



**Electronic fetal monitoring, cerebral palsy, and the high rate of cesarean births**

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4 **Electronic fetal monitoring, cerebral palsy, and the high rate of cesarean**  
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10 *Electronic fetal monitoring does not enable prevention of cerebral palsy, but EFM*  
11 *and expert testimony that contradicts evidence of good medical quality in “birth injury”*  
12 *litigation contribute to the high rate of cesarean deliveries.*  
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17 *Electronic fetal monitoring does not enable prevention of cerebral palsy, but EFM*  
18 *and expert testimony that contradicts evidence of good medical quality in “birth injury”*  
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5 Electronic fetal monitoring, cerebral palsy, and  
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7 the high rate of cesarean births.  
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10 One in three babies born in the United States, [1] one in four in England, [2] is delivered  
11 by cesarean section. Those rates are sharply higher than in the past: the cesarean delivery rate in  
12 the US was 5% in 1970 and 20% in 1996, with comparable increases over recent decades in  
13 England and other developed countries. Current rates exceed the those optimal for the health of  
14 mothers and infants.[3] Electronic fetal monitoring in labor (EFM, a term synonymous with  
15 cardiotocography) is an important driver of operative deliveries as its exceedingly high rate of  
16 false positive identification of the fetus in danger [4] too often suggests a need for rapid  
17 intervention to prevent fetal death or brain injury.  
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24 Cerebral palsy (CP) was once thought to be due chiefly to birth asphyxia. Early advocates  
25 of electronic fetal monitoring expected that it would enable birth caregivers to recognize and  
26 rescue fetuses undergoing asphyxia in labor and thereby largely eliminate CP and markedly  
27 reduce intellectual deficits. Studies using surrogate endpoints such as low neonatal pH and low  
28 Apgar scores encouraged that expectation. Clinical trials were not conducted before the  
29 introduction of electronic monitoring because it was considered unethical to deny controls its  
30 anticipated benefits.[5] EFM became widely disseminated and became the most frequently  
31 performed procedure in obstetrics. Now, with half a century of experience, it is possible to  
32 assess the results.  
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## 42 **EFM and CP**

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45 Randomized clinical trials are the most reliable method for examining the effect of an  
46 intervention, and are especially important for evaluating EFM because in a country in which  
47 electronic monitoring is virtually ubiquitous, reasons for its non-use-- birth outside a medical  
48 facility, delivery for medical indication in mother or fetus, etc. -- might themselves be related to  
49 risk.  
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55 CP cannot be diagnosed at birth, so investigating its association with fetal monitoring  
56 requires that infants be followed for several years, until a diagnosis can reliably be made. To date  
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3 only two randomized trials have compared CP rates with and without EFM. In the large Dublin  
4 trial, the rate of CP in children whose births were monitored electronically was not lower than in  
5 those monitored by intermittent auscultation.[6] In preterm births, the CP rate was significantly  
6 *higher* in the electronically monitored group.[7] Thus, data from randomized trials do not  
7 support the hypothesis that EFM protects against CP. Results of both these trials were published  
8 more than 25 years ago.

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14 As a predictor of CP, abnormalities on EFM have a false positive rate of 99.8%, [4] so  
15 almost all positives are false positives. Using additional observations including depression of the  
16 ST-segment of the fetal electrocardiogram has not improved reliability or prediction of neonatal  
17 outcome. [8]

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21 Over the years in which EFM became widely adopted, rates of cesarean section rose  
22 about five-fold but the CP rate was unchanged.[9,10] Nor were rates of perinatal death,  
23 intrapartum stillbirth, neonatal death, low or very low Apgar scores, need for special neonatal  
24 care, or neonatal death less frequent with electronic monitoring.[11]

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28 Aberrant fetal heart rate patterns are neither sensitive nor specific indicators of current or  
29 future brain status. The obstetrical societies of the United States, Canada, Australia and New  
30 Zealand acknowledge that electronic monitoring provides no long-term benefit for children. [12]

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34 The number of children with CP in the relevant randomized trials was small,  
35 interpretation of monitoring traces has changed somewhat over the period of its use, and  
36 procedures for delivery have undergone changes. The evidence that EFM does not aid in  
37 prevention of CP is imperfect, but we know of no evidence of good medical quality [13 ] that  
38 contradicts it. New trials of EFM for prevention of CP could be contemplated, but it is doubtful  
39 that such studies warrant priority for limited research funding.  
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### 46 **Why doesn't it work?**

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48 Use of EFM in the hope of preventing CP was based on several erroneous assumptions.  
49 First, the basic physiology of fetal heart rate decelerations may have been misinterpreted.[14]  
50 Second, most CP in births at or near term is not caused by birth asphyxia, according to consistent  
51 evidence from studies of human infants in representative populations.[11,15,16] Third, a test that  
52 identifies abnormalities in a high percentage of births will inevitably produce a high false  
53 positive rate if used in an effort to identify an uncommon outcome such as CP, guaranteeing an  
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3 “arithmetic of failure.” [17] Tightening criteria in order to reduce false positives would further  
4 lower the test’s already-low sensitivity. [4]  
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7 Reliability of interpretation of fetal heart rate tracings is low. Experienced obstetricians  
8 had only mediocre agreement with one another in reading monitoring tracings, and when shown  
9 the same tracing months later agreed with their *own* earlier interpretations even *less* well. [18].  
10 The United States Preventive Services Task Force gave electronic fetal monitoring a grade of D,  
11 the lowest grade possible. [19]  
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### 19 **Why does EFM remain in use?**

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21 Whether EFM contributes to lowering the risk of intrapartum death remains somewhat  
22 uncertain because rates of perinatal death rates were already falling at the time EFM was  
23 introduced, and randomized trials showed no decrease in perinatal deaths with EFM. However,  
24 most observational studies are compatible with the conclusion that use of electronic monitoring  
25 does reduce risk of intrapartum or neonatal death. [20] Although electronic monitoring has no  
26 demonstrated value for preventing CP, it may thus have other applications and is less expensive  
27 than one-on-one auscultation. [21]  
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35 Only obstetricians can decide whether and how to use electronic monitoring. Informed  
36 decisions will require clinical trials to establish whether specific monitoring patterns in specific  
37 clinical situations aid in improving clinical management. Perhaps the future publication of the  
38 INFANT study,[22] a randomized trial of computerized interpretation of fetal heart rate patterns  
39 and decision-support software will prove helpful.  
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### 49 **EFM and cesarean sections**

50 All relevant randomized clinical trials have shown that use of electronic monitoring is  
51 associated with more interventions in labor, more surgical vaginal deliveries and more cesarean  
52 births.[11] In the United States each year, 900,000 women undergo primary cesarean delivery,  
53 of whom at least 80% (720,000) attempt vaginal birth. [23] Of those attempting vaginal birth,  
54 86% (620,000) are managed with EFM. [24] In randomized clinical trials comparing EFM to  
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3 intermittent auscultation, EFM increased the risk of cesarean by 63% (RR 1.63, 95% CI 1.29 to  
4 2.07). [11] If EFM had not been employed in those 620,000 women, 240,000 fewer of them  
5 would have undergone cesarean deliveries. Because 80% of women who have undergone  
6 cesarean do not attempt vaginal delivery in a subsequent pregnancy, if 2/3 of women have  
7 another birth after primary cesarean as many as 150,000 more cesarean deliveries each year in  
8 the United States can be attributed to the use of EFM. Results in subgroups at low-risk or high-  
9 risk, preterm birth and high-quality trials were consistent with overall results. All told, almost  
10 400,000 women a year in the United States—1 in every 10 who give birth— undergo cesarean  
11 delivery without known benefit as a direct consequence of being managed with EFM.  
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19 Noting this evidence, Alfirevic et al. [11] conclude that “women should be informed that  
20 continuous CTG during labour is associated with a reduction in the incidence of neonatal  
21 seizures, but has no obvious impact on cerebral palsy or perinatal mortality but is associated with  
22 an increase in the incidence of caesarean section and instrumental vaginal births.”  
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26 It is a high proportion of cesarean deliveries that are undertaken partly or wholly in  
27 response to abnormal monitoring tracings. [25,26] For medical caregivers, not performing a  
28 cesarean delivery can be a basis for lawsuit but they are seldom sued for doing a section. “[T]he  
29 only cesarean section you will regret is the one you didn’t perform.” [27]  
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### 37 **Why is high cesarean section rate a problem?**

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39 Surgical delivery increases risks to mothers, immediate and long-term.[28,29] Maternal  
40 death (adjusted for confounders) was 3.6 times more frequent after cesarean than vaginal  
41 delivery, [30] Operative deliveries increase risks of maternal hemorrhage, infection, and  
42 thromboembolism, and respiratory depression in the neonate. Complications in subsequent  
43 pregnancies include a high rate of repeat cesarean delivery, abnormally invasive placentation  
44 with potential for catastrophic hemorrhage, and uterine rupture. [30]  
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50 It seems intuitively likely that electronic monitoring occasionally enables rescue of a  
51 threatened fetus, even if such events are too rare to register in randomized trials or cerebral palsy  
52 rates. But do the unproven benefits exceed the known harms? Even a few uterine ruptures –  
53 with their high risk of death or disability-- in subsequent pregnancies of women who had an  
54 unnecessary surgical delivery because of EFM would have to be weighed against the  
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3 hypothetical benefit. **“The evidence is overwhelming that continuous EFM... has overall**  
4 **caused more harm than good.” [25]**  
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8 Cesarean sections are among the most frequently performed surgical procedures in the  
9 United States. Higher medical care costs accompany a high section rate: an uncomplicated  
10 vaginal delivery typically costs \$9000 to \$17,000, while for an uncomplicated cesarean section  
11 cost ranges from about \$14,000 to \$25,000 or more. [31] Even a modest reduction in surgical  
12 deliveries would contribute to lowering health care costs.  
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18 Ethical problems arise when doctors use ready recourse to surgical intervention to protect  
19 themselves against litigation, thereby placing their own interests above those of their patients in  
20 whom risks are increased without established benefit. And there is the injustice to medical  
21 caregivers of using bad science in courtrooms to charge them with harms they did not cause.  
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## 26 27 28 29 **EFM and litigation**

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32 Failure to prevent CP due to alleged birth asphyxia by proper use of EFM is a frequent  
33 allegation in malpractice cases in the United States and elsewhere, [32,33] despite the evidence  
34 that such monitoring is irrelevant to prevention of CP. Responding to the threat of litigation,  
35 medical caregivers move more quickly to surgery.[34,35] “There is overwhelming evidence that  
36 part of the recent rise in the cesarean section rate in this country is the result of the medical-legal  
37 environment.” [25]  
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44 EFM is the cudgel in most CP claims. [36] Plaintiffs’ experts can usually find something  
45 worrisome to point to in any monitoring strip. According to a plaintiff’s attorney, he “can take  
46 any fetal monitor strip and make a malpractice case out of it.” [37]  
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51 Importantly, knowledge of neurologic abnormality in a child with alleged birth injury  
52 influences interpretations of monitoring tracings and judgments about the appropriateness of the  
53 clinical care provided. [18,38,39] In a “birth injury” trial, it can safely be assumed that  
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3 neurologic outcome was unfavorable. That prior knowledge builds a high level of bias into  
4 interpretation of fetal monitoring as employed in courts.  
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7 “Birth injury” lawsuits are among the most expensive of claims: the verdict for one  
8 plaintiff was \$212 million. “Birth injury” cases accounted for half of British National Health  
9 Service litigation costs in 2013, almost 20% of the total budget for maternity  
10 services.[40] Judgments in the tens of millions of dollars or pounds sterling are not rare, most of  
11 the money from settlements going to lawyers, experts, and court costs.[41] The current  
12 medicolegal approach is expensive, irrational and highly inefficient, and benefit to disabled  
13 children and their families is minimal.[41]  
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16 Obstetricians and surgeons are the specialty groups most often sued. [42] Three of four  
17 American obstetricians surveyed had had at least one professional liability claim, and most had  
18 had more than one. [43] The most frequent claims related to neurologically impaired  
19 infants. Many of the obstetricians polled had altered their practice in response, increasing the  
20 number of cesarean deliveries, decreasing their availability to high-risk patients, or decreasing  
21 the number of deliveries performed.  
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24 The same few individuals do much of the testifying for plaintiffs in “birth injury” cases.  
25 [44] Professional societies can censure members for spurious testimony, but have no power  
26 beyond withdrawing membership. Most are slow to do even that, fearing counter-litigation.  
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29 Plaintiff expert witnesses often testify that cesarean section, or cesarean section earlier,  
30 would have prevented CP in a child whose case is before the court. Such testimony is gross  
31 speculation because actions based upon electronic monitoring patterns have never been shown in  
32 evidence of good medical quality to prevent CP.  
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35 Litigation and fear of litigation have contributed to a high rate of cesarean deliveries  
36 often performed in the hope of preventing CP.[45] The consequence is that around the world  
37 each year hundreds of thousands of cesarean deliveries are performed needlessly, a baneful effect  
38 of bad science on health care decisions.  
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41 In summary [Figure], although EFM was introduced with the expectation that it would  
42 enable prevention of CP, decades of experience have shown that hope to be unfounded.  
43 Electronic monitoring *is*, however, linked with more cesarean sections, increasing risks and  
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3 costs. Since the introduction of electronic monitoring, litigation related to CP has become  
4 common and costly, and such litigation is associated with further increase in the cesarean section  
5 rate.  
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### 10 11 12 **Is there a way forward?** 13

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16 In an effort to reach a more evidence-based approach to the issues relating EFM, CP, and  
17 the rate of surgical births, a two-pronged but related approach might be considered. First there is  
18 a strong need for consensus among birth-related professions and the health service concerning  
19 the evidence. A major step in this direction would be a review by an impartial expert task force  
20 with focus on a narrow question: does use of EFM in labor reduce risk of CP? Such a task force  
21 would include evidence brought forward by all concerned parties and might be participated in  
22 and supported by national and professional health care-providing organizations, the trial bar, and  
23 consumer groups. An important first step, then, would be clear delineation of medical evidence  
24 of good quality [13] as it relates to whether EFM reduces risk of CP. For the related professional  
25 organizations to speak in a unified and clear voice on this issue would improve teaching and  
26 practice.  
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37 A second step in achieving a more rational approach to EFM, CP, and CS requires  
38 dealing with issues of litigation because these influence practitioner behavior. Testimony of  
39 expert witnesses often does not acknowledge best medical evidence, and unwarranted  
40 assumptions as to the ability of EFM-drive surgical deliveries are the major fault-finding tool in  
41 “birth injury” lawsuits. [36,40] A potential remedy is the ruling of the United States Supreme  
42 Court that expert witness testimony of poor scientific quality should be excluded from  
43 evidence. The Daubert standard is applied in US federal and in most state courts, and in many  
44 other countries including Britain. Daubert requires the dual standard of reliability and relevance  
45 to make expert testimony admissible. It is the responsibility of trial judges, often scientifically  
46 unschooled, to assess whether the experts’ reasoning and methodology are compatible with good  
47 science and applicable to the facts at issue. Complicating that task in birth injury cases is the fact  
48 that the current literature, the internet, and plaintiff expert testimony contain a great deal that is  
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3 erroneous and unscientific, and there are few clear and forceful statements from relevant  
4 professional societies that EFM does not enable prevention of CP.  
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8 A consensus document reviewing the relevant medical evidence would help to provide  
9 judges with contemporary evidence by which to decide Daubert challenges. Such challenges  
10 would occur one at a time, but once one plaintiff expert was excluded that precedent would beget  
11 others.  
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16 With decades of evidence that electronic monitoring is ineffective in prevention of  
17 cerebral palsy but contributes to a heightened rate of surgical births, that evidence should be  
18 made clear by relevant professional societies to medical practitioners and trainees, lawyers, and  
19 the public.  
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24 Wide application of the Daubert junk science doctrine to exclude as irrelevant testimony  
25 about EFM in CP lawsuits should be encouraged to aid in controlling the pressure to surgical  
26 intervention that litigation produces.  
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31 Our current high rate of cesarean births exceeds levels that benefit mothers or babies,  
32 increases costs, involves serious ethical issues, and fosters injustice. This is an important  
33 problem in current health care and a significant women's health issue. Any serious discussion of  
34 reducing our high rate of surgical deliveries should include consideration of the role of electronic  
35 fetal monitoring and related litigation in maintaining the high rate of cesarean births.  
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## Key messages

- Electronic fetal monitoring of the fetus in labor (EFM) was introduced with an expectation that it would enable caregivers to lower the rate of cerebral palsy, but randomized trials and time trends in population-based data establish that it has not done so.
- Cesarean deliveries, with their higher risks and costs in the current and subsequent pregnancies, are more frequent when EFM is used.
- Expert witness testimony in “birth injury” lawsuits that use of EFM can aid in prevention of cerebral palsy is bad science, and it is the cardinal driver of defensive obstetrics which influences physicians to perform yet more cesarean sections.
- Control of the high rate of cesarean sections will require addressing the contributions of EFM and related litigation, and will involve uniform application of the Daubert junk science doctrine to exclude specious testimony that EFM is relevant to prevention of cerebral palsy.

## FIGURE LEGEND

Expected vs. observed: relationship of electronic fetal monitoring in labor with increase, decrease, or no change in rate of cerebral palsy, cesarean section, risks to mothers, medical care costs and litigation related to cerebral palsy. Heavy connecting lines indicate evidence based on randomized clinical trials, lighter connecting lines indicate other sources of information (See text.)



### Contributors and sources

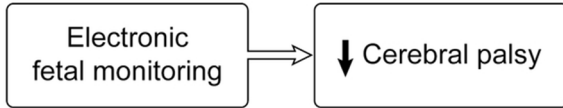
KBN is a child neurologist who has studied the etiology of congenital neurologic disorders and is an author of 84 papers on cerebral palsy. TSP is an attorney who has defended EFM-cerebral palsy cases and published papers on the subject, becoming convinced that the Daubert ruling is a potential remedy for this manifestation of junk science. Dwight Rouse is an academic obstetrician and maternal-fetal medicine physician who has led or participated in multiple NIH funded clinical trials including large trials of fetal monitoring.

The information on which this article is based is derived from published studies of good medical quality, centering on randomized clinical trials and on population-based controlled studies in human populations.

All have contributed to this paper and concur in its content. Dr. Nelson is guarantor.

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**Expected**



**Observed**

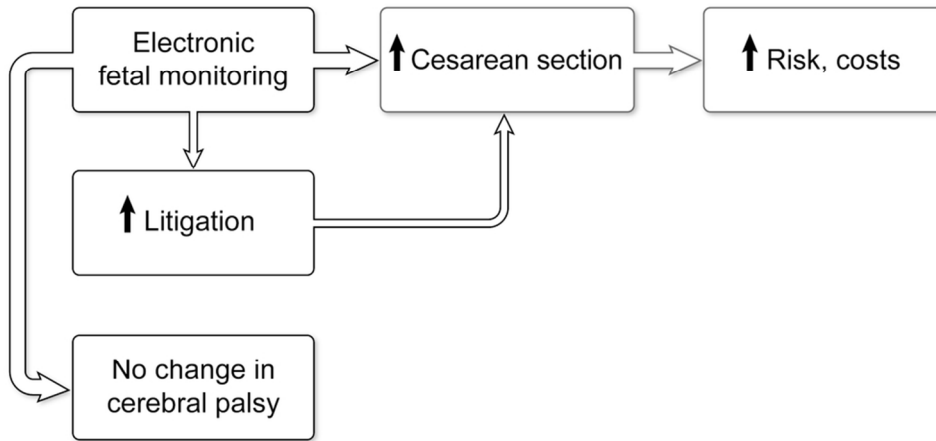


FIGURE LEGEND

Expected vs. observed: relationship of electronic fetal monitoring in labor with increase, decrease, or no change in rate of cerebral palsy, cesarean section, risks to mothers, medical care costs and litigation related to cerebral palsy. Heavy connecting lines indicate evidence based on randomized clinical trials, lighter connecting lines indicate other sources of information (See text.)

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