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Provisional Section on Minority Health, Equity, and Inclusion Program

1. Prevalence of HPV infection in the United States: A Comparison of HPV Infection Trends Pre and Post-HPV Vaccine Implementation

Patrick Fueta, MD, MPH, Onyema Chido-Amajuoyi, MD, MPH

Background

Human papilloma virus (HPV) is the most common sexually transmitted infection in the US, with an annual incidence rate of approximately 14 million people. The HPV vaccine has been demonstrated to be highly effective in the prevention of HPV infection and HPV associated diseases. This study aims to evaluate the impact of HPV vaccine on the prevalence of HPV infection in the US.

Methods

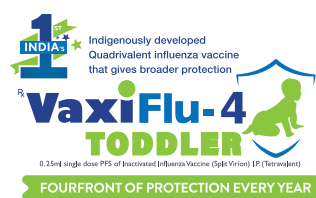
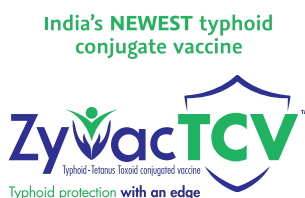
- The investigators conducted secondary data analysis of the National Health and Education Survey (NHANES) for trends in HPV infection from 2003 to 2016.
- Analysis were grouped into a pre-HPV vaccine implementation (2003 – 2006) cohort including 4064 females, aged 18 – 59 years; and a post-HPV vaccine implementation (2007 – 2016) cohort which included 10718 females, aged 18 – 59 years.
- Further analysis of HPV infection prevalence, pre and post HPV vaccine implementation, stratified by sociodemographic characteristics were conducted.

Results

- The prevalence of HPV infection prior to HPV vaccine implementation was 43.98% (95 CI 42.71% - 46.58%) compared to 40.55% (95 C.I 40.55% - 40.56%) in the post-HPV vaccine implementation era. Among females with HPV infections in the post-HPV vaccine implementation cohort 82.6% (95% CI 80.41% - 83.42%) were unvaccinated.
- In both cohorts, black females had a significantly higher prevalence of HPV with a prevalence rate of 18.56% (95% CI 18.23% - 20.56%) in the pre-HPV vaccine implementation cohort, and 15.61% (95% CI 14.82 – 19.4%) in the post-HPV vaccine implementation cohort.
- Females with less than high school education had a higher prevalence of HPV in the pre and post- HPV vaccine implementation cohorts with prevalence rates of 25.77% (95% CI 23.44% – 28.72%) and 24.96% (95% CI 23.41% - 25.67%) respectively.

Conclusions

The results suggest that HPV infection prevalence has declined since the implementation of HPV vaccine to US national immunization program. Our findings highlight disparities in HPV infection prevalence by race and educational status, and these patterns are in keeping with HPV associated disease such as warts and HPV-associated cancers.



2. Meeting the need for Primary Care and Academic Pediatric Clinical Experiences: An innovative academic practice partnership

Stacey Wall, DNP, APRN, CPNP-AC/PC, Maya Bunik, MD, MPH

Background

A primary care practice within a large academic pediatric center identified the need to expand access to after-hours care for the underserved pediatric population in the community. The clinic serves approximately 14,000 pediatric patients aged 0-18 years with over 30,000 visits annually. Over 85% of the clinic patients have public health insurance. State wide, approximately 16% of children live in poverty and 46% are on Medicaid. The minority population is 43% statewide and 77% in counties surrounding the clinic. The partnering academic institution identified the need for additional clinical education experiences for pediatric nurse practitioner (PNP) students. Nationally, academic programs are challenged to find quality clinical placements due to lack of preceptors. Nursing organizations support partnerships between academic programs and clinical practices to meet student educational needs (American Association of College of Nursing white paper, 2015, Manatt Report, 2016).

Objectives

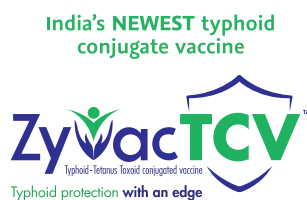
- Develop a partnership between the primary care pediatric practice and graduate nursing program to increase access to primary care for the underserved pediatric population in the community and expand clinical education for PNP students.

Design/Methods

- Key stakeholders from the primary care clinic and graduate nursing program developed an innovative practice model to expand clinic hours and provide clinical education opportunities for PNP students.
- Stakeholders included representatives from hospital administration, advanced practice and nursing leadership, the faculty medical practice group, and graduate nursing program.
- The innovative model included development of new PNP faculty positions to expand clinic hours and precept PNP students.
- The stakeholder group collaborated throughout the process of interviewing, hiring, and orienting the PNP faculty.

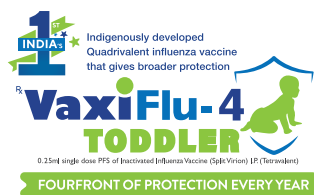
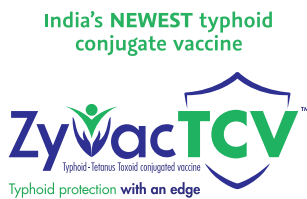
Results

- New PNP Faculty positions were created within the nursing program in Fall 2016 as part-time positions with clinical and teaching responsibilities.
- The model includes two part-time and one prn PNP Faculty who see patients and precept PNP students during expanded evening clinic hours.
- The evening clinic staffing model allows these PNP Faculty work side by side with the established clinic Faculty providers, and provides opportunities for physician trainees PNP students to learn together.
- The model was fully staffed in July 2018 and has demonstrated an increase in patient encounters, income, and PNP student clinical rotations.



Conclusion

This innovative model demonstrated the value of collaboration between a graduate nursing program and pediatric primary care clinic. This academic-practice partnership improved access to primary care for the underserved pediatric population in the community and expanded clinical education opportunities for PNP students.



3. Vision Screening by Primary Care Pediatricians of Minority Children with Neurodevelopmental Disorders

Jamie Sklar, MD

Background

The AAP/Bright Futures recommendations are that vision screening should be done at least every 1-2 years for children between the ages of 3 and 17 years old. Vision can affect all aspects of functioning and may be particularly problematic in children with developmental delays (DD). Children with DD may not be able to articulate visual concerns, so regular screening and evaluation of visual acuity is essential. At this time, it is unclear to what extent children with DD receive vision screening by their primary care provider (PCP). Since minority race populations are already at risk for healthcare disparities, this research focuses on non-white populations.

Objectives

The objective of this study was to examine whether minority children are less likely to have vision screening done by their PCP and to what extent the presence of one or more developmental disorders put minority children at greater risk for not having their vision screened by their PCP.

Methods

- A secondary analysis of the 2016-2017 National Survey of Children's Health, a nationally representative survey of children in the US.
- Analysis focused on children ages 6-17 who were not identified by their parent or caregiver as having non-correctable vision problems. Logistic regressions controlling for child age, sex, family income, insurance, highest adult education in household, and medical home were run to calculate adjusted Odds Ratios (aOR) and Risk Differences (RD) for PCP vision testing.
- A regression was run for differences in PCP vision testing rates between white and non-white populations, and a series of regressions were run for exclusively minority populations for associations between specific developmental conditions and PCP vision testing.

Results

- After adjusting for demographics, minority children were found to be slightly more likely to have had vision screening by PCP, compared to the white population (aOR: 1.11, 95% CI: 1.01-1.23). However, within the subset of minority children, those with DD, Learning Disability (LD), and Autism Spectrum Disorder (ASD) were significantly less likely to have had vision screened by PCP compared to the general non-white population.
- Likelihood of vision screening by PCP was 11.7% lower for DD, 10.9% lower for LD, and 18.1% lower for ASD.
- Children with any neurodevelopmental disorder were less likely to have PCP vision testing; PCP vision testing rates were even lower for children with a moderate/severe developmental condition. (All P values <0.05).

Conclusion

After adjustment, minority children are more likely to have vision testing by their PCP. However, among minority children, those with neurodevelopmental disabilities were less likely to be tested.



4. A stroke that didn't quite fit the mould

Aishwarya Pareek, MD, Timothy Lotze, MD

Introduction

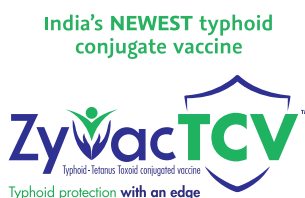
Cladophialophora bantiana is a rare, but well-recognized neurotropic fungus that affects immunocompetent hosts with significant morbidity and mortality. Infections due to C. bantiana are difficult to diagnose due to their ability to clinically and radiologically mimic primary neurologic etiologies. Presented here is a case of a 9-year-old, previously healthy female with two recent admissions for presumed diagnosis of ADEM who re-presented with worsened headache, facial asymmetry, and ataxic gait and imaging concerning for stroke.

Case Report

- The patient initially presented two months prior with URI symptoms, acute ataxia, facial asymmetry and abnormal eye movements. Her MRI revealed brainstem and cerebellar lesions concerning for ADEM.
- It also showed lesions extending to the 4th ventricle with mass effect, a nonspecific finding atypical for demyelinating processes.
- Given negative infectious and rheumatologic work up, she was treated with IVIG and steroids and demonstrated considerable clinical improvement during her first two admissions.
- Four days after her second discharge, she presented with symptom relapse and severe occipital headache.
- On examination, she was alert and oriented, but ill-appearing with speech barely audible.
- Neurologic exam showed bilateral right-beating nystagmus, left eye in the “down and out” position, and asymmetric smile. She displayed generalized weakness, though sensation remained intact.
- Repeat MRI revealed worsening brainstem and cerebellar lesions, a new pontine diffusion restriction concerning for ischemic infarction, and acute communicating hydrocephalus requiring emergent EVD placement.
- These new findings broadened the differential to include undiagnosed infection, demyelinating disorders, and primary or secondary vasculopathy, though work up was unrevealing.
- Ultimately, brain biopsy was performed with visualization of gross intraventricular pus and black, web-like material.
- Microscopic analysis showed branching hyphae, later identified as Cladophialophora bantiana.

Conclusion

Treatment was initiated with systemic and intraventricular antifungals. She was downgraded to a non-ICU setting with an EVD, but soon returned to the PICU with acute respiratory distress and subsequent cardiac arrest of unknown cause, necessitating 45 minutes of resuscitation interventions. She continued to grow fungus in her CSF for 3 months after treatment initiation. Her clinical status is slowly improving and she currently remains in the PICU with tracheostomy, gastric tube, and EVD awaiting transfer for inpatient rehabilitation. Discussion: C. bantiana, and other fungal infections should remain on the differential for patients with relapsing neurologic symptoms when peripheral studies fail to yield a diagnosis, particularly if imaging is atypical for primary neurologic etiologies. Inter-specialty collaboration is crucial for diagnosis of this pathogen, as it may present with nonspecific clinical and radiographic findings. Management in an ICU setting is appropriate for patients with this and similar infections, as aggressive, prolonged antifungal therapy is required, and acute decompensation and death are possible even after appropriate treatment initiation.



5. Ascites of unknown origin

Evan Ball, MD, Vickren Pillay, MD

Case presentation

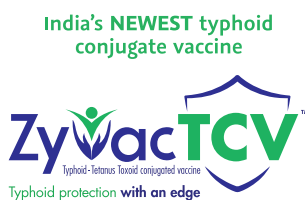
A 4 year-old female with a history of Dandy-Walker Syndrome with VPS, repaired VSD, chromosome 8/9/ partial trisomy, and developmental delay was admitted to PICU for sepsis. She had a prodrome of diarrhea, respiratory distress and fever prior to admission. Her presenting labs were remarkable for leukocytosis with hemoconcentration, metabolic acidosis, uremia, and elevated transaminases in the setting of low blood pressure consistent with septic shock. Vasopressor support was initiated along with aggressive IV fluid resuscitation as well as broad spectrum antibiotics. Initial workup was only notable for right sided suprahilar infiltrate. Blood cultures grew MSSA and patient was transitioned from vancomycin and rocephin to nafcillin. She improved hemodynamically, but ascites was noted on hospital day 12 (HD 12).

Investigations

Initial ultrasound of the abdomen showed minimal ascites but her abdominal distension worsened which prompted CT scan of abdomen which revealed massive ascites but no hepatobiliary abnormality, or intra-abdominal masses. Workup was negative for liver disease, renal disease or hypoproteinemic state as a cause for her ascites, she had normal LDH and uric acid levels. Examination of ascites fluid was consistent with transudative process. A peritoneal drain was placed by interventional radiology and patient continued to have significant ascites (700 ml initially, 2200 ml total). Neurosurgery was consulted for possible externalization of shunt, due to concern for possibly ascites related to VP shunt but patient was ultimately transferred to outside facility for further workup of possibly non-cirrhotic portal-hypertension. VPS externalized on HD 19, with resolution of her ascites and ultimately, ventriculoatrial shunt revision was performed on HD 33. Her condition improved and she was able to be discharged 35 days after presentation. CSF ascites is considered to be a rare complication of VP shunts. It is most commonly secondary to infection (either CNS or peritoneal) or an abdominal pathology. In this patient, sterile ascites and normal cell counts on CSF were consistent with sterile ascites. Mechanisms underlying this are poorly understood, but inflammatory reactions likely play a role, whether by infection or malignancy and may impair absorption or increase oncotic forces within the peritoneum.

Conclusion

Ascites as a complication of a VP shunt is a diagnosis of exclusion and shunt revision should be considered in patients who have been adequately treated for potential infectious insults.



6. Adverse Childhood Experiences (ACEs) Screening in the Pediatric Intensive Care Unit

Jordan Derck, MD, Tessie October, MD MPH

Purpose

Adverse Childhood Experiences (ACEs), defined as strong, frequent or prolonged events that cause an upregulation of the stress response during childhood, have been associated with increased morbidity and mortality both in childhood and later in life. The ACEs screening tool is an instrument widely used to measure toxic stressors that a child may experience, ranging from physical abuse to parental separation. Toxic stress can cause neuroendocrine dysregulation leading to an altered response to illness. These stress-related outcomes have been demonstrated in a number of diseases that often present themselves in the critical care setting. To date, there has been no ACEs screening described in the pediatric intensive care unit (PICU). In this study we evaluated the feasibility of obtaining ACEs screening in the PICU.

Methods

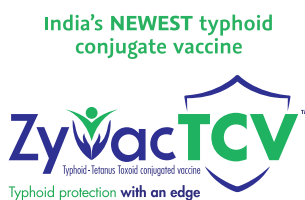
- The investigators conducted a cross-sectional prospective study in a single, quaternary institution.
- The PICU social workers adapted their routine psychosocial intake screen to include ACEs screening as standard of care for all patients.
- Social workers introduced the screening tool to families at the patient bedside, and families were asked to complete a paper version of the screen in the absence of the social worker to promote anonymity.
- Social workers were available to families for further discussion about topics on the form as needed.
- Only one parent per patient completed ACE screening.

Results

- To date, 25 patient families have been approached for screening and 17 (68%) have agreed to participate.
- Patients were all English speaking, primarily African American or black (58%) and insured through Medicaid (58%).
- Of those with completed ACEs screens, 5 patients, (29%) had an ACE score of 2 or greater.
- Data from the National Survey of Child Health (NSCH) demonstrates that children living the Washington, D.C. metro area have a population prevalence of 21% among those with an ACEs score ≥ 2 .

Conclusion

Based on preliminary sampling, it is feasible to collect ACEs scores as standard of care for all patient families approached by social workers in the critical care setting. Continued collection of ACEs screening data will enable further characterization of the effects of ACEs on critically ill children, ultimately creating a better understanding of these patient's medical and social needs.



7. A multidisciplinary staffing task force: highlighting the dynamic role of advanced practice providers

Sarah Zachary, MS, PA-C, Paul Checchia, MD

Recently, Texas Children's Hospital underwent a significant expansion. In preparation, a multidisciplinary Staffing Task Force was formed to address the unique demands of the growing Cardiac Intensive Care Unit (CICU). This group was challenged to address coverage as the CICU grew from 36 beds on 2 floors to 48 beds separated into 4 units spread across 3 floors.

Program Goals

This task force was comprised of attending physicians, fellows from Cardiology and Critical Care, and Advanced Practice Providers (APPs). The group operated on the premise of previously agreed upon ground rules guiding the discussions. Shared goals were aimed at delivering high quality and safe care to our critically and chronically ill children, balancing clinical and academic interests, protecting work-life balance to reduce burnout, and creating a work environment where all are equally valued. The specific targets of the task force were aimed at improving high patient/provider ratios, establishing continuity in dedicated clinical service time, and protecting opportunities for academic pursuits. Additionally, the roles of each sub-group were further developed and defined. The CICU APP cohort was identified as an invaluable resource not only to provide excellence and continuity in patient care but as the backbone of the CICU frontline staffing model.

Evaluation

Each meeting included time for collaboration and consensus building within sub-groups. Large group discussions focused on reviewing sub-group opinions on current staffing issues, formulating the ideal staffing models, and trouble-shooting the projected staffing model in the interim. Even prior to the move, identified concerns had corrective actions developed and implemented. This model of invested collaboration, honest feedback, and mutual respect allowed for team-centered input from all sub-groups, for the benefit of the unit as a whole. As a result of the collaboration, we achieved patient/provider ratios of 6:1 from 8:1, moved the end of dayshift earlier to 5pm, improved efficiency of morning rounds, and utilized frontline providers to their full potential while protecting required shifts maximums.

Discussion

To date, the new and improved staffing model remains intact. Follow-up meetings have ensured continued feedback on the staffing paradigm and allowed for ongoing improvement. This collaborative effort has strengthened rapport across multidisciplinary groups, improved job satisfaction, enhanced professional identity, and ultimately improved retention and increased recruiting. These focused efforts toward equity and work-life balance have empowered the APP group to participate in a variety of educational, research, and quality improvement initiatives. Championed by a multidisciplinary and collaborative approach, we believe this team model could be applied in other hospital settings as it demonstrates the benefits and value of APP participation in the creation of a staffing framework that is reproducible and beneficial to all involved.



8. The routine use of post-operative NSAIDs in pediatric patient is effective and safe

Renuka Mehta, MBBS, FAAP, FCCM, CHSE

Introduction

Effective and appropriate post-operative pain management in the pediatric population is important for a safe and comfortable recovery process. Opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and acetaminophen remain the current pharmacologic therapy for postoperative pain management, with an increasing preference for the use of scheduled NSAIDs to avoid opioid-related side effects. The objective of this study is to examine the renal and hematologic complications of scheduled post-operative NSAID use in the pediatric population (ages 0-18). It was hypothesized that pediatric patients started on a scheduled regimen of NSAIDs immediately post-operatively are at an equal risk of bleeding and renal complications for the first 5 days post-op in comparison to those not receiving the medications.

Methods

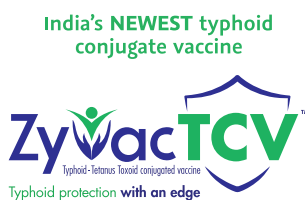
- A retrospective chart review of 170 patients admitted to pediatric intensive care unit from July 2015-May 2018 status post congenital heart defect or other surgery requiring pain control.
- Renal effects were evaluated by serum creatinine values, while significant bleeding events were evaluated by clinically documented intracranial hemorrhage, GI consult or significant upper GI bleed, bleeding requiring additional surgical exploration or transfusion.
- Analyses were conducted using descriptive statistics to evaluate the significance of abnormal creatinine values by age.
- Due to a low frequency of abnormal creatinine levels, the percent of days with an abnormal creatinine level was used to assess for differences between groups.

Results

- There was no overall statistically significant difference between cardiac surgery and NSAID groups in creatinine levels over time $p = 0.2950$.
- There was also not a significant association between patients with scheduled NSAIDs and the presence of an increased number of days of abnormal creatinine levels or bleeding events $p = 0.0621$. There was a significant difference among groups for age ($p < 0.0001$), height ($p < 0.0001$), and weight ($p < 0.0001$).

Conclusion

There is a no association with increased bleeding or adverse renal effects use of NSAIDs in the pediatric post-operative setting in both cardiac and non-cardiac surgeries. Post-operative cardiac patients undergoing scheduled NSAID therapies are older as there is hesitancy to use NSAIDs in infants less than less six months. A randomized prospective study may analyze the dose-dependent nature of any reported adverse side effects and the reduction in opioid medications as a result of NSAID.



9. Antibiotic Resistance Among Ocular Bacterial Pathogens from Pediatric Patients: Ten-Year Results from the ARMOR Surveillance Study

Samuel Bouchillon, MD

Purpose

Bacterial eye infections are frequently encountered in pediatric medical care, and empirical treatment may contribute to, and be complicated by, antibiotic resistance among causative pathogens. In vitro data from large, multi-center, multi-year surveillance studies are useful for tracking resistance to commonly used antibiotics. The Antibiotic Resistance Monitoring in Ocular Microorganisms (ARMOR) study, having completed its 10th year, is the only ongoing nationwide antibiotic resistance surveillance program specific to ocular bacteria. Here, we report antimicrobial susceptibility data for isolates collected from pediatric patients (≤ 17 years of age) from 2009 through 2018.

Methods

- Clinical centers across the United States submitted ocular isolates of *Staphylococcus aureus*, coagulase-negative staphylococci (CoNS), *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Pseudomonas aeruginosa* from the cornea, conjunctiva, and aqueous or vitreous humor to a central laboratory.
- Minimum inhibitory concentrations (MICs) were determined by broth microdilution methodology for up to 16 antibiotics according to the Clinical and Laboratory Standards Institute guidelines, and isolates were categorized as susceptible or resistant based on systemic breakpoints, where available.

Results

- A total of 1274 isolates (386 *S. aureus*, 265 CoNS, 181 *S. pneumoniae*, 359 *H. influenzae*, and 83 *P. aeruginosa* isolates were collected from pediatric patients.
- Among the staphylococci (*S. aureus* and CoNS, respectively), 56% and 72% were resistant to azithromycin and 23% and 49% were methicillin-resistant (MR); multidrug resistance to ≥ 3 drug classes (MDR) was prevalent among MR strains (47% and 73%).
- Resistance among *S. pneumoniae* was notable for azithromycin (40%) and penicillin (35%), while isolates of *H. influenzae* and *P. aeruginosa* were generally susceptible to the antibiotics tested. Besifloxacin was the most potent ophthalmic agent tested against Gram-positive bacteria, while besifloxacin MICs were comparable to other fluoroquinolones against *H. influenzae* and *P. aeruginosa* isolates.
- Results were similar among bacterial isolates from the patient subpopulation aged 0-3 years.

Conclusion

In vitro antibiotic resistance appears common among staphylococcal and pneumococcal isolates collected from pediatric patients, with MR staphylococci exhibiting substantially more MDR than methicillin-susceptible strains. Because culture of common eye infections is rarely performed, and in vitro resistance may predict treatment failure, these susceptibility data may be especially important when selecting first-line agents for the management of ocular infections in pediatric patients.



10. Benefits of IVIG in Pediatric Acute-Onset Neuropsychiatric Syndrome

Isaac Melamed, MD, Roger Kobayashi, MD

Purpose

Pediatric acute-onset neuropsychiatric syndrome (PANS) is a clinical diagnosis given to children who have an acute manifestation of varied neuropsychiatric symptoms, including obsessive compulsive disorder (OCD) or a severe eating disorder plus at least two other symptoms including tics, anxiety, irritability and problems with attention and concentration. Others have demonstrated that PANS may develop as a result of a post-infectious syndrome and our hypothesis is that PANS may represent a new form of post-infectious autoimmunity, through molecular mimicry, which may be the potential mechanism by which the disorder evolves. To test the hypothesis that the disorder is related to an autoimmune dysfunction, a multi-site study was conducted in the United States (Colorado, Nebraska and North Carolina) to explore the use of intravenous immunoglobulin (IVIG) [Octagam 5%] for the treatment of PANS.

Methods

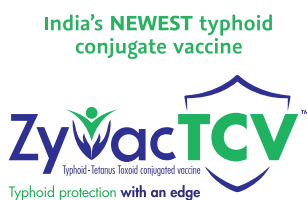
- The primary endpoint of the study was evaluation of the efficacy of IVIG in PANS in pediatric subjects over a period of 6 months (6 infusions) based on mean changes in psychological evaluation scores using 6 different assessments: Pediatric Acute Neuropsychiatric Symptom Scale Phone Interview (PANNS-PI); Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS); Yale Global Tic Severity Scale; Anxiety Disorders Interview Schedule for DSM-IV; Clinical Global Impression; Parent-Rated Symptom Survey.
- Secondary endpoints included evaluation of presenting immune/autoimmune panels as well as the immunomodulatory effect of IVIG on key biomarkers associated with PANS.

Results

- The final cohort consisted of 21 subjects (7 per site) with moderate to severe PANS. The mean age was 10.86 years (range: 4-16 years).
- There were 8 females (38%) and 13 (62%) males.
- Results demonstrated statistically significant reductions in symptoms from baseline to end of treatment (infusion 6) in all 6 assessments measured. Dramatic results can be seen in the PANSS-PI.
- Statistically significant reductions in symptoms were demonstrated beginning at infusion 3 through infusion 6 compared to baseline, with steady improvement from infusion 1 to infusion 6.
- Additional results from CY-BOCS demonstrated statistically significant reductions in obsessive compulsive symptoms, resulting in > 50% improvement, that were sustained for 8 weeks after the final infusion.

Conclusion

In patients presenting with PANS, which may be associated with an underlying immune dysregulation, IVIG [Octagam 5%] successfully ameliorated psychological symptoms and dysfunction, and beneficial effects were sustained for at least 8 weeks following the final infusion. In addition, baseline immune and autoimmune profiles demonstrated significant elevations in a majority of subjects, which requires further evaluation, characterization and study to clarify the hypothesis that precipitation of immune dysfunction leading to a post-infectious syndrome may be the mechanism by which PANS manifests and progresses.



11. Febrile seizures following vaccination do not impact on children's development or behavior

Lucy Deng, MBBS

Purpose

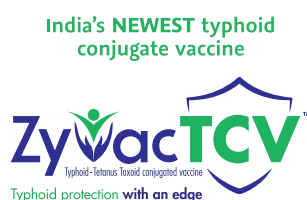
Febrile seizures (FSs) occur in 3-5% of children under 6 years of age, with peak incidence in the second year of life. This coincides with the timing of the first dose of measles-containing vaccine in the United States, which has been shown to have a two-fold increased risk of FS in the two weeks following vaccination. Whole-cell pertussis and some influenza vaccines in combination with pneumococcal vaccines have also been associated with an increased rate of FSs when fever peaks after vaccination. Concerns about potential adverse neurocognitive outcomes following a vaccine proximate febrile seizure (VP-FS) can affect public and immunisation provider confidence in vaccine safety and impact on receipt of further vaccines. In this study, we compared the developmental and behavioural outcomes of children who have experienced an initial VP-FS to children who have had a non-vaccine proximate FS (NVP-FS) and to healthy controls who have not had a seizure.

Methods

- This first ever prospective case-control study was conducted across four tertiary paediatric hospitals.
- Children who had their first FS before 30 months of age between May 2013 and April 2016 were recruited.
- They were either recruited as a VP-FS case, defined as a FS occurring on day 0-2 following receipt of an inactivated vaccine, day 5-14 following a live-attenuated vaccine or day 0-14 following a combination of inactivated and live-attenuated vaccines or an NVP-FS participant, defined as a FS outside of this period.
- Similar aged children with no history of seizures were recruited as controls.
- The Bayley Scales of Infant and Toddler Development, Third Edition (Bayley-III) was administered to all FS participants 12-24 months following their initial FS and controls of similar age to VP-FS cases at the time of their assessment.
- Pre-academic skills of children were assessed using Woodcock-Johnson Tests of Achievement, Third Edition.
- Parents rated their child's behaviour and executive functioning using Behaviour Rating Inventory of Executive Function, Preschool Version and Child Behaviour Checklist – Preschool. The primary outcome was the Bayley-III cognitive score.

Results

- There was no significant difference in cognitive function between VP-FS (n=62), NVP-FS (n=70) and controls (n=86) ($F(2,215)=2.142$, $P=0.12$).
- There was no significant difference between the groups for all other measures and no increased risk of borderline/significant developmental impairment or clinically significant behaviour in children with VP-FS or NVP-FS when compared to controls.
- Socio-economic status (maternal education) was the only significant predictor of cognitive functioning for children who had a FS ($B=1.628$, $P=0.04$).



Conclusion

VP-FS were not associated with an increased risk of cognitive, developmental or behavioural problems in young children compared to children with NVP-FS or healthy controls. This study provides important reassurance for parents and providers on the absence of adverse effects of VP-FS on the developmental functioning of children.



12. Is a single dose of hepatitis B vaccination enough to restore immunity in children with inflammatory bowel disease on biological therapy?

Alexandru Firan, MD

Background

Children with Inflammatory Bowel Disease (IBD) are screened for Hepatitis B infection and immunity prior to starting a biologic therapy. The rate of non-immunity amongst these children is high. It is unknown whether a three part Hepatitis B series versus a single booster immunization in IBD patients undergoing biologic therapy is needed to achieve immunity.

Purpose

To assess the titer response to a three part Hepatitis B series versus single booster immunization in IBD patients undergoing biologic therapy previously found to be non-immune to Hepatitis B.

Methods

A prospective randomized un-blinded trial was conducted. Enrolled subjects were randomized to receive a single Hepatitis B vaccine or three part vaccine series. Hepatitis B titers were checked a minimum of two weeks after vaccine administration.

Inclusion Criteria

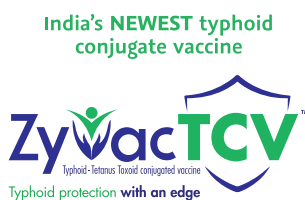
Subjects with a diagnosis of IBD, between the ages of 5 and 23 years, currently being treated with or soon to be treated with a biologic therapy, and found to have a Hepatitis B Surface Antibody less than 10 and Hepatitis Surface Antigen negative. Exclusion Criteria: Subjects found to have Hepatitis B Surface Antibody level greater than 10, Hepatitis Surface Antigen positive, or with history of allergic reaction to vaccine administration.

Results

- 14 patients were analyzed. 11 had Crohn's Disease and 3 had Ulcerative Colitis. Mean age was 14 years (range 11-18); 12/14 were males.
- 9 patients were treated with Infliximab, 2 with Adalimumab, 1 with both Infliximab and Adalimumab, 1 with Infliximab, Adalimumab, Ustekinumab, and Vedolizumab, and 1 was not receiving treatment with biologics yet. 14/14 children had a positive titer considered immune (≥ 10 mIU/mL).
- The type of biological therapy they received did not affect whether there was a satisfactory immune response.
- However, those who received the complete series had higher post vaccination antibody levels (mean titer level from single booster=150mIU/mL, mean titer level from 3 shot series = 620mIU/mL; $p=0.026$)

Conclusion(s)

A single Hepatitis B booster vaccine was sufficient to provide immunity to children with IBD. Immunity was not dependent on the type of biologic therapy a patient was receiving.



13. Multicenter, Randomized Crossover Preference Study of Bidose Epinephrine Nasal Spray vs EpiPen(R)

Jennifer Soosaar, PhD

Purpose

Medical devices that are easier to use are typically safer and more effective at delivering their intended therapies. Usability is especially pivotal in emergency situations, when lay users are under stress, for example during anaphylaxis when epinephrine is needed. In particular for patients with severe allergies, portability is very important for emergency epinephrine devices, because fast accessibility impacts overall treatment. Considering the importance of timely administration of epinephrine, devices that are more usable, portable, and preferred by patients may support earlier use of a lifesaving drug, mitigate the worsening of symptom progression, and reduce the incidence of anaphylactic deaths. In this study, we investigated patient preferences between two medical devices that could be used in anaphylactic emergencies: the EpiPen® autoinjector and the Bidose epinephrine nasal spray. The EpiPen autoinjector functions by removing the safety cap, pushing the tip that houses the needle into the outer thigh until it clicks, holding for three seconds, and then removing the needle. The needle-free Bidose epinephrine nasal spray functions by inserting the nozzle in the nostril, pushing the plunger, and then removing the nozzle. Each EpiPen autoinjector contains one dose so patients are instructed to carry two EpiPen autoinjectors with them to ensure adequate treatment while the Bidose epinephrine nasal spray contains two equivalent doses so patients will only carry one device.

Methods

Preference in this study was evaluated via an eight question survey that was validated through a pilot study in advance of pivotal testing. Fifty-six (56) participants with severe allergies (27 pediatric patients and 29 adult patients), distributed in six states across the United States, were each engaged in a one-on-one moderated session. All participants had been prescribed EpiPen but were only characterized as EpiPen-experienced if they had used an EpiPen autoinjector previously. Participants were presented with the EpiPen trainer and an empty Bidose epinephrine nasal spray device and simulated use of each one with counterbalanced presentation order between participants. Participants then responded to the survey questions. Each question was analyzed separately for EpiPen-experienced participants (n = 24) and EpiPen-inexperienced participants (n = 32) with an exact binomial test using the binomial test function in R. For statistical significance, $p = 0.05$ was used.

Results

The results indicate a significant preference for the Bidose epinephrine nasal spray over the EpiPen autoinjector on various metrics including portability, ease of learning, ease of use, overall preference, likelihood of recommending to others, safety, size, and comfort.

Conclusion

Considering that the most common cause of death from food allergies is delayed epinephrine administration, prescription and use of a small, portable, easy to use device like the Bidose epinephrine nasal spray device might decrease the incidence of anaphylactic deaths.



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