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Implementing and Infantile Spasms Guideline and Order Set

for Inpatient Healthcare Providers

Scholarly Paper Draft

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Background: In 2010, a Task Force of the Commission of Pediatrics developed a consensus document focused on the treatment of children with infantile spasms (Wilmshurst, Gaillard, Vinayan, Tsuchida, Plouin, Van Bogaert, & Nordli, 2015). This report suggested that evidence-based guidelines, or recommendations, for the management of infants with seizures are lacking and that evidence-based guidelines that clarify the optimal management of seizures in the infantile period are essential for all healthcare providers treating children with infantile spasms. Misdiagnosis of infantile spasms is potentially catastrophic, with unsuccessful treatment associated with devastating neurodevelopmental arrest and enduring epilepsy.

<u>Purpose:</u> The overall purpose of this QI project was to implement a guideline and electronic medical record order set for inpatient neurology providers caring for patients with infantile spasms, to determine provider knowledge of the evaluation and treatment of these patients prior to and after an educational intervention, and to determine provider adherence to the guidelines using an audit tool.

Methodology: This quality improvement project utilized a pre-post test design to determine the effect of the educational intervention, a guideline review meeting for inpatient healthcare providers, on provider knowledge. Provider knowledge on treating patients with infantile spasms was expected to increase after the educational meeting as evidenced by a pre-post knowledge test. In addition, a retrospective chart review was completed to evaluate provider adherence to evidence based practice care of patients with infantile spasms. It was hypothesized that provider adherence would increase after the implementation of the clinical intervention.

<u>Results</u>: The educational intervention of the guideline review meeting for inpatient neurology providers increased provider knowledge on current evidence based treatment for infants with

infantile spasms by a significant value. In addition, there a statistically significant increase in provider adherence to the implemented guideline.

Implications for Practice: Throughout the U.S. there is a lack of current evidence based guidelines available for providers in an inpatient setting for specific syndromes. This can lead to greater variability in treatment and higher risks for patients due to inaccurate management. As a result, health care providers may not be adequately prepared to care for vulnerable populations. Establishing current evidence based practice guidelines for inpatient specialty settings and choosing an effective implementation strategy to educate inpatient healthcare providers are first steps toward improving the care of vulnerable patient populations such as those with infantile spasms.

Introduction

Infantile spasms (IS), also known as West syndrome, is a severe epilepsy diagnosis defined by a triad infantile spasm seizures, abnormal rhythm on electroencephalogram (EEG) of hypsarrhythmia, and developmental regression (Wheless, Gibson, Rosbeck, Hardin, O'Dell, Whittemore, & Pellock, 2012). Misdiagnosis of infantile spasms is potentially catastrophic, with unsuccessful treatment associated with devastating neurodevelopmental arrest and continued epilepsy (Hussain, Lay, Cheng, Weng, Sankar, & Baca, 2017). IS therefore is the epitome of an epileptic encephalopathy where urgent and accurate diagnosis, evaluation, and treatment is essential, as poor developmental outcome is correlated with increased length of time to treatment and inadequate seizure control (Wheless et al., 2012).

Suspected cases of infantile spasms should be evaluated by acute care neurologists immediately so that a timely diagnosis can be established and correct treatment initiated. In 2010, a Task Force of the Commission of Pediatrics developed a consensus document focused on

the treatment of children with infantile spasms (Wilmshurst, Gaillard, Vinayan, Tsuchida, Plouin, Van Bogaert, & Nordli, 2015). This report suggested that evidence-based guidelines, or recommendations, for the management of infants with seizures are lacking and that evidence-based guidelines that clarify the optimal management of seizures in the infantile period are essential for all healthcare providers treating children with infantile spasms. Subsequently, there has been a significant focus on promoting adherence to evidence based evaluation and treatment guidelines aimed at healthcare providers treating patients with infantile spasms. Even with the exponential growth of publicly available clinical practice guidelines, providers often have difficulty in equipping themselves with the evidence necessary to provide the standard of care. As healthcare providers caring for patients with this devastating diagnosis, use of evidence based treatment recommendations to guide treatment is critical to patient safety.

For this reason, both an evidence based infantile spasms treatment guideline and electronic medical record order set were implemented on the inpatient neurology unit at Ann and Robert H. Lurie Children's Hospital.

Background and Significance

Wheless et al (2012) reports IS affects infants between 4 and 12 months old, accounts for as much as 5% of all childhood-onset epilepsy, and accounts for up to 20% of new-onset epilepsy cases in children under 2 years of age. IS is diagnosed in about 1.6–4.5/10,000 live births, about 1,200 infants diagnosed in the United States each year (Wheless et. al, 2012). Epilepsy and seizures may affect more than 3 million Americans of all ages, at an estimated annual cost of \$15.5 billion in direct and indirect costs (Kurth, Lewis, & Walker, 2010). Kurth, Lewis, & Walker (2010) also reported the population of patients with infantile spasms is reported to have the highest utilization of health care costs as compared to other epilepsy diagnoses and a large

societal burden. Overall patients with infantile spasms averaged about 10 physician visits a year, although only two of them were coded to epilepsy and some 24 diagnostic tests or procedures annually according to Kurth, Lewis, & Walker (2010). In addition, patients averaged more than 30 drug dispensing's yearly, about one-fourth of these being for anticonvulsant medications. In one study of epilepsy cost burden, Kurth, Lewis, & Walker (2010) reported that the small group of patients with infantile spasms had the highest mean values of almost all classes of healthcare resources utilized. This included outpatient physician visits, days hospitalized, diagnostic procedures, and medical supplies. At the Ann and Robert H. Lurie Children's Hospital, an average of 32.2 patients are admitted and diagnosed with infantile spasms each year, approximately 2.6 patients each month.

Despite distinctive presentation and a common procedure for confirming the diagnosis (EEG), the identification of infantile spasms can be challenging because spasms are often mistaken for gastroesophageal reflux or "normal" infant movements (Hussain, Lay, Cheng, Weng, Sankar, & Baca, 2017). The diagnostic challenge of infantile spasms is the urgency of treatment, as even a brief delay (as little as one week) has been associated with poor long-term neurodevelopmental outcomes (Hussain et. al, 2017). Hussain et. al (2017) also reports that approximately 30% of children with infantile spasms, those treated successfully and those with "mild" underlying causes of infantile spasms, can become developmentally normal and seizure-free. However, due to to either treatment delay and/or severe underlying causes of infantile spasms, the majority of children experience continued seizures and/or poor cognitive outcomes, and nearly 10% will die by their second birthday.

After seizures are treated, the infant's brain has a longer period to recover and gain developmental ground that may have been lost while the seizures occurred (Saemundsen,

Ludvigsson, & Rafnsson, 2008). Thus, a thorough etiological work up and immediate evidence based treatment with medication is essential to improving neurological and developmental outcomes. In addition, monitoring and follow up is essential for patients with IS, as over 40% of patients do not respond to the first treatment therapy (Saemundsen, Ludvigsson, & Rafnsson, 2008).

Guidelines for the evaluation, treatment, monitoring, and follow up of patients with infantile spasms are currently available for utilization by pediatric epilepsy providers.

Problematically, a multitude of pediatric epilepsy providers are not utilizing or adhering to the present guidelines established by several consensus reports for management of infantile spasms.

The primary benefit of the quality improvement project is improving quality of care by increasing provider adherence to a standardized guideline on the evaluation and treatment of patients with new onset infantile spasms.

Review of Literature

A search was conducted to evaluate effective guideline implementation strategies for inpatient units using PubMed, the Cochrane Library database, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and EMBASE. An initial search was conducted in October 2017, and the publication time frame included studies published between January 2008 and October 2017. MeSH terms utilized during the search included 'implementation,' 'strategies,' 'inpatient,' and 'guideline.' A total of 325 titles were identified and reviewed. Of these, 108 studies were considered to be relevant with 14 total studies meeting the inclusion and exclusion criteria. The inclusion criteria for the review were articles written or translated in the English language, included at least one guideline implementation strategy, and implementation strategies

targeted at inpatient healthcare providers or units. Exclusion criteria included those articles that focused solely on barriers to implementation, articles not written or translated in the English language, and articles focused on any setting other than an inpatient hospital unit.

Results showed that studies on implementation strategies limited due to the inpatient setting, therefore several health care specialties were included in the literature review. All 14 of the studies reviewed evaluated implementation strategies to improve provider compliance and adherence to a policy, guideline, or protocol. The Mazza et al. (2013) taxonomy was used the classify all strategies used in the reviewed studies as either professional, provider oriented, or structural.

According to Mazza et al. (2013), professional interventions included subcategories of distribution of educational materials (print or electronic), educational meetings, and reminders. Several studies included more than one professional intervention. Provider oriented interventions included clinical multidisciplinary teams, and case discussion. A systematic review by Forsetlund et al. (2009) evaluated several studies with the interventions of educational meetings alone, educational workshops, and both team meetings and workshops together. Forstlund et. al (2009) was the only study that focused solely on multidisciplinary teams. Forsetlund et al. (2009) concluded that interactive workshops alone or with other interventions are likely to improve the professional practice and health care outcomes compared with didactic lectures alone. In addition, the other six systematic reviews included studies with a provider oriented intervention concluding an overall improvement of adherence in each review for provider oriented interventions. Structural interventions include changes in medical records systems and presence and of quality monitoring mechanisms. There was no study that evaluated the efficacy of this single intervention alone. However, a systematic review by Suman et al. (2016) investigated the

effectiveness of multifaceted implementation strategies including quality monitoring mechanisms compared to minimal, single, or no implementation strategy for the implementation of pain guidelines in health care. This review concluded a combination of strategies for the implementation pain guidelines in health care did not significantly improve professional behavior outcomes compared to minimal, single, or no implementation strategy.

Several strategies have been used to implement guidelines, however this review determined that overall effectiveness of one strategy over another is unreliable. There remains a lack of knowledge in the most effective strategies implementing guidelines in different practice settings.

This review revealed that guidelines are most often implemented using educational approaches (professional intervention) such as group meetings or conferences as reported by Gigliardi et al., 2015. In comparison with more complex interventions such as organizational, financial or regulatory strategies, educational approaches were identified as less resource intensive and more easily employed by guideline developers or implementers with limited funding.

Of 14 eligible studies, all seven systematic reviews were determined to have a low risk of bias. The other seven studies were labeled with a moderate risk of bias, and for this reason, findings must be taken with some restraint. In addition, publication bias may have influenced the number and type of positive studies that were evaluated. Effective implementation strategies are essential for cultivating the uptake and use of clinical practice guidelines by the proposed guideline audience. Rycroft et al. (2013) suggests, successful implementation of evidence into practice is a planned facilitated process involving interplay between individuals, evidence, and

context to promote evidence-informed practice. In regards to an infantile spasms guideline implementation for an inpatient neurology unit, it was concluded that a tailored approach on implementation was necessary.

Purpose

The overall purpose of this QI project was to implement a guideline and electronic medical record order set for inpatient neurology providers caring for patients with infantile spasms, to determine provider knowledge of the evaluation and treatment of these patients prior to and after an educational intervention, and determine provider adherence to the guidelines using an audit tool.

Aims

- I. To determine baseline knowledge of inpatient neurology providers on current infantile spasms guidelines. To determine if an in person guideline review meeting for inpatient neurology providers will increase provider knowledge on current infantile spasms guidelines.
- II. To determine if guideline implementation increases provider guideline adherence through a retrospective chart review audit evaluation utilizing a bundle tool 12 weeks after guideline implementation.

Methods

Study Design

This quality improvement project was approved by the Institutional Review Board (IRB)

at Johns Hopkins University on 05/31/2018 as an exempt non-human subject study.

This project utilized a pre-post test design to determine the effect of the educational intervention, a guideline review meeting for inpatient healthcare providers. Provider knowledge on treating patients with infantile spasms was expected to increase after the educational meeting as evidenced by a pre-post knowledge test.

In addition, a retrospective chart review was completed to evaluate provider adherence to evidence based practice care of patients with infantile spasms. It was hypothesized that provider adherence would increase after the implementation of the clinical intervention.

Setting and Sample

This QI project for both the educational and clinical intervention was completed on the neurology inpatient floor at Lurie Children's Hospital, comprised of 34 inpatient beds. All inpatient healthcare providers recruited for the educational intervention are routinely assigned to the care of patients with infantile spasms on the neurology inpatient floor.

Educational Intervention

A convenience sample of these inpatient healthcare providers responsible for the care of patients with infantile spasms were included in the educational intervention. Specific inclusion criteria were all inpatient healthcare providers with capabilities to enter electronic medical record orders for the management of patients with infantile spasms on the inpatient floor. Medical students were excluded along with members of the multidisciplinary team who had taken part in literature review or guideline/order set creation. No further inpatient provider demographic data was collected.

Clinical Intervention

Retrospective chart reviews were completed for 16 patients presenting with infantile spasms on the Lurie Children's inpatient neurology floor prior to and after the clinical implementation. Specific inclusion criteria were patients presenting for initial diagnosis of infantile spasms under the age of 24 months. Patients excluded were those who were previously treated by an outside provider for infantile spasms and those involved in any medication research trials. No inpatient provider demographic data was collected.

Measurement Instruments

A multi-disciplinary team consisting of a registered nurse, an advanced practice nurse, an inpatient pharmacist, two inpatient Epic electronic medical record specialists, and two epilepsy attending physicians convened weekly over from 03/07/2018-07/11/2018 with a goal of generating a new inpatient inpatient guideline and electronic medical record (EMR) order set for the evaluation and treatment of patients with infantile spasms.

During the weekly meetings, this multidisciplinary team reviewed several published evidence based recommendations in the treatment and management of children with infantile spasms to establish a new guidelines and electronic medical record order set including the 2004 American Academy of Neurology/Child Neurology Society Practice Parameter on the Treatment of Infantile Spasms, the 2012 Evidence-Based Guideline Update on the Medical Treatment of Infantile Spasms, the 2010 Consensus Report of the U.S. Infantile Spasms Working Group, the 2013 Cochrane Review of the Treatment of Infantile Spasms, and the 2015 International League Against Epilepsy (ILAE) Summary of Recommendations for the Management of Infantile Seizures. In addition, three other inpatient infantile spasms guidelines were reviewed that were requested by the multidisciplinary team from other children's hospitals in the United States

including Children's Hospital of Colorado, Nationwide Children's Hospital, and Children's Hospital of Philadelphia. After the inpatient guideline and electronic medical record order set was completed by the multidisciplinary team, a pre-post knowledge test was generated for the educational intervention with 12 questions pertaining to topics in the guideline including presentation and diagnosis, treatment, evaluation, and monitoring of patients with infantile spasms.

In addition, to measure provider adherence to the new guideline and order set, an audit tool was generated by the multidisciplinary team titled the "Infantile Spasms Bundle Tool" (Figure 2). The "Infantile Spasms Bundle Tool" is a 7-item checklist of essential orders/actions that inpatient healthcare providers should carry out with each patient. Both a pre-post knowledge test and audit tool were selected by the inpatient team after a thorough review of best methods to elicit practice change from healthcare providers. According to Titler (2008) performance gap assessment (PGA) and audit and feedback have dependably demonstrated a positive effect on changing practice behavior of providers. Titler (2018) further suggests that auditing and feedback allows staff to understand how their efforts to improve care and patient outcomes are progressing throughout the process of implementation, in this case, of guideline adherence.

Intervention

Educational Intervention

A 45 minute educational meeting (educational intervention) was held with all recruited inpatient healthcare providers to review the infantile spasms guideline and EMR order set prior to clinical implementation. This meeting reviewed both the infantile spasms guideline and the

EMR order set with use of a PowerPoint presentation and EpicPlay Module. Participants were solicited to the in-person meeting by use of email reminders.

Clinical Intervention

On 08/01/2018, an electronic infantile spasms guideline and order set was made available on the Epic under the "Policies and Protocols" link. Reminder emails were sent at bi-weekly intervals to all inpatient healthcare providers after the clinical intervention.

Data Collection and Analysis

Educational Intervention

Data was collected prior to and after the 45 minute educational intervention using a novel 12 question pre-post knowledge test produced by the co-investigator and multidisciplinary team. Overall, 24 participants were evaluated with the pre-post knowledge test, representing > 80% of the inpatient neurology team responsible for the care of patients with infantile spasms. Pre-tests were numbered prior to dissemination. Providers taking the test were instructed to write their assigned pre-test number on their post-test. After the post-test, hard copy scores were converted into an Excel file and stored on the secured JHU cloud drive. Data was then transitioned and analyzed using SPSS version 25. A paired t-test (alpha=0.05) was used to evaluate change in provider knowledge. In addition, a paired t-test (alpha=0.05) was used to evaluate change in provider knowledge by specific subtopics on the test including clinical presentation and diagnosis, evaluation, treatment, and monitoring.

Clinical Intervention

To evaluate inpatient provider adherence to the clinical intervention, a retrospective chart review was completed fo 16 patients prior to and after the clinical intervention. Data was collected with use of the Infantile Spasms Bundle Tool.

All patients presenting with infantile spasms prior to the clinical intervention during the time frame period of 08/01/2013 to 07/31/2018 were identified by Lurie Children's Hospital Data Access Requests Department. A total of 86 patients met inclusion criteria, and patients were randomized and sent in an Excel spreadsheet format. Patients 1-16 were selected for chart review.

Data from 16 patients presenting with infantile spasms meeting inclusion criteria after guideline and order set implementation from the time frame period of 08/01/2018 to 03/01/2019 were selected for chart review.

Data was collected utilizing the 7-question Infantile Spasms Bundle Tool and recorded in an Excel file on the co-investigator's encrypted computer. It was then stored on the secured JHU cloud drive. Data was transitioned and analyzed using SPSS version 25.

This data to evaluate provider adherence was analyzed using an independent t-test (alpha=0.05) in SPSS version 25.

Results

Educational Intervention-Provider Knowledge Outcomes

The educational intervention of guideline and order set review meeting for inpatient neurology providers increased provider knowledge on current evidence based treatment for infants with infantile spasms by a significant value. 24 inpatient healthcare providers including

advanced practice nurses (n=3), resident physicians (n=10), fellow physicians (n=5), and attending physicians (n=6) participated in the educational intervention of the guideline and order set review, and all participants completed the 12 question pre-post questionnaire. No further demographic information was collected to describe the providers. Questionnaire scores increased significantly (p < 0.001) after the educational intervention (Table 1) with a lower pretest raw score (mean \pm SD: 7.33 \pm 3.595) as compared to higher post-test raw score (mean \pm SD: 10.96 \pm .999). Participant scores were also evaluated by question topics including presentation and clinical diagnosis, evaluation, treatment, and monitoring. Questionnaire scores were statistically increased after the educational intervention in all topic categories (Table 1). The most notable low pre-test scores were in the evaluation topics (mean pre-test raw score: 6.04).

Clinical Intervention-Guideline Adherence Outcomes

Data from 16 patients presenting with infantile spasms meeting inclusion criteria after guideline and order set implementation from the time frame period of 08/01/2018 to 03/01/2019 was collected and documented utilizing the 7-question Infantile Spasms Bundle Tool. This data was analyzed using an independent t-test with data from 16 patients (selected from randomized from pool of 86 patients) from the time frame period of 08/01/2013 to 07/31/2018 prior to guideline and order set implementation (Table 2). Sample size was increased from 12 patients to 16 patients due to additional patients with infantile spasms meeting inclusion criteria after guideline implementation.

There overall was a statistically significant increase in provider adherence to the implemented guideline as shown in Table 2. Total provider adherence raw score prior to guideline implementation using the Infantile Spasm Bundle Tool completion was 4.57. Total

provider adherence score post-intervention was 6.86, p-value: <0.025). However, there were 3 questions on the Infantile Spasms Bundle Tool that did not show a statistically significant change (See Table 2). Of note, all of the questions not reported to have a statistically significant change had a pre-intervention score of >94%. All other questions reported an increased statistical significance for increased provider adherence to implemented guideline and order set.

Discussion

These findings suggest that after the educational intervention of an in-person meeting with inpatient healthcare providers to review the infantile spasms guideline and EMR order set, inpatient healthcare providers were significantly more knowledgeable on evidence based medical care of patients with infantile spasms. Strengths that led to success of an increase in provider knowledge included a tailored approach to guideline implementation as recommended by Mazza et al. (2013), where professional interventions that were highly successful included subcategories of distribution of educational materials (print or electronic), educational meetings, and reminders.

In addition, these findings suggest that after the educational meeting when the infantile spasms guideline and EMR order set were available for provider use, that provider adherence to the guideline increased. The retrospective chart review using the Infantile Spasms Bundle Tool indicated an increased adherence to evidence based treatment. Titler (2008) reported audit and feedback have dependably demonstrated a positive effect on changing practice behavior of providers. This process may allow staff to understand how their efforts to improve care and patient outcomes through continued auditing and patient outcome data collection after the process of implementation.

Limitations

A noteworthy limitation of this intervention for both aims is the small sample size. In addition, no comparison group was present to further identify if the intervention of the in-person educational meeting with pre-post knowledge test was superior to other methods of guideline establishment. There was also no comparison group in using the Infantile Spasms Bundle Tool to evaluate provider adherence as this center was the only center the infantile spasms guideline and order set was implemented, and there were no comparable outside studies. Future studies of guideline implementation could assess different strategies of implementation across several centers to evaluate which strategies are most effective in eliciting provider adherence to inpatient guidelines.

Another limitation of this project was the production of an investigator pre-post knowledge test to evaluate provider knowledge increase after implementation. In addition, there was a lack of established tools to evaluate provider adherence to newly implemented guidelines other than obtaining utilization information, or how many times an EMR order set is used since implementation. This study investigated adherence through chart review of every patient meeting inclusion criteria with the use of the bundle tool instead of utilization information to further clarify if newly established guidelines were adhered to.

Dissemination

The results of this project will be first discussed at host site, the Ann and Robert H. Lurie Children's Hospital of Chicago by means of the advanced practice nursing grand rounds series.

Following, an abstract will be submitted to the Association of Child Neurology Nurses (ACNN) 2019 conference and the manuscript will be submitted for publication by the Journal of Neuroscience Nursing (JNN).

Conclusion

This QI project demonstrated that an educational intervention with an in-person meeting was successful in increasing inpatient healthcare provider knowledge on a newly implemented guideline on the evidence based treatment of patients with infantile spasms. Guideline implementation for inpatient healthcare providers on the treatment of vulnerable populations may be useful in providing evidence based care to a larger percentage of patients with time sensitive diagnoses. In this case, a thorough etiological work up and immediate evidence based treatment with medication is essential to improving neurological and developmental outcomes in patients with infantile spasms.

Adherence to the newly established guideline also increased as evidenced through auditing charts with the Infantile Spasms Bundle Tool. Adherence to the newly established guideline may be due to educational intervention, but also due to the available EMR order set tool. In future studies, an evaluation of implementation strategies in implementing guidelines may indicate which strategies are more successful for provider adherence and knowledge gain. In addition, the use of information technology tools like the EMR order set could be evaluated themselves versus guideline alone in evaluating provider adherence to guidelines.

Throughout the U.S. there is a lack of current evidence based guidelines available for providers in an inpatient setting for specific syndromes. This can lead to greater variability in treatment and higher risks for patients due to inaccurate management. As a result, health care providers may not be adequately prepared to care for vulnerable populations. Establishing current evidence based practice guidelines for inpatient specialty settings and choosing an

effective implementation strategy to educate inpatient healthcare providers are first steps toward improving the care of vulnerable patient populations such as those with infantile spasms.

Tables and Figures

Figure 1. Infantile Spasms Bundle Tool

Infantile Spasms Bundle Tool				
Question	Result			
1. Were all infantile spasms imaging tests ordered for this patient?	Y/N			
2. Were all infantile spasms metabolic tests ordered for this patient?	Y/N			
3. Was there a medication dosing schedule listed on this patient's discharge instructions?	Y/N			
4. Were all infantile spasms genetic tests ordered for this patient?	Y/N			
5. Was this patient treated with an FDA approved medication for the treatment of infantile spasms?	Y/N			
6. Was a video electroencephalogram completed for this patient?	Y/N			
7. Was there an appointment scheduled for this patient for a repeat video electroencephalogram within 14-21 days post treatment?	Y/N			
TOTAL SCORE: X out of 7				
Note: This tool was generated by investigator for use in auditing provider adherence to guideline and order set implementation by evaluating variance in treatment.				

Table 1				
Infantile Spasms Guideline Provider Questionnaire Scores-Total and Topic Subset Scores*,				
N=24				
	Pre-Intervention	<u>Post</u>		

<u>Intervention</u>					
Outcome	Mean	SD	Mean	SD	p-value ^b
Total Score ^a Questions 1-3: Presentation &	7.33	3.59	10.96	0.99	.000
Diagnosis ^a	8.67	2.20	11.52	1.05	.000
Questions 4-6: Evaluation ^a	6.04	3.37	10.2	0.89	.000
Questions 7-9: Treatment ^a	8.2	2.52	11.52	0.97	.000
Questions 10-12: Monitoring ^a	6.72	2.79	10.56	2.34	.000

Note: *Mean difference in all pre-post test scores were analyzed using paired-t test.

Table 2.

Pre-Post Clinical Intervention Adherence Scores Using 7-Question Infantile Spasms Bundle Tool

^a Raw score from 12 question investigator generated questionnaire. ^b Statistical significance when p <0.05.

Question	Pre Intervention Bundle Raw Score Mean (out of 16)	Post Intervention Bundle Raw Score Mean (out of 16)	p value ^b
1. Were all infantile spasms imaging tests ordered for this patient?	7	7	NS°
2. Were all infantile spasms metabolic tests ordered for this patient?	2.66	6.51	0.012
3. Was there a medication dosing schedule listed on this patient's discharge instructions?	3.01	7	0.000
4. Were all infantile spasms genetic tests ordered for this patient?	6.58	7	NS ^c
5. Was this patient treated with an FDA approved medication for the treatment of infantile spasms?	2.66	6.51	0.000
6. Was a video electroencephalogram completed for this patient?	6.58	7	NS ^c
7. Was there an appointment scheduled for this patient for a repeat video electroencephalogram within 14-21 days post treatment?	3.50	7	0.000
Total Adherence Score Mean (out of 16) Total Adherence Score (Percentage)	4.57 65.3	6.86 98	0.025

Note: *Mean difference in all pre-post clinical intervention scores were analyzed using independent samples -t test. A Mean score derived from 16 patients meeting inclusion criteria. Statistical significance when p < 0.05. Not Significant

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