliance are rooted in incorporating providers' perspectives on barriers and facilitators to protocol adherence [71, 76]. Several barriers to protocolization include the guidelines themselves: not feasible, credible, accessible, or attractive; providers' level of awareness or attitude towards change; network-level or department-level culture; organizational capabilities at implementing protocolized elements; and economic issues [71, 76, 83]. Especially when clinical equipoise exists, the opportunity for providers to play a personal role in protocol development is vital to ensure long-term adherence [76]. Institutional culture also influences protocol adherence with value placed on respectful interdepartmental communication and interdisciplinary leadership with collaborative decision-making [76]. The success of the protocols listed above often rested on multiple departments: Chiari protocol involving nursing and physical therapy for optimal pain control and early mobilization; baclofen pump pathway embracing physiatry, developmental pediatrics, and neurosurgery; and many infection reduction protocols necessitating buy-in at an institutional level, increasing upfront costs via incorporation of various infection reduction techniques towards a long-term goal of cost reduction via decreased hospitalizations and treatments for infections.

Once a protocol is established, PDSA cycles allow ongoing discussion and refinement, further contributing to ongoing compliance [90]. Compliance rates in the above studies was high, partially from the flexibility incorporated: for instance, the HCRN protocol devised a series of mandatory steps, while permitting surgeons freedom to incorporate any additional steps of their choosing. As a result, a single center's use of vancomycin irrigation as an additional measure proved to be a notable component for reduced infections, likely to be integrated into further protocol iterations [25]. Preserving this element of autonomy fostered compliance and contributed to an improved protocol.

The protocols highlighted above could lay the foundation for individual institutional protocols, refined based on their stakeholders' beliefs, hospital resources, and their unique patient population. Given that all quality-assessed publications in the categories of VPS, baclofen pump, Chiari malformation, and spinal fusion surgeries scored highly according to the Newcastle–Ottawa Scale (and were therefore designated as "good" quality according to the AHRQ standards) (Tables 5, 6, 7 and 8), we can conclude that each of these works provides a unique and meaningful contribution to the standardization of pediatric neurosurgery. Reservations about protocols formed by outside institutions should prompt individual institutions to form their own; the power of standardized protocols lies largely in the consistency and uniformity generated, and less so on their composition. While originally designed to reduce inadvertent medical errors and improve efficiency, the surgical protocols reviewed in this article demonstrate the power of applying similar principles of conformity to surgical technique, implant selection, and postoperative care, thereby realizing gains in economic costs, surgical complications, and duration of hospitalization. This nascent, exciting frontier of standardization in pediatric neurosurgery has only begun, and future works with wider adoption can be expected.

Standardization has a powerful, long history in manufacturing and aviation industries, with more recent applications in healthcare. Originally aimed at reducing medical errors, the pediatric neurosurgical community has extrapolated these principles to surgical technique in the most common pathologies. Their positive results suggest greater adoption of standardization could optimize care by reducing unnecessary clinical variation in a range of hospital settings (Table 9, 10, 11, and 12).

Limitations

While this systematic review provides a baseline with which to alter clinical practice, there are areas within this study which have bias. There is inherent selection bias in the papers included in this protocol. While we minimized this bias by following strict guidelines for inclusion, any review study suffers from this issue. Further, as this paper is dependent on other papers, there is reporting bias which is present in all research. In general, articles will only be published with positive results. As such, potential protocols/articles showing negative results are not included as these results are unpublished. Further, as many of these protocols were based as a single institution, observer bias is rampant in the articles. Taken together, while these articles provide a good basis to understand what can be done to improve outcomes through standardization, these articles are by no means the only method to standardize protocols. Rather, these articles are only articles that worked within this process.

Another limitation of this study is the lack of adherence to a standardized protocol in each individual study. It is unclear whether after a protocol was initiated if it was followed exactly every time. Therefore, the utility of adopting any particular protocol discussed would be dependent on the corresponding study.

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Declarations

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