

November 20, 2014

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Optimal Resources for Children’s Surgical Care
From the Committee on Children’s Surgery
American College of Surgeons
2014

November 20, 2014

9 The American College of Surgeons (ACS) Committee on Children's Surgery has prepared these
10 optimal resource standards.

11
12 The Committee on Children's Surgery is derived from the ad hoc Task Force for Children's
13 Surgical Care which met on 3 occasions:

14
15 **April 30-May 1, 2012**

16 Fizan Abdullah, MD, PhD, FACS, Baltimore, MD
17 Marjorie Arca, MD, FACS, Milwaukee, WI
18 Douglas Barnhart, MD, MSPH, FACS, Salt Lake City, UT
19 Stuart Berger, MD, Milwaukee, WI
20 Mary Brandt, MD, FACS, Houston, TX
21 Laura Cassidy, PhD, Milwaukee, WI
22 Clinton Cavett II, MD, FACS, Indianapolis, IN
23 Li Ern Chen, MD, FACS, Dallas, TX
24 Jacquelyn Evans, MD, Philadelphia, PA
25 Keith Georgeson, MD, FACS, Spokane, WA
26 Adam Goldin, MD, FACS, Seattle, WA
27 David Hoyt, MD, FACS, Chicago, IL
28 Bruce Kaufman, MD, FACS, Milwaukee, WI
29 Jacqueline Kueser, Kansas City, KS
30 Lynn Martin, MD, Seattle, WA
31 R. Lawrence Moss, MD, FACS, Columbus, OH
32 Keith Oldham, MD, FACS, Milwaukee, WI
33 Shawn Rangel, MD, FACS, Boston, MA
34 Thomas Ricketts, PhD, Chapel Hill, NC
35 Marshall Schwartz, MD, FACS, Philadelphia, PA
36 Thomas Tracy, MD, FACS, Providence, RI
37 Mark Wietecha, Washington, DC

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39 **May 30-31 2013**

40 Rick Abbott, MD, Bronx, NY
41 Fizan Abdullah, MD, PhD, FACS, Baltimore, MD
42 Marjorie Arca, MD, FACS, Milwaukee, WI
43 Douglas Barnhart, MD, MSPH, FACS Salt Lake City, UT
44 Stuart Berger, MD, Milwaukee, WI
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49 Craig Derkay, MD, FACS, Norfolk, VA
50 Jay Deshpande, MD, Little Rock, AK
51 Jacquelyn Evans, MD, Philadelphia, PA
52 Mary Fallat, MD, FACS, Louisville, KY
53 Keith Georgeson, MD, FACS, Spokane, WA,

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- 54 Constance Houck, MD, Boston, MA
55 Adam Goldin, MD, FACS, Seattle, WA
56 David Hoyt, MD, FACS, Chicago, IL
57 Bruce Kaufman, MD, FACS, Milwaukee, WI
58 Michael Klein, MD, FACS Detroit, MI
59 Thomas Krummel, MD, FACS, Palo Alto, CA
60 Jacqueline Kueser, Kansas City, KS
61 Lynn Martin, MD, Seattle, WA
62 R. Lawrence Moss, MD, FACS, Columbus, OH
63 Keith Oldham, MD, FACS, Milwaukee, WI
64 Shawn Rangel, MD, FACS, Boston, MA
65 Robert Sawin, MD, FACS, Seattle, WA
66 Mark Wietecha, Washington, DC
67
68 **May 21-22, 2014**
69 Rick Abbott, MD, Bronx, NY
70 Fizan Abdullah, MD, PhD, FACS, Baltimore, MD
71 Marjorie Arca, MD, FACS, Milwaukee, WI
72 Douglas Barnhart, MD, MSPH, FACS, Salt Lake City, UT
73 Stuart Berger, MD, Milwaukee, WI
74 Mary Brandt, MD, FACS, Houston, TX
75 Clinton Cavett II, MD, FACS, Indianapolis, IN
76 Li Ern Chen, MD, FACS, Dallas, TX,
77 Jim Couto, MA, Elk Grove Village, IL
78 Craig Derkay, MD, FACS, Norfolk, VA
79 Jay Deshpande, MD, Little Rock, AK
80 Jacquelyn Evans, MD, Philadelphia, PA
81 Mary Fallat, MD, FACS, Louisville, KY
82 Randall Flick, MD, MPH, Rochester, MN
83 Henri Ford, MD, FACS, Los Angeles, CA
84 Keith Georgeson, MD, FACS, Spokane, WA (not in attendance)
85 Adam Goldin, MD, FACS, Seattle, WA
86 BJ Hancock, MD, FACS, Winnipeg, MB, Canada
87 Constance Houck, MD, Boston, MA
88 David Hoyt, MD, FACS, Chicago, IL
89 Tyler G. Hughes, MD, FACS, McPherson, KS
90 Bruce Kaufman, MD, FACS, Milwaukee, WI
91 Mehresh Khalid, Chicago, IL
92 Michael Klein, MD, FACS, Detroit, MI
93 Clifford Ko, MD, FACS, Chicago, IL
94 Amy Knight, CHA, Washington, DC
95 Thomas Krummel, MD, FACS, Palo Alto, CA (not in attendance)
96 Lynn Martin, MD, Seattle, WA (not in attendance)
97 R. Lawrence Moss, MD, FACS, Columbus, OH
98 Keith Oldham, MD, FACS, Milwaukee, WI
99 James Perrin, MD, FAAP, Boston, MA

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- 100 David Plager, MD, Indianapolis, IN
- 101 Shawn Rangel, MD, FACS, Boston, MA
- 102 Karen Richards, Chicago, IL
- 103 Thomas Ricketts, PhD, Chapel Hill, NC
- 104 Ramesh Sachdeva, MD, FAAP, Chicago, IL
- 105 Robert Sawin, MD, FACS, Seattle, WA
- 106 Marshall Schwartz, MD, FACS, Philadelphia, PA
- 107 Mark Wietecha, Washington, DC (not in attendance)
- 108
- 109

Executive Summary

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111
112 The Task Force for Children’s Surgical Care, an ad hoc multidisciplinary group of invited
113 leaders in relevant disciplines, assembled in Rosemont, IL initially April 30-May 1, 2012, and
114 subsequently in 2013 and 2014 to consider approaches to optimize the delivery of children’s
115 surgical care in today’s competitive national healthcare environment. Specifically, a mismatch
116 between individual patient needs and available clinical resources for some infants and children
117 receiving surgical care is recognized as a problem in the U.S. and elsewhere. While this
118 phenomenon is apparent to most practitioners involved with children’s surgical care,
119 comprehensive data are not available and relevant data are imperfect. The scope of this problem
120 is unknown at present. However, it does periodically, and possibly systematically result in
121 suboptimal patient outcomes. The composition of the Task Force is detailed above. Support was
122 provided by the Children’s Hospital Association (CHA) and the American College of Surgeons
123 (ACS). The group represented key disciplines and perspectives. Published literature and data
124 were utilized when available and expert opinion when not, as the basis for these
125 recommendations. The objective was to develop consensus recommendations that would be of
126 use to relevant policy makers and to providers. Principles regarding resource standards, quality
127 improvement and safety processes, data collection and a verification process were initially
128 published in March 2014 [*J Am Coll Surg* 2014;218(3):479-487]. This document details those
129 principles in a specific manner designed to inform and direct a verification process to be
130 conducted by the American College of Surgeons and the ACS Committee on Children’s Surgery.
131
132 A summary of key recommendations follows.
133

134 LEVELS OF CARE

135 Table 1. Summary of Children’s Surgical Center Standards with Scope of Practice

	I	II	III
Age	Any	Any	> 6 months
ASA	1-5	1-3*	1-2
Multidisciplinary management of co-morbidities	Multiple medical and surgical specialties; pediatric anesthesiology	Typically single surgical specialties; neonatology; pediatric anesthesiology	None
Operations [†]	Major congenital anomalies and complex disease including those that are uncommon or require significant multidisciplinary coordination	Common anomalies and diseases typically treated by most pediatric surgical specialists and that do not require significant multi-specialty coordination.	Common, low-risk procedures typically performed by a single specialty.
Ambulatory [‡]	ASA 1-3 Full term infants and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants < 4 weeks or preterm infants < 50 weeks PMA weeks to be monitored for at least 12 hours postoperatively.	ASA 1-3 Full term and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants < 4 weeks or preterm infants < 50 PMA to be monitored for at least 12 hours postoperatively.	Otherwise healthy (ASA 1-2) Age > 6 months

136 PMA = Post menstrual age

137 *Emergent procedures in some patients > ASA 3 may be appropriate in neonatal patients such as
 138 those with necrotizing enterocolitis.

139 †Types of anomalies and diseases that should have pediatric subspecialty care are further
140 delineated in Appendix 1. Depending upon patient age, co-morbidities and need for multi-
141 disciplinary surgical approach, these may be appropriate for either Level I or Level II centers.

142 ‡Ambulatory sites of care are included in these recommended levels of institutional designation
143 when the onsite provider team possesses the requisite pediatric training and experience. The site
144 of care may be physically attached/integrated into the hospital or may be a component of a
145 demonstrably integrated children’s health care delivery system that provides these defined
146 resources.

147

148 Required access to subspecialty surgical and medical providers is defined and detailed
149 subsequently within this document.

150

151 PEDIATRIC SURGERY

152

153 Level I Centers

154

155 Two or more pediatric surgeons must be on the medical staff (CD 2-7). These individuals should
156 serve as the primary operating surgeon for children 5 years of age or younger undergoing
157 relevant general and thoracic procedures (as defined by the Pediatric Surgery Board of the
158 American Board of Surgery). A pediatric surgeon’s physical presence is required in the
159 operating room for operative procedures for which he/she is the primary surgeon (CD 2-8). A
160 pediatric surgeon is defined as an individual certified or eligible for certification in pediatric
161 surgery by the Pediatric Surgery Board of the American Board of Surgery or equivalent body. A

162 pediatric surgeon must be available and respond to the bedside within 60 minutes 24/7 when
163 required (CD 2-9). A relevant published call schedule must be readily available (CD 2-10).
164 Local criteria must be established to define conditions requiring the attending surgeon's physical
165 presence and a PIPS program must verify compliance (CD 2-11).

166

167 Level II Centers

168

169 Level II children's surgical centers are required to have one or more pediatric surgeons available
170 on a consultant basis to provide care within 60 minutes of such a request 24/7 (CD 2-59) and
171 provide relevant care for children 5 years of age or less as for a Level I center. An appropriate
172 published call schedule must be readily available (CD 2-60). Local criteria must be established
173 to define conditions requiring the attending surgeon's physical presence and a PIPS program
174 must monitor compliance (CD 2-61).

175

176 Level III Centers

177

178 A Level III children's surgical center must have continuous 24/7 availability within 60 minutes
179 of general surgeons and anesthesiologists with pediatric expertise (CD 2-83). A general surgeon
180 with pediatric expertise is defined as a surgeon either eligible for certification or certified by the
181 American Board of Surgery or equivalent in general surgery. In addition, this individual will
182 demonstrate ongoing clinical engagement and expertise in children's surgery as evidenced by
183 performing 25 or more procedures annually in patients less than 18 years of age, as well as
184 completion of 10 or more relevant Category I CME credit hours annually. (CD 2-84)

185

186 PEDIATRIC ANESTHESIA

187

188 Level I Centers

189

190 For Level I children’s surgical centers, two or more pediatric anesthesiologists must be on the
191 medical staff (CD 2-12) and one must serve as the primary anesthesiologist for all children 5
192 years of age or less (CD 2-13). A pediatric anesthesiologist’s physical presence is required for
193 procedures for which he/she is the primary credentialed provider (CD 2-14). A pediatric
194 anesthesiologist is defined as an individual certified or eligible for certification in pediatric
195 anesthesiology by the American Board of Anesthesiology or equivalent body. A pediatric
196 anesthesiologist must be available to respond to the bedside and provide service within 60
197 minutes 24/7 when required (CD 2-15). A relevant published call schedule must be readily
198 available (CD 2-16). Local criteria must be established to define conditions requiring the
199 attending anesthesiologist’s physical presence and a patient improvement/patient safety (PIPS)
200 program must verify compliance (CD 2-17).

201

202 Level II Centers

203

204 For Level II children’s surgical centers, one or more pediatric anesthesiologists must be on the
205 medical staff (CD 2-62) and must be available 24/7 within 60 minutes to serve as the primary
206 anesthesiologist for children 5 years of age or less (CD 2-63). A relevant published call schedule
207 must be readily available (CD 2-64). Local criteria must be established to define conditions

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208 requiring the attending anesthesiologist's physical presence and a PIPS program must verify
209 compliance (CD 2-65).

210

211 Level III Centers

212

213 A Level III children's surgical center must have continuous 24/7 availability within 60 minutes
214 of general surgeons with pediatric expertise and anesthesiologists with pediatric expertise (CD 2-
215 83).

216

217 An anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible to
218 certify or with a current certificate from the American Board of Anesthesiology or equivalent.
219 He or she would demonstrate continuous experience with children < 24 months of age, defined
220 as 25 patients per anesthesiologist per year. In addition, this individual will demonstrate ongoing
221 pediatric clinical engagement in patients less than 18 years of age, and complete 10 or more
222 relevant Category I CME credit hours annually. (CD 2-85)

223

224 DATA COLLECTION

225

226 Every verified children's surgical center must collect and analyze its surgical outcome data and
227 contribute it to the national collaborative effort (CD 7-1). For centers designated Level I or II this
228 will be fulfilled by participation in the American College of Surgeons National Quality
229 Improvement Program-Pediatric (NSQIP Pediatric) (CD 7-2). For Level III centers and

230 ambulatory surgical centers this requirement will be fulfilled by reporting of specific adverse
231 events detailed in Appendix 3 (CD 7-3).

232

233 PERFORMANCE IMPROVEMENT AND PATIENT SAFETY (PIPS)

234

235 A children's surgery Performance Improvement and Patient Safety (PIPS) program is an
236 essential component of a high quality clinical surgical program. (CD 8-29) The unique elements
237 of perioperative care of children with surgical diseases require a focused quality and safety
238 construct that supplements existing hospital QI activities. The PIPS program for a Level I or
239 Level II center must be a specific children's surgical program (CD 8-30); Level III and
240 ambulatory centers may utilize processes integrated within existing institution wide efforts to
241 achieve these stated objectives. (CD 8-31) The programs for Level I and II centers must include
242 the following elements:

- 243 • Shall be a confidential quality improvement activity that is protected by all pertinent state
244 and federal statutes. (CD 8-32)
- 245 • Must be integrated with all appropriate hospital quality improvement and safety programs
246 and with the Board of Trustees quality committee or equivalent. (CD 8-33)
- 247 • May be a dedicated sub-committee of a hospital's existing PIPS program but must be
248 focused on improving children's surgical care within the institution. (CD 8-29, CD 8-30)
- 249 • Must be chaired or co chaired by the medical director of children's surgery (MDCS) or
250 her/his designee. (CD 8-34)
- 251 • Must include representatives of all surgical disciplines that provide care to children in the
252 participating center, as well as pediatric anesthesiology and radiology. When within

253 scope of hospital surgical services, neonatology, pediatric intensive care, and emergency
254 medicine representatives must also participate. (CD 8-35)

- 255 • Must meet at least quarterly. (CD 8-36)
- 256 • Members or designees must attend at least 50% of the PIPS meetings. (CD 8-37)
- 257 • Must establish criteria for care delivery by providers in each specialty, including
258 individual providers' credentials that document their validity as pediatric specialists in
259 the respective disciplines. (CD 8-38)
- 260 • Must establish criteria for conditions that require physical presence of specific specialty
261 providers. (CD 8-39)
- 262 • Must monitor the compliance of providers and the program with all criteria including
263 physical presence of providers when indicated. (CD 8-40)
- 264 • Must review all surgical deaths, a significant cohort of surgical complications, and any
265 serious safety events related to children's surgical care. (CD 8-41)
- 266 • Should review the program's quality performance metrics compared to national
267 benchmarks and develop plans to address any significant outlying metrics.
- 268 • Must review all transfers to Level I programs for appropriateness, timeliness, and
269 outcome. (CD 8-42)
- 270 • Will disseminate the reviews of the PIPS to all pertinent participants in the children's
271 surgical care program and the hospital leadership. (CD 8-43)

272 VERIFICATION

273

274 The American College of Surgeons has a long history of activities directed toward the
275 improvement of surgical care. This new program defines the resources believed necessary to

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276 achieve optimal patient outcomes for children’s surgical care at designated centers and offers
277 institutional consultation and/or verification. This program is administered by the American
278 College of Surgeons (ACS) Committee on Children’s Surgery. This document, *Optimal*
279 *Resources for Children’s Surgical Care* is to be used as a guide for the development and
280 verification of centers throughout the United States. It is the basis upon which centers will
281 evaluated by ACS approved site surveyors.

282

283

284 **Introduction**

285

286 The American College of Surgeons (ACS) was founded in 1913 on the basic principles of
287 improving the care of surgical patients and strengthening the education of surgeons. With this in
288 mind, the ACS Committee on Children's Surgery was created in 2014 to continue on a
289 permanent basis within the ACS the work of the ad-hoc Task Force on Children's Surgical Care.
290 This group was first convened in 2012 and has worked continuously since that time, including
291 assemblage as an entire group on three occasions for in person discussion. The
292 recommendations of this Task Force have been disseminated [*J Am Coll Surg* 2014;218(3):479-487].
293 The ACS Committee on Children's Surgery was established with the goal of improving the care
294 of children with surgical needs. This process includes defining optimal resource standards and
295 matching these prospectively to an individual child's needs. Achievement of this goal requires
296 an appropriately designed system of care and includes verification that these standards are met in
297 individual children's surgical centers. We intend to continuously review and improve this
298 document as new information and more data are developed that can be applied to its content.
299 Our intent is to use evidence-based scientific methods to support recommendations. We used
300 existing data where possible and combined this with expert opinion to establish consensus and
301 formulate these current standards. Multiple research efforts are underway to strengthen the
302 evidence base as well.

303

304 We believe that these standards reflect a realistic assessment of our current resource capability
305 while emphasizing the goal of providing the highest quality patient care. We recognize that
306 these standards will certainly challenge our existing models of children's surgical care. We are

307 confident that the objective of improving children’s surgical care is correct and that it is a
308 collective professional responsibility. It is an expectation of the public as well. These standards
309 are meant to be positive and constructive. We believe they are likely to improve clinical
310 outcomes for children. This effort is envisioned to provide impetus for a broad based initiative
311 that includes process improvement of systems of care as well as research and provider education.
312 It is a multidisciplinary effort undertaken with specialty societies and representatives who speak
313 for those across the entire continuum of children’s surgical care. This initial standards document
314 will be subject to evolution and revision as practice continues to change and improve.

315

316 Few individual facilities can provide all resources to all children in all situations. Ultimately, all
317 patients who require the resources of the Level I center should have access to it. This reality
318 requires the development of systems of care for children with surgical needs, not simply the
319 development of children’s surgical centers.

320

321 An ideal children’s system includes all of the components identified to be optimal for children’s
322 surgical care. Elements include considerations such as appropriate access, high quality
323 developmentally appropriate acute hospital care and ambulatory care, rehabilitation and relevant
324 research and education activities. Although the focus of this document is children’s surgical
325 center consultation and verification, it also emphasizes the need for various levels of children’s
326 surgical centers to cooperate to meet children’s surgical needs in order to avoid poor use of
327 precious medical resources. In an era where value is a public demand, we must strive not only
328 for optimal care, but we must provide this care in a cost effective manner.

329

330 Emphasis has been placed on identifying criteria that are judged essential for each level of
331 children’s surgical center designation. These criteria are referenced in each chapter by terms
332 such as “must”, “essential”, “required”, and so forth and are delineated by number identifying
333 the criterion and chapter; for example (CD 5-2) is the second criterion in Chapter 5. The authors
334 recognize that some criteria will change or be added or deleted as more knowledge is obtained
335 based on data that become available. These current standards represent expert consensus on
336 resource standards judged most likely to yield optimal clinical outcomes for patients. We are
337 hopeful they will supplement rather than supplant various state and other existing administrative
338 processes such as Certificate of Need (CON) regulations.

339

340 **Definitive Care Facilities**

341

342 Essential to the development of a children’s surgical care system is the designation of definitive
343 children’s surgical care facilities. The children’s surgical care system is ideally a network of
344 definitive care facilities that provides the spectrum of care necessary for all children with
345 surgical needs. Ideally, every center that provides surgical services to children would define its
346 scope of practice and provide appropriate resources as defined by the level designations
347 described in this document. Some population dense areas may have multiple Level I centers as
348 well as Level II and III centers. A Level I facility will provide support for centers with less
349 intensive children’s resources. This should be determined locally to insure appropriate use of
350 available resources. In less densely populated and rural areas, Level II and III hospitals will be
351 essential. Likewise, cooperative relationships with other centers are needed. Because a large
352 proportion of children with surgical needs receive care in an outpatient environment, ambulatory

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353 surgery must also be considered in this discussion. In any such system, determining the
354 anticipated number and character of children with surgical needs and assessing available
355 resources to determine the optimal number and level of children's surgical centers in a given area
356 is essential.

357

358 In most children's health care systems, a combination of levels of designated centers will coexist
359 with other facilities. The children's surgical care system must establish relevant facility and
360 personnel standards. This document is the initial effort to establish these standards. We have
361 attempted to emphasize resource differentiation between centers. We do not view our
362 classification scheme as a ranking of medical quality. We expect the commitment to quality care
363 to be the same regardless of resources.

364

365 We hope that one of the outcomes of this initiative is that all children who require health care
366 services including surgical care will receive the appropriate care regardless of ability to pay. The
367 Emergency Medicine Treatment and Labor Act imposes obligations on Medicare participating
368 hospitals that offer emergency services to provide medical screening examination or treatment
369 for an emergency medical condition, regardless of ability to pay. Hospitals are required legally
370 and ethically to provide stabilizing treatment for a child, as well as appropriate transfer when
371 required.

372

373

374 **Level I**

375

376 The Level I children's surgical center is a regional resource that is a tertiary care facility central
377 to the children's health care system. This facility must have the capability of providing
378 leadership and comprehensive care for all aspects of children's surgical needs. In this central
379 role, the Level I center must have adequate depth of resources and personnel.

380

381 In addition to acute care responsibilities, Level I children's centers have the major responsibility
382 of providing leadership in education, research and system planning. This responsibility includes
383 the expectation of cooperation and prospective planning with all hospitals caring for children
384 with surgical needs in their region. Recognizing that they will need to provide care for young
385 families with few resources who may be far from home and local support systems, Level I
386 centers also have responsibility for assisting the families with managing travel burden as well as
387 psychological, spiritual, and social support.

388

389 Research and education programs, as defined in this document, are essential for Level I
390 children's surgical center verification. Medical education programs require relevant residency
391 program support and postgraduate training in children's surgical care for physicians, nurses and
392 other providers. Education can be accomplished through a variety of mechanisms including
393 related fellowship training programs, continuing medical education (CME), preceptorships,
394 personnel exchanges and other approaches appropriate to the local situation.

395

396

397 **Level II**

398

399 The Level II children's surgical center is a hospital that is expected to provide initial children's
400 surgical care regardless of the complexity of the need and definitive care when appropriate.

401 Depending on geographic location, patient volume, personnel and resources, the Level II center
402 will not be able to provide the same comprehensive care as a Level I children's surgical center.

403 Therefore, patients with more complex, particularly multidisciplinary needs may require transfer
404 to a Level I center. In some areas where a Level I center does not exist, the Level II center will
405 take on the responsibility for education and regional leadership.

406

407 **Level III**

408

409 The Level III children's surgical center serves communities that do not have immediate access to
410 a Level I or II institution. These Level III children's surgical centers can provide prompt

411 assessment, resuscitation, emergency operations and stabilizations and also arrange for possible
412 transfer to a facility that can provide definitive surgical care. Additionally, Level III children's

413 surgical centers may provide a limited scope of services in areas where there is a Level I or II

414 institution. Procedures that are less complex for patients who are generally low risk may be
415 definitively cared for in this environment. General surgeons with pediatric expertise and

416 anesthesiologists with pediatric expertise are required at a Level III children's surgical center.

417 Ideally these centers provide these services as part of an organized system of care in coordination

418 with Level I or II centers. Planning for care of children with surgical needs at these hospitals

419 requires transfer agreements and standardized treatment protocols. Level I and II children's

420 surgical centers have an obligation to extend their educational activities to rural areas in the form
421 of professional education, consultation, or community outreach. A process should exist to
422 provide feedback about individual patient care and outcome analysis to the referring hospital.

423

424 **Children's Ambulatory Surgical Centers**

425

426 These standards were developed because a large proportion of children's surgical needs are
427 managed on an outpatient basis in a contemporary environment; this may be half or more of all
428 children who undergo surgical procedures. While these children are generally healthy and do
429 well, the uncommon consequences of perioperative problems, particularly related to anesthesia,
430 may be life threatening. These standards have been developed in an effort to minimize this risk.

431 Children's ambulatory surgery centers must have treatment protocols for resuscitation, transfer
432 protocols, data reporting and participate in systems performance improvement. Children's
433 ambulatory centers must have good working relationships and be fully integrated with a Level I,
434 II or III inpatient children's surgical center. This relationship is vital to the development of a
435 children's surgical system in which realistic standards must be based on available resources.

436 Optimal ambulatory children's surgical care in rural areas can be provided by skillful use of
437 existing professional and institutional resources supplemented by guidelines that result in
438 enhanced education, resource allocation, and appropriate designation for all levels of providers.

439 It is essential for the children's ambulatory surgical center to have the involvement of one or
440 more committed and appropriately trained health care providers to provide leadership and sustain
441 the integration with other relevant centers.

442

443 No ambulatory surgical facility without a defined relationship demonstrating integration with a
444 Level I, II or III children's surgical center will be verified by the ACS. This relationship requires
445 a plan to facilitate expeditious transfer of seriously ill children who require a higher level of care.
446 Exchange of medical personnel between Level I, II and III inpatient and ambulatory surgical
447 centers may be an excellent way to develop this relationship.

448

449 **Consultation and Verification Process**

450 An obvious corollary for this type of document defining resource standards for children's
451 surgical needs is the development of a consultation and verification process whereby a hospital
452 or health system can be evaluated to determine whether ACS criteria are being met. This
453 verification process for children's surgical centers is now available through the American
454 College of Surgeons. This document was developed to aid the process of consultation and
455 verification of children's surgical centers. Attention is given to defining resources available
456 within an inclusive system for children's surgical care. As this verification process matures, it
457 will yield better definitions and new standards for many of the assessed areas within the hospital.

458

459 **Principles for this 1st Edition**

460

461 This is the first edition of the ACS-Committee on Children's Surgery document entitled *Optimal*
462 *Resources for Children's Surgical Care*. It is intended to establish resource standards that assure
463 that individual patient needs are matched prospectively with available institutional resources in
464 an effort to provide the safest and highest quality care possible. It will, over time, undergo
465 substantial change. Many individuals volunteered a significant amount of their time, energy,

466 experience and knowledge drafting this document. The individuals involved include those
467 delineated as Task Force members and also participants from all of the surgical disciplines
468 represented within the American College of Surgeons, with much additional multidisciplinary
469 input from other individuals and professional organizations relevant to children's surgical care.
470 This document attempts to define the resources needed at various types of facilities to provide
471 optimal care. The authors were guided by a number of principles that are worth mentioning.

472

473 **Emphasis on a Children's Health System Rather Than the Children's Surgical Center**

474

475 Optimal care of children with surgical needs requires a systems approach. No one children's
476 center can do everything alone. Thus, a systems approach is necessary within a community
477 regardless of its size. In some cases, the system may encompass a region or even an entire state.
478 If resources for optimal care of children's surgical needs are to be used wisely, then some
479 concentration of resources should occur. This type of resource distribution should allow patients
480 to move to the appropriate level of available care and, ideally, match to a child's individual
481 perioperative needs. This should avoid excessive, inadequate or inappropriate resource
482 expenditure in a time of limited resources.

483

484 **Difference in External Environment**

485

486 It is recognized that we provide surgical care to children in urban and rural environments that
487 are often very different. Rural environments often, but not always, have fewer clinicians and less
488 complex facilities and technology. Although a perfect definition cannot be found for these

489 environments, an attempt is made to recognize the needs of these different settings. However, in
490 either environment, the matrix is predicated on the fact that children with the most complex
491 needs must be treated at more resource-intensive facilities. Facilities must interact with one
492 another to optimize care within and across both environments.

493

494 **Differentiation Between Levels of Care**

495

496 A sincere attempt was made to clearly differentiate resource needs between the defined levels of
497 care. Although the quality of care is expected to be similar at all levels of care, the complexity
498 and volume of children with surgical needs were accepted as the drivers of resource needs and
499 level designation. As complexity and volume increase, more human and capital resources are
500 required to ensure optimal care. Hopefully, the differences in resource requirements will allow
501 each facility at each level to allocate acceptable resources based on the needs of the patient
502 population served. Our resource standards have been developed with an effort to be pragmatic
503 given the current medical economic environment.

504

505 **Human Resource Commitment**

506

507 The capacities and skill sets of pediatric surgeons, specialty children's surgeons, pediatric
508 anesthesiologists and others with specialized pediatric training have been defined elsewhere.
509 Defining their roles in teams related to systems of children's surgical care is a point of emphasis
510 in this document. Individuals from these specialties who intend to care for children must take an
511 active role in the children's surgical program in any system providing care to children. As the

512 level of care increases, these physicians must become more involved and be part of the resource
513 commitment for a successful children's surgical program. The role of the administrative support
514 team is defined as well.

515

516 **Involvement of Surgeons and Physicians**

517

518 Resources necessary for optimal children's surgical care include human capital, facilities,
519 technology and the organization of care. The optimal care goal assumes that the human
520 resources include the most highly trained and qualified medical professionals available to treat
521 our children. This document establishes the level of responsibility for surgeons,
522 anesthesiologists and others involved in the perioperative care of children with surgical needs.
523 These individuals must be readily available 24 hours a day in facilities providing the highest
524 level of care.

525

526 **Neonatology and Critical Care Services**

527

528 The need for access to perioperative critical care services for infants and children undergoing
529 surgery is evident. Resource requirements defining and delineating these are provided in this
530 document. It is required that critically ill patients of any age have appropriate and immediate
531 physician and nursing coverage when needed.

532

533

534 **Anesthesia**

535

536 Available data emphasize the critical role of specialty trained pediatric anesthesiology providers
537 for infants and young children undergoing surgery. For several decades, it has been apparent
538 that the highest perioperative risk for anesthesia is in neonates and infants, and furthermore that
539 this risk can be diminished by the deployment of individuals with the unique skills acquired in
540 pediatric anesthesiology specialty training. In October 2013, the American Board of
541 Anesthesiology administered for the first time a certifying examination leading to a certificate of
542 added qualification in pediatric anesthesiology. This standard is incorporated into this document.

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CHAPTER 1

Responsibilities of Regional Systems of Care

More than 5 million infants and children undergo a surgical procedure in the United States annually. Some are relatively simple; some are quite complex. Patient risk factors that influence outcome include a host of medical and surgical comorbidities; notably young age is an important one of these. Optimal anesthesia and airway management in infants and children require specific training and skills; infrequently encountered problems may be life threatening. Neonatal and other pediatric critical care capacity may be necessary to provide appropriate perioperative care. The volume of surgical care and the potential complexity are enormous. Given the large number of infants and children involved, uncommon negative events are certain to occur. Given the potential consequences to an individual patient, optimal care of a population requires a planned system of care for children’s surgical services. All verified children’s surgical centers must participate in state and/or regional system planning/development or operation. (CD 1-1)

As a means for further assisting the development of state and regional children’s surgical systems, the ACS-Committee on Children’s Surgery will initiate a program for system consultation. Unlike center verification, this program is purely consultative and designed to be applied to a system at any stage of development. The consultative process for a children’s surgical system involves a site visit by a multidisciplinary team and a comprehensive analysis of all of the components and the functionality of the state or regional system.

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Role of Designated Children’s Surgical Centers in the Development of Regional Systems

As the scope of activity for the provision of children’s surgical care expands from single centers to multifaceted systems, it becomes increasingly important that designated centers be effectively engaged in all aspects of system planning, implementation and evaluation within their region. Designated centers are a key element in a system and the focal point for treatment. Centers typically contribute administrative leadership, medical leadership and academic expertise to a state or regional system. Lead facilities in a given region (Level I or II) have the additional challenge of engaging all other acute care facilities, designated centers and nonspecialty hospitals in the performance improvement process for an inclusive children’s surgical system.

Meaningful participation in state and regional system planning, development and operation is essential for all designated facilities within a region (CD 1-1). This participation will be dependent on local administrative structures, history, vision and the state of system development.

Examples of participation by center staff include the following:

- Participation in state and regional advisory committees
- Leadership in state and regional medical committees responsible for children’s medical and surgical care
- Regular collaboration with regional committees , or other relevant entities to promote development of state and regional systems
- Participation in media and legislative education to promote and develop children’s care systems

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- 593 • Participation in state and regional needs assessment or surveillance
- 594 • Participation in the development of a state or regional plan or registry
- 595 • Provision of technical assistance and education to regional hospitals and providers for the
- 596 purposes of improving system performance
- 597 • Leadership in development of regional transport systems for infants and children
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CHAPTER 2

Children’s Surgical Center Levels and Their Roles in a System of Care

An ideal children’s health system provides all of the elements of optimal care, including prompt and appropriate access, high quality acute hospital and ambulatory care, rehabilitation, health maintenance and relevant research and education activities. Our focus here is children’s surgical care and central to an ideal system is a relatively large, resources-rich center. The need for resources is based primarily on the patient centered concept of being able to provide the right medical care to an individual patient at the right time.

Optimal resources at a Level I children’s surgical center includes immediate availability of board-certified or board eligible pediatric specialty anesthesiologists, pediatric surgeons, subspecialty children’s surgeons, neonatologists, pediatric intensivists and pediatric emergency physicians. Other board-certified pediatric specialists would be similarly available, within a short time, to all patients who require their expertise. To assure adequate experience, this center would require a certain volume of patients to be admitted each year and would include the most complex and high-risk patients from the system. In addition, certain needs that occur infrequently should be concentrated in this special center to ensure that these patients are properly treated and studied. Research activities are necessary to enhance our knowledge of the care of children with complex surgical needs. Research in areas relevant to children’s surgical care should be present. This center would have an integrated, concurrent performance improvement and patient safety (PIPS) program to ensure optimal care and continuous improvement in care. This center would be responsible not only for assessing care provided

624 within its surgical program, but also for helping to organize the assessment of care within the
625 entire system or region. This center should serve as a comprehensive resource for all entities
626 dealing with children's surgical patients in the system and potentially the region. Verified
627 centers should demonstrate commitment toward reaching this ideal.

628

629 Surgeon commitment is essential for a properly functioning children's surgical center (CD 2-1).

630 In fact, without surgical leadership, the program will not be able to meet all the requirements
631 outlined in *Optimal Resources for Children's Surgical Care*. Although this commitment may be
632 difficult to measure objectively, it can be recognized in a number of ways, including a children's
633 surgeon who is the medical director of the program, surgeons who take an active role in all
634 aspects of caring for surgical infants and children, active surgical participation in the PIPS
635 program, and surgeons who take an advocacy role for patients. The PIPS program must be
636 inclusive of relevant medical and surgical providers actively participating in children's surgical
637 care (CD 2-2). Surgical leaders who promote the program to the community, hospital, and other
638 colleagues also should be easily recognized. Therefore, surgical commitment is a valuable
639 resource that is integral to a successful children's surgical program.

640

641 The ACS supports children's surgical center and system development and related public health
642 policies, including needs assessment, policy development and quality assurance. Each
643 community should assess its true needs for children's surgical care, emphasizing a system
644 approach. The center classification scheme (Level I, Level II, Level III, and Ambulatory) is
645 intended to assist communities in the development of their system for children's surgical care.
646 Centers developed should match the medical and access needs of the pediatric population which

647 is reasonably expected to require and use these surgical services. Every community of providers
648 should ensure that resources are used appropriately to achieve the stated goal of optimal care for
649 children undergoing surgery. The goal of every system is to match the needs of patients to the
650 capabilities of the facility. Proper triage is a critical feature of a good system and is necessary to
651 achieve this goal. Transport to appropriate facilities will optimize outcome and utilization of
652 resources. Although payor status is an important feature of the U.S. health care system, medical
653 necessity is paramount. Children's surgical centers at all levels of verification must accept
654 referrals of all medically appropriate patients within their region from centers without the
655 necessary children's surgical capacity regardless of payor (CD 2-3). To properly function, the
656 system requires proper communication systems and clear, well-defined protocols for triage and
657 transport. In addition, well-designed systems facilitate the acquisition of new knowledge
658 through effective clinical research.

659

660 Objective, extramural verification of a hospital's resources, commitment, and capability is an
661 important early step in the development of a regional system. Owing to the inherent differences
662 in population density, geography, and health care resources, each regional system will be
663 individualized to achieve optimal patient care.

664

665 Regardless of the size of an area, each system should have an identified lead hospital. Ideally,
666 one hospital, typically a Level I center, would be looked upon as the resource leader within a
667 given region. This hospital would serve as a resource to all other hospitals within the system.
668 Outside major population centers, Level II centers may serve as the lead hospital for extended
669 geographic areas. In some rural areas, where population densities are low and distances great, a

670 Level III center may be the only resource for miles. Ambulatory surgery centers are considered
671 separately, but in any system will have clearly identified relationships and demonstrable
672 integration with one or more verified Level I, II or III children's inpatient facilities (CD 2-4).

673

674 **Description of Children's Surgical Center Levels**

675

676 Children's surgical centers must be able to provide on their campuses the necessary human and
677 physical resources to properly provide children's surgical care consistent with their level of
678 verification. (CD 2-5)

679

680 **Level I**

681 A Level I children's surgical center should be a regional resource center and generally serve
682 large cities, population-dense or large catchment areas. This institution will usually serve as the
683 lead hospital for the system. In larger population-dense areas, more than one Level I designated
684 center may be appropriate. This institution is expected to manage large numbers of patients. A
685 Level I children's surgical center must perform surgical procedures for at least 1000 patients less
686 than 18 years of age annually. (CD 2-6)

687

688 A Level I children's surgical center is expected to provide optimal care to neonates, infants,
689 children and adolescents regardless of age and medical and surgical comorbidities. This requires
690 access to a comprehensive portfolio of medical and surgical subspecialists on the medical staff
691 who are readily available 24/7 to provide bedside care. The scope of service includes care for

692 major congenital anomalies and complex diseases including those that are uncommon or require
693 significant multidisciplinary coordination.

694

695 Two or more pediatric surgeons must be on the medical staff (CD 2-7). These individuals should
696 serve as the primary operating surgeon for children 5 years of age or younger undergoing
697 relevant general and thoracic procedures (as defined by the Pediatric Surgery Board of the
698 American Board of Surgery). A pediatric surgeon's physical presence is required in the
699 operating room for operative procedures for which he/she is the primary surgeon (CD 2-8). A
700 pediatric surgeon is defined as an individual certified or eligible for certification in pediatric
701 surgery by the Pediatric Surgery Board of the American Board of Surgery or equivalent body. A
702 pediatric surgeon must be available and respond to the bedside within 60 minutes 24/7 when
703 required (CD 2-9). A relevant published call schedule must be readily available (CD 2-10).
704 Local criteria must be established to define conditions requiring the attending surgeon's physical
705 presence and a PIPS program must verify compliance (CD 2-11).

706

707 For Level I children's surgical centers, two or more pediatric anesthesiologists must be on the
708 medical staff (CD 2-12) and one must serve as the primary anesthesiologist for all children 5
709 years of age or less (CD 2-13). A pediatric anesthesiologist's physical presence is required for
710 procedures for which he/she is the primary credentialed provider (CD 2-14). A pediatric
711 anesthesiologist is defined as an individual certified or eligible for certification in pediatric
712 anesthesiology by the American Board of Anesthesiology or equivalent body.

713

714 A pediatric anesthesiologist must be available to respond to the bedside and provide service
715 within 60 minutes 24/7 when required (CD 2-15). A relevant published call schedule must be
716 readily available (CD 2-16). Local criteria must be established to define conditions requiring the
717 attending anesthesiologist's physical presence and a PIPS program must verify compliance (CD
718 2-17).

719

720 In a Level I center, all surgical specialists require institutional credentials for specific privileges
721 for operative procedures to be done in children (CD 2-18).

722

723

724

725 A Level I children's surgical center must maintain appropriate neonatal and pediatric critical care
726 services with demonstrable surgical leadership participating in their operational management.
727 (CD 2-19) Children's surgeons must participate in the care of surgical patients specific to their
728 surgical fields, including planning and implementation of major therapeutic decisions (CD 2-20),
729 presence at major resuscitations (CD 2-21), presence at operative procedures (CD 2-22), and
730 involvement in the critical care of all infants and children receiving perioperative care (CD 2-
731 23). A Level I children's surgical center must participate in the training of surgical residents
732 (CD 2-24), be a leader in surgical education and outreach activities (CD 2-25), and conduct
733 surgical research (CD 2-26).

734

735 A Level I children's surgical center is required to provide resources consistent with Level IV
736 NICU designation (CD 2-27). Neonatal Intensive Care Unit (NICU) designations are those

737 delineated by current American Academy of Pediatrics recommendations [*American Academy of*
738 *Pediatrics. Committee on Fetus and Newborn. Pediatrics 2012;130:587-597*]. (Appendix 1)
739 Level I children's surgical center designation requires 24/7 neonatologist availability when a
740 neonatologist is not on site. (CD 2-28) This must be verified in the PIPS process (CD 2-29). A
741 neonatologist is defined as an individual who is either sub-board eligible or certified by the
742 American Board of Pediatrics in Neonatal-Perinatal Medicine or equivalent. Level IV NICUs
743 must maintain a full complement and range of pediatric medical subspecialists, children's
744 surgical subspecialists and pediatric anesthesiologists on site (index institution is the primary site
745 of practice). (CD 2-30)

746

747 A Level I children's surgical center must have a dedicated pediatric intensive care unit (CD 2-
748 31). A dedicated pediatric intensive care unit requires pediatric intensivist availability 24/7 with
749 individuals certified in critical care medicine by the American Board of Pediatrics, the American
750 Board of Anesthesiology or the American Board of Surgery or equivalent organizations. (CD 2-
751 32) This must be verified in the PIPS process (CD 2-33). This unit must be fully dedicated to
752 pediatric patients (CD 2-34) and support staff must have demonstrable relevant pediatric training
753 and expertise (CD 2-35). Appropriate pediatric equipment must be available for the scope of
754 service (CD 2-36).

755

756 Two or more pediatric radiologists must be on the medical staff of a Level I children's surgical
757 center (CD 2-37) and one must be available to provide appropriate service within 60 minutes
758 24/7 (CD 2-38). A pediatric radiologist is defined as an individual certified by the American
759 Board of Radiology or equivalent in addition to being certified or eligible for certification in

760 pediatric radiology by the American Board of Radiology or equivalent. Remote electronic image
761 analysis is a permissible adjunct, however individuals trained and skilled in hands on pediatric
762 imaging such as fluoroscopy must be physically available within 60 minutes. (CD 2-39) This
763 must be verified in the PIPS process (CD 2-40). In addition to 24/7 pediatric radiologist
764 coverage, interventional radiology physicians and support personnel must be available 24/7 for
765 designation as a Level I children's surgical center. This must be verified in the PIPS process
766 (CD 2-41).

767

768 Level I children's surgical centers must have pediatric emergency physician coverage 24/7 (CD
769 2-42). A pediatric emergency physician is an individual who is Board certified or eligible either
770 in pediatrics or emergency medicine with ACGME-approved or equivalent pediatric fellowship
771 training for this specialized designation. In addition, children's specific emergency department
772 resources must be in place to support Level I designation, including dedicated facilities (CD 2-
773 43), pediatric appropriate equipment (CD 2-44) and nonphysician personnel with specific
774 pediatric training (CD 2-45).

775

776 Level I children's surgical centers must have pediatric medical and surgical specialists promptly
777 and readily available for consultation; these specialists must be on the medical staff and available
778 within 60 minutes, 24/7 to provide care at the bedside (CD 2-46). A portion of this 24/7 coverage
779 may be provided by appropriately trained specialists who lack pediatric certification. In this case
780 the medical director of children's surgery and institutional surgical subspecialty leaders must
781 prospectively define the scope of practice of these providers. (CD 2-47) There must be a plan for
782 provision of pediatric subspecialty care outside this limited scope of practice if needed during

783 periods when call coverage is provided by surgeons without pediatric certification. (CD 2-48)
784 The medical director of children’s surgery and institutional subspecialty leaders must monitor
785 compliance with this plan (CD 2-49). Here and elsewhere in this document, pediatric medical
786 and surgical specialists are defined as those who are either eligible for or Board certified after
787 relevant children’s specialty fellowship training (either medical or surgical) and recognized by
788 the appropriate Board of the American Board of Medical Specialties or equivalent. Relevant
789 children’s surgical specialists will be available to support the entire scope of institutional surgical
790 practice in infants and children. (CD-50) Where providers with pediatric specific training and
791 experience are designated as “available”, the requirement is that patient care will be
792 demonstrably provided by these specialized children’s medical and surgical providers (CD 2-51).

793

794 A pediatric rapid response and/or resuscitation team is required for Level I designation (CD 2-
795 52). This requires 24/7 physical presence of a pediatric specialty physician or surgeon to include
796 PALS certification, in the leadership role. (CD 2-53)

797

798 Level I centers are required to participate in a data collection program which yields peer
799 performance assessments against which an individual program may be externally measured (CD
800 2-54) This should include the ability to assess clinical outcomes at an individual level as well as
801 for the population served. This requirement is detailed in Chapter 7.

802

803 It is appropriate to include ambulatory sites of care in Level I institutional designation if a fully
804 integrated or onsite ambulatory surgery care team possesses pediatric training and experience
805 consistent with the above requirements, and the site of care is a component of a demonstrably

806 integrated children's health care delivery system that does provide resources appropriate for the
807 scope of practice. (CD 2-55)

808

809 **Level II**

810

811 A Level II children's surgical center provides comprehensive surgical care in two distinct
812 environments that are recognized in the verification program sponsored by the ACS. The first
813 environment is a population-dense area where a Level II children's surgical center may
814 complement the clinical activity and level of resources of a Level I institution to serve the needs
815 of a broad regional population. In this scenario, the Level I and II children's surgical centers
816 should work together to optimize resources expended to care for all children with surgical needs
817 in their area. This implies a cooperative environment between institutions that allows patients to
818 flow between hospitals, depending on resources and clinical expertise.

819

820 The second Level II environment occurs in less population-dense areas. The Level II hospital
821 serves as the lead children's facility for a geographic area when a Level I institution is not
822 geographically close. This may be the best model for many rural areas. This lead hospital
823 should have an outreach program that incorporates smaller institutions in the same service area.

824

825 In either environment, children's surgeons must participate in the care of surgical patients
826 specific to their surgical fields, including planning and implementation of major therapeutic
827 decisions (CD 2-56), presence at major resuscitations (CD 2-57), presence at operative

828 procedures (CD 2-58), and involvement in the critical care of all infants and children receiving
829 perioperative care (CD 2-59).

830

831 The scope of service for Level II children's surgical centers potentially includes definitive care
832 for neonates, infants, children and adolescents; it may be limited to neonates or other specific
833 populations (i.e. Women's and Children's centers or military hospitals). Generally, the surgical
834 care will include children with low risk or moderate comorbidities (ASA 1-3), although it may
835 include infrequent emergency procedures in higher risk patients. Typically the procedures
836 involve a single specialty treating common anomalies and diseases typically treated by most
837 pediatric surgical specialists in that discipline, and that do not require significant multispecialty
838 coordination.

839

840 Level II children's surgical centers are required to have one or more pediatric surgeons available
841 on a consultant basis to provide care within 60 minutes of such a request 24/7 (CD 2-60) and
842 provide relevant care for children 5 years of age or less, as in a Level I center. An appropriate
843 published call schedule must be readily available (CD 2-61). Local criteria must be established
844 to define conditions requiring the attending surgeon's physical presence and a PIPS program
845 must monitor compliance (CD 2-62).

846

847 For Level II children's surgical centers, one or more pediatric anesthesiologists must be on the
848 medical staff (CD 2-63) and must be available 24/7 within 60 minutes to serve as the primary
849 anesthesiologist for children 5 years of age or less (CD 2-64). A relevant published call schedule
850 must be readily available (CD 2-65). Local criteria must be established to define conditions

851 requiring the attending anesthesiologist's physical presence and a PIPS program must verify
852 compliance (CD 2-66).

853

854 A Level II children's surgical center is required to have a Level III or higher NICU as delineated
855 in Appendix 1 (CD 2-67). Level III NICUs must provide prompt and readily available access to
856 a full range of pediatric medical subspecialists and neonatologists, pediatric surgeons, pediatric
857 anesthesiologists and pediatric ophthalmologists (CD 2-68) (this requirement may be fulfilled by
858 on site specialists or by individuals at a closely related institution by prearranged consultative
859 agreement). Level II centers that limit the scope of practice to neonatal patients are not required
860 to have ICU services beyond that of the Level III NICU. Pediatric ICU service must be available
861 to correspond with the scope of service offered (CD 2-69). For example, infrastructure and
862 providers would be in place in a Level II center to provide mechanical ventilation to an infant or
863 a child following a surgical procedure if necessary (CD 2-70). Critical care physicians,
864 respiratory therapists, nurses and others with demonstrable pediatric training and experience are
865 required (CD 2-71).

866

867 A Level II children's surgical center is required to have an appropriate radiologist available to
868 provide service within 60 minutes 24/7 (CD 2-72). In a Level II center, coverage for this
869 immediate availability requirement may be provided by a combination of pediatric radiologists
870 supplemented by radiologists with pediatric expertise. A radiologist with pediatric expertise is
871 defined as a radiologist with certification by the American Board of Radiology or equivalent,
872 demonstrable pediatric experience to support the scope of actual practice, and 10 or more
873 relevant Category 1 CME hours annually. Here and throughout this document, annual CME

874 requirements may be averaged over a 3 year period. Local policy will define credentials, the
875 need for physical presence and this will be monitored by PIPS (CD 2-73).

876

877

878 A Level II children’s surgical center must have 24/7 emergency department capability to care for
879 children with surgical needs within the scope of practice (CD 2-74). This may be provided by
880 emergency physicians with pediatric expertise. An emergency physician with pediatric expertise
881 is defined as an individual certified by the American Board of Emergency Medicine, the
882 American Board of Pediatrics or equivalent and who has demonstrable pediatric experience to
883 support the actual scope of emergency medicine practice, as well as 10 hours annually of
884 relevant Category I CME. Children’s specific emergency department resources must be in place
885 to support the level of designation including facilities, equipment and nonphysician personnel
886 (CD 2-75). Level II centers that limit the scope of practice to neonatal patients are not required to
887 meet these emergency department requirements.

888

889 For Level II children’s surgical center verification, medical and surgical specialists within the
890 scope of practice must be available for consultation within 60 minutes, 24/7 (CD 2-76). Where
891 providers with pediatric specific training and experience are designated as “available”, the
892 requirement is that the care of patients will be demonstrably provided by these children’s
893 specialists. (CD 2-77) Here and elsewhere, pediatric medical and surgical specialists are defined
894 as those who are either eligible for or have current certification after relevant pediatric specialty
895 fellowship training (either medical or surgical) recognized by the appropriate Board of the
896 American Board of Medical Specialties or equivalent. This requirement is met by holding or

897 being eligible to hold a certificate with added qualification for pediatric patients when offered.
898 This requirement must be monitored by PIPS (CD 2-78).

899

900 A pediatric rapid response and/or resuscitation team is required for Level II center designation
901 (CD 2-79). This requires 24/7 physical presence of a pediatric provider to include PALS
902 certification, in a leadership role. (CD 2-80)

903

904 Level II centers are required to participate in a data collection program that yields peer
905 performance assessments against which an individual program may be externally measured (CD
906 2-81). This is detailed in Chapter 7.

907

908 It is appropriate to include ambulatory sites of care in Level II institutional designation if a fully
909 integrated or on site ambulatory surgical care team possesses the requisite pediatric training and
910 experience as defined in this document, and the site of care is a component of a demonstrably
911 integrated children's health care delivery system that provides resources appropriate for the
912 scope of practice. (CD 2-82)

913

914 Performing procedures outside the defined scope of practice for a Level II center should be
915 uncommon.

916

917

918 Table 1. Requirements for Level I and II Children's Surgical Centers

Requirement	Children's Level I	Children's Level II	Children's Level II (neonatal scope of service only)
Freestanding children's hospital or comprehensive pediatric care unit within general hospital organization	E	E	-
Children's Surgical Service	E	E	-
Pediatric surgeons	E	E	E
Pediatric anesthesiologists	E	E	E
Pediatric emergency medicine physicians	E	D	-
Pediatric pulmonary and gastroenterology specialists	E	D	D
Other surgical specialists	E	E	E
Other pediatric medical specialists	E	D	D
Surgery specific children's continuing medical education for children's surgery medical director and liaisons	E	E	E
Neonatal intensive care unit	Level IV	Level III or greater	Level III or greater
Neonatologists	E	E	E
Pediatric emergency department area	E	E	-
Pediatric intensive care unit	E	D	-
Pediatric critical care medicine physicians	E	D	-
Pediatric acute care unit	E	E	-
Pediatric resuscitation equipment in all appropriate patient care areas	E	E	E
Children's surgical program manager or coordinator	E	E	E
Surgical data collection	E	E	E
Child life and family support programs	E	E	E
Pediatric social work and child protective services	E	E	E
Community outreach programs	E	E	-
Children's education programs	E	E	-
Surgical research	E	D	D
Minimum No. of annual surgical procedures of children younger than 18 years	1,000	500	-
Children's surgical performance improvement and patient safety program (PIPS)	E	E	E

919 *E indicates essential; and D, desired.

920

921 **Level III**

922 For many areas, a Level III children's surgical center will be an important part of the health care
923 system. A Level III center will potentially provide definitive care for well children greater than
924 6 months of age. Generally these will be children without comorbidities (ASA 1-2), without the
925 need for multidisciplinary care, and the procedures will generally be common, low risk
926 procedures typically performed by a single specialty. A Level III center will have transfer
927 agreements with a Level I or Level II center for patients whose needs exceed their resources (CD
928 2-83). A Level III children's surgical center must have continuous 24/7 availability within 60
929 minutes of general surgeons and anesthesiologists with pediatric expertise (CD 2-84). A general
930 surgeon with pediatric expertise is defined as a surgeon either eligible for certification or
931 certified by the American Board of Surgery or equivalent in general surgery. In addition, this
932 individual will demonstrate ongoing clinical engagement and expertise in children's surgery as
933 evidenced by performing 25 or more procedures annually in patients less than 18 years of age, as
934 well as completion of 10 or more relevant Category I CME credit hours annually. (CD 2-85) An
935 anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible to certify
936 or with a current certificate of the American Board of Anesthesiology or equivalent. He or she
937 will demonstrate continuous experience with children < 24 months of age, defined as 25 patients
938 per anesthesiologist per year. In addition, this individual will demonstrate ongoing pediatric
939 clinical engagement in patients less than 18 years of age, and complete 10 or more relevant
940 Category I CME credit hours annually (CD 2-86). General surgeons and anesthesiologists must
941 remain knowledgeable regarding children's surgical care whether treating patients locally or
942 transferring them to a center with more resources, therefore 10 relevant category I CME credit
943 hours are required annually. Here and throughout this document, the annual CME requirement

944 may be averaged over 3 years. (CD 2-87) General surgeons and anesthesiologists with pediatric
945 expertise are required to participate in children’s surgery performance review activities (CD 2-
946 88). Through the PIPS program and hospital policy, the medical director of children’s surgery
947 must have responsibility for performance review and authority for determining each general
948 surgeon’s ability to participate on the children’s panel based on an annual review (CD2-89).

949
950 A radiologist with pediatric expertise must be available to provide care at the bedside within 60
951 minutes 24/7 at Level III centers (CD 2-90). This is an individual defined as a radiologist with
952 certification by the American Board of Radiology or equivalent, demonstrable ongoing pediatric
953 experience to support the scope of actual practice, and 10 or more relevant Category 1 CME
954 hours annually. (CD 2-91) The PIPS process will monitor services provided by these individuals
955 (CD 2-92).

956
957 Level III centers may treat patients who ultimately need to be transferred to a higher level of
958 care. Transfer guidelines approved by the medical director of children’s surgery that define
959 appropriate patients for transfer and retention are required (CD 2-93) and these must be
960 monitored by the PIPS program. (CD 2-94).

961

Indications for transfer of infants and children with surgical needs to Level I or II Centers
< 60 weeks post menstrual age
Patient less than 6 months of age
High level of acuity, need for ICU

962

963

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964 Outreach activities to the local community and education programs for nurses, physicians, and
965 allied healthcare workers involved with children are also functions of a Level III children's
966 surgical center.

967

968 Performing procedures outside the defined scope of practice in Level III centers should be
969 uncommon.

970

971 Table 1. Summary of Children's Surgical Center with Scope of Practice

	I	II	III
Age	Any	Any	> 6 months
ASA	1-5	1-3*	1-2
Multidisciplinary management of co-morbidities	Multiple medical and surgical specialties; pediatric anesthesiology	Typically single surgical specialties; neonatology; pediatric anesthesiology	None
Operations [†]	Major congenital anomalies and complex disease including those that are uncommon or require significant multidisciplinary coordination	Common anomalies and diseases typically treated by most pediatric surgical specialists and that do not require significant multi-specialty coordination.	Common, low-risk procedures typically performed by a single specialty.
Ambulatory [‡]	ASA 1-3 Full term infants and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants < 4 weeks or preterm infants < 50 weeks PMA weeks to be monitored for at least 12 hours postoperatively.	ASA 1-3 Full term and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants < 4 weeks or preterm infants < 50 PMA to be monitored for at least 12 hours postoperatively.	Otherwise healthy (ASA 1-2) Age > 6 months

972 PMA = Post menstrual age

973 *Emergent procedures in some patients > ASA 3 may be appropriate in neonatal patients such as
974 those with necrotizing enterocolitis.

975

976 †Types of anomalies and diseases that should have pediatric subspecialty care are further
977 delineated in Appendix 1. Depending upon patient age, co-morbidities and need for multi-
978 disciplinary surgical approach, these may be appropriate for either Level I or Level II centers.

979 ‡Ambulatory sites of care are included in these recommended levels of institutional designation
980 when the onsite provider team possesses the requisite pediatric training and experience. The site
981 of care may be physically attached/integrated into the hospital or may be a component of a
982 demonstrably integrated health care delivery system that provides these defined resources.

983

984 The ability to stabilize and transfer critically ill children must be demonstrated at all levels of
985 designation (CD 2-95). This includes critically ill children and neonates whose care may be
986 initiated at an internal site, such as radiology or the emergency department distinct from
987 definitive care, or at another institution for which a formal transfer agreement is in place.

988

989 Congenital heart centers are not specifically verified or designated in this program, although it is
990 relevant to note that resource standards for this have been developed by the American Academy
991 of Pediatrics [Bricker JT, Fraser CD, Fyfe DA, et al. AAP Section on Cardiology and Cardiac
992 Surgery: Guidelines for Pediatric Cardiovascular Centers. *Pediatrics* 2002; 109(3):544-549.]

993

994

995

996 **Ambulatory Surgical Centers**

997

998 The American College of Surgeons does recognize the critical role of ambulatory surgical
999 centers (ASCs) in the care of infants and children. Ambulatory surgery centers that meet the
1000 resource standards for children delineated and which are demonstrably integrated with a Level I,
1001 II or III Children's Surgery Center will be so verified. The safety of performing outpatient
1002 surgical procedures in children is substantially dependent upon the provision of a safe anesthetic,
1003 but is enhanced by having appropriate high quality surgical equipment with operating room
1004 personnel experienced in its use. The major postoperative risk is apnea. Risk factors for
1005 postoperative apnea are prematurity, history of apnea, and anemia. In general, the risk of
1006 postoperative apnea is highest among infants born at younger gestational and post-conceptual
1007 ages. The most relevant data are found in Cote's analysis of 255 preterm infants undergoing
1008 inguinal herniorrhaphy under general anesthesia [*Cote CJ, Zaslavsky A, Downes JJ, et al.*
1009 *Postoperative apnea in former preterm infants after inguinal herniorrhaphy. Anesthesiology*
1010 *1995; 82: 809-821*]. In the non-anemic child with a gestational age of 32 weeks and a post-
1011 menstrual age (PMA) of 56 weeks, the probability of apnea was <1%. With a gestational age of
1012 35 weeks, a post-menstrual age of 54 weeks was the threshold for apnea to be <1%.

1013

1014 It is widely accepted that one can safely administer anesthesia on an ambulatory basis for
1015 preterm infants with a post-menstrual age > 50 weeks and who are without other risk factors.
1016 (www.asahq.org.) Ambulatory surgery in infants born before 37 weeks gestation may be safely
1017 done after 50 weeks post-menstrual age as long as there is no anemia, prior apnea or coexisting

1018 disease. Institutional guidelines generally require full term infants less than 4 weeks or preterm
1019 infants < 50 post-menstrual weeks to be monitored for at least 12 hours postoperatively.

1020

1021 Optimal ambulatory children's surgery should be performed in facilities with specific children's
1022 resources and policies as described below:

- 1023 • A pediatric anesthesiologist, pediatric surgeon or other specialty trained and certified
1024 children's surgeon must serve as medical director (CD 2-96)
- 1025 • A pediatric anesthesiologist or anesthesiologist with pediatric expertise must administer
1026 or directly oversee the administration of a general anesthetic and/or sedation to all
1027 patients less than two years of age undergoing a surgical procedure. (CD 2-97).
- 1028 • The preoperative preparation and post-operative recovery of children must occur in an
1029 area appropriate for pediatric patients. (CD 2-98)
- 1030 • The special needs of a child's social and emotional comfort must be considered in the
1031 construction and protocols of a pediatric ambulatory surgery center. (CD 2-99)
- 1032 • Anesthesia and other equipment including resuscitation devices and appropriate
1033 pharmacologic supplies and drug doses for all sizes of children must be readily available
1034 in the operating room and recovery areas. (CD 2-100)
- 1035 • One or more persons certified in pediatric advanced life support (PALS) must be present
1036 and available to the pediatric patient who is sedated, anesthetized, recovering from
1037 anesthesia, or receiving perioperative opioids. (CD 2-101)
- 1038 • Healthy full term infants > 4 weeks and less than 6 months of age should be monitored at
1039 least 2 - 4 hours after surgery and should be scheduled early in the day. Prolonged

1040 postoperative monitoring should be provided for infants less than 3 months who receive
1041 perioperative opioids.

- 1042 • Full term infants less than 4 weeks of age and preterm infants younger than 50 weeks
1043 post-menstrual age are not appropriate for surgery on an ambulatory outpatient basis
- 1044 • Formal transfer agreement must be in place to allow planned processes and prompt
1045 transfer to an appropriate (Level I, II or III) inpatient children's facility when medically
1046 necessary. (CD 2-102)

1047

1048

1049 **Chapter 3**

1050

1051 **Triage and Transfer for Seriously Ill Infants and Children**

1052

1053 The system is driven by the goal of getting the child with surgical needs to the right place at the
1054 right time. Imprecision results in overtriage and undertriage. In general, priority is given to
1055 reduction of undertriage because this may result in preventable mortality or morbidity for a
1056 seriously ill child. Although overtriage has minimal or no adverse consequences for the patient,
1057 it can result in excessive costs and burden for higher level centers in the routine care of patients
1058 as well as a travel burden for families. The medical community needs to be more concerned
1059 about undertriage and the medical consequences that result from inadequate use of a system.
1060 The system's performance improvement program should evaluate triage (referral) and transfer
1061 criteria to provide the best quality care to patients.

1062

1063

1064 **Interhospital Transfer**

1065

1066 The development of agreements for transfer of seriously ill patients between institutions is an
1067 essential part of a system. (CD 3-1) These agreements should be made well in advance of the
1068 need to implement them and should define which patients should be transferred and the process
1069 for doing so. Once the need for transfer or referral is recognized, the process should not be
1070 delayed for laboratory or diagnostic procedures that have no impact on resuscitation, immediate
1071 needs or the transfer process. Minimizing the time to appropriate definitive care can have a

1072 positive influence on outcome. Regional systems facilitate transfer and referral processes and
1073 improve the efficiency of patient movement through the system by designing and implementing
1074 plans that deal with transfer and referral issues before the acute patient need.

1075

1076 Written agreements between hospitals help ensure the consistent, timely, proper, and efficient
1077 movement of seriously ill children between institutions, allow for review of the structure of
1078 transfer and referral processes with the goal of performance improvement, and result in mutual
1079 educational benefit for both originating and recipient institutions. An example is provided in
1080 Appendix 2. The value of these agreements is to design a process before it is necessary that
1081 allows patients to receive the specialty care needed. This process avoids delays that prolong the
1082 time to definitive care. The transferring and receiving hospitals benefit by having predetermined
1083 the needs and expectations of both institutions and resolving problematic areas before the actual
1084 transfer process. The best plans are carefully considered, mutually approved, written and
1085 frequently reviewed.

1086

1087 Once the decision for referral or transfer has been made, it is the responsibility of the referring
1088 physician to initiate resuscitation and any needed stabilization measures within the capabilities of
1089 the local hospital. The referring physician should select a mode of transport for the patient's
1090 needs so that the level of care is appropriate during transport. Effective communication between
1091 the referring center and receiving center is essential (CD 3-2). Specifically, the accepting
1092 physician should review the current physiologic status of the patient and discuss the initial
1093 management and the optimal timing of transfer.

1094

1095 There are identifiable needs and combinations of needs that result in high mortality, even when
1096 patients are managed in Level I centers. Patients with these critical needs should be considered
1097 for early transfer. Physicians in community hospitals should develop specific guidelines for the
1098 identification of patients who would benefit from early transfer based on available local
1099 resources. Written agreements for transfer of patients between hospitals have their greatest
1100 utility in establishing a system in which patients can be moved expeditiously to an institution that
1101 has been identified by prior agreement to be capable and willing to provide needed children's
1102 specialty surgical services.

1103

1104 The decision to transfer a patient to a children's specialty care facility in an acute situation must
1105 be based solely on the needs of the patients and not on the requirements of the patient's specific
1106 provider network (such as health maintenance organization or preferred provider organization) or
1107 the patient's ability to pay (CD 3-3). Subsequent decisions regarding transfer to a facility within
1108 a managed care network should be made only after stabilization of the patient's medical/surgical
1109 condition.

1110

1111 **Obligations of the referring physician and facility include the following:**

1112

- 1113 1. Identifying an appropriate children's facility with available space and qualified surgical
1114 personnel that has agreed to accept the patient before beginning the transfer.
- 1115 2. Not transferring patients with physiologic instability, except for medical necessity and only
1116 after providing medical treatment within the facility's capacity that minimizes the risks to the
1117 patient's health.

1118 3. Providing appropriate transportation with a vehicle augmented with infant and child specific
1119 life-support equipment and staff to meet the anticipated contingencies that may arise during
1120 transportation.

1121 4. Sending all records, test results, radiologic studies, and other relevant reports or data with the
1122 patient to the recipient facility unless delay would increase the risks of transfer, and then sending
1123 the information as soon as possible.

1124 5. Issuing a physician transfer summary and consent for transfer to accompany the patient.

1125

1126 Receiving hospitals also have obligations. Hospitals that have specialized children's care
1127 capabilities or facilities are obligated to accept the appropriate transfer of patients requiring such
1128 services if they have the capacity to treat them.

1129

1130 Another important aspect of interhospital transfer is an effective performance improvement and
1131 patient safety program that includes evaluating transport activities. These activities can be
1132 accomplished in a number of ways depending on the transport service. Regardless of how the
1133 process is accomplished, the receiving hospital should have input and feedback with the
1134 personnel responsible for the transport process to ensure that problems occurring during and
1135 associated with transport are addressed in a timely manner. The input, feedback, and
1136 communication also should allow recognition of transportation efforts that are consistent with
1137 optimal care.

1138

1139

1140 **Guidelines for Transferring Patients**

1141

1142 1. Transferring physician responsibilities

1143 a. Identify patients needing transfer.

1144 b. Initiate the transfer process by direct contact with the receiving surgeon.

1145 c. Initiate appropriate resuscitation and stabilization measures within the capabilities of the
1146 facility.

1147 d. Determine the appropriate mode of transportation in consultation with the receiving
1148 surgeon.

1149 e. Transfer all records, test results, and radiologic evaluations to the receiving facility.

1150

1151 2. Receiving physician responsibilities

1152 a. Ensure that resources are available at the receiving facility.

1153 b. Provide consultation regarding specifics of the transfer, additional evaluation, or
1154 resuscitation before transport.

1155 c. Once transfer of the patient is established, clarify medical control

1156 d. Identify a performance improvement and patient safety process for transportation,
1157 allowing feedback from the receiving surgeon to the transport team directly or at least to
1158 the medical director for the transport team. (CD 3-4)

1159

1160 3. Management during transport

1161 a. Children's specific personnel and equipment should be available during transport to meet
1162 anticipated contingencies.

- 1163 b. Sufficient supplies should accompany the patient during transport, such as intravenous
- 1164 fluids, blood, and medications, as appropriate for age and size of the patient.
- 1165 c. Vital signs should be monitored frequently.
- 1166 d. Vital functions should be supported.
- 1167 e. Records should be kept during transport.
- 1168 f. Communication should be maintained with online medical direction during transport.

1169

1170 4. System responsibilities

- 1171 a. Ensure prompt transport once a transfer decision is made.
- 1172 b. Review all hospital transfers for performance improvement and patient safety as well as
- 1173 overtriage and undertriage. (CD 3-5)
- 1174 c. Ensure transportation commensurate with the patient's need.

1175

1176 5. Information to accompany patient

1177

1178 Appropriate family members and available patient demographic information should accompany
1179 the seriously ill child. Information about the nature of the medical problem and prehospital care
1180 constitute important facts that can influence subsequent treatment. A summary of evaluation and
1181 care provided at the transferring facility should include the results of laboratory tests and
1182 radiologic evaluations, the needs identified, the patient's response to treatment, and a
1183 chronologic record of the patient's vital signs. Additional information that is helpful includes the
1184 medical history, current medications, medications and immunizations administered, and

1185 allergies. The name, address, and phone number of the referring physician is important. The
1186 name of the surgeon who accepted the patient at the receiving hospital also should be indicated.

1187

1188 **Transport Teams**

1189

1190

1191 A Level I children's surgical center is required to have a dedicated transport team for neonatal

1192 and pediatric patients (CD 3-6). The complement of personnel, mode of transport and medical

1193 control policies will vary by location, but performance must be monitored by PIPS (CD 3-7).

1194 Written policies must address personnel, mode of transport and medical control at a minimum

1195 (CD 3-8). Quality improvement efforts require data documenting timeliness and appropriateness

1196 of response as well as missed transports (CD 3-9). Level II centers are not required to provide

1197 their own transport team but must have a relationship with and use pediatric specific transport

1198 teams when transferring infants and children to or from their center. (CD 3-10)

1199

1200

1201 **CHAPTER 4**

1202

1203 **Hospital Organization and the Children’s Surgical Program**

1204

1205 A decision by a hospital to become a children’s surgical center requires the commitment of the
1206 institutional governing body and the medical staff (CD 4-1). The commitment and collaboration
1207 of these two bodies are necessary to facilitate the allocation of resources and the development of
1208 programs designed to improve the care of children with surgical needs. Elements include the
1209 following: (1) hospital organization, (2) medical staff support, (3) the surgical program, (4) the
1210 medical director of children’s surgery (MDCS), (5) the children’s surgery program manager
1211 (CSPM), (6) data collection, and (7) the children’s surgery performance improvement and patient
1212 safety (PIPS) program.

1213

1214 **Hospital Organization**

1215

1216 The administrative structure must support the children’s surgical program. Written commitment
1217 by the hospital’s governing body and the medical staff is necessary (Table 1). This support must
1218 be reaffirmed continually (every 3 years) and must be current at the time of verification (CD 4-
1219 2). Administrative support of the surgical program helps provide adequate resources for the
1220 optimal care of children with surgical needs. The responsible administrator works closely with
1221 the medical director to establish and maintain the components of the children’s surgery program.
1222 Participation of an administrator helps ensure that the written commitment to the surgery
1223 program is implemented to ensure optimal multidisciplinary surgical care.

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The administrative structure of the hospital should demonstrate institutional support and commitment and must include an administrator, medical director of children’s surgery and the children’s surgical program manager. (CD 4-3) Sufficient authority for the surgery program to achieve all programmatic goals should be reflected in the organizational structure. Administrative support includes human resources, educational activities, and community outreach activities to enable community cooperation and a systematic approach to the care of children with surgical needs. Adequate funding of the children’s surgery program is the direct responsibility of the institution.

Medical Staff Support

The medical staff commitment ensures that the members of the medical staff support the children’s surgery program by their professional activities. This support includes a current written commitment acknowledging the medical staff’s willingness to provide appropriate specialty care to support the optimal care of children with surgical needs (Table 1). This support must be reaffirmed continually (every 3 years) and must be current at the time of verification (CD 4-4).

1243

1244 Table 1. Sample Commitment and Support Statements

Hospital Commitment
Resolved, that the XYZ Hospital Board of Directors (or other administrative governing authority) approves the establishment of a Level ____ children’s surgical center (or “applies for verification or reverification of a Level ____ children’s surgical center”). The Board commits to maintain the high standards needed to provide optimal care of children with surgical needs.
Medical Staff Support
Resolved, that the Medical Staff or Executive Committee of XYZ Hospital (or other governing body of the medical staff) supports the establishment of a Level ____ children’s surgical center (or “supports verification or reverification of a Level ____ center”). This statement acknowledges the commitment to provide appropriate specialty care as required to support optimal care of children with surgical needs.

1245

1246 **The Children’s Surgical Program**

1247

1248 The children’s surgery program involves multiple disciplines that transcend normal departmental
1249 hierarchies. Because optimal care extends from diagnosis of a surgical need through the acute
1250 care setting to discharge and outpatient convalescence, the program should have appropriate
1251 specialty representation from all phases of care. Representatives of all disciplines provide the
1252 appropriate skills as team members working in concert to implement treatment based on a
1253 prioritized plan of care. To ensure optimal and timely care, a multidisciplinary program must
1254 continuously evaluate its processes and outcomes (CD 4-5).

1255

1256 **The Medical Director of Children's Surgery (MDCS)**

1257

1258 The medical director of children's surgery (MDCS) is the surgeon who leads the
1259 multidisciplinary activities of the children's surgery program. This individual may have a title
1260 such as Surgeon-in-Chief or others, but the following are requirements for this program. For
1261 Level I and II centers, the director must be a surgeon with current board certification (or
1262 equivalent) with special interest and qualifications in children's surgical care (CD 4-6) and
1263 participate in surgical call. (CD 4-7) The MDCS must maintain an appropriate level of
1264 extramural continuing medical education to meet American Board of Medical Specialties
1265 (ABMS) maintenance of certification requirements in his/her discipline (CD 4-8). Membership
1266 and active participation in appropriate regional or national children's organizations is essential
1267 for the MDCS in Level I and II centers (CD 4-9) and desirable in Level III facilities.

1268

1269 The MDCS's responsibilities extend far beyond the technical skills of surgery. The MDCS
1270 should have the authority to manage the surgery program. The MDCS participates in the
1271 credentialing of surgeons with children's privileges, works in cooperation with nursing
1272 administration to support the nursing needs of children with surgical needs, develops treatment
1273 protocols along with the surgical teams and coordinates the performance improvement and peer
1274 review process. The surgery director must have the authority to correct deficiencies in surgical
1275 care (CD 4-10). In partnership with the hospital administration and the children's surgery
1276 program manager, the MDCS should participate in coordination and management of the
1277 budgetary processes for the surgery program. The MDCS should identify representatives from

1278 appropriate disciplines to determine which physicians from individual disciplines are qualified to
1279 be members of the children's surgery program.

1280

1281 **The Surgical Service**

1282

1283 A children's surgical service represents a structure of care for children with surgical needs. The
1284 service includes personnel and other resources necessary to ensure appropriate and efficient
1285 provision of surgical care. The precise character and composition of a service will vary based on
1286 specific needs of the medical facility, available personnel and other resources. In a Level I or II
1287 children's surgery center, infants and children with primary surgical problems must be admitted
1288 to or evaluated by an identifiable surgical service staffed by credentialed children's surgical
1289 providers (CD 4-11). Sufficient infrastructure and support to ensure adequate provision of care
1290 must be provided for this service (CD 4-12). To be sufficient, the infrastructure and support may
1291 require additional qualified physicians, residents, nurse practitioners, physician assistants, or
1292 other allied health professionals. The number and type of individuals required for a surgery
1293 service should be determined by the volume of patients requiring care and the complexity of
1294 their conditions. In teaching facilities, the relevant requirements of the Accreditation Council for
1295 Graduate Medical Education (ACGME) and appropriate Residency Review Committees also
1296 must be met (CD 4-13).

1297

1298

1299 **The Children's Surgical Program Manager (CSPM)**

1300

1301 The CSPM is fundamental to the development, implementation, and evaluation of the surgery
1302 program. In addition to administrative ability, qualified candidates must show evidence of
1303 educational preparation and clinical experience in the care of children with surgical needs (CD 4-
1304 14). The CSPM works in close collaboration with the medical director of children's surgery and
1305 complements the director's efforts. A constructive, mutually supportive relationship between
1306 these key leaders is important to the success of the program.

1307

1308 The CSPM, usually a full-time registered nurse, is responsible for the organization of services
1309 and systems necessary for a multidisciplinary approach to providing care to children with
1310 surgical needs. The CSPM, in particular, assumes day-to-day responsibility for process and
1311 performance improvement activities as they relate to nursing and ancillary personnel and assists
1312 the MDCS in carrying out the same functions for the physicians. Accountability for all activities
1313 of the surgery program resides with the medical director. The role of the CSPM in the
1314 educational, clinical, research, administrative, and outreach activities of the surgery program is
1315 determined by the needs of the MDCS and institution. (Various responsibilities of CSPMs are
1316 detailed in Table 2).

1317

1318 Administrative and budgetary support needed for the CSPM depends on the size of the program.
1319 Relevant data collection is required and must be appropriately staffed (CD 4-15). A comparable
1320 level of administrative assistant and clinical nursing personnel helps fulfill needs for outreach,

1321 concurrent case review, and discharge planning. The data collection personnel, administrative
1322 assistant, and surgical nurse clinician(s) should be supervised by the CSPM.

1323

1324 **The Surgery Data Collection Personnel**

1325

1326 The individuals responsible for surgery data collection are important members of the team.

1327 These individuals may come from a background such as nursing, medical records, computer

1328 science, medical informatics, and other fields. Ideally, he/she should work directly with the

1329 surgical team and report to the CSPM. This children's surgery data collection leader must

1330 receive initial training when starting the job. (see Chapter 7) (CD 4-16) He/she also should

1331 complete at least 4 hours of registry specific continuing education per year. Technical support,

1332 locally and from relevant national vendors or agencies, should be available to assist with these

1333 training requirements.

1334

1335 It is important to acknowledge that high quality data begin with high quality data entry, and it is

1336 the children's surgery data collection leader who is responsible to perform this task.

1337

1338 **Performance Improvement and Patient Safety Program**

1339

1340 Level I and Level II centers must have a multidisciplinary peer review committee chaired by the

1341 medical director of children's surgery or designee, with representatives from all surgical

1342 services, anesthesiology, radiology (CD 4-17), and emergency medicine, neonatology and

1343 critical care physicians if within scope of service (CD 4-18). The purpose of the committee is to

1344 improve surgical care by reviewing all deaths, selected complications, and sentinel events with
 1345 objective identification of issues and appropriate responses. The aforementioned representatives
 1346 or designees must attend at least 50% of these multidisciplinary peer review committee meetings
 1347 (CD 4-19). The frequency of meetings is to be determined by the medical director of children’s
 1348 surgery based on the needs of the performance improvement and patient safety program, but
 1349 must be at least quarterly (CD 4-20).

1350
 1351 Evidence for participation and acceptable attendance must be documented. (CD 4-21) The
 1352 medical director of children’s surgery must ensure and document dissemination of information
 1353 and findings from the peer review meetings (CD 4-22).

1354
 1355
 1356
 1357 Table 2. The Children’s Surgery Program Manager

1358

Qualifications of the Children’s Surgery Program Manager (CSPM)	
The CSPM, usually a registered nurse, must show evidence of educational preparation, with a minimum of 16 hours (internal or external) of surgery-related continuing education per year and clinical experience in the care of children with surgical needs (CD 4-23). There should be a written job description that defines sufficient authority to do the job and clearly outlines the responsibilities of the individual. Qualifications and activities should include the following:	
Clinical Activities	Coordinate management across the continuum of children’s surgical care, which includes planning and implementation of clinical protocols and practice management guidelines, monitoring care of in-hospital patients and serving as a resource for clinical practice
Education Responsibilities	Provide the intrafacility and regional professional staff development, participate in case review, implement practice guidelines, and direct community education programs.
Performance Improvement	Monitor clinical processes and outcomes and system issues related to the quality of care provided; develop quality filters, audits, and

	case reviews; identify trends and sentinel events; and help outline remedial actions while maintaining confidentiality.
Administration	Manage, as appropriate, the operational, personnel, and financial aspects of the children’s surgery program. Serve as a liaison to administration, and represent the children’s surgery program on various hospital and community committees to enhance and foster optimal care management.
Supervision of Data Collection	Supervise collection, coding, and developing processes for validation of data. Design and oversee the data collection to facilitate performance improvement activities, trend reports, and research while protecting confidentiality.
Consultant and Liaison	Stabilize the complex network of many disciplines that work in concert to provide high-quality children’s surgical care. Serve as an internal resource for staff in all departments, and act as an extended liaison for other system entities.
Research	Be involved in research projects, analysis, and distribution of findings. Facilitate protocol design for accurate data collection, feedback and analysis, and understand the requirements of research oversight.
Community and National Engagement in Children’s Surgical Care Systems	Participate in the development of children’s surgical care systems at the community, state, provincial, or national levels.

1359
1360

1361
1362 **Children’s Operating Room Committee**

1363

1364 Efficient and safe children’s surgical practice requires an operating room environment tailored to
1365 specifically meet children’s needs. Although the personnel and processes will vary with the
1366 local environment, Level I and II centers are required to have a dedicated children’s operating
1367 room committee charged with oversight of day to day OR operations and which insures that

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1368 children's surgical needs are met (CD 4-24). This group must meet regularly and it should be
1369 chaired by the medical director of children's surgery or designee (CD 4-25). Members (or
1370 designees representing each surgical service) as well as anesthesiology, nursing and
1371 administrative representatives must attend 50% of meetings (CD 4-26). Agendas and minutes
1372 must be distributed to members and be available for review at site visitation (CD 4-27). Level III
1373 and ambulatory children's surgical centers must demonstrate similar oversight and support
1374 specific to children's surgical needs, although the operating room committee structure may be
1375 integrated into a larger institutional body. (CD 4-28)

1376 **CHAPTER 5 Clinical Functions-Surgeons**

1377

1378 **Qualifications**

1379 Surgeons caring for children must meet certain requirements as described herein. (CD 5-1) These
1380 requirements may be considered in 4 categories: board certification or equivalent, clinical
1381 involvement, education, and regional or national commitment. The medical director of children's
1382 surgery (MDCS) must have the responsibility and authority to ensure compliance with these
1383 requirements (CD 5-2).

1384

1385 **Board Certification**

1386

1387 Basic to qualification for any surgeon is board certification by the American Board of Surgery,
1388 other relevant Board of the American Board of Medical Specialties (ABMS), or an equivalent
1389 organization such as the Bureau of Osteopathic Specialists and Board of Certification, or the
1390 Royal College of Physicians and Surgeons of Canada. Board certification is essential for
1391 surgeons who take call and provide care in Level I, II, III and ambulatory children's surgical
1392 centers (CD 5-3). It is acknowledged that many boards require a practice period and that
1393 completion of certification may take 3 to 5 years after completing a residency approved by the
1394 Accreditation Council for Graduate Medical Education (ACGME), the American Board of
1395 Osteopathic Specialties or equivalent entity. A surgeon is specifically permitted to meet these
1396 program requirements during this period of eligibility for certification if credentialed by the
1397 applicant organization. If a physician has not been certified within 5 years after successful
1398 completion of an ACGME or Canadian residency, the physician usually is not eligible for

1399 inclusion on the children's surgical team. A physician may be included when given recognition
1400 by a major professional organization in his or her specialty. On a case by case basis, alternative
1401 training and certification may be judged equivalent by the applicant organization and the
1402 American College of Surgeons. The credentialing body of the hospital will assure that
1403 qualifications of the practicing providers are current and relevant to the care of children. (CD 5-
1404 4)

1405

1406 **Clinical Involvement**

1407

1408 In a hospital committed to children's surgical care, surgeons with demonstrable expertise should
1409 be identified. Specifically, qualified children's surgeons must be involved in the care of all
1410 infants and children. (CD 5-4) Participation in the organization of protocols, teams, call rosters
1411 and rounds are clear indicators of commitment to excellence in children's surgical care. It is
1412 important for children's surgeons to maintain their surgical skills. Surgeons must have privileges
1413 in children's surgery (CD 5-5). To maintain operative skills, surgeons must remain actively
1414 involved in clinical surgery. (CD 5-6) One of the ways that this is demonstrated is participation
1415 in elective surgery and emergency surgery.

1416

1417 In Level I children's surgical centers, the pediatric surgeons and pediatric anesthesiologists on
1418 call must be dedicated to the center while on duty and available to provide care at the bedside
1419 24/7 within 60 minutes of such a request. (CD 5-7) A published call schedule for pediatric and
1420 subspecialty surgeons and pediatric anesthesiologists must be available (CD 5-8). A Level II
1421 center is required to have a pediatric surgeon available on a consultant basis to care for a patient

1422 in the relevant institution within 60 minutes of such a request (CD 5-9). In Level III centers this
1423 requirement may be met by general surgeons or general anesthesiologists with pediatric expertise
1424 (CD 5-10).

1425
1426 **Performance Improvement and Patient Safety**
1427

1428 In Level I, II, III and ambulatory children's surgical centers, there must be a multidisciplinary
1429 peer review process with leadership by the medical director of children's surgery or designee and
1430 representatives from anesthesiology and all surgical and medical specialties relevant to level of
1431 verification and scope of service (CD 5-11). The purpose is to improve surgical care by
1432 reviewing all deaths, selected complications and sentinel events with the objective of identifying
1433 issues and developing appropriate responses. Each member must attend at least 50% of the
1434 multidisciplinary peer review committee meetings (CD 5-12).

1435
1436 **Education**

1437
1438 It is important that all members of the surgical team are knowledgeable about current practices in
1439 children's surgical care. In Level I and II centers, external CME is the recommended method of
1440 keeping current. The medical director of children's surgery must accrue an average of 16 hours
1441 annually or 48 hours in the 3 years prior to site visit of relevant children's surgical Category I
1442 external CME (CD 5-13). Programs given by visiting professors or invited speakers are
1443 considered outside education. It is important that other surgeons who take children's surgical
1444 call be knowledgeable and current in the care of children with surgical needs. In Level I and II
1445 centers, this requirement must be met by acquisition of 16 hours of children's surgical CME per

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1446 year on average as above, or by demonstrating participation in an internal educational process
1447 conducted by the program based on the principles of practice-based learning and the
1448 performance improvement and patient safety program (CD 5-14).

1449

1450 **Regional or National Commitment**

1451

1452 Membership and active participation in regional or national organizations relevant to children's
1453 surgery is essential for the medical director of children's surgery in Level I or II centers and
1454 desirable in Level III facilities (CD 5-15).

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CHAPTER 6 Collaborative Clinical Services and Resources

Children’s specialists should be promptly available and qualified in their areas of expertise.

A) Anesthesiology

Specialist pediatric anesthesiology services are critical in the management of infants and children with surgical needs and must be promptly available for elective and emergency operations (CD 6-1) and for managing airway problems (CD 6-2). These needs must be fulfilled in Level I and Level II centers by pediatric anesthesiologists and may be fulfilled in Level III centers by an anesthesiologist with pediatric expertise as defined below. Although anesthesia services are often based primarily in the operating room, the responsibilities of the anesthesiology team extend beyond the operating room. Examples include airway management, assisting with resuscitation, providing preoperative and postoperative cardiorespiratory support, and assisting with pain management.

Level I and II Centers

The anesthetic care of children with surgical needs in a Level I or II center must be organized and overseen by a pediatric anesthesiologist who is highly experienced and devoted to the care of infants and children. (CD 6-3) A pediatric anesthesiologist medical director for the children’s surgical program must be designated for both Level I and II centers (CD 6-4).

1481
1482 Pediatric anesthesia services in Level I centers must be immediately available on site 24 hours a
1483 day (CD 6-5). This requirement may be fulfilled by anesthesiology residents in their final year
1484 of training, pediatric anesthesiology fellows or certified registered nurse anesthetists (CRNAs)
1485 who are capable of assessing emergency situations in children and of providing any indicated
1486 treatment, including airway management and initiation of surgical anesthesia. When
1487 anesthesiology chief residents, pediatric fellows or CRNAs are used to fulfill availability
1488 requirements, the staff pediatric anesthesiologist on call must be advised of clinical activities,
1489 promptly available at all times (able to respond to the bedside within 60 minutes of request) (CD
1490 6-6), and be physically present for all operations (CD 6-7). The availability of appropriate
1491 pediatric anesthesia services and the absence of delays in airway control or operations must be
1492 documented by the hospital performance improvement and patient safety (PIPS) process (CD 6-
1493 8).

1494
1495 In a Level II children's surgical center, a pediatric anesthesiologist must be available 24 hours a
1496 day to respond within 60 minutes to bedside (CD 6-9). Protocols must be in place to ensure the
1497 timely arrival of a pediatric anesthesiologist at the bedside at the time of need (CD 6-10). The
1498 attending pediatric anesthesiologist on call must be promptly available at all times and present
1499 for all operations (CD 6-11). The onsite presence of a physician or allied health professional
1500 with demonstrable pediatric airway management skills is required 24 hours a day. (CD 6-12)
1501 The availability of pediatric anesthesia services and the absence of delays in airway control or
1502 operations must be documented by the hospital PIPS process (CD 6-13).

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Level III Centers

At Level III children’s surgical centers, anesthesiologists or CRNAs with expertise in pediatrics must be promptly available 24 hours a day to respond to the bedside within 60 minutes (CD 6-14). Local criteria must be established to allow the anesthesia provider to take call from outside the hospital, but with the clear commitment that the provider will be immediately available and provide airway and operative management for children (CD 6-15). Under these circumstances, the presence of a physician or allied health professional demonstrably skilled in emergency airway management for children within the scope of service must be documented (CD 6-16). In Level III facilities, operative pediatric anesthesia may also be provided by a CRNA with pediatric expertise under the supervision of an anesthesiologist with pediatric expertise (defined below). The availability of pediatric anesthesia services and the absence of delays in airway control or operations must be documented by the hospital PIPS process (CD 6-17).

Qualifications

In Level I and II children’s surgical centers, anesthesiologists taking call for infants and children must be board certified in anesthesiology and either possess or be eligible for a certificate of added qualifications in pediatric anesthesiology (CD 6-18). Furthermore, in Level I and Level II facilities, at least 1 anesthesiologist should put forth a specific effort and commitment to education in pediatric related anesthesia and educate other anesthesiologists and the entire team. In Level III centers, call obligations may be met by anesthesiologists with pediatric expertise as defined below (CD 6-19).

1528

1529 • Pediatric anesthesiologist is defined as an individual certified in anesthesia by the
1530 American Board of Anesthesiology or equivalent, in addition to being certified or eligible
1531 for certification in pediatric anesthesia by the American Board of Anesthesiology or
1532 equivalent organization. Such an individual must demonstrate adequate ongoing
1533 engagement in the practice of pediatric anesthesia in patients less than 18 years of age.

1534 • Anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible
1535 to certify or with a current certificate of the American Board of Anesthesiology, or
1536 equivalent. He or she would demonstrate continuous experience with children < 24
1537 months of age, defined as 25 patients per anesthesiologist per year. In addition, this
1538 individual will demonstrate ongoing pediatric clinical engagement in patients less than 18
1539 years of age, as well as 10 relevant Category 1 CME credit hours annually.

1540 • A CRNA with pediatric expertise is defined as a credentialed CRNA provider with
1541 continuous supervised experience with children < 24 months of age, defined as 25
1542 patients per practitioner per year. In addition, this individual will demonstrate ongoing
1543 pediatric clinical engagement in patients less than 18 years of age, as well as 10 relevant
1544 Category 1 CME credit hours annually.

1545

1546 The above continuing education credit hours may be averaged over 3 years to achieve the annual
1547 requirement, here and elsewhere in this document.

1548

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1551 Performance Improvement and Patient Safety

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1553 In Level I, II, III and ambulatory children's surgical centers an anesthesiology medical director

1554 or liaison to the children's surgical performance improvement and patient safety program must

1555 be identified (CD 6-20). In all centers, participation in the PIPS program by this anesthesiology

1556 representative is essential (CD 6-21). The anesthesiology representative to the program must

1557 attend at least 50% of the multidisciplinary peer review meetings with documentation by the

1558 PIPS program (CD 6-22).

1559

1560

1561 **B) Operating Room**

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1563

1564 Personnel

1565

1566 A dedicated children's operating room must be adequately staffed and immediately available in a

1567 Level I children's surgical center (CD 6-23). This criterion is met by having a complete

1568 operating room team in the hospital at all times, so if a patient requires emergency operative

1569 care, the patient can receive it in the most expeditious manner. This criterion cannot be met by

1570 individuals who also are dedicated to other functions within the institution. Their primary

1571 function must be the operating room (CD 6-24). If the first operating room becomes occupied in

1572 a Level I center, a mechanism for providing additional staff must be in place to staff a second

1573 room (CD 6-25).

1574

1575 In Level II and III centers, a children's operating room with appropriate and adequate children's
1576 staff must be readily available in a medically appropriate and timely manner (CD 6-26). This
1577 criterion can be met by a team on call from outside the hospital, depending on the patient
1578 population served, prehospital communications, the volume of urgent cases, and other relevant
1579 factors. In Level I and II centers, prompt and appropriate OR response times, both provider and
1580 institutional, must be demonstrable for emergencies such as critical airway foreign bodies,
1581 malrotation with midgut volvulus, and others of similar life or limb threatening medical urgency
1582 (e.g. less than 60 minutes from diagnosis to OR (CD 6-27).

1583
1584 Availability of children's specialty operating room personnel and timeliness of starting
1585 operations must be evaluated by the hospital PIPS process for Level I, II and III centers and
1586 measures implemented as required to ensure optimal response times which yield optimal care
1587 (CD 6-28).

1588
1589 Equipment

1590
1591 Level I, II, III, and ambulatory children's surgical centers must have age and size appropriate
1592 operating room equipment for the patient populations they serve (CD 6-29). All centers must
1593 have pediatric specific equipment for the scope of service to include airway management,
1594 vascular access, thermal control, surgical instruments, intraoperative imaging capabilities,
1595 equipment for endoscopic evaluation (airway and gastrointestinal endoscopy) and minimally
1596 invasive surgery (CD 6-30). In addition, age appropriate resuscitation fluids, medications and
1597 pharmacy support must be available to support the operative services provided. (CD 6-31)

1598

1599 **C) Postanesthesia Care Unit**

1600

1601 Postoperative care of infants and children may be provided in a postanesthesia care unit (PACU),
1602 depending on the patient's needs. At Level I, II, III and ambulatory children's centers, a
1603 designated PACU or other unit with dedicated personnel and functional capacity, including
1604 qualified pediatric nurses, must be available 24 hours per day to provide care for the patient if
1605 needed during the recovery phase (CD 6-32). If this availability requirement is met with a team
1606 on call from outside the hospital, absence of delays must be documented by the PIPS program
1607 (CD 6-33). The PACU or other unit utilized must have the necessary equipment to monitor and
1608 resuscitate pediatric patients within the scope of services offered, consistent with the processes of
1609 care designated by the institution and monitored by the PIPS program (CD 6-34). The PIPS
1610 program must, at a minimum, address the need for appropriate personnel, postoperative pulse
1611 oximetry, end-tidal carbon dioxide detection, arterial pressure monitoring, patient rewarming,
1612 and intracranial pressure monitoring (CD 6-35).

1613

1614 **D) Radiology**

1615

1616 Specialized radiology services are critical in the management of infants and children with
1617 surgical needs. Qualified pediatric radiologists must be promptly available in person when
1618 requested for the interpretation of diagnostic imaging studies or interventional procedures in
1619 Level I centers (CD 6-36). Teleradiology is a permissible adjunct, but is not alone sufficient to

1620 meet this requirement. This need may be met in Level II and III centers by radiologists with
1621 pediatric expertise as defined below.

1622

1623 Diagnostic information from imaging studies must be communicated in a written form and in a
1624 timely manner (CD 6-37). Critical information that is deemed to immediately affect patient care
1625 must be verbally communicated to the surgical team (CD 6-38). The preliminary report should
1626 be permanently recorded. The final report must accurately reflect the chronology and content of
1627 communications with the surgical team, including changes between the preliminary and final
1628 interpretation (CD 6-39). Changes in interpretation must be monitored through the PIPS
1629 program (CD 6-40).

1630

1631 Collaboration between the children's radiology team and the children's surgical program is
1632 important. In Level I and II facilities, a pediatric radiologist must be appointed as liaison to the
1633 surgical program (CD 6-41). The pediatric radiology liaison or designee should attend peer
1634 review meetings and should educate and guide the entire surgical team in the appropriate use of
1635 radiologic services. The most important imaging process and outcome measures to support the
1636 PIPS program should be defined collaboratively and should include system or individual case
1637 factors that materially affect time to diagnosis and/or treatment, patient morbidity or mortality,
1638 and efficient resource use. In Level I and II centers, participation in the PIPS program process
1639 by the pediatric radiology liaison is essential (CD 6-42). At a minimum, a pediatric radiologist
1640 must be involved in protocol development and trend analysis that relates to diagnostic imaging
1641 (CD 6-43). In Level III centers, it is desirable for radiologists with pediatric expertise to be
1642 involved in the PIPS program.

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Radiology Support Services

Level I and II children’s surgical centers must have policies designed to ensure that infants and children who may require resuscitation and monitoring are accompanied by appropriately trained providers and relevant children’s specific support equipment during transportation to and from the department, and while in the radiology department (CD 6-44).

Conventional radiography and computed tomography (CT) at radiation dosing suitable for infants and children and within the scope of services must be available in Level I and II centers 24 hours per day (CD 6-45). This includes both equipment and personnel. This requirement can be fulfilled with a combination of technicians, residents, fellows, allied health professionals and teleradiology (CD 6-46). The PIPS process must document appropriate and timely availability (CD 6-47). An in-house CT technologist is required at Level I centers (CD 6-48). In Level II and III centers, if the CT technologist takes call from outside the hospital, the PIPS program must document the technologist’s response time (CD 6-49). Interventional radiology and ultrasonography must be available 24 hours per day at Level I centers (CD 6-50). Magnetic resonance imaging capability must be available 24 hours per day at Level I centers (CD 6-51). Technologists and others relevant may respond from outside the hospital, but appropriate timeliness of arrival must be documented by PIPS program (CD 6-52).

1665 Qualifications

1666

- 1667 • In Level I, II, III and ambulatory children’s surgical centers, all staff radiologists
1668 providing imaging services must have successfully completed a radiology residency
1669 program approved by the Accreditation Council for Graduate Medical Education, and
1670 should either have or be eligible for board certification by the American Board of
1671 Radiology; or have completed equivalent residency training either in a foreign radiology
1672 residency, or a program approved by the American Board of Osteopathic Specialties
1673 (Radiology) and have equivalent certification and/or credentials (CD 6-53).. Level I
1674 centers are required to have a pediatric radiologist (defined below) available within 60
1675 minutes 24 hours a day (CD-6-54) and PIPS verification of appropriate and timely
1676 response is required (CD 6-55). Electronic image analysis is a permissible adjunct,
1677 however individuals trained and skilled in hands on imaging such as fluoroscopy must be
1678 physically available within 60 minutes (CD 6-56). In a Level II center, coverage for this
1679 immediate availability may be provided by a combination of pediatric radiologists and
1680 radiologists with pediatric expertise (CD 6-57). In addition to 24/7 pediatric radiologist
1681 coverage, interventional radiology availability 24/7 is required for designation as a Level
1682 I children’s surgical center (CD 6-58).

1683

1684

1685 Level II and III centers may meet similar requirements for 60 minute response with radiologists
1686 with pediatric expertise as defined below (CD 6-59).

1687

- 1688 • Pediatric radiologist is defined as an individual certified by the American Board of
1689 Radiology or equivalent in addition to being certified or eligible for certification in
1690 pediatric radiology by the American Board of Radiology or equivalent.
- 1691 • Radiologist with pediatric expertise is defined as a radiologist with certification by the
1692 American Board of Radiology or equivalent, demonstrable pediatric experience to
1693 support the scope of actual practice, and 10 or more relevant Category 1 CME hours
1694 annually.

1695

1696 **E) Critical Care**

1697

1698 In Level I and II children's surgical centers the surgical services will remain clinically involved
1699 and maintain responsibility for the care of infants and children with primary surgical problems
1700 throughout their admission to an intensive care unit, including both NICU and PICU (CD 6-60).

1701

1702 **ICU Organization**

1703

1704 In a Level I children's center, an ICU physician team with direct surgeon involvement in the day
1705 to day management of the patient is essential for the care of surgical infants and children (CD 6-
1706 61). This team provides continuous in-house coverage by appropriately trained physicians and
1707 advanced practice providers for all infants and children in an ICU environment. This team can
1708 be staffed by critical care trained physicians from different specialties. A pediatric intensive care
1709 unit with pediatric intensivists requires coverage 24/7 with individuals certified in critical care

1710 medicine by the American Board of Pediatrics, the American Board of Anesthesiology or the
1711 American Board of Surgery or equivalent. (CD 6-62)

1712

1713 In Level I and Level II children’s surgical centers, there must be a children’s surgeon that serves
1714 within the medical leadership body of the PICU (may be designated as the “Surgical Director”)
1715 and is responsible for setting policies and defining administrative needs related to pediatric ICU
1716 patients with surgical needs (CD 6-63). In Level III centers, a surgeon must remain responsible
1717 for the surgical issues of the patients while in the ICU (CD 6-64). In Level I and II centers,
1718 pediatric specialty physician and surgeon coverage of critically ill surgical infants and children
1719 must be promptly available 24 hours a day (CD 6-65). These physicians must be capable of
1720 rapid response to deal with urgent problems as they arise (CD 6-66). Generally, Level III centers
1721 transfer most critically ill patients, but when patients are treated locally, there must be
1722 documentation of medical decision making and a process in place to ensure prompt availability
1723 of ICU physician coverage 24 hours a day (CD 6-67).

1724

1725 In a Level I children’s surgical facility, it is strongly recommended that the surgical critical care
1726 director will have obtained critical care training during residency or fellowship. He/she must
1727 have expertise in the perioperative care of infants and children who are surgical patients (CD 6-
1728 68). This expertise may be demonstrated by having board certification or a certificate of added
1729 qualification in surgical critical care from the American Board of Surgery, or other ABMS board
1730 which offers critical care certification (Pediatrics or Anesthesiology). In a Level I children’s
1731 surgical center, critical care qualifications of the surgical director require documentation of
1732 active participation in ICU administration specifically as it pertains to children’s surgical care

1733 and PIPS activities (CD 6-69); and direct involvement in the ICU care of surgical infants and
1734 children during the preceding 12 months (CD 6-70). In Level I, II and III centers surgeons who
1735 are credentialed by the hospital to care for infants and children in the ICU must participate in the
1736 PIPS process (CD 6-71).

1737

1738 Surgeon Responsibility for Infants and Children with Surgical Needs in the ICU.

1739

1740 The surgical service that assumes initial responsibility for the care of an infant or child with
1741 surgical needs in an ICU should maintain that responsibility and involvement either throughout
1742 the acute care phase of hospitalization or until formal transfer to another service upon adequate
1743 resolution of acute surgical issues. For centers of all levels, the children's surgeon must remain
1744 involved with the surgical needs of the patient while in the ICU (CD 6-72), the surgical service
1745 must retain responsibility for the surgical needs of the patient and be involved in the therapeutic
1746 decisions (CD 6-73). The structure designed to care for critically ill ICU patients will differ
1747 between hospitals, but the concept of the surgeon retaining responsibility for the surgical needs
1748 of the patient is essential (CD 6-74). Many of the daily care requirements can be managed by a
1749 dedicated ICU team, but the surgeon must be kept informed, participate in and concur with major
1750 therapeutic and management decisions made by the ICU team (CD 6-75). Infants and children in
1751 Level 1 surgical centers must have on site specialty pediatric provider coverage for intensive care
1752 at all times (CD 6-76).

1753

1754 The children's surgeon in Level II centers must also retain responsibility for the surgical aspects
1755 of patient care, although it is recognized that the surgeon will seek daily input from physicians

1756 with critical care credentials consistent with the medical staff privileging process of the
1757 institution (CD 6-77). This coverage may be provided by the patient's primary surgical service
1758 or by physicians credentialed in critical care by the hospital. This coverage is not intended to
1759 replace the primary children's surgeon in caring for the patient in the ICU; it is to ensure that the
1760 patient's immediate needs are met while the primary surgeon is being contacted. The PIPS
1761 program must document that surgical responsibility is appropriate (CD-78).

1762

1763 ICU Support Services

1764

1765 At Level I, II, and III children's surgical centers, a qualified nurse with relevant children's
1766 specialty training must be available 24 hours per day to provide care for infants and children with
1767 surgical needs during any ICU phase of care (CD 6-79). The nurses caring for pediatric patients
1768 must maintain current certification in PALS or document similar proficiency in pediatric specific
1769 life support knowledge and skills annually. (CD 6-80) The patient/nurse ratio must be
1770 consistent with institutional ICU standards depending on the severity of illness of the patient (CD
1771 6-81). The ICU must have necessary equipment to monitor and resuscitate infants and children
1772 within the scope of service (CD 6-82). This equipment includes that appropriate for airway
1773 management, vascular access, pulse oximetry, end-tidal carbon dioxide detection, arterial
1774 pressure monitoring, intracranial pressure monitoring and patient rewarming. Respiratory
1775 therapy (CD 6-83) and pharmacy services (CD 6-84) must have demonstrable expertise in the
1776 care of pediatric patients.

1777

1778

1779 **F. Neonatal Intensive Care Unit (NICU)**

1780

1781 Neonatal Intensive Care Unit (NICU) designations in this document are consistent with current
1782 American Academy of Pediatrics recommendations in Appendix 1. [*American Academy of*
1783 *Pediatrics Committee on Fetus and Newborns. Level of Neonatal Care. Pediatrics 2012; 130(3):*
1784 *579-587.*]. Facilities, nonphysician personnel and equipment are detailed. Surgeon engagement
1785 with neonates with surgical problems who require the NICU environment must be as delineated
1786 above for surgical critical care in a PICU. (CD 6-85) Level IV NICU resources are required for
1787 designation as a Level I children’s surgical center (CD 6-86). Level III or higher NICU resources
1788 are required for Level II children’s surgical center designation (CD 6-87).

1789

1790 A Level I children’s surgical center requires 24/7 neonatologist coverage (CD 6-88). A
1791 neonatologist is defined as an individual who is either sub-board eligible or certified by the
1792 American Board of Pediatrics in Neonatal-Perinatal Medicine or equivalent. Level IV NICUs
1793 must maintain a full range of pediatric medical subspecialists, children’s surgical subspecialists,
1794 and pediatric anesthesiologists on site; (index institution is the primary site of practice) (CD 6-
1795 89). Level III NICUs must provide prompt and readily available access to a full range of
1796 pediatric medical subspecialists, pediatric surgeons, pediatric anesthesiologists and pediatric
1797 ophthalmologists (this can be done at the site or at a closely related institution by prearranged
1798 consultative agreement) (CD 6-90).

1799

1800

1801 **G) Emergency Services**

1802

1803 The ability to rapidly evaluate, respond to and resuscitate an infant or child is essential when
1804 caring for surgical patients of all ages. Level I, II or III designation requires that pediatric
1805 specific rapid response and/or resuscitation teams with experience and training to support the
1806 scope of service must be in place 24/7 to respond to any site within a designated facility (CD 6-
1807 91). 24/7 physical presence of a certified pediatric provider to include PALS certification in the
1808 leadership role for such a team is required for Level I, II or III designation (CD 6-92).

1809

1810 Level I children's surgical center designation requires on site pediatric emergency medicine
1811 coverage 24/7 (CD 6-93). In addition to pediatric emergency physician coverage 24/7,
1812 children's specific emergency department resources must be present to support the entire scope
1813 of emergency care for infants and children including facilities, equipment and nonphysician
1814 personnel (CD 6-94).

1815

1816 Level II and III children's surgical centers are required to have emergency coverage by
1817 physicians with pediatric expertise (CD 6-95) and to have emergency department resources in
1818 place to support the scope of practice, including facilities, equipment and nonphysician personnel
1819 (CD 6-96). Level II centers that limit the scope of practice to neonatal patients are not required
1820 to have emergency physicians with pediatric experience or pediatric emergency physicians.

1821

1822

1823 **H) Primary Care Physicians and Pediatricians**

1824

1825 The patient's personal physician or pediatrician is important to infants and children of any age.

1826 The primary care physician or pediatrician is helpful in providing information about the patient's

1827 history, dealing with long-term problems, and meeting the family's psychosocial health needs.

1828 Primary care physicians and pediatricians are also important to provide continuity of care

1829 throughout the patient's home recovery period and return to health. The immediate presence of

1830 the primary care physician or pediatrician is not a requirement.

1831

1832 When a committed surgeon has assumed responsibility for an infant or child with a surgical

1833 problem in a Level I, II or III children's surgical center, he/she should recognize the primary care

1834 physician or pediatrician as a valuable resource. Depending on the local circumstances, a

1835 primary care physician may serve as a member of the care team or may provide continuity of

1836 care and act as a liaison with the family. Children with surgical needs should not be admitted or

1837 transferred by the primary care physician without the knowledge and active involvement of the

1838 surgical service.

1839

1840 Hospitalists have become important members of the acute care team in many institutions. A

1841 Level I, II or III children's surgical center should have a pediatric trained hospitalist or general

1842 pediatrician available 24/7 if acute hospital care for perioperative infants and/or children is

1843 provided outside of NICU and PICU environments.

1844

1845

1846 **I) Other Surgical Specialists**

1847

1848 Many surgical subspecialists are needed to properly serve a population of infants and children.

1849 Level I facilities must be prepared to manage the most complex patients and must have available

1850 a full spectrum of children’s surgical specialists beyond pediatric surgeons and pediatric

1851 anesthesiologists. (CD 6-97) Pediatric orthopedic surgery, pediatric neurosurgery, pediatric

1852 cardiac surgery, pediatric plastic surgery, pediatric ophthalmology, pediatric otolaryngology, and

1853 pediatric urology are required in Level I children’s surgical centers (CD 6-98). Level II centers

1854 may not have the local resources to provide all of these specialists, but must have appropriate

1855 children’s surgical specialists to match the scope of services offered. (CD 6-99).

1856

1857 Here and elsewhere children’s surgical specialists are defined as those who are either eligible for

1858 or board certified after relevant specialty fellowship training and recognized by the appropriate

1859 board of the American Board of Medical Specialties or equivalent.

1860

1861 For Level I and Level II verification, children’s surgical specialists must be on the medical staff

1862 and readily available (within 60 minutes) 24/7 to provide care at the bedside (CD 6-100).

1863

1864 Where individuals with pediatric specific training and experience are designated above as

1865 “available”, it is required that the care of infants and children will be demonstrably provided by

1866 these specialized providers (CD 6-101).

1867

1868

1869 **J) Medical Consultants**

1870

1871 Contemporary management of many infants and children with surgical needs requires support
1872 from pediatric medical specialists as well. In a Level I children's surgical center, pediatric
1873 medical specialists on staff must be available from the following disciplines: cardiology,
1874 hematology/oncology infectious disease, gastroenterology, pulmonary medicine, neurology and
1875 nephrology. (CD 6-102) Available is defined as a 24/7 response to the bedside within 60 minutes
1876 of request with care demonstrably provided by the pediatric specialist. (CD 6-103) In addition,
1877 their respective children's specific support teams (for example, children's respiratory therapy,
1878 pediatric dialysis team and pediatric nutrition support team) must be readily available. (CD 6-
1879 104). A multidisciplinary cancer program is highly recommended for a Level I children's
1880 surgical center.

1881

1882 In a Level II facility, providers from pediatric medical specialties appropriate for the scope of
1883 services must be available on staff (CD 6-105). In Level II facilities, specialty consultations for
1884 problems related to pediatric pulmonary medicine, cardiology, gastroenterology, neurology,
1885 hematology/oncology and infectious disease must be available (CD 6-106). A multidisciplinary
1886 cancer program is highly recommended for a Level II facility.

1887

1888 In a Level I, II or III facility, a general pediatrician or pediatric hospitalist must be readily
1889 available within 60 minutes 24/7 if perioperative acute hospital care beyond the NICU or PICU
1890 is within the scope of service. (CD 6-107)

1891

1892 As for “available” surgical specialists above, children’s medical specialists must demonstrably
1893 provide needed bedside care and this must be monitored by the PIPS program (CD 6-108).

1894
1895

1896 **K) Support Services**

1897

1898 Specialized support services are required to care optimally for infants and children with surgical
1899 needs. In Level I and II centers, a respiratory therapist with pediatric expertise must be available
1900 in-house 24/7 to care for patients within the scope of institutional service (CD 6-109). Acute
1901 pediatric dialysis must be available in Level I centers (CD 6-110). If a Level II center does not
1902 have pediatric dialysis capability, it must have a transfer agreement in place (CD 6-111).
1903 Pediatric nutrition support must be available in Level I and II centers (CD 6-112).

1904

1905 **L) Child Life**

1906

1907 A child life support program is required at Level I and II children’s surgical centers (CD 6-113).

1908

1909 **M) Clinical Laboratory**

1910

1911 Pediatric laboratory services to support the scope of service offered must be available 24/7 for
1912 the standard analyses of blood, urine, and other body fluids, including microsampling when
1913 appropriate, in Level I, II and III children’s surgical centers (CD 6-114). Likewise, coagulation
1914 studies, blood gases, and microbiology must be available 24/7 (CD 6-115). The blood bank must
1915 be capable of blood typing and cross-matching (CD 6-116) and must have an adequate supply of

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1916 red blood cells, fresh frozen plasma, platelets, cryoprecipitate, and appropriate coagulation
1917 factors to meet the needs of infants and children within the scope of services. (CD 6-117)

1918

1919 The department of laboratory services in Level I centers should have a dedicated pediatric
1920 component that meets the needs of the patients and their caregivers. The anatomic pathology
1921 component should be represented by one or more anatomic pathologists fully committed to
1922 children's issues. The best indicator of achieving this will be the children's surgeons'
1923 confirmation that the patients' needs in this area are being met. (CD 6-118)

1924

1925 The department of laboratory services in Level II centers (including anatomic pathology) should
1926 have a dedicated pediatric component that meets the needs of the patients and their caregivers.
1927 The best indicator of achieving this will be the children's surgeons' confirmation that the
1928 patients' needs in this area are being met. (CD 6-119)

1929

1930 **N) Transfer of Patients**

1931

1932 The ability to stabilize and transfer critically ill infants and children must be demonstrated all
1933 levels of designation (CD 6-120). This must include processes to safely move patients from one
1934 location to another either within or between institutions (CD 6-121).

1935

1936 **CHAPTER 7 Data Collection and Reporting**

1937

1938

1939 **Participation in data collection**

1940

1941 An overarching principle of this *Optimal Resources for Children's Surgical Care* document is to
1942 support the program using evidence based information to the maximum extent possible. While
1943 many core recommendations in this document are evidence based, a large proportion of the
1944 recommendations are guided by expert opinion and consensus. Expansion of the existing
1945 evidence base is not only necessary for improvement in the program, it is a critical mission of the
1946 Optimal Resources for Children's Surgical Care initiative. Institutions providing optimal care for
1947 children have an obligation to participate in collection of data locally, to contribute these data to
1948 the program for collation and distribution, and to use the data to improve the care of children.

1949

1950 Every verified children's surgical center must collect and analyze its surgical outcome data and
1951 contribute it to the national collaborative effort (CD 7-1). For centers seeking Level I or II
1952 verification this requirement will be fulfilled by participation in the American College of
1953 Surgeons National Quality Improvement Program-Pediatric (NSQIP Pediatric) (CD 7-2). For
1954 Level III centers and ambulatory surgical centers this will be fulfilled by reporting specific safety
1955 events detailed in accompanying Appendix 3 (CD 7-3). Level I and II centers are also required
1956 to report the events detailed in Appendix 3. (CD 7-4)

1957

1958

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1959 These data should be directly viewed by the medical director of children's surgery and the
1960 children's surgery program manager. It is essential that programs demonstrate that these
1961 individuals receive both institution-specific and national aggregate data on a regular basis (CD 7-
1962 5) and that these data are used to guide specific quality improvement initiatives within the
1963 institution (CD 7-6)

1964

1965 The relationship with the medical center's electronic medical record and other data collection
1966 systems continues to evolve. The ACS supports efforts to reduce redundancy in data collection
1967 efforts. However, it is imperative that the data populating the NSQIP-Pediatric and Children's
1968 Surgery Safety Report databases be as accurate as possible. It is expected that participating
1969 institutions be actively engaged in using the electronic resources within the institution to
1970 optimize accuracy of data and efficiency of collection. Institutions must be able to demonstrate
1971 engagement in this effort (CD 7-7). The outcome data collected via NSQIP-Pediatric will be
1972 guided by the NSQIP-Pediatric sampling algorithm [Saito JM, Chen LE, Hall BL, et al. Risk-
1973 adjusted hospital outcomes for children's surgery. Pediatrics, 2013 Sep; 132(3):e677-88]. The
1974 data regarding safety events is expected to include all such events at the center, verified centers
1975 will be able to demonstrate the effectiveness of their data collection process at capturing all
1976 relevant events (CD 7-8).

1977

1978 **ACS-NSQIP-Pediatrics**

1979

1980 The NSQIP Pediatric is the first comprehensive risk adjusted peer reviewed outcomes program
1981 in children's surgery. The program has demonstrated the ability to create valid risk adjusted

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1982 models that discriminate performance between participating institutions for all-cause combined
1983 morbidity, morbidity in neonatal surgery, specific morbidities (i.e. surgical site infections,
1984 pneumonia etc.), and for morbidity in specific specialties (i.e. spine surgery, pediatric abdominal
1985 surgery, others). The incidence of mortality in the pediatric surgical population is generally
1986 insufficient for this to be a discriminating variable.

1987

1988 Experience with the adult NSQIP program, which has been in existence for about 20 years has
1989 conclusively demonstrated that the program has produced a marked reduction in surgical
1990 morbidity and mortality in the United States. This benefit was observed in essentially all
1991 participating institutions to varying degrees. While NSQIP provides periodic reports of an
1992 institution's adverse event rates compared to peer institutions, there is conclusive data showing
1993 that the baseline incidence of these events has progressively declined after implementation of the
1994 program. This clear demonstration that the adult NSQIP program has directly benefited patients
1995 is the basis for requiring participation in the pediatric program by Level I and II centers.

1996

1997 ACS-NSQIP-Pediatrics is an entity that is independent of but closely aligned with the Optimal
1998 Resource for Children's Surgical Care initiative. Currently the program is focused on measuring
1999 system wide events such as infections, renal failure, and pulmonary complications among others.
2000 The NSQIP pediatric program is evolving to examine complications that are more operation and
2001 specialty specific and to address resource utilization. For example, a pilot project is examining
2002 the use of ionizing radiation in the diagnosis of appendicitis in children. Another project is
2003 examining functional outcomes after spinal surgery.

2004

2005 ACS-NSQIP-Pediatrics seeks to provide a sample of surgical practice that allows assessment of
2006 key relevant issues in children's surgery at participating institutions and provide national
2007 comparable data to identify opportunities for improvement at the institutional level. The specific
2008 data collected by NSQIP-Pediatric is determined by the ACS-NSQIP-Pediatric steering
2009 committee composed of leaders in children's surgery and an experienced staff of investigators
2010 and statisticians. It is expected that institutions that participate in ACS-NSQIP-Pediatric and
2011 actively utilize the information will have created a culture that is in the best interest of all
2012 patients undergoing surgery at the institution, not only those with procedures or diagnoses
2013 currently being assessed by ACS-NSQIP-Pediatrics.

2014

2015 **Major Adverse Perioperative Events**

2016 An important but not sole focus of the Optimal Resources for Children's Surgical Care initiative
2017 is to insure that the operating room and immediate proximate care is provided in the safest
2018 manner possible. Much of this care is provided or strongly influenced by non-surgeon members
2019 of the surgical team. This team includes but is not limited to anesthesiologists, CRNAs, nurses,
2020 technicians, and operating room support staff. It is imperative that every verified children's
2021 surgical center accurately track and report 100% of the major adverse events that occur in the
2022 center (CD 7-9) and address them in a systematic manner with a culture of improvement and
2023 prevention (CD 7-10).

2024

2025 These safety events to be monitored in all surgical patients ≤ 18 years are detailed in Appendix 3.
2026 ACS-NSQIP-Pediatrics has historically not collected these types of data. Children's surgical
2027 centers at all levels of verification will report these data directly to the American College of

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2028 Surgeons as part of the Optimal Resources for Children’s Surgical verification program. All
2029 levels of verified children’s surgical centers will be expected to develop detection and reporting
2030 processes for these events and to articulate this process for the ACS verification team at the time
2031 of site visit. (CD 7-11) This will allow better understanding of the strengths, limitations, and
2032 cost of detection methods so that detection may be improved as the program evolves.

2033

2034 **Use of the data**

2035 There are two primary purposes for collecting data as described above. The first is for the
2036 American College of Surgeons Committee on Children’s Surgery to better understand the
2037 processes and outcomes of children’s surgical care in the United States and to develop
2038 benchmarks, standards, and expectations that will guide the evolution of the Optimal Resources
2039 for Children’s Surgical Care program. The second is to give the institutions providing the care
2040 the information and tools to develop and execute meaningful and impactful quality improvement
2041 initiatives that directly improve the quality of care for children at the facility. Verified centers
2042 will receive regular reports from the American College of Surgeons providing aggregate and
2043 institution specific data and will be expected to demonstrate the presence of ongoing quality
2044 improvement projects that derive directly from analysis of collected data (CD 7-12). Further,
2045 they will be able to provide evidence of the manner in which these projects have improved care
2046 of patients. This information must be quantitative and specific (CD 7-13). The institutions will
2047 also be able to demonstrate that these improvements have been sustained or that there is a plan in
2048 place for sustainability (CD 7-14).

2049

2050

2051 **Public Health**

2052 The Optimal Resources for Children’s Surgical Care program and ACS-NSQIP-Pediatrics are
2053 part of a comprehensive data system needed to describe the current status of children’s surgery in
2054 the United States. These data will provide important information about the safety, quality, cost,
2055 and outcomes of the system. They can be further stratified and analyzed by age, gender, race,
2056 ethnicity, and socioeconomic status. In combination with other public health data, this
2057 information can provide a crucial resource to governments, policy makers, and agencies
2058 interested in the health and welfare of children. These data may also be used to inform public
2059 officials about major opportunities for improvement in children’s surgical care, thus serving as a
2060 basis for legislative and regulatory efforts.

2061

2062 **Research**

2063 Generation of new knowledge is an effective means of advancing the quality of care provided to
2064 children. This requires reliable, accurate and available data. The data collected by participation in
2065 this program can be a rich source of information to answer research questions or provide
2066 background data for new studies. All children’s surgical centers are encouraged to use their own
2067 data and national pooled data for research. Level I centers should demonstrate active research
2068 efforts utilizing the data collected, ideally resulting in peer-reviewed publication of findings.

2069

2070 **Data entry and maintenance**

2071 High quality data begins with high quality data entry and requires ongoing maintenance to insure
2072 the quality endures. For Level I and II centers, the primary individual responsible for data entry
2073 and quality will be the Surgical Clinical Reviewer (SCR) for the institution’s NSQIP-Pediatric

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2074 program. These individuals undergo a rigorous and closely monitored period of training that is
2075 well described elsewhere. [*Saito JM, Chen LE, Hall BL, et al. Risk-adjusted hospital outcomes*
2076 *for children's surgery. Pediatrics, 2013 Sep; 132(3):e677-88*] For children's surgical safety
2077 reports a process must be developed and implemented that insures the data collection staff are
2078 appropriately trained and monitored to insure high quality data. (CD 7-15) The medical director
2079 of children's surgery and children's surgery program manager will be responsible for insuring
2080 this(CD 7-16).

2081

2082 **Confidentiality**

2083 Hospitals are responsible for ensuring patient and hospital confidentiality. The passage of the
2084 Health Insurance Portability and Accountability Act (HIPAA) by Congress in 1996 brought
2085 about major changes in the way internal and external data are handled at health institutions. The
2086 children's surgery program must ensure that appropriate measures are in place to meet the
2087 confidentiality requirements of the data (CD 7-17). All reasonable means should be used to
2088 protect against threats, hazards, and unauthorized uses or disclosures of these data. The
2089 responsible parties should ensure that all persons dealing with these data are trained in protecting
2090 the confidentiality of patients. Actions to protect confidentiality should be firmly integrated in
2091 the administration of the data collection effort at all levels so that identifying information is
2092 available only to people who have a need to know. Facilities that submit data to the ACS-
2093 NSQIP-Pediatrics or Optimal Resources for Children's Surgical Care program or that are
2094 participating in children's surgery center verification must have a current and fully executed
2095 business associate agreement with the American College of Surgeons (CD 7-18).

2096

2097 **Data Collection**

2098 In the planning stages of a data collection effort, it is useful to consider the mechanisms for data
2099 collection and entry from medical records and the hospital information system. Data
2100 downloading from hospital information systems is expanding. The use of portable computers and
2101 handheld devices for data extraction and data entry is popular. It allows SCRs and data collectors
2102 to work concurrently from the medical record and interviews. Alternatively, a paper data form
2103 may be designed to record patient information for subsequent batch data entry. The least
2104 desirable method is post-discharge data extraction from the medical record. Once collected, these
2105 data are downloaded to the central registry. Provisions should be made to ensure timely and
2106 complete availability of pre-hospital care reports, operative notes, medical examiner reports, and
2107 other documents that may not always be present in the active medical record.

2108

2109 The amount of time and effort that will be necessary to maintain the data collection process
2110 should not be underestimated. A designated and well-trained SCR is critical to the success of a
2111 registry. The ACS-NSQIP-Pediatrics program has a track record of effective training and
2112 support of SCRs and further information is available from this program. At Level I and II centers
2113 one full-time equivalent employee dedicated to the SCR duties must be available to process the
2114 data (CD 7-19). At Level III centers and children's ambulatory surgery centers, appropriate
2115 staffing must be demonstrated(CD 7-20). This staffing need increases if additional data elements
2116 are collected. Hospitals must also take into account the additional tasks, above the abstraction
2117 and entry of patient data, which are assigned to the data collecting staff. (CD 7-21) Processes
2118 such as report generation, data analysis, research assistance, and meeting various submission
2119 requirements will decrease the time dedicated to the meticulous collection of patient data.

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2120 Electronic downloads into the system also create additional tasks, as does ongoing data
2121 validation prior to data acceptance. Additional staff will be required to perform these tasks to
2122 ensure the integrity and quality of registry data that are used for prevention, quality
2123 improvement, and other essential aspects of the children's surgery program.
2124
2125

2126 **CHAPTER 8 - Performance Improvement and Patient Safety**

2127
2128 This chapter describes the concept of monitoring, evaluating and improving the performance of
2129 a children’s surgical program. Although there is no consensus prescription for performance
2130 improvement and patient safety (PIPS), the American College of Surgeons Committee on
2131 Children’s Surgery requires a structured effort by the program to demonstrate a continuous
2132 process for improving care for children with surgical needs at all levels of verification. (CD 8-1)

2133
2134 Current health care imperatives emphasize the value proposition; demonstrably high quality care
2135 delivered in a cost effective manner. Although this may be difficult to translate to the care of
2136 some infants and children, an evidence-based rather than an empiric approach presents more
2137 meaningful criteria against which our care can be measured. A standardized approach to
2138 recurring problems minimizes unnecessary variation, allows better outcome assessment and
2139 makes changes in care easier to implement and more uniform. Coordination of the PIPS
2140 children’s surgical program into a hospital-wide program offers a reduction in labor while
2141 producing more impact on quality.

2142
2143 Patient safety is a core focus of the PIPS process and underscores an important program goal.
2144 Safety in medical practice once was considered a “given,” but it is now recognized as an issue
2145 that clearly requires monitoring and focused attention to achieve. The patient safety process
2146 directs its efforts at the environment in which care is given, and the performance improvement
2147 process is directed at the care itself. The boundary between the performance improvement and
2148 patient safety processes is indistinct and overlap is common. A combined PIPS program is
2149 necessary to ensure optimal outcomes.

2150

2151 The PIPS method, which involves guideline development, process assessment, process
2152 correction, and monitoring for improvement, may seem unnecessary to surgeons who are highly
2153 motivated and work hard at providing good patient care. However, health care experts believe
2154 that individual physicians simply trying harder will not result in better quality and safer patient
2155 care. Contemporary care processes are complex and require an entire multidisciplinary team, so
2156 responsibility for a patient's safety and optimal outcome should be shared by all involved. In
2157 centers with residency programs, residents should be exposed to the PIPS process. This
2158 exposure is valuable training and may be used to demonstrate compliance with Accreditation
2159 Council for Graduate Medical Education core competency requirements (Table 1).

2160

2161

2162

2163 **Table 1. ACGME Core Competencies and Related Areas within a Children’s Surgical Program**

ACGME Competency	Related Program Areas-Examples:
Patient Care	Patient-centered emphasis on all aspects of children’s surgical program ----- Ease of patient access to children’s surgical care
Medical knowledge	Board-certification requirements of physician care providers ----- Mandatory children’s surgery-related continuing education requirements for team ----- ACS center verification process ----- Children’s surgical research ----- Local, regional and national educational conferences
Professionalism	Commitment by the surgeons to accountability for dutiful action on behalf of patients in the framework of a public contract for care
System-based practice	Design of the health care system as a coordinated system of care from diagnosis to operation through patient recovery ----- Development, use and periodic reevaluation of standardized care processes ----- Use of electronic medical record and physician order entry systems when available -----
Practice-based learning and improvement	Development, use and assessment of evidence-based practice guidelines ----- Data Collection/Outcomes Assessment ----- Emphasis placed on performance improvement and patient safety process ----- Children’s surgical center committee activities
Interpersonal and communication skills	Multidisciplinary team approach to care (rounds, conferences) ----- Communication training related to patients, families, other professional staff ----- Conflict resolution training

2164 ACGME indicates Accreditation Council for Graduate Medical Education; and ACS, American College
 2165 of Surgeons

2166
 2167

2168 **Operational Concepts**

2169 Children’s surgical care should be efficacious, safe and cost-effective. All hospitals and
2170 providers in the United States are expected to measure, evaluate and improve their performance.
2171 Quality assurance began with retrospective chart reviews by nonphysicians looking for
2172 documentation of predetermined criteria thought to reflect acceptable quality of physician
2173 performance. Quality assurance evolved through concepts known as total quality management
2174 and continuous quality improvement to what is known today as performance improvement.
2175 Performance improvement emphasizes a continuous, multidisciplinary effort to measure,
2176 evaluate and improve the processes of care and the related outcomes. A major objective of PIPS
2177 is to reduce inappropriate variation in care and to improve patient safety. All children’s surgical
2178 centers (Levels I, II, III and children’s ambulatory surgical centers) must demonstrate a clearly
2179 defined PIPS program for their populations that should be coordinated with an institution wide
2180 program (CD 8-2).

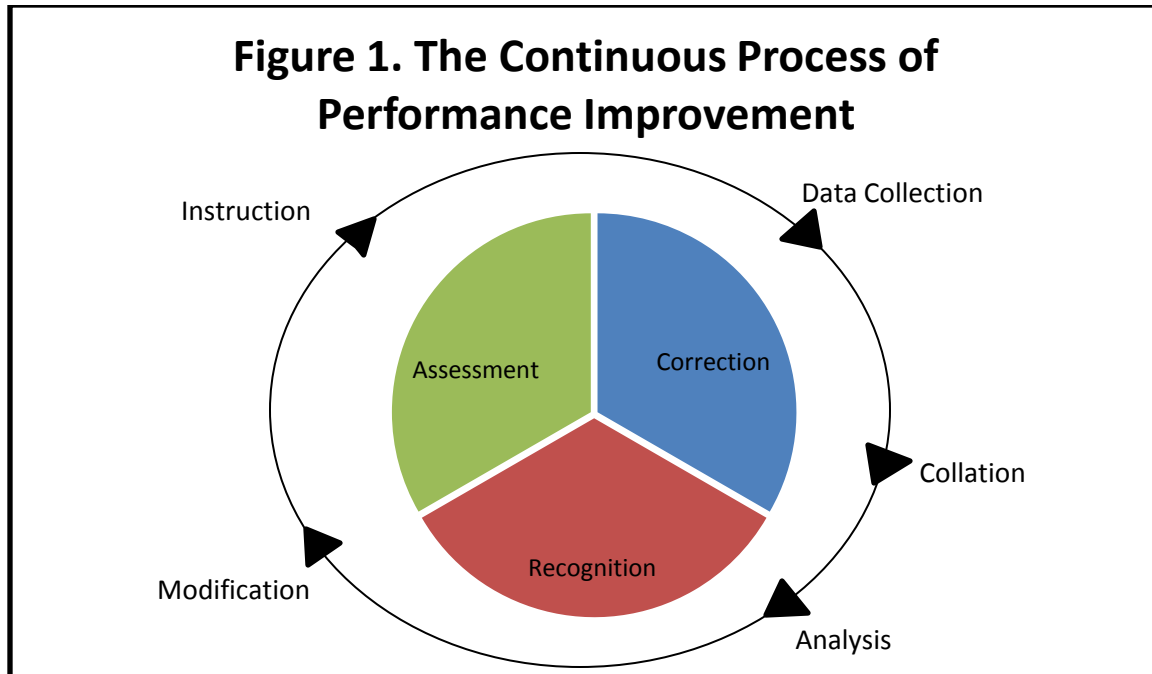
2181 The traditional use of empiric “audit filters” or “indicators” to measure the effectiveness of the
2182 process of care has had limited value because many of these resource-intensive tools do not
2183 correlate with outcome. However, some filters, such as those readily available in registries or
2184 hospital-wide PIPS programs (for example, unplanned readmissions) are reasonable for trending,
2185 especially when comparative risk-adjusted benchmarking data are available. The development
2186 of expectations from evidence-based guidelines, pathways and protocols presents an alternative
2187 for measuring the process, expected outcomes and consistency of care. This model also allows
2188 for assessment of the cost-effectiveness of care.

2189

2190 Modern performance improvement and patient safety in surgical care is a continuous cycle of
2191 monitoring, assessment and management (Figure 1). Performance improvement must be
2192 supported by a reliable method of data collection that consistently obtains valid and objective
2193 information necessary to identify opportunities for improvement (CD 8-3). At a minimum, the
2194 program must be able to demonstrate that the data collection relevant to the children's surgical
2195 program supports the PI process (CD 8-4). The process of analysis must include
2196 multidisciplinary review (CD 8-5) and must occur at regular intervals to meet the needs of the
2197 program (CD 8-6). The results of analysis must define corrective strategies (CD 8-7) and must
2198 be documented (CD 8-8). The effect of this change then is evaluated as the cycle repeats itself.
2199 A patient safety program evaluates the overall care process to see whether it minimized risk of
2200 harm related to the care process itself. Various agencies concerned with patient safety have
2201 proposed specific program initiatives to improve safety of care that is often complex and
2202 delivered by multiple providers.

2203

2204 An effective PIPS program is characterized by a certain number of elements: (1) authority and
2205 accountability for the program; (2) a well-defined organizational structure; (3) appropriate,
2206 objectively defined standards to determine quality of care; and (4) explicit definition of outcomes
2207 derived from relevant standards.



2208

2209

2210 **Program Configuration**

2211

2212 **Administrative Accountability**

2213 Because it crosses many traditional specialty lines, the surgical program must be empowered to

2214 address issues that involve multiple disciplines (CD 8-9). The program, including PIPS, should

2215 be approved by the hospital governing body as part of its commitment to optimal care of children

2216 with surgical needs. This commitment must include adequate administrative support and defined

2217 lines of authority that ensure comprehensive evaluation of all aspects of surgical care for infants

2218 and children (CD 8-10). The children’s surgical program must have a medical director with the

2219 authority and administrative support to lead the program (CD 8-11). A children’s surgery

2220 program manager is a critical component of a surgery program. Although the physician director

2221 remains responsible for the overall function of the program, the surgery program manager

2222 usually is responsible for logistic information, coordination of daily data processing and

2223 monitoring of the effectiveness of interaction of all involved services, including case
2224 management and resource utilization.

2225

2226 **Surgery Privilege Assessment**

2227 The medical director of children's surgery must review the qualifications for the children's
2228 surgical service members (CD 8-12) and have sufficient authority to recommend changes based
2229 on performance review (CD 8-13). This review may include evaluation of the practitioners'
2230 continuing education, resource utilization, complications, mortality rates and participation in
2231 evidence-based guidelines, pathways and protocols.

2232 The granting of privileges and credentialing are departmental and medical staff functions.

2233

2234 **Categories of Performance**

2235

2236 **General Principles**

2237 The meaning of outcome measurement varies depending on the perspective from which it is
2238 viewed. The patient and family anticipate a complete and rapid recovery; the administrator and
2239 payer focus upon the cost of care; and the surgeon emphasizes the quality of care, most often
2240 based upon morbidity and mortality. Regardless of individual perspective, most would agree
2241 with a goal of improving the value of surgical care. The spectrum of performance evaluation can
2242 extend from institution-wide assessment to measures of individual practitioner performance.
2243 Determinants of patient outcomes include modifiable variation in care as well as factors not so
2244 readily managed (for example, patient comorbidities and systems performance). Another useful
2245 method of viewing performance is through the "value equation" concept:

2246 **Value = $\frac{\text{Quality of Process} + \text{Quality of Outcome}}{\text{Cost}}$**

2247 Value can be increased by improving the quality of process or outcome or by decreasing cost.

2248 However, a modest increase in cost that significantly improves quality also can add value. This

2249 perspective can help prioritize performance improvement initiatives. It is clear that high quality

2250 care in the United States can be delivered at lower cost.

2251 Process Measures (Examples)

2252 The following categories of process variables require defined criteria (expectations), which can

2253 be determined from consensus, institutional guidelines, or, ideally, nationally derived, evidence-

2254 based guidelines. Some require peer review for determination. It is practical to monitor several

2255 rather than all of the following examples:

- 2256 • Compliance with guidelines, protocols and pathways
- 2257 • Appropriateness of prehospital and emergency department triage/referral
- 2258 • Delay in assessment, diagnosis, technique or treatment
- 2259 • Error in judgment, communication or treatment
- 2260 • Appropriateness of documentation
- 2261 • Timeliness and availability of imaging reports
- 2262 • Timely participation of subspecialists
- 2263 • Availability of operating room
- 2264 • Professional behavior
- 2265 • Availability of family services
- 2266 • Consistency of outpatient follow-up

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- 2267 • Care processes should be evaluated to determine if they are adequate to achieve the
2268 desired outcome. Ineffective processes should be identified, revised and reevaluated to
2269 determine if the revisions are effective.

2270 Outcome Measures (Examples)

2271

2272 Clinical outcomes as well as those that reflect patient and/or family perspective are
2273 fundamental to a children's surgical program. These examples may reflect quality of patient
2274 care

- 2275 • Mortality
- 2276 • Morbidity (complications)
- 2277 • Length of stay – intensive care unit and total
- 2278 • Patient safety initiatives
- 2279 • Cost
- 2280 • Quality of life
- 2281 • Functional outcomes
- 2282 • Patient satisfaction

2283

2284 **Performance Review and Educational Programs**

2285

2286 The goals of multidisciplinary review are as follows: (1) review the performance of the surgical
2287 program, (2) review the safety of the program, (3) provide focused education and (4) provide
2288 peer review. These activities can be accomplished in a variety of formats depending on the
2289 volume of patients. Patient care may be evaluated initially by individual specialties within their
2290 usual departmental PIPS review structures; however, identified problem trends must undergo
2291 multidisciplinary peer review by a dedicated children's surgical peer review committee in Level
2292 I and II centers (CD 8-14). This function may be integrated into existing institution wide
2293 processes for Level III and ambulatory centers. The center must be able to demonstrate that
2294 specific patient populations can be identified for separate review regardless of the institutional
2295 PIPS processes (CD 8-15). This identification usually is done through a registry or similar
2296 monitoring process. Risk adjusted outcomes assessment using NSQIP-Pediatrics data is required
2297 for Level I and II children's surgical center verification. (Chapter 7)

2298

2299 **Program Operational Process Performance Committee**

2300

2301 There must be a process to address children's surgical program operational issues (CD 8-17).
2302 Typically, this function is accomplished by a multidisciplinary committee that examines related
2303 hospital operations and includes representatives from all phases of care provided to surgical
2304 patients. This is often the operating room committee or surgical authorities committee, but may
2305 take other forms. Besides physicians, this committee may include, nurses, technicians,
2306 administrators and other relevant personnel. In Level I and II centers this committee must be

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2307 dedicated to the children's surgical services; in Level III and ambulatory centers, this may be
2308 integrated into existing institution wide processes. (CD 8-18) This committee should meet at
2309 least quarterly, but may need to meet more often as necessary, to review operational performance
2310 issues. Documentation (minutes) must reflect the review of operational issues and, when
2311 appropriate, the analysis and proposed corrective actions (CD 8-19). This process must identify
2312 problems (CD 8-20) and must demonstrate problem resolutions (loop closure) (CD 8-21).

2313

2314 **Peer Review Committee**

2315

2316 Center staff should be familiar with state laws governing peer review. Most peer review
2317 activities are protected from discovery. Minutes from peer review activities should be written
2318 carefully but document a candid discussion.

2319

2320 There must be a dedicated multidisciplinary children's peer review committee in Level I and II
2321 centers chaired or co-chaired by the medical director of children's surgery or designee and with
2322 participation of representatives from pediatric anesthesiology, radiology, and other children's
2323 surgical specialties; as well as neonatology, critical care medicine and emergency medicine if
2324 within the scope of service. The committee will improve surgical care by reviewing all deaths,
2325 selected complications and sentinel events with the objectives of identifying issues and
2326 developing appropriate responses (CD 8-22). Participation must include attendance by the
2327 aforementioned representatives (or designees) at a minimum 50% of the multidisciplinary peer
2328 review committee meetings (CD 8-23). The medical director of children's surgery must ensure
2329 dissemination of information with documentation (CD 8-24). Dissemination of information

2330 typically is achieved by attendance at peer review meetings and by letter or minutes. Evidence
2331 for appropriate participation and acceptable attendance must be documented in the PIPS process
2332 (CD 8-25). The frequency is to be determined by the medical director of children's surgery
2333 based on the needs of the PIPS program, but must be at least quarterly (CD 8-26).

2334

2335 All deaths of infants and children occurring within 30 days of an operative procedure must be
2336 systematically reviewed and categorized as unanticipated mortality with opportunity for
2337 improvement, mortality without opportunity for improvement or anticipated mortality with
2338 opportunity for improvement through a peer review process (CD 8-27). Likewise, these will be
2339 characterized as patient, system or provider related.

2340

2341 **Corrective Action**

2342

2343 Monitoring and evaluation may determine that performance meets or exceeds expectations. It
2344 may be useful to monitor trends continuously or periodically. When a consistent problem or
2345 inappropriate variation is identified, corrective actions must be taken and documented (CD 8-28).

2346 Examples of corrective actions include the following:

- 2347 • Guideline, protocol or pathway development and revision
- 2348 • Targeted education (for example: rounds, conferences, journal clubs)
- 2349 • Enhanced resources, facilities or communication
- 2350 • Process improvement/team implementation
- 2351 • Counseling
- 2352 • Peer review presentations

- 2353 • Change in provider privileges or credentials
- 2354 • External review

2355

2356 **Closing the Loop (Result)**

2357

2358 Performance improvement entails demonstrating that a corrective action has the desired effect as
2359 determined by continuous evaluation. As the definition of quality is neither exact nor constant,
2360 improvement cannot always be demonstrated with compelling data; however, systematic use of a
2361 defined PIPS process can do so. Although some process loops may never be completely closed,
2362 all children’s surgical centers (Levels I, II, III and ambulatory) should demonstrate the
2363 continuous pursuit of performance improvement and patient safety.

2364

2365 **Summary of Performance Improvement and Patient Safety (PIPS) Program**

2366

2367 A children’s surgery Performance Improvement and Patient Safety (PIPS) program is an
2368 essential component of a high quality clinical surgical program. (CD 8-29) The unique elements
2369 of perioperative care of children with surgical diseases require a focused quality and safety
2370 construct that supplements existing hospital QI activities. The PIPS program for a Level I or
2371 Level II center must be a specific children’s surgical program (CD8-30); Level III and
2372 ambulatory centers may utilize processes integrated with institution wide efforts to achieve these
2373 stated objectives. (CD8-31)

2374

2375

2376 The programs for Level I and II centers must include the following elements:

2377

2378 • Shall be a confidential quality improvement activity that is protected by all pertinent state
2379 and federal statutes. (CD 8-32)

2380 • Must be integrated with all appropriate hospital quality improvement and safety programs
2381 and with the Board of Trustees quality committee. (CD 8-33)

2382 • May be a dedicated sub-committee of a hospital's existing PIPS program but must be
2383 focused on improving children's surgical care within the institution. (CD 8-29, CD 8-30)

2384 • Must be chaired or co chaired by the medical director of children's surgical care
2385 (MDCS) or her/his designee. (CD 8-34)

2386 • Must include representatives of all surgical disciplines that provide care to children in the
2387 participating center, as well as pediatric anesthesiology and radiology. When within
2388 scope of hospital surgical services, neonatology, pediatric intensive care, and emergency
2389 medicine representatives must also participate. (CD 8-35)

2390 • Must meet at least quarterly. (CD 8-36)

2391 • Members or designees must attend at least 50% of the PIPS meetings. (CD 8-37)

2392 • Must establish criteria for participation of providers in each specialty, including
2393 individual providers' credentials that document their validity as pediatric specialists in
2394 the respective disciplines. (CD 8-38)

2395 • Must establish criteria for conditions that require physical presence of specific specialty
2396 providers. (CD 8-39)

2397 • Must monitor the compliance of providers and the program with all criteria including
2398 physical presence of providers when indicated. (CD 8-40)

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- 2399 • Must review all surgical deaths, a significant cohort of surgical complications, and any
2400 serious safety events related to children's surgical care. (CD 8-41)
- 2401 • Should review the program's quality performance metrics compared to national
2402 benchmarks and develop plans to address any significant outlying metrics.
- 2403 • Must review all transfers to Level I programs for appropriateness, timeliness, and
2404 outcome. (CD 8-42)
- 2405 • Will disseminate the reviews of the PIPS to all pertinent participants in the children's
2406 surgical care program and the hospital leadership. (CD 8-43)

2407

2408

2409 **CHAPTER 9: Optimal Resources For Children’s Surgical Care Verification/Consultation**
2410 **Program for Hospitals - Research and Scholarship Requirements**

2411

2412 **Research and Scholarship**

2413

2414 Research and scholarly activity are some of the activities which distinguish a Level I children’s
2415 surgical center from other centers. Research, the process to advance knowledge, is essential to
2416 optimize the care of patients. The unique combination of a large volume of complex and/or
2417 severely ill infants and children, a core of experienced specialty pediatricians and pediatric
2418 surgeons, pediatric anesthesiologists, other children’s specialty surgeons and an academic
2419 infrastructure enable Level I children’s surgery centers to be effective and productive in research
2420 and scholarly activity. The research portfolio of a Level I children’s surgery center seeking
2421 American College of Surgeons verification should be balanced to reflect the diverse aspects of
2422 children’s surgical care. Mechanistic questions regarding pathophysiology and clinical care are
2423 answered using rigorous scientific methods, whereas evidence-based clinical investigations use
2424 large relational databases and other tools to evaluate standard operating procedures and patient
2425 outcomes, including cost-effectiveness. Either basic or clinical investigative approaches meet
2426 the requirements delineated herein. This chapter outlines the fundamental components of a
2427 successful research program in a Level I children’s surgical center. It also may serve as a
2428 template for research endeavors in other centers and is desirable for Level II centers.

2429

2430

2431 The concept of scholarship entails the following elements.

- 2432 1. Discovery
- 2433 2. Leadership in major children's surgery related organizations
- 2434 3. Extramural funding
- 2435 4. Dissemination of information
- 2436 5. Application of clinical knowledge
- 2437 6. Participation in clinical discussions and conferences
- 2438 7. Support of trainee participation in scholarly activities
- 2439 8. Mentorship of junior faculty, residents, and fellows

2440

2441 There are 2 alternatives to fulfill the research and scholarship criteria for Level I verification:

- 2442 1. For a Level I children's surgery center at the minimum, a program must have 20 peer-
2443 reviewed articles published in journals in *PubMed* in the most recent 3-year period (CD
2444 9-1). These publications must result from work related to the center (CD 9-2). Of the 10
2445 publications, at least 1 must be authored or coauthored by members of the children's
2446 general pediatric surgery team (CD 9-3). Related articles authored by members of other
2447 disciplines or work done in collaboration with the surgical services and/or with other
2448 centers and participation in multicenter investigations may be included in the remainder.

2449 Or

- 2450 2. A Level I program must meet requirements A and B below (CD 9-4):
 - 2451 A. The center must have 10 peer-reviewed articles in journals included in *PubMed* in the
2452 most recent 3-year period. (CD 9-5) These publications must result from work
2453 related to the center. (CD 9-6) Of the 10 articles, at least 1 must be authored or

2454 coauthored by members of a children's specialty surgical service. (CD 9-7) Related
2455 articles authored by members of other disciplines or work done in collaboration with
2456 surgical services and/or with other centers and participation in multicenter
2457 investigations may be included in the remainder,

2458

2459 And

2460

2461 B. Of the 7 following related scholarly activities, 4 must be demonstrated: (CD 9-8)

2462 (1) Leadership in major organizations relevant to children's surgical care. Evidence
2463 includes membership in committees of any of the regional and national
2464 organizations.

2465 (2) Peer-reviewed funding for related research. There should be demonstrated
2466 evidence of funding of the center from a recognized government or extramural
2467 private agency or organization.

2468 (3) Evidence of dissemination of knowledge to include review articles, book chapters,
2469 technical documents, Web-based publications, editorial comments, training
2470 manuals, and related course material

2471 (4) Display of scholarly application of knowledge as evidenced by case reports or
2472 reports of clinical series in journals included in *PubMed*

2473 (5) Participation as a visiting professor or invited lecturer at relevant national or
2474 regional conferences

2475 (6) Support of resident participation in institution-focused scholarly activity,
2476 including laboratory experiences, clinical trials, or resident paper competitions at
2477 the state, regional, or national level

2478 (7) Mentorship of residents and fellows, as evidenced by the development of a
2479 children's surgical fellowship program or successful matriculation of graduating
2480 residents into such fellowship programs

2481

2482 **Research Infrastructure**

2483

2484 There is renewed emphasis on translational research in recent years. Discoveries in basic science
2485 require engagement of enlightened clinicians to make them applicable at the bedside, and queries
2486 at the bench are not relevant to patients until pursued from a clinical perspective. Capitalizing on
2487 the unique coexistence of expert children's surgeons and committed basic and social scientists
2488 benefits a structured research program. It is likely that most Level I centers will be housed in
2489 academic medical centers.

2490

2491 Perhaps the most important resource is a core of children's surgeons with interests and dedicated
2492 training in research methodology. Specifically, the Level I center medical director of children's
2493 surgery (MDCS) should have a record of established basic science or clinical research
2494 productivity with regular participation in academic forums. A children's surgeon who remains
2495 clinically active in patient care should direct formal, regularly scheduled research meetings with
2496 documentation of the ongoing activities. Basic or social scientists should participate in the
2497 regularly scheduled research meetings, but the majority of the attendees should be surgeons and

2498 surgical residents or research fellows. Finally, the administration of the Level I children's
2499 surgical center must demonstrate support for the research program, such as by providing basic
2500 laboratory space, research equipment, advanced information systems, biostatistical support,
2501 salary support for basic and social scientists, research support personnel, or seed grants for less
2502 experienced faculty (CD 9-9).

2503

2504 **Research Activity**

2505

2506 Every children surgery center should continually evaluate its own outcomes and compare these
2507 with regional and national benchmarks. Trend analyses of morbidity and mortality and
2508 assessment of pertinent selected events to monitor the quality of care often raise important
2509 research questions. In addition to morbidity and mortality, outcome assessment should include
2510 age appropriate functional outcome and quality of life measures.

2511

2512 Nurse coordinators and registrars are an integral part of the research team for ensuring the
2513 collection of complete and accurate data and regularly providing clinical outcomes reports.

2514 Clinical research nurses and clinical specialists are also valuable for the research program by
2515 coordinating patient selection, adherence to protocols, timely specimen acquisition, and ongoing
2516 surveillance of patient outcomes. All of these personnel should be involved in the research effort
2517 and should participate in the presentation and publication of reports and major meetings and in
2518 the peer-reviewed literature.

2519

2520 The more sophisticated the performance improvement process the more likely it will generate
2521 appropriate research questions. The distinguishing quality of a Level I children's surgery center
2522 is development of timely research questions well beyond established national standards.
2523 Because of the fortuitous combination of expert children's surgeons and patients with complex
2524 illness in a scholarly environment, Level I centers are ideal settings to generate novel study
2525 hypotheses that explore clinical dilemmas from a unique perspective. Furthermore, Level I
2526 centers are positioned to engage the collaboration of qualified basic and social scientists to
2527 design studies to address these complex issues.

2528

2529 Residents and fellows in surgical training are another key component of research activity in a
2530 Level I children's surgery center. Involving them in research projects, presentations at major
2531 meetings, and publications are important elements in the mentorship function of centers and a
2532 valuable part of surgical education that fosters development of the next generation of children's
2533 surgeons. The Level I children's surgery center should demonstrate resident participation and
2534 authorship in related publications.

2535

2536 **Research Productivity**

2537

2538 Level I children's surgery centers have a responsibility to disseminate their research findings in a
2539 timely and effective manner. The best measure of research productivity is peer-reviewed
2540 publication. In addition, currently, the most effective means to convey novel and provocative
2541 research findings is by presentations at meetings of national and regional academic societies.
2542 Level I centers should be presenting their research results at these venues annually. The medical

2543 director of children's surgery and other children's surgeons in each discipline should be
2544 presenting their research work regularly as well. The medical director of children's surgery and
2545 surgeons participating in patient care at a Level I center should be actively engaged in research
2546 and coauthor peer-reviewed articles. Furthermore, because Level I children's surgery centers
2547 provide comprehensive care for severely ill infants and children with multidisciplinary needs,
2548 other key team members also are expected to be academically productive. Each of these groups
2549 should have peer-reviewed articles and presentations at their respective national academic
2550 society meetings.

2551

2552 **Research Funding**

2553

2554 The administration of a Level I children's surgery center should contribute substantively to the
2555 research program, but extramural funding may be necessary to conduct and sustain meaningful
2556 research. Level I centers should be competitive for extramural research funds.

2557

2558 **Research Role Models**

2559

2560 The leadership in surgery should continue to demonstrate, by personal example, that quality
2561 research is an integral and gratifying part of the discipline. Implicitly, the medical director of
2562 surgery of a Level I children's center ideally should have an established record of research
2563 productivity and continue to be an active participant and a spokesperson for children's surgical
2564 research at the national level. For example, Level I centers should participate in large
2565 collaborative research programs sponsored by the National Institutes of Health, the Department

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2566 of Health and Human Services, ACS or other professional societies. Research is important to
2567 advance the field of children's surgical care and train the future generation of children's
2568 surgeons. The Level I center serves as the role model within the community. Research is an
2569 opportunity and an obligation.

2570

2571

2572 **CHAPTER 10 Outreach and Education**

2573

2574 Children’s surgical centers are important community and regional resources. In addition to the
2575 patient care services they provide, these centers are sources of information, expertise, and public
2576 leadership. Programs to strengthen and foster community engagement are an integral part of
2577 children’s surgical center services designed to help improve outcomes through the public and
2578 professional dissemination of information and by facilitating access to clinical and educational
2579 resources. The components of an outreach program may include public awareness and education
2580 or professional education through course offerings, lectures, conferences, visitation programs,
2581 web sites, newsletters, and other means. The scope of educational and outreach programs will
2582 depend on many factors in a given region, including population size, type and level of the center,
2583 and regional needs and resources. All verified children’s surgical centers, however, must engage
2584 in public and professional education (CD 10-1). Level I and II centers also must provide some
2585 means to facilitate referral and access to children’s surgical center resources (CD 10-2).

2586

2587 **Professional Education and Training**

2588 Principles of children’s surgical care are introduced in medical school, nursing school,
2589 prehospital provider programs, and other allied health training programs. Graduate medical
2590 education (GME) in the form of relevant residency and fellowship training programs is highly
2591 desirable within a children’s health care system. The ACS recognizes that residency programs
2592 provide service to surgical centers, but the educational experience should be the prime focus.
2593 The residency training programs should emphasize direct supervision and teaching of residents
2594 by dedicated attending surgeons who have demonstrated interest and expertise in children’s

2595 surgery. Centers that support residency training programs and fellowships in children's surgery
2596 should have a clear written curriculum for the development of trainee expertise and appropriate
2597 trainee supervision within the program. In addition, residents should be given an introduction to
2598 the surgical services and meet the ACGME educational requirements for their respective
2599 programs. At a minimum, a Level I children's surgical center must have a continuous rotation in
2600 surgery for senior residents that is part of an Accreditation Council for Graduate Medical
2601 Education-accredited program in at least one of the following disciplines: general surgery,
2602 orthopedic surgery, urology, neurosurgery or otolaryngology. (CD 10-3)

2603

2604 Continuing medical education (CME) programs are important to maintain and enhance the
2605 knowledge and skills to care for children with surgical needs. Cooperative arrangements with
2606 other institutions may enhance available educational programs. Postgraduate education courses
2607 for nurses are available. Some nurse practitioners may choose to specialize in pediatric care.
2608 Nurses and other allied health professionals who are involved in the children's surgical program
2609 should have their educational needs identified and served. In Level I, II, III and ambulatory
2610 centers, the hospital must provide a mechanism to offer relevant children's surgical education to
2611 nurses and other allied health professionals who are part of the children's surgical team (CD 10-
2612 4).

2613

2614 Multidisciplinary education should be ongoing in all children's surgery centers. Performance
2615 improvement programs should be an important part of educational activities. Intramural
2616 educational programs are an efficient means of providing information to the surgical team.

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2617 Children's surgery centers should expend financial resources to facilitate intramural and
2618 extramural educational programs.

2619

2620 It is important that all members of the children's surgical team are knowledgeable about current
2621 practices in children's surgical care. External CME is the recommended method of keeping
2622 current. The medical director of children's surgery, the liaison representatives from each of the
2623 surgical subspecialties performing children's surgery, as well as the liaison or medical director of
2624 pediatric anesthesiology, emergency medicine and radiology, must accrue an average of 16 hours
2625 annually or 48 hours in 3 years of related external Category I CME (CD 10-5). Programs given
2626 by visiting professors, invited external speakers, and teaching done by children's surgeons
2627 elsewhere are considered external CME.

2628

2629 All members of children's surgical specialties who take call also must be knowledgeable and
2630 current in the care of children's with surgical needs (CD 10-6). This requirement may be met by
2631 documenting acquisition of 16 hours of relevant CME per year on average as above or by
2632 demonstrating participation in an internal educational process conducted by the children's
2633 surgical program and the specialty liaison based on the principles of practice-based learning and
2634 the performance improvement and patient safety program.

2635

2636 Medical specialists and other providers involved in children's surgical care are encouraged to
2637 participate in related CME activities on a regular basis.

2638

2639

2640 **Outreach: Engaging the Center in Regional Care and Education**

2641 Outreach is the act of providing center expertise, information, and leadership to institutions,
2642 agencies, and individuals within a region for the purpose of improving the care of infants and
2643 children with surgical needs. A good outreach program allows the verified center to serve as a
2644 regional resource for the benefit of patients and providers. The goals of an outreach program are
2645 as follows:

2646

- 2647 • To improve regional outcomes for children’s surgery by the dissemination of knowledge
2648 and expertise regarding the care of infants and children
- 2649 • To participate with regional agencies, organizations, and providers in improving the care
2650 within the geographic region
- 2651 • To facilitate access to center resources (such as educational programs, performance
2652 improvement, consultation, and referral)
- 2653 • To support educational programs of regional facilities and health care personnel

2654

2655 Regional hospitals, including pediatric and non-pediatric center facilities, should have access to
2656 consultation by staff members from larger children’s centers for a variety of purposes: (1) to
2657 improve and facilitate care on a case-by case basis, including referrals, transfers and follow-up
2658 care as appropriate; (2) to enhance institutional performance improvement activities, including
2659 protocol development; and (3) to facilitate the adaptation of children’s surgical center programs,
2660 including performance improvement and patient safety and prevention, to other institutions. It
2661 falls to the regional referral center (typically Level I and II) to facilitate this access.

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2662 Children's surgical centers also should promote the quality and continuity of care in cases of
2663 referral or transfers out, by good communication with referring and receiving providers and
2664 establishment of guidelines applicable to referrals and repatriation transfers.

2665

2666

2667

2668

2669

2670

2671 **CHAPTER 11 Consultation/Verification Program**

2672

2673 The American College of Surgeons has a long history of activities directed toward the
2674 improvement of surgical care. This new program defines the resources believed necessary to
2675 achieve optimal patient outcomes for children’s surgical care at verified centers. The verification
2676 program is administered by the American College of Surgeons (ACS) Committee on Children’s
2677 Surgery. This document, *Optimal Resources for Children’s Surgical Care* is to be used as a
2678 guide for the development and verification of centers throughout the United States. It is the basis
2679 upon which centers will be reviewed by ACS approved site surveyors. The ACS does not
2680 designate centers; rather, it verifies the presence of the resources detailed in *Optimal Resources*
2681 *for Children’s Surgical Care*.

2682

2683 The ACS Consultation/Verification Program is designed to assist institutions in the evaluation
2684 and improvement of children’s surgical care and provide objective, external review of
2685 institutional capability and performance. These functions are accomplished by an on-site review
2686 of the hospital by a peer review team composed of individuals experienced in the field of
2687 children’s surgical and anesthetic care. The team assesses commitment, readiness, resources,
2688 policies, patient care, performance improvement, and other relevant features of the program as
2689 outlined in *Optimal Resources for Children’s Surgical Care*.

2690

2691

2692 **Consultation**

2693

2694 The ACS-Committee on Children’s Surgery will provide a consultation visit, at the request of a
2695 hospital, community, or other relevant institution to assess children’s surgical care or to prepare
2696 for a verification review. The core two-surgeon team or a multidisciplinary team may be
2697 requested. A consultation visit will follow the same format as a verification review. It will
2698 provide recommendations and aid the facility in attaining verification.

2699

2700 **Verification**

2701

2702 Center verification is the process by which the ACS confirms that the hospital is performing as a
2703 children’s surgical center and meets the criteria delineated in *Optimal Resources for Children’s*
2704 *Surgical Care*. A verification review process results in a report outlining the findings and, if
2705 successful, a certificate of verification. This certificate is valid for 3 years, after which a
2706 reverification site visit may be requested.

2707

2708 If, during a verification review, a hospital is found to have criterion deficiencies, it must
2709 demonstrate that they have been corrected before a certificate is issued. If the deficiencies are
2710 significant, at the discretion of the ACS Committee on Children’s Surgery, an on-site focused
2711 review may be necessary, in which a team returns to the facility. Generally, one member of the
2712 original team will be involved in this review process. The focused review will be accomplished
2713 in no less than 6 months and not more than 1 year from the time of the notification of the results
2714 of the initial review.

2715

2716 When the correction of deficiencies can be demonstrated by submitting data to the ACS
2717 Committee on Children's Surgery, the focused review can be completed without an on-site
2718 review. The information submitted must be signed by the medical director of children's surgery
2719 (MDCS) and the hospital chief executive officer. If the deficiencies are remedied and their
2720 correction can be demonstrated in writing, a certificate will be issued.

2721

2722 If a hospital has previously been verified and criterion deficiencies are identified at the time of a
2723 reverification visit, the verification status may be extended for up to 6 months. During this time,
2724 the hospital must document the correction of all identified deficiencies. If all deficiencies are not
2725 corrected, further extensions will not be considered.

2726

2727 **Multidisciplinary Review**

2728

2729 The on-site review is led by two surgeons (core team) from the ACS; there may be a requirement
2730 or desire that center capability be evaluated by a multidisciplinary team. The ACS can assist in
2731 this process. Other members may include a representative of any discipline identified by the
2732 requesting institution or hospital.

2733

2734

2735 **The Consultation/Verification Process**

2736

2737 Following the receipt of a request (application for site visit) and the completion of the prereview
2738 questionnaire, a review team is selected. A mutually acceptable date for the review will be
2739 established. All reviewers will be from out-of-state or province unless there is a special request
2740 for in-state or province reviewer. Surgeon reviewers are selected from specialty qualified
2741 children's surgeons. The hospital is required to provide medical records needed at the time of
2742 the visit. A description of the medical records needed to conduct a site visit will be provided to
2743 allow the hospital 2 to 3 weeks or more to identify the charts and obtain or access the records.

2744

2745 Consistency of the review process is facilitated by the following:

2746

2747 1. A Pre Review Questionnaire (PRQ) allows site visitors to have a better understanding of the
2748 existing care capabilities and the performance of the hospital and medical staff before beginning
2749 the review. This questionnaire may be completed online by the hospital.

2750

2751 2. Guidelines for site visitors: A document describing the guidelines for a review is provided to
2752 all site visitors. This document is designed to ensure that reviews are conducted consistently. It
2753 defines the process of the review and elements of appropriate conduct by a reviewer.

2754

2755 3. An organized agenda is prepared for the review so that all reviews are performed in an
2756 efficient manner.

2757

2758 4. Every site visit team is led by a senior reviewer approved by the ACS.

2759

2760 5. The report is written in a standardized format.

2761

2762 6. A final review of all reports is done by the ACS Committee on Children's Surgery.

2763

2764 **Prereview Meetings**

2765

2766

2767 A prereview meeting facilitates an efficient on-site review process. The review team will meet
2768 with the medical director of children's surgery, surgery program manager, and a hospital
2769 administrator selected by the applicant organization. Other individuals may be invited who are
2770 needed to clarify the prereview questionnaire and describe existing center activities. The
2771 meeting is intended to include discussion of the overall children's surgery program, clarification
2772 of the prereview questionnaire, specific concerns, unique features of the institution, regional
2773 context, and clarification of the review process.

2774

2775 The on-site review will require approximately 6 to 8 hours. All children's surgical care areas of
2776 the hospital may be visited. Emphasis is placed on evaluating medical records of selected
2777 surgical infants and children and correlating patient care with the performance improvement
2778 program. The visit concludes with an exit interview to discuss the reviewers' findings and
2779 conclusions. The reviewers will prepare a report that reflects the statements made at the exit
2780 interview. This report is forwarded to the ACS Committee on Children's Surgery which will
2781 review this report and determine the presence or absence of deficiencies and whether a hospital

2782 can be verified. The ACS Committee on Children’s Surgery has the authority to issue final
2783 approval. This process ensures accurate interpretation of the findings, well-documented
2784 conclusions, and consistency and professionalism in the final report. This final process may
2785 modify the conclusions of the individual site reviewers’ report to ensure consistent interpretation
2786 of the resources documented. Confidentiality of the entire review process ensures an institution
2787 that the program is designed to be a constructive process in which a hospital can place its trust.
2788 If verified, a hospital will be included on an ACS list of currently verified children’s surgical
2789 centers which will be available publicly. This list will be updated every 3 months.

2790

2791 **Appeal Process**

2792

2793 If the applicant organization or hospital does not agree with the review process, the reviewers’
2794 findings, or the final report, it may appeal in writing to the ACS Committee on Children’s
2795 Surgery. The ACS Committee on Children’s Surgery may require additional documentation, a
2796 new review team may be sent for another review, or the issue may be referred to the ACS.

2797

2798 **Verification Quality Assurance Process**

2799

2800 In keeping with the concept of self-evaluation for the purpose of improvement, the ACS
2801 Committee on Children’s Surgery will institute a process to ensure that the needs of applicant
2802 hospitals/organizations are being met in a satisfactory manner. At the time the final report is
2803 sent, an extensive questionnaire will be sent to the medical director of children’s surgery and
2804 surgery program manager. This survey will cover the entire process, from the purpose of the

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2805 prereview meeting to the quality of the final report. Comments will be solicited about the
2806 conduct of the reviewers and obtain an assessment of the total program. The chair of the ACS
2807 Committee on Children's Surgery, as well as other selected members of the Committee, will
2808 carefully review these comments.

2809
2810 Changes will be made in certain areas identified and, if appropriate, reviewers will be counseled.
2811 For similar reviews in other programs, the biggest concern occurs when the institution is told one
2812 thing at the exit interview and additional deficiencies appear in the final report. A concentrated
2813 effort will be made at the time of the review to inform the organization or hospital that the ACS
2814 Committee on Children's Surgery makes the final decision.

2815

2816 **Application Forms and Site Visit Information**

2817 Requests for verification or consultation information should be addressed to:

2818 American College of Surgeons

2819 Children's Surgical Care

2820 Verification Review Program

2821 633 N. St. Clair St.

2822 Chicago, IL 60611-3211

2823

2824 312/202-5456

2825

2826 These forms also are available from the American College of Surgeons web site at

2827 www.facs.org/??/application.doc.

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POLICY STATEMENT

Levels of Neonatal Care

COMMITTEE ON FETUS AND NEWBORN

KEY WORDS

neonatal intensive care, high-risk infant, regionalization, maternal and child health, health policy, very low birth weight infant, hospital newborn care services, nurseries

ABBREVIATIONS

AAP—American Academy of Pediatrics

aOR—adjusted odds ratio

CI—confidence interval

CON—certificate of need

ELBW—extremely low birth weight

TIOP—“Toward Improving the Outcome of Pregnancy”

VLBW—very low birth weight

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abstract

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Provision of risk-appropriate care for newborn infants and mothers was first proposed in 1976. This updated policy statement provides a review of data supporting evidence for a tiered provision of care and reaffirms the need for uniform, nationally applicable definitions and consistent standards of service for public health to improve neonatal outcomes. Facilities that provide hospital care for newborn infants should be classified on the basis of functional capabilities, and these facilities should be organized within a regionalized system of perinatal care. *Pediatrics* 2012;130:587–597

OBJECTIVE

This revised policy statement reviews the current status of the designation of levels of newborn care definitions in the United States, which were delineated in a 2004 policy statement by the American Academy of Pediatrics (AAP).¹ Since publication of the 2004 policy statement, new data, both nationally and internationally, have reinforced the importance of well-defined regionalized systems of perinatal care, population-based assessment of outcomes, and appropriate epidemiologic methods to adjust for risk. This revised statement updates the designations to provide (1) a basis for comparison of health outcomes, resource use, and health care costs, (2) standardized nomenclature for public health, (3) uniform definitions for pediatricians and other health care professionals providing neonatal care, and (4) a foundation for consistent standards of service by institutions; state health departments; and state, regional, and national organizations focused on the improvement of perinatal care.

BACKGROUND

The availability of neonatal intensive care has improved the outcomes of high-risk infants born either preterm or with serious medical or surgical conditions.^{2–4} Many of these improvements can be attributed to the concept and implementation of regionalized systems of perinatal care, broadly articulated in the 1976 March of Dimes report “Toward Improving the Outcome of Pregnancy” (TIOP I).⁵ The TIOP I report included criteria that stratified maternal and neonatal care into 3 levels of complexity and recommended referral of high-risk patients to higher-level centers with the appropriate resources and personnel to address the required increased complexity of care. However, since the initial TIOP I report was published more than 3 decades ago, there have been signs of deregionalization, including (1)

an increase in the number of NICUs and neonatologists, without a consistent relationship to the percentage of high-risk infants, (2) a proliferation of small NICUs in the same regions as large NICUs,^{6–11} and (3) failure of states to reach the Healthy People 2010 goal that 90% of deliveries of very low birth weight (VLBW; <1500 g) infants occur at level III facilities.^{12,13}

In the environment of deregionalization, preterm birth rates have increased 13% overall from 1990 to 2010 (10.6%–12.0%) as a result of a variety of factors, including increases in elective early cesarean deliveries, multiple births, advanced maternal age, and complications of pregnancy.^{14–20} The majority of the increase in the preterm birth rate (>70%) is attributable to late preterm births.²¹ Infants born late preterm can experience significant morbidity that may result in the need for specialized care and advanced neonatal services.^{22,23} An increase in the supply of specialty staff^{24,25} and availability of new neonatal therapies (eg, bubble continuous positive airway pressure), have expanded the scope of care in level II facilities.²⁶ Some have expressed concern that level II hospitals have expanded their scope of care without sufficient evidence of favorable outcome. Because most infant deaths in the United States occur among the most immature infants in the first few days after birth,^{27,28} improvements in regionalized systems may reduce mortality among the most preterm newborn infants.

REVIEW OF THE LITERATURE ON NEONATAL LEVELS OF CARE SINCE THE 2004 AAP POLICY STATEMENT

In 2004, the AAP defined neonatal levels of care, including 3 distinct levels with subdivisions in 2 of the levels.¹ Level I centers provided basic care; level II centers provided specialty care, with further subdivisions of IIA and IIB

centers; and level III centers provided subspecialty care for critically ill newborn infants with subdivisions of level IIIA, IIIB, and IIIC facilities. Data published since the 2004 statement have informed the development of the levels of care in this new policy statement.

A meta-analysis of the published literature from 1978 to 2010 clearly demonstrates improved outcomes for VLBW infants and infants <32 weeks' gestational age born in level III centers. Lasswell et al reviewed 41 English-language US and international studies, which included >113 000 VLBW infants and found that VLBW infants born at non-level III hospitals had a 62% increase in odds of neonatal or predischarge mortality compared with those born at level III hospitals (adjusted odds ratio [aOR], 1.62; 95% confidence interval [CI], 1.44–1.83). Subset comparisons of studies identifying infants <32 weeks' gestation and extremely low birth weight (ELBW) infants (<1000 g) demonstrated similar effects (aOR, 1.55; 95% CI, 1.21–1.98; aOR, 1.64; 95% CI, 1.14–2.36, respectively). When only higher-quality studies were included, the findings were consistent (VLBW aOR, 1.60; 95% CI, 1.33–1.92; <32 weeks' gestation aOR, 1.42; 95% CI, 1.06–1.88; ELBW aOR, 1.80; 95% CI, 1.31–2.36). The effect of level of care on VLBW mortality did not vary by decade of publication²⁹; hence, the risk of death for VLBW infants born in level I or II facilities remained higher than those born within a level III facility. Figures 1, 2, and 3 summarize the findings of these studies.

As Lasswell and colleagues found, part of the difficulty in collecting evidence to provide accurate assessments of VLBW outcomes has been in obtaining appropriate standardized measures. Heterogeneity among studies on neonatal levels of care suggests the need for a quality standard for comparison which includes the following

elements: (1) population-based studies within well-defined geographic regions, (2) clear definitions of the “intervention” or hospital level of care, and (3) appropriate adjustment for confounding factors to include maternal social and demographic risk factors, pregnancy and perinatal risks, and severity of illness at delivery.

Current Controversies in Levels of Care Designation

Although little debate exists on the need for advanced neonatal services for the most immature and surgically complex neonates, ongoing controversies exist regarding which facilities are qualified to provide these services and what is the most appropriate measure for such qualification. These issues are, in general, based on the need for comparison of facility experience (measured by patient volume or census), location (inborn/outborn deliveries, regional perinatal center, or children's hospital), or case mix (including stillbirths, delivery room deaths, and complex congenital anomalies).

Several studies have explored the topic of center experience as measured by volume or census of VLBW infants.^{30–35} Phibbs et al conducted a population-based retrospective cohort study of 48 237 California VLBW infants to examine differences in neonatal mortality among NICUs with various levels of care and patient volumes. When compared with high-volume, high-level centers, the odds ratio of death was 1.19 (range, 1.04–1.37) for level IIIB, IIIC, or IIID centers with <100 annual admissions, 1.78 (range, 1.35–2.34) for level IIIA centers with 26 to 50 annual admissions, and 2.72 (range, 2.37–3.12) for level I centers with <10 annual admissions. The authors also found that the percentage of VLBW infants delivered in level IIIB, IIIC, or IIID centers decreased from 36% in 1991 to 22% in

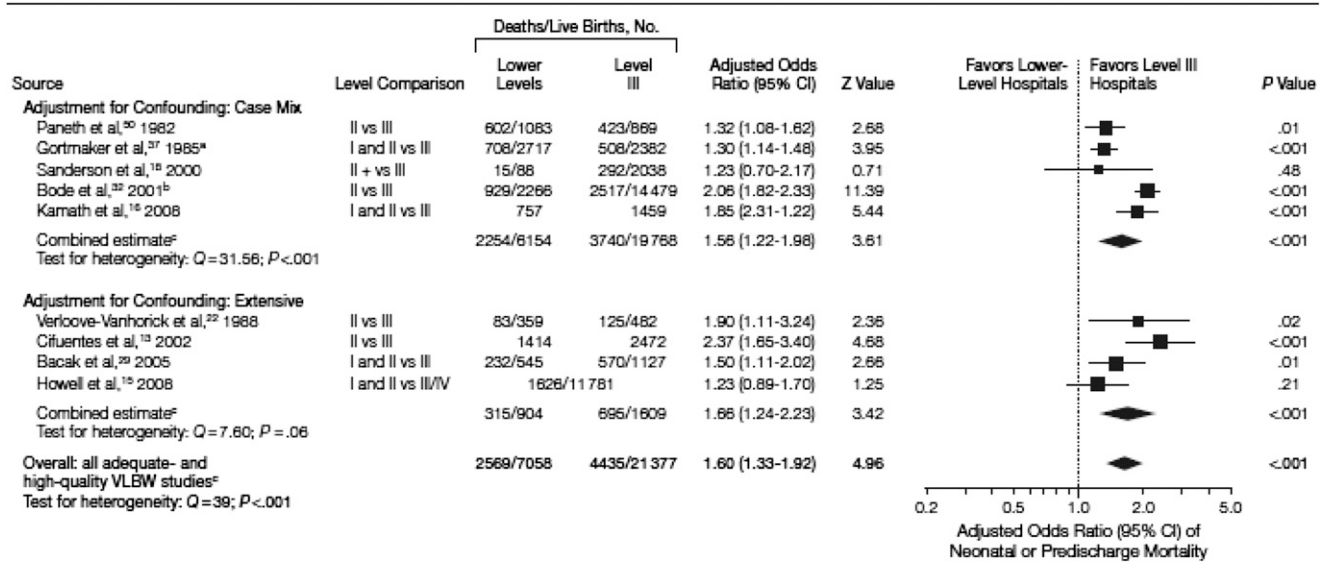


FIGURE 1 Meta-analysis of adequate- and high-quality publications on VLBW infants, stratified by level of adjustment for confounding. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304 [9]:992–1000.²⁹)

Case mix indicates adjustment for demographic and/or socioeconomic status variables; extensive indicates adjustment for case mix plus maternal/perinatal risk factors and infant illness severity. CI indicates confidence interval. Size of data markers indicates size of study population.

^a Included data are for urban populations and combine reported black/white race strata and birth weight strata (750-1000 g and 1001-1500 g).

^b Included data combine reported birth date interval strata (1980-1984, 1985-1989, and 1990-1994) and birth weight strata (500-1000 g and 1001-1500 g).

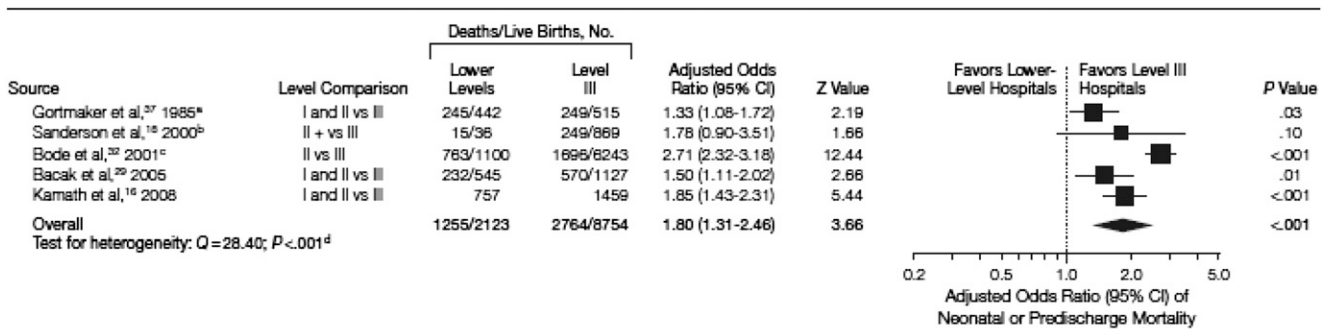
^c Raw death counts are not reported in Cifuentes et al.¹³ and Kamath et al.¹⁶ and are not stratified by hospital level in Howell et al.¹⁵ These studies are not included in combined death/birth counts.

FIGURE 2 Meta-analysis of adequate- and high-quality publications on ELBW infants. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304[9]:992–1000.²⁹)

2000 and estimated that shifting VLBW births in urban areas (92% of VLBW births) to level III or level II centers with >100 annual admissions would have prevented 21% of VLBW deaths in 2000.³⁰ In a secondary data analysis, Chung et al found that deregionalization of

California perinatal services resulted in 20% of VLBW deliveries occurring in level I and level II hospitals, with lower-volume hospitals having the highest odds of mortality.³¹ A population-based study of 4379 VLBW infants who were born between 1991

and 1999 in Lower Saxony, Germany, evaluated neonatal mortality in relation to both the annual volume of births and NICU volume.³² There was an increased odds of mortality in centers with annual NICU admissions of fewer than 36 VLBW infants; the largest



CI indicates confidence interval. Size of data markers indicates size of study population.

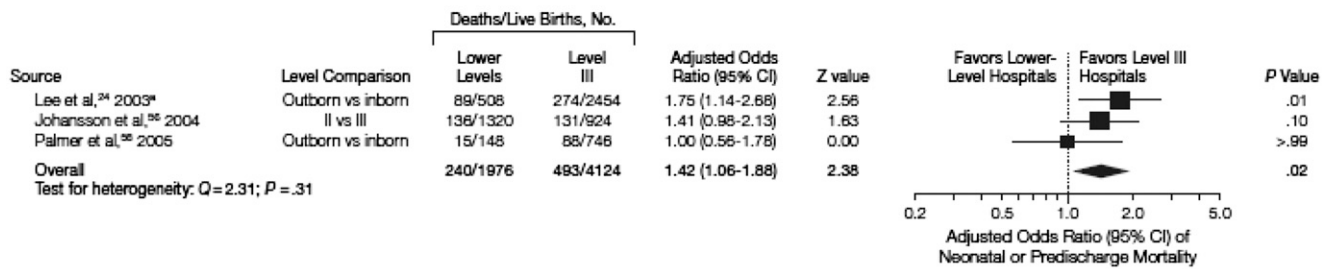
^a Included data are for urban populations and combine reported black/white race strata.

^b Included data combine reported birth weight strata (500-749 g and 750-1000 g).

^c Included data combine reported birth date interval strata (1980-1984, 1985-1989, and 1990-1994).

^d The study by Kamath et al.¹⁶ does not report raw death count data and is not included in combined death/birth counts.

FIGURE 2 Meta-analysis of adequate- and high-quality publications on ELBW infants. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304[9]:992–1000.²⁹)



CI indicates confidence interval. Size of data markers indicates size of study population. Inborn infants are those born in a level III hospital; outborn infants are those born in a lower-level hospital then transferred to a level III hospital.

^a Included data combine reported gestational age strata (<26 weeks, 27-29 weeks, and 30-31 weeks).

FIGURE 3

Meta-analysis of adequate- and high-quality publications on very preterm infants (<32 weeks' gestation). (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304(9):992-1000.²⁹)

effect on mortality was for infants born at less than 29 weeks' gestation.

Other studies assessing NICU volume suggest caution in using this measure as an effective indicator of quality of care. Rogowski and colleagues assessed the potential usefulness of NICU volume as a quality indicator among 94 110 VLBW infants entered into the Vermont Oxford Network database between 1995 and 2000 and compared NICU volume with other indicators based on hospital characteristics and patient outcomes.³³ They found that although annual volume explained 9% of the variation in hospital mortality rates, other hospital characteristics explained another 7%. They suggested that direct measures based on patient outcomes are more useful quality indicators than volume for the purpose of selective referral.

Several studies assessed the effects of level of care, patient volume, and racial disparities on mortality of VLBW infants based on births in minority-serving hospitals. Morales³⁴ and Howell³⁵ evaluated mortality of VLBW infants born in minority-serving hospitals. In both studies, neonatal level of care and patient volume were each independently associated with mortality, suggesting that delivery of all VLBW infants at high-volume hospitals would

reduce black-white disparities in VLBW mortality rates. Rogowski and colleagues further suggest that the quality of care in poor-outcome hospitals could be improved through collaborative quality improvement, and evidence-based selective referral.³⁶

Several studies have compared the short-term outcome of VLBW infants born in centers with level III units (inborn) compared with those born at lower level centers and soon transferred to a higher level (level III or children's hospital; outborn). Many of these studies are retrospective and may be subject to selection bias because infants who were transferred most likely had the highest chance of survival and thus gave the impression of lower mortality.²⁴ In a secondary analysis of a randomized placebo-controlled study of preemptive morphine analgesia on neonatal outcomes, Palmer et al compared neonatal mortality as related to place of birth for 894 infants who were born at 23 to 32 weeks' gestation. Outborn babies were more likely to have severe intraventricular hemorrhage ($P=.0005$), and this increased risk persisted after controlling for severity of illness. However, when adjusted for antenatal steroids, the effect of birth center was no longer significant.³⁷

Evaluating and controlling for confounding variables and "case-mix" presents another set of challenges because these factors vary by population. For example, race and insurance status may have more of an effect on birth outcomes in the United States^{34-36,38} than in countries with a more homogenous population and universal national health care.³⁹ There are also potential confounding factors for which measurement is frequently lacking, such as parental wishes regarding aggressive resuscitation of an infant. Arad et al noted that parental wishes varied by religious affiliation in their 2-hospital study. Because religious affiliation was unequally distributed between the 2 hospitals, fewer attempts at resuscitation may have been made at the level III hospital, with a result of improved survival at the level II facility.⁴⁰ More comprehensive studies controlling for confounding factors are needed.

Measured outcomes other than VLBW mortality (notably, fetal mortality, postdischarge mortality, and long-term physical and neurodevelopmental outcomes) may offer important information in assessing the evidence for newborn levels of care and perinatal regionalization. Studies measuring the effect of hospital level of birth on fetal

and neonatal outcomes stratified by gestational age, as well as by birth weight, are also helpful, because gestational age is a better gauge of fetal maturity.^{41–44} Although some studies include stillbirths and intrapartum fetal deaths, measurement and surveillance of fetal death varies widely.⁵ Congenital anomalies are often excluded from studies of perinatal regionalization but should be considered in the provision of risk appropriate care.⁴⁵

Additional studies are also needed to assess the effectiveness and potential cost savings of centralizing expensive technologies and provider expertise for relatively rare conditions at a few locations and to assess the effectiveness, including costs, of antenatal transport.

IMPORTANCE OF NEONATAL LEVELS OF CARE

Provision of Standardized Nomenclature for Public Health

Since 2004, efforts have been made to improve the comparison of health outcomes by hospital facility through the use of standardized nomenclature on the US birth certificate. The National Center for Health Statistics at the Centers for Disease Control and Prevention has worked with states to use the newly revised US Standard Certificate of Birth.⁴⁶ This 2003 revised certificate defines a NICU as a “hospital facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn infant.” It also includes information on the use of antenatal therapies and postpartum surfactant, which may be useful in monitoring population-based utilization of technologies at birth.⁴⁷ In an analysis of 16 states using the revised certificate of birth, Barfield et al found that overall, 77.3% of VLBW infants were admitted to NICUs; this estimate varied by state and ranged from 63.7% in California to 93.4% in North Dakota. Among VLBW infants of Hispanic mothers, 71.8% were

admitted to NICUs, compared with 79.5% of VLBW infants of non-Hispanic black mothers and 80.5% of VLBW infants of non-Hispanic white mothers. In multivariable analysis, preterm delivery, multiple gestation, and cesarean delivery were associated with higher prevalence of NICU admission among VLBW infants.¹³ State variations in the receipt of intensive care for VLBW infants may explain, in part, variation in VLBW outcomes across the country.

Use of Uniform Definitions of Levels of Care for Pediatricians and Other Health Care Professionals

Variation in definition, criteria, and state enforcement still occurs despite the TIOP I guidelines. Blackmon et al conducted an extensive review of all 50 states and the District of Columbia governmental Web sites to assess state definitions and levels terminology, functional and utilization criteria, regulatory compliance and funding measures, and citation of AAP documents on levels of neonatal care. The authors found that state definitions, criteria, compliance, and regulatory mechanisms for the specific type of care neonatal centers provide varied considerably, and they suggested a consistent national approach.⁴⁸ Lorch et al assessed all 50 states and the District of Columbia to identify state certificate of need (CON) legislation, a mechanism that regulates the expansion of NICU facilities and NICU beds. Thirty states regulated the construction of NICUs through CON programs, and non-CON program states were associated with more NICU facilities and more NICU beds (relative risk, 2.06; 95% CI, 1.74–2.45; and relative risk, 1.96; 95% CI, 1.89–2.03, respectively). In large metropolitan areas, non-CON states had higher infant mortality for all birth weight groups.⁴⁹

The Maternal and Child Health Bureau of the Health Resources and Services Administration has worked with state Title

V agencies to document the percentage of VLBW infants delivered in level III hospitals or subspecialty perinatal clinics. In 2009, only 5 states met the goal of at least 90% of VLBW infants delivered at high-risk facilities.¹² Yet, the interpretation and reporting of these facilities may be inconsistent as some states had unclear facility definitions or included level II facilities in their reporting. Recently, several states, in partnership with national organizations, have taken more definitive action in defining and regulating organization of perinatal care.⁵⁰

Development of Consistent Standards of Service

Efforts by quality-improvement collaborators, health services researchers, and public health officials will continue to improve the standards by which to measure quality of care.^{51,52} Quality-improvement activities have begun to flourish at all levels to improve maternal and perinatal health and ideally prevent preterm births; this includes provider-level quality-improvement activities, hospital-level performance measures, and regional, state, and national performance measures.⁵³ Organizations such as the March of Dimes have promoted standard definitions of levels of care since the introduction of perinatal regionalization in the 1970s, reaffirmed its importance in 1993 (TIOP II),⁵⁴ and included the concept of quality care for the prevention of preterm birth with a new TIOP (TIOP III) in 2010.⁵⁵

DEFINITIONS OF LEVELS OF NEONATAL CARE

The updated classification consists of basic care (level I), specialty care (level II), and subspecialty intensive care (level III, level IV; Table 1). These definitions reflect the overall evidence for risk-appropriate care through the availability of appropriate personnel, physical space, equipment, technology, and

TABLE 1 Definitions, Capabilities, and Provider Types: Neonatal Levels of Care

Level of Care	Capabilities	Provider Types ^a
Level I Well newborn nursery	<ul style="list-style-type: none"> • Provide neonatal resuscitation at every delivery • Evaluate and provide postnatal care to stable term newborn infants • Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable • Stabilize newborn infants who are ill and those born at <35 wk gestation until transfer to a higher level of care 	Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses
Level II Special care nursery	Level I capabilities plus: <ul style="list-style-type: none"> • Provide care for infants born ≥ 32 wk gestation and weighing ≥ 1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis • Provide care for infants convalescing after intensive care • Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both • Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility 	Level I health care providers plus: Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.
Level III NICU	Level II capabilities plus: <ul style="list-style-type: none"> • Provide sustained life support • Provide comprehensive care for infants born <32 wks gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness • Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists • Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide • Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography 	Level II health care providers plus: Pediatric medical subspecialists ^b , pediatric anesthesiologists ^b , pediatric surgeons, and pediatric ophthalmologists ^b .
Level IV Regional NICU	Level III capabilities plus: <ul style="list-style-type: none"> • Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions • Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site • Facilitate transport and provide outreach education 	Level III health care providers plus: Pediatric surgical subspecialists

^a Includes all providers with relevant experience, training, and demonstrated competence.

^b At the site or at a closely related institution by prearranged consultative agreement.

organization.⁵⁵ Each level reflects the minimal capabilities, functional criteria, and provider type required. Currently, there are 148 specialty care units and 809 subspecialty care units self-identified in the 2009 AAP perinatal section directory.

Level I

Level I facilities (well newborn nurseries) provide a basic level of care to

neonates who are low risk. They have the capability to perform neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy newborn infants. In addition, they can care for preterm infants at 35 to 37 weeks' gestation who are physiologically stable and can stabilize newborn infants who are less than 35 weeks of gestation or who are ill until they can be transferred to

a facility at which specialty neonatal care is provided. Because late preterm infants (34–36 weeks' gestation) are at risk for increased neonatal morbidity and mortality, more evidence is needed to determine their outcomes by level of care.

Level II

Care in a specialty-level facility (level II) should be reserved for stable or

moderately ill newborn infants who are born at ≥ 32 weeks' gestation or who weigh ≥ 1500 g at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis. These situations usually occur as a result of relatively uncomplicated preterm labor or preterm rupture of membranes. There is limited evidence to support the specific subdivision of level II care, in part because of the lack of studies with well-defined subdivisions. Level II facilities should take into consideration geographic constraints and population size when assessing the staffing resources needed to care appropriately for moderately ill newborn infants.

Level II nurseries may provide assisted ventilation on an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility. Delivery of continuous positive airway pressure should be readily available by experienced personnel, and mechanical ventilation can be provided for a brief duration (less than 24 hours). Level II nurseries must have equipment (eg, portable x-ray machine, blood gas analyzer) and personnel (eg, physicians, specialized nurses, respiratory therapists, radiology technicians, laboratory technicians) continuously available to provide ongoing care as well as to address emergencies. Referral to a higher level of care should occur for all infants when needed for pediatric surgical or medical subspecialty intervention.

Level III

Evidence suggests that infants who are born at < 32 weeks' gestation, weigh < 1500 g at birth, or have medical or surgical conditions, regardless of gestational age, should be cared for at a level III facility. Designation of level III

care should be based on clinical experience, as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists. Subspecialty care services should include expertise in neonatology and also ideally maternal-fetal medicine, if mothers are referred for the management of potential preterm birth. Level III NICUs are defined by having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists) and equipment to provide life support for as long as necessary. Facilities should have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care.

Level III facilities should be able to provide ongoing assisted ventilation for 24 hours or more, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III facility capabilities should also be based on a region's consideration of geographic constraints, population size, and personnel resources. If geographic constraints for land transportation exist, the level III facility should ensure availability of rotor and fixed-wing transport services to quickly and safely transfer infants requiring subspecialty intervention.⁵⁶ Potential transfer to higher-level facilities or children's hospitals, as well as back-transport of recovering infants to lower-level facilities, should be considered as clinically indicated.

A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily accessible on site or by prearranged consultative agreements. Prearranged consultative agreements can be performed by using telemedicine technology and/or telephone consultation, for example,

from a distant location.⁵⁰ Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity should be readily available in level III facilities.⁵⁷ Level III units should have the capability to perform major surgery on site or at a closely related institution, ideally in close geographic proximity. Because the outcomes of less complex surgical procedures in children, such as appendectomy or pyloromyotomy, are better when performed by pediatric surgeons compared with general surgeons, it is recommended that pediatric surgical specialists (including anesthesiologists with pediatric expertise) perform all procedures in newborn infants.⁵⁸

Level III facilities should have the capability to perform advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography. Level III facilities should collect data to assess outcomes within their facility and to compare with other levels.

Level IV

Level IV units include the capabilities of level III with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and should have pediatric medical and pediatric surgical specialty consultants continuously available 24 hours a day. Level IV facilities would also include the capability for surgical repair of complex conditions (eg, congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). More evidence is needed to assess the risk of morbidity and mortality by level of care for newborn infants with complex congenital cardiac malformations. A recent study by Burstein et al⁵⁹ was not able to note a difference in postoperative morbidity or mortality

associated with dedicated pediatric cardiac ICUs versus NICUs and PICUs but did not separately assess the newborn and postneonatal periods. Although specific supporting data are not currently available, it is thought that concentrating the care of such infants at designated level IV centers will allow these centers to develop the expertise needed to achieve optimal outcomes.

Not all level IV hospitals need to act as regional centers; however, regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and back-transport,⁶⁰ and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. These functions usually are best achieved when responsibility is concentrated in a single regional center with both perinatal and neonatal subspecialty services. In some cases, regional coordination may be provided adequately by the collaboration of a children's hospital with a subspecialty perinatal facility that is in close geographic proximity.⁶¹

STANDARDS OF SERVICE FOR HOSPITALS PROVIDING NEONATAL CARE

Current evidence indicates that family and cultural considerations are important for care of sick neonates.^{62–65} These considerations include family- and patient-centered care, culturally effective care, family-based education, and opportunities for back-transport to level II facilities or transfer to the family's local community facility when medically and socially indicated.^{64–67}

SUMMARY AND RECOMMENDATIONS

1. Regionalized systems of perinatal care are recommended to ensure that each newborn infant is delivered and cared for in a facility most appropriate for his or her health care needs, when possible, and to facilitate the achievement of optimal health outcomes.

- Because VLBW and/or very preterm infants are at increased risk of predischARGE mortality when born outside of a level III center, they should be delivered at a level III facility unless this is precluded by the mother's medical condition or geographic constraints.

2. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly on the basis of geographic and population parameters in collaboration with state health departments, as follows:

- Level I: a hospital nursery organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable, and stabilize ill newborn infants or infants born at less than 35 weeks' gestational age until transfer to a facility that can provide the appropriate level of neonatal care.
- Level II: a hospital special care nursery organized with the personnel and equipment to provide care to infants born at 32 weeks' gestation or more and weighing 1500 g or more at birth who have physiologic immaturity, such as apnea of prematurity, inability to maintain

body temperature, or inability to take oral feedings; who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; or who are convalescing from a higher level of intensive care. A level II center has the capability to provide continuous positive airway pressure and may provide mechanical ventilation for brief durations (less than 24 hours).

- Level III: a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness. This includes infants born weighing <1500 g or at <32 weeks' gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units can facilitate transfer to higher-level facilities or children's hospitals, as well as back-transport recovering infants to lower-level facilities, as clinically indicated.
- Level IV units have the capabilities of a level III NICU and

are located within institutions that can provide on-site surgical repair of serious congenital or acquired malformations. Level IV units can facilitate transport systems and provide outreach education within their catchment area.

- The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly and with clear definitions that include requirements for equipment, personnel, facilities, ancillary services, training, and the organization of services (including transport) for the capabilities of each level of care.

- Population-based data on patient outcomes, including mortality, morbidity, and long-term outcomes, should be obtained to provide level-specific standards for patients requiring various categories of specialized care, including surgery.

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REFERENCES

- Stark AR; American Academy of Pediatrics Committee on Fetus and Newborn. Levels of neonatal care. *Pediatrics*. 2004;114(5):1341–1347
- Bode MM, O'shea TM, Metzguer KR, Stiles AD. Perinatal regionalization and neonatal mortality in North Carolina, 1968–1994. *Am J Obstet Gynecol*. 2001;184(6):1302–1307
- MacDorman MF, Kirmeyer S. Fetal and perinatal mortality, United States, 2005. *Natl Vital Stat Rep*. 2009;57(8):1–19
- Clement MS. Perinatal care in Arizona 1950–2002: a study of the positive impact of technology, regionalization and the Arizona perinatal trust. *J Perinatol*. 2005;25(8):503–508
- March of Dimes, Committee on Perinatal Health. *Toward Improving the Outcome of Pregnancy: Recommendations for the Regional Development of Maternal and Perinatal Health Services*. White Plains, NY: March of Dimes National Foundation; 1976
- Richardson DK, Reed K, Cutler JC, et al. Perinatal regionalization versus hospital competition: the Hartford example. *Pediatrics*. 1995;96(3 pt 1):417–423
- Yeast JD, Poskin M, Stockbauer JW, Shaffer S. Changing patterns in regionalization of perinatal care and the impact on neonatal mortality. *Am J Obstet Gynecol*. 1998;178(1 pt 1):131–135
- Goodman DC, Fisher ES, Little GA, Stukel TA, Chang CH. Are neonatal intensive care resources located according to need? Regional variation in neonatologists, beds, and low birth weight newborns. *Pediatrics*. 2001;108(2):426–431
- Howell EM, Richardson D, Ginsburg P, Foot B. Deregionalization of neonatal intensive care in urban areas. *Am J Public Health*. 2002;92(1):119–124
- Haberland CA, Phibbs CS, Baker LC. Effect of opening midlevel neonatal intensive care units on the location of low birth weight births in California. *Pediatrics*. 2006;118(6). Available at: www.pediatrics.org/cgi/content/full/118/6/e1667
- Dobrez D, Gerber S, Budetti P. Trends in perinatal regionalization and the role of managed care. *Obstet Gynecol*. 2006;108(4):839–845
- US Department of Health and Human Services, Health Resources and Service Administration, Maternal and Child Health Bureau. National Performance Measure # 17. Available at: <https://perfdta.hrsa.gov/mchb/TVISReports/>. Accessed July 12, 2012
- Centers for Disease Control and Prevention (CDC). Neonatal intensive-care unit admission of infants with very low birth weight—19 States, 2006. *MMWR Morb Mortal Wkly Rep*. 2010;59(44):1444–1447
- Martin JA, Hamilton BE, Ventura SJ, et al. Births: final data for 2009. *Natl Vital Stat Rep*. 2011;60(1):1–70
- Yoder BA, Gordon MC, Barth WH Jr. Late-preterm birth: does the changing obstetric paradigm alter the epidemiology of respiratory complications? *Obstet Gynecol*. 2008;111(4):814–822
- Schieve LA, Ferre C, Peterson HB, Macaluso M, Reynolds MA, Wright VC. Perinatal outcome among singleton infants conceived through assisted reproductive technology in the United States. *Obstet Gynecol*. 2004;103(6):1144–1153
- Joseph KS, Marcoux S, Ohlsson A, et al; Fetal and Infant Health Study Group of the Canadian Perinatal Surveillance System. Changes in stillbirth and infant mortality associated with increases in preterm birth among twins. *Pediatrics*. 2001;108(5):1055–1061
- Kaaja RJ, Greer IA. Manifestations of chronic disease during pregnancy. *JAMA*. 2005;294(21):2751–2757
- Shapiro-Mendoza CK, Tomashek KM, Kotelchuck M, et al. Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk. *Pediatrics*. 2008;121(2). Available at: www.pediatrics.org/cgi/content/full/121/2/e223
- Yang Q, Greenland S, Flanders WD. Associations of maternal age- and parity-related factors with trends in low-birthweight rates: United States, 1980 through 2000. *Am J Public Health*. 2006;96(5):856–861
- Davidoff MJ, Dias T, Damus K, et al. Changes in the gestational age distribution among U.S. singleton births: impact on rates of late preterm birth, 1992 to 2002. *Semin Perinatol*. 2006;30(1):8–15
- Engle WA, Tomashek KM, Wallman C; Committee on Fetus and Newborn, American

- Academy of Pediatrics. "Late-preterm" infants: a population at risk. *Pediatrics*. 2007;120(6):1390–1401
23. Ramachandrapa A, Rosenberg ES, Wagoner S, Jain L. Morbidity and mortality in late preterm infants with severe hypoxic respiratory failure on extra-corporeal membrane oxygenation. *J Pediatr*. 2011;159(2):192–198, e3
 24. Philip AG. The evolution of neonatology. *Pediatr Res*. 2005;58(4):799–815
 25. Thompson LA, Goodman DC, Little GA. Is more neonatal intensive care always better? Insights from a cross-national comparison of reproductive care. *Pediatrics*. 2002;109(6):1036–1043
 26. Gould JB, Marks AR, Chavez G. Expansion of community-based perinatal care in California. *J Perinatol*. 2002;22(8):630–640
 27. Stoll BJ, Hansen NI, Bell EF, et al; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neonatal outcomes of extremely preterm infants from the NICHD Neonatal Research Network. *Pediatrics*. 2010;126(3):443–456
 28. Heron M, Sutton PD, Xu J, Ventura SJ, Strobino DM, Guyer B. Annual summary of vital statistics: 2007. *Pediatrics*. 2010;125(1):4–15
 29. Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal regionalization for very low-birth-weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304(9):992–1000
 30. Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. *N Engl J Med*. 2007;356(21):2165–2175
 31. Chung JH, Phibbs CS, Boscardin WJ, Kominski GF, Ortega AN, Needleman J. The effect of neonatal intensive care level and hospital volume on mortality of very low birth weight infants. *Med Care*. 2010;48(7):635–644
 32. Bartels DB, Wypij D, Wenzlaff P, Dammann O, Poets CF. Hospital volume and neonatal mortality among very low birth weight infants. *Pediatrics*. 2006;117(6):2206–2214
 33. Rogowski JA, Horbar JD, Staiger DO, Kenny M, Carpenter J, Geppert J. Indirect vs direct hospital quality indicators for very low-birth-weight infants. *JAMA*. 2004;291(2):202–209
 34. Morales LS, Staiger D, Horbar JD, et al. Mortality among very low-birthweight infants in hospitals serving minority populations. *Am J Public Health*. 2005;95(12):2206–2212
 35. Howell EA, Hebert P, Chatterjee S, Kleinman LC, Chassin MR. Black/white differences in very low birth weight neonatal mortality rates among New York City hospitals. *Pediatrics*. 2008;121(3). Available at: www.pediatrics.org/cgi/content/full/121/3/e407
 36. Rogowski JA, Staiger DO, Horbar JD. Variations in the quality of care for very-low-birthweight infants: implications for policy. *Health Aff (Millwood)*. 2004;23(5):88–97
 37. Palmer KG, Kronsberg SS, Barton BA, Hobbs CA, Hall RW, Anand KJ. Effect of inborn versus outborn delivery on clinical outcomes in ventilated preterm neonates: secondary results from the NEOPAIN trial. *J Perinatol*. 2005;25(4):270–275
 38. Wall SN, Handler AS, Park CG. Hospital factors and nontransfer of small babies: a marker of deregionalized perinatal care? *J Perinatol*. 2004;24(6):351–359
 39. Zeitlin J, Gwanfobge CD, Delmas D, et al. Risk factors for not delivering in a level III unit before 32 weeks of gestation: results from a population-based study in Paris and surrounding districts in 2003. *Paediatr Perinat Epidemiol*. 2008;22(2):126–135
 40. Arad I, Baras M, Bar-Oz B, Gofin R. Neonatal transport of very low birth weight infants in Jerusalem, revisited. *Isr Med Assoc J*. 2006;8(7):477–482
 41. Institute of Medicine. *Preterm Birth: Causes, Consequences, and Prevention*. Washington, DC: National Academies Press; 2007
 42. Rautava L, Lehtonen L, Peltola M, et al; PERFECT Preterm Infant Study Group. The effect of birth in secondary- or tertiary-level hospitals in Finland on mortality in very preterm infants: a birth-register study. *Pediatrics*. 2007;119(1). Available at: www.pediatrics.org/cgi/content/full/119/1/e257
 43. Johansson S, Montgomery SM, Ekbohm A, et al. Preterm delivery, level of care, and infant death in sweden: a population-based study. *Pediatrics*. 2004;113(5):1230–1235
 44. Vieux R, Fresson J, Hascoet JM, et al; EPIPAGE Study Group. Improving perinatal regionalization by predicting neonatal intensive care requirements of preterm infants: an EPIPAGE-based cohort study. *Pediatrics*. 2006;118(1):84–90
 45. Audibert F. Regionalization of perinatal care: did we forget congenital anomalies? *Ultrasound Obstet Gynecol*. 2007;29(3):247–248
 46. Martin JA, Menacker F. Expanded health data from the new birth certificate, 2004. *Natl Vital Stat Rep*. 2007;55(12):1–22
 47. Menacker F, Martin JA. Expanded health data from the new birth certificate, 2005. *Natl Vital Stat Rep*. 2008;56(13):1–24
 48. Blackmon LR, Barfield WD, Stark AR. Hospital neonatal services in the United States: variation in definitions, criteria, and regulatory status, 2008. *J Perinatol*. 2009;29(12):788–794
 49. Lorch SA, Maheshwari P, Even-Shoshan O. The impact of certificate of need programs on neonatal intensive care units. *J Perinatol*. 2012;32(1):39–44
 50. Nowakowski L, Barfield WD, Kroelinger CD, et al. Assessment of state measures of risk-appropriate care for very low birth weight infants and recommendations for enhancing regionalized state systems. *Matern Child Health J*. 2012;16(1):217–227
 51. Acolet D, Elbourne D, McIntosh N, et al; Confidential Enquiry Into Maternal and Child Health. Project 27/28: inquiry into quality of neonatal care and its effect on the survival of infants who were born at 27 and 28 weeks in England, Wales, and Northern Ireland. *Pediatrics*. 2005;116(6):1457–1465
 52. Ohlinger J, Kantak A, Lavin JP Jr; et al. Evaluation and development of potentially better practices for perinatal and neonatal communication and collaboration. *Pediatrics*. 2006;118(suppl 2):S147–S152
 53. March of Dimes. *Toward Improving the Outcome of Pregnancy III: Enhancing Perinatal Health Through Quality, Safety, and Performance Initiatives (TIOP3)*. White Plains, NY: March of Dimes Foundation; 2010
 54. Committee on Perinatal Health. *Toward Improving the Outcome of Pregnancy: The 90s and Beyond*. White Plains, NY: March of Dimes Foundation; 1993
 55. American Academy of Pediatrics, American College of Obstetrics and Gynecology. *Guidelines for Perinatal Care*. 6th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2007
 56. American Academy of Pediatrics. *Section on Transport Medicine. Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*. 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012
 57. Fiererson WM; Section on Ophthalmology American Academy of Pediatrics; American Academy of Ophthalmology; American Association for Pediatric Ophthalmology and Strabismus. Screening examination of premature infants for retinopathy of prematurity. *Pediatrics*. 2006;117(2):572–576
 58. Kosloske A; American Academy of Pediatrics, Surgical Advisory Panel. Guidelines for referral to pediatric surgical specialists. *Pediatrics*. 2002;110(1 pt 1):187–191; reaffirmed in *Pediatrics*. 2007;119(5):1031

59. Burstein DS, Jacobs JP, Li JS, et al. Care models and associated outcomes in congenital heart surgery. *Pediatrics*. 2011;127(6). Available at: www.pediatrics.org/cgi/content/full/127/6/e1482
60. Attar MA, Lang SW, Gates MR, Iatrow AM, Bratton SL. Back transport of neonates: effect on hospital length of stay. *J Perinatol*. 2005;25(11):731–736
61. Berry MA, Shah PS, Brouillette RT, Hellmann J. Predictors of mortality and length of stay for neonates admitted to children's hospital neonatal intensive care units. *J Perinatol*. 2008;28(4):297–302
62. American College of Obstetricians and Gynecologists. Cultural sensitivity and awareness in the delivery of health care. Committee Opinion No. 493. *Obstet Gynecol*. 2011;117(5):1258–1261
63. American College of Obstetricians and Gynecologists. Effective patient-physician communication. Committee Opinion No. 492. *Obstet Gynecol*. 2011;117(5):1254–1257
64. Tucker CM. *US Department of Health and Human Services Advisory Committee on Minority Health. Reducing Health Disparities by Promoting Patient-Centered Culturally and Linguistically Sensitive/Competent Health Care*. Rockville, MD: US Public Health Service; 2009
65. Britton CV; American Academy of Pediatrics Committee on Pediatric Workforce. Ensuring culturally effective pediatric care: implications for education and health policy. *Pediatrics*. 2004;114(6):1677–1685
66. Eichner JM, Johnson BH; Committee on Hospital Care. American Academy of Pediatrics. Family-centered care and the pediatrician's role. *Pediatrics*. 2003;112(3 pt 1):691–697
67. Kattwinkel J, Cook LJ, Nowacek G, et al. Regionalized perinatal education. *Semin Neonatol*. 2004;9(2):155–165

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American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



SAMPLE

PATIENT TRANSFER AGREEMENT

THIS AGREEMENT is made effective as of _____ by and between _____ (Children’s Hospital) _____ a nonprofit corporation, and _____ (“Hospital”), a _____ corporation.

WHEREAS, _____ operates a tertiary level acute care pediatric hospital to provide access to patient care for the residents of its primary service area and to provide tertiary level services on a regional and national basis to individuals requiring specialized pediatric care; and

WHEREAS, Hospital operates a general acute care hospital to provide access to patient care for the residents of its primary service area; and

WHEREAS, _____ and Hospital (the “Institutions”) have determined that it would be in the best interest of patient care and it would promote the optimum use of facilities, including addressing surge capacity, to enter into a transfer agreement for transfer of patients between the respective Institutions;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, and for other valuable consideration, the receipt and sufficiency of which is acknowledged, _____ and Hospital agree as follows:

1. **Term.** This Agreement shall commence on the date written above and shall continue for a period of one year. Thereafter it shall be renewed automatically for successive periods of one year unless terminated earlier as provided in this Agreement.

2. **Purpose of Agreement.** Each Institution agrees to transfer to the other Institution and to receive from the other Institution patients in need of the care which may not be available in the other Institution and provided by their respective Institutions for the purpose of providing continuity of patient care and treatment appropriate to the needs of each patient.

3. **Patient Transfer.** This Agreement shall apply to transfers between _____ hospital location and referring Hospital. The need for transfer of a patient from one Institution to another shall be determined by the patient’s attending physician who will contact the receiving hospital regarding the need for transfer. The receiving Institution shall confirm its acceptance of the patient after confirming the following: a) the receiving Institution has appropriate space, equipment and personnel to provide safe patient care; and b) the receiving physician has been identified and has agreed to accept responsibility for the care of the patient. Requests for transfer shall be made only after the patient has been evaluated and the referring Institution has provided appropriate treatment, personnel and equipment to stabilize the patient within the capabilities of the referring Institution in compliance with EMTALA. The receiving

Institution agrees to admit the patient as promptly as possible. However, the receiving Institution is not obligated to accept a patient if the receiving Institution determines, in its sole discretion, it does not then have the capacity to provide the services required for the patient, that the care required can be provided at the referring Institution (unless transfer is required by a third party payor) or that the transfer request is based solely on the patient's lack of financial resources. The receiving Institution may deny requests for non-emergent transfers to a specific hospital program if the patient does not meet the specific admission criteria of the program to which transfer is proposed.

4. **Medical Staff Membership.** Once the receiving Institution has accepted the transfer, if the attending physician responsible for determining the medical need for transfer is not a member of the receiving Institution's medical staff with admitting privileges, that physician shall arrange for transfer of responsibility for the care of the patient to a member of receiving Institution's medical staff for the period of hospitalization, or the non-member physician must apply for and obtain appropriate clinical privileges to admit and attend the patient during hospitalization.

5. **Provision of Information to Each Institution.** The Institutions agree to provide to each other information about the type of resources offered at their respective facilities and the types of patients and health conditions that each Institution will accept and/or transfer. Each Institution shall provide the other Institution with the names or classifications of persons authorized to initiate, confirm and accept the transfer of patients on behalf of their respective Institution and shall update such information at least annually.

6. **Patient Record and Personal Effects.** Each Institution agrees to provide the following information to accompany the patient from one Institution to the other. The information shall include the following when available:

- a. Patient's name, address, patient identification number, age and the name, address and telephone number of at least one of the following (in the order of priority): the patient's legal guardian or other person authorized to make medical decisions for the patient;
- b. Pertinent administrative and social information;
- c. Patient's third party billing data, if any, including information regarding whether the patient participates in a managed care plan and any prior authorizations for treatment, provided, with respect to emergency transfers, that this information can be obtained without delaying treatment;
- d. All medical records (or copies of such records) related to the patient's condition that are available at the time of transfer, including available history, records relating to the patient's emergency medical condition, observation of signs or symptoms, preliminary diagnosis, results of

diagnostic studies or telephone reports of the studies, treatment provided and results of any tests;

- e. Written informed consent to transfer signed by the patient or the patient's legally authorized representative or written certification by a physician that the medical benefits reasonably expected from the provision of appropriate treatment at the receiving Institution outweigh the risks to the patient (or unborn child) from being transferred;
- f. Name, address and phone number of physician referring patient;
- g. Name of physician in receiving Institution to whom patient is to be transferred, if different from the referring physician;
- h. Name of physician at receiving Institution who has been contacted about patient; and
- i. Name of any on-call physician at the referring Institution who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment.

Each Institution agrees to supplement the above information as necessary for the maintenance of the patient during transport and treatment upon arrival at the receiving Institution and to send other pertinent records not readily available at the time of transfer to the receiving Institution as soon as practicable after transfer. Each Institution shall provide the other with a receipt for any original medical records received from the other and the patient's valuables and personal effects exchanged between the parties as a result of a transfer.

7. **Transfer Consent.** The referring Institution shall have the responsibility for obtaining the patient's or guardian's written informed consent to the transfer or that of the patient's authorized representative prior to the transfer. If such consent is not possible, the Institution shall obtain certification of the need for the transfer from the attending physician or other qualified medical personnel in accord with the requirements of the Emergency Medical Treatment and Active Labor Act ("Act"). When the patient has an emergency medical condition that has not been stabilized within the meaning of the Act, the referring Institution shall comply with the requirements of the Act in securing the patient's consent to transfer or certification of the need for transfer by a physician or other qualified medical personnel in accord with the Act's requirements.

8. **Return of Patient.** In the event the transfer is only temporary and for a specific procedure or service with the intent that the patient is to be returned to the referring Institution, the referring Institution agrees to accept the patient for continued care upon completion of the procedure or service that necessitated the transfer, provided the patient is stabilized within the meaning of the Act.

9. **Payment For Services.** The patient is primarily responsible for payment for care received from each Institution. Except as otherwise agreed to in writing between transferring hospital and receiving hospital, each Institution shall be responsible for collecting its own payment for services rendered to the patient by it from the patient, insurer or Medicare/Medicaid programs, as appropriate. No clause of this Agreement shall be construed to authorize either party to look to the other to pay for services rendered as a result of a transfer pursuant to this Agreement, except to the extent that such liability for a particular transfer is set forth in a written agreement signed by both parties or is negotiated between the parties, or where such liability would exist separate and apart from this Agreement.

10. **Transfer Arrangements.** Transfer arrangements will be made by mutual consent of the referring and receiving physicians. It shall be the responsibility of the receiving physician to arrange the admission of the patient to the receiving Institution. The referring physician, in collaboration with the receiving physician (pursuant to ss 146.50, 2006 Interfacility Transport Guidelines, U.S. Department of Health and Human Services), shall determine the mode of transport and team configuration based on patient needs and the scope of practice of the transporting team.

Requests for children's Transport Team and Medical Control support and patient transfer can be generated by telephone to:

11. **Transportation of Patient.** Unless contrary arrangements have been mutually agreed upon in advance, referring Institution shall have responsibility for arranging and paying for transportation of the patient to the other Institution, including selection of the appropriate mode of transportation and providing appropriate health care practitioner(s) to accompany the patient. The referring Institution retains the right to seek payment from the patient or other third party payor for the cost of transfer. Subject to Section 13 below, the receiving Institution's responsibility for patient care shall begin when the patient is physically delivered into the hands of a health care professional authorized by the receiving Institution to accept transfers under this Agreement.

12. **Responsibility For Care or Treatment of Patients Transported by Transport Team.** The Transport Team provides care based on patient specific orders submitted by on-line Medical Control. The team assumes primary care responsibilities in collaboration with the referring Institution for transferring patients while the patient is within the referring Institution and after formal patient hand-off has been completed. The referring physician and patient care team should remain available to the Transport Team for mutual support as patient acuity dictates and to provide further information.

13. **Responsibility For Care or Treatment.** The receiving Institution shall not be responsible for any care or treatment provided by the referring Institution. The referring Institution is responsible for any care or treatment given any transferred patient or any untoward

event concerning such patient unless and until the referring Institution fulfills its responsibility for all of the following: a) notifying the receiving Institution promptly and providing all information appropriate under the circumstances whenever it wants to transfer a patient to the receiving Institution; b) obtaining any necessary medical authorization by a physician or other qualified medical person and any necessary consent by or on behalf of the patient for the transfer; c) documenting the medical justification for the transfer in the patient's medical records; d) making all transportation arrangements required to accomplish the transfer; and e) delivering the patient to the receiving Institution or the receiving Institution's Transport Department, with his or her billing information (if, in the case of an emergency transfer, the referring Institution is able to obtain the same without causing delay in providing appropriate treatment or screening to patient), valuables, medical records and other information sufficient to allow knowledgeable treatment of the patient at the receiving Institution.

To the extent possible, stabilization and treatment will be initiated prior to transfer to ensure that the transfer will not, within reasonable medical probability, result in harm or jeopardize survival of the patient or transporting team.

14. **Advertising and Public Relations.** Neither Institution shall use the name of the other Institution in any promotional or advertising material unless review and approval of the intended advertisement is first obtained from the party whose name is to be used. Both Institutions shall deal with each other publicly and privately in an atmosphere of mutual respect and support.

15. **Medicare/Medicaid Certification.** Each Institution shall remain Medicare/Medicaid certified, shall accept and treat Medicare/Medicaid patients and shall remain eligible for payment from the Medicare/Medicaid programs.

16. **Applicable Standards.** Each Institution shall assure that all duties performed and services provided pursuant to this Agreement are in compliance with applicable standards, rulings and regulations of The Joint Commission, the United States Department of Health and Human Resources, the State Department of Health Services, and/or any other government agency, corporate entity or individual exercising authority with respect to the Institution.

17. **Compliance With COBRA.** Each Institution acknowledges that it is aware of and agrees to comply with the requirements of the Consolidated Omnibus Budget Reconciliation Action of 1985, as amended, as it relates to patient transfers.

18. **Confidentiality.** Each party agrees to maintain the confidentiality of patient information disclosed for the purposes of providing necessary medical care and not to disclose any such information except where permitted by law. Both parties acknowledge that in receiving or otherwise dealing with any records or information relating to patients receiving treatment for alcohol or other drug abuse, both Institutions are fully bound by the provisions of the federal regulations governing confidentiality of alcohol and drug abuse patient records (42 C.F.R. Part 2, as amended from time to time).

19. **Independent Contractor Status.** Both Institutions are independent contractors. Neither Institution is authorized or permitted to act as an agency or employee of the other. Nothing in this Agreement is intended nor shall be construed to create an employer/employee partnership, or joint venture relationship or to allow either party to exercise control or direction over the manner or method by which either party provides services to patients, provided that such services are performed in accordance with all applicable medical standards and the terms and conditions of this Agreement.

20. **Liability.** Each Institution shall be responsible for its own acts and omissions and agrees to indemnify and hold the other Institution harmless from any actual or threatened harm caused by or arising out of any claimed improper, negligent or wrongful act or omission of the indemnifying Institution, its trustees, officers, agents and employees. The term “harm” as set forth in the preceding sentence includes any and all: claims, suits or legal proceedings; damages or injuries; interest; costs, expenses or fees, including costs associated with investigating and defending claims, suits or legal proceedings and including reasonable attorneys’ fees attributable to such investigation or defense or attributable to enforcing the provisions of this Agreement; loss of profits; and all other loss or liability of whatever kind or nature.

21. **Insurance.** Each Institution shall secure and maintain, or cause to be secured and maintained during the term of this Agreement, comprehensive general and professional liability insurance and property damage insurance providing adequate limits of liability for their respective operations. Each party shall cause its insurance carrier to file a certificate of continuous coverage with the other party, and each party shall immediately notify the other of any notice received from its insurance carrier of intent to modify or cancel such insurance coverage.

22. **Termination.**

- a. **Voluntary Termination.** This Agreement may be terminated by either party for any reason, by giving at least thirty (30) days’ written notice of its intention to withdraw from this Agreement, and by ensuring the continuity of care to patients who already are involved in the transfer process.
- b. **Involuntary Termination.** This Agreement shall be terminated immediately upon the occurrence of any of the following:
 - 1) Either Institution is destroyed to such an extent that the patient care provided by such Institution cannot be carried out adequately;
 - 2) Either Institution loses or has its operating license or approval, its Joint Commission accreditation or its Medicare/Medicaid certification suspended or revoked;

- 3) Either Institution no longer is able to provide the services for which this Agreement was sought; or
- 4) Either Institution is in default under any of the terms of this Agreement.

23. **Nonwaiver.** No waiver of any term or condition of this Agreement by either party shall be deemed a continuing or further waiver of the same term or condition or a waiver of any other term or condition of this Agreement.

24. **Governing Law.** This Agreement is made and entered into in the State of _____ and shall be governed and construed in accordance with the laws of _____.

25. **Assignment.** This Agreement shall not be assigned in whole or in part by either party without the express written consent of the other party.

26. **Severability.** If any provision of this Agreement shall be held or declared to be invalid, illegal or unenforceable under any applicable law, such provision shall be deemed deleted from this Agreement and shall be replaced by a valid and enforceable provision which so far as possible achieves the same objectives as the severed provision was intended to achieve and the remaining provisions of this Agreement shall continue in full force and effect.

27. **Amendment.** This Agreement may be amended at any time by a written agreement signed by the parties, which amendment shall be attached to and become a part of this Agreement.

28. **Notices.** All notices regarding the transfer or care of patients shall be made via telephone to the parties designated in this Agreement, as amended from time to time. Any other notice required or allowed to be given under this Agreement shall be deemed to have been given upon facsimile transmission with confirmation of receipt, upon personal delivery, or upon deposit in the United States mail, registered or certified, with return receipt requested and addressed as follows, unless and until either of the parties notifies the other in accordance with this section of a change of address:

Attention: _____

29. **Entire Agreement.** This Agreement constitutes the entire agreement between the parties and contains all of the agreements between them with respect to the subject

matter hereof and supersedes any and all other agreements, either oral or in writing, between the parties with respect to the subject matter of this Agreement.

30. **Binding Agreement.** This Agreement shall be binding upon the successors or assigns of the parties.

31. **Confidentiality of Information.** Neither party shall disclose information relating to the operations of the other persons other than to authorized agents or employees of the other, state licensing boards, The Joint Commission or third-party reimbursement agencies and professional organizations, without the prior written consent of the other party.

32. **Headings.** The headings to the various sections of this Agreement have been inserted for convenience only and shall not modify, define, limit or expand express provisions of this Agreement.

IN WITNESS WHEREOF, CHW and Hospital have executed this Agreement effective the day and year first above written.

Appendix 3 - Children's Surgery Safety Report

Appendix 3 – Anesthesia related safety

The following events are to be monitored and reported in all patients ≤ 18 years who have undergone a surgical procedure requiring anesthesia services during the 12 months of the reporting period.

Death within 48 hours of procedure (not including ASA 6)
Cardiac arrest within 48 hours of procedure (defined as need for cardiac compressions or defibrillation)
Anaphylaxis – severe intraoperative allergic response with sudden drop in blood pressure
Malignant hyperthermia – clinical or suspected and/or use of dantrolene
Transfusion reaction - intraoperative
Stroke, CVA or coma after anesthesia – within 48 hours
Visual loss – permanent impairment or total loss of sight
Operation on incorrect site – sentinel event
Operation on incorrect patient – sentinel event
Medication error – wrong medication or wrong dosing (intraoperative)
Unplanned ICU admission within 48 hours
Intraoperative awareness – explicit awareness during anesthesia Yes/No
Reintubation within 6 hours after extubation due to respiratory distress, hypoxia, hypercapnia or acidosis
Dental trauma – unanticipated loss of permanent tooth
Perioperative aspiration with consistent radiologic findings
Vascular access complication with vascular injury or pneumothorax
Infection following epidural or spinal anesthesia – abscess, meningitis or sepsis
Epidural hematoma following epidural or spinal anesthesia
Unintentional high spinal with bradycardia, respiratory insufficiency or intubation
Postdural puncture headache within 72 hours
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia – residual sensory, motor or autonomic block 72 hours after placement
Infection following peripheral nerve block
Unanticipated need for ECMO within 72 hours of a procedure
Unanticipated need for hemodynamic (vasopressor) support within 72 hours of a procedure
Unanticipated perioperative seizure
Post-operative hemorrhage requiring transfusion within 48 hours or reoperation for control
Surgical fire and/or patient burns
Pressure ulcers related to events in the OR or perioperative environment within 30 days
Unplanned return to the operating room within 72 hours of operation
Unscheduled admission to the hospital for inpatient care within 30 days
Unscheduled admission or transfer to the intensive care unit or a higher level of care within 72 hours of operation

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Transfer to another institution for higher level of care within 72 hours of operation
Venous thromboembolic event (VTE) within 30 days