Written Public Comments

IACC Full Committee Meeting

December 13, 2013

List of Written Public Comments

Note: Personally Identifiable Information (PII) has been redacted in this document

Eileen Nicole Simon

December 6, 2013

Subject: Comment on language, auditory system damage by toxic substances and/or asphyxia at birth, which can result when the umbilical cord is clamped before the first breath:

Developmental language disorder is the most serious handicap for children with autism. What causes this disability should be added as an addendum question.

Auditory processing problems, hypersensitivity and/or failure to orient to sounds are also prominent. Language is learned in early childhood via the auditory sense.

Evidence has been available for decades, for example in the article by William Windle in the October 1969 issue of the Scientific American, that nuclei of the brainstem auditory pathway are damaged by oxygen insufficiency at birth.

Evidence that blood flow is higher in nuclei of the auditory pathway than in any other area of the brain was presented in a paper by Seymour Kety (Bull N Y Acad Med. 1962 Dec;38:799-812, free online via PubMed).

The auditory system is thus vulnerable to both anoxic and toxic injury. Difficult birth and/or prenatal exposure to alcohol and valproic acid have been identified as etiologic predispositions for autism.

Oxygen insufficiency is likely when the umbilical cord is clamped before a baby has begun breathing. Clamping off placental circulation before the first breath is a clear medical error. The IACC should have at least enough authority to call an immediate halt to this procedure.

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Conrad Simon Memorial Research Initiative
To seek understanding of brain system impairments in autism.
http://conradsimon.org/

Anne Z. Bauer

December 9, 2013

Subject: ACETAMINOPHEN (TYLENOL) RESEARCH SHOULD BE A PRIORITY!

There is new, strong, evidence supporting the plausibility of acetaminophen use as a causal factor in autism spectrum disorder (ASD). Acetaminophen is a prevalent, causally plausible and modifiable exposure. A very well controlled, prospective cohort study found that children exposed to long-term acetaminophen use during pregnancy had substantially adverse developmental outcomes at 3 years of age. Children prenatally exposed for more than 28 days had poorer gross motor development, communication, externalizing behavior, internalizing behavior and higher activity levels[1]. These are typical autism phenotypes[2]. This study finds a strong association, with the results suggesting that prenatal exposure to acetaminophen for more than 28 days increases the risk of adverse psychomotor and behavioral outcomes by almost 70% and doubles the risk of language problems. Children exposed prenatally to short term use of acetaminophen had poorer gross motor skills but these effects were smaller. These researchers, importantly, also looked at the relationship to ibuprofen and found no associations.

A randomized clinical trial cannot ethically be done in this situation. This study by Brandlistuen et al. 2013 is a well done, large, observational study that provides extensive control of other factors that may influence the relationship between acetaminophen and autism spectrum disorder. These factors included febrile illness, infection and use of co-medications. The sibling design utilized keeps maternal factors as constant as possible, providing additional control of familial and genetic factors.
Studies in the U.S. show that about 65% of women will take acetaminophen at some time during their pregnancy and it is the most common drug given through age 2[3,4]. Prenatal exposure to other medications- valproic acid, thalidomide and misoprostol has been shown to be associated with an increased incidence of autism and neurodevelopmental delays, this alone should be reason to investigate acetaminophen[5]. It is known that acetaminophen freely crosses the placenta and the adverse effects of acetaminophen are numerous[6]. Acetaminophen is the nation's leading cause of acute liver failure[7]. Prenatal exposure has been associated with maternal preeclampsia and offspring development of asthma and cryptorchidism[8-10].

This hypothesis is supported by ecologic and biologic data[11,12]. Acetaminophen has a narrow safety margin so for individuals who are ill and not eating conversion to the toxic metabolite of acetaminophen N-Aceyl-p benzoquinone-Imine (NAPQI) may occur even at recommended doses[13]. NAPQI has been shown to be a neurotoxin in animals at doses below those required to produce hepatotoxicity[14, 15]. NAPQI has been shown to alter cerebellar Purkinje cell development in rats, Purkinje cell alteration is a consistent finding in ASD[16, 17]. A recent paper in Nature stated "chemicals and genetic mutations that impair topoisomerases could commonly contribute to ASD and other neurodevelopmental disorders"[18]. NAPQI is a topoisomerase poison and likely inhibitor[19]. Other pharmaceuticals that impair topoisomerases appear limited in use during pregnancy and in early life[20].

Acetaminophen is a prevalent, causally plausible and modifiable exposure. Further research is urgently warranted to replicate these findings for prenatal exposure with an ASD diagnosis and to study perinatal exposure.

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Mark Jackson

December 9, 2013

I am writing to request that the IACC object to the proposed changes to home-and-community based service waivers.

Medicaid "home and community-based waivers" (HCBS) were established under section 1915(c) of the federal Social Security Act of 1981. HCBS essentially "waive" the original requirements of the Social Security Act and give states flexibility in providing care options. Currently, the Center for Medicaid and Medicare Services (CMS) is attempting to define what actually constitutes a "community-based setting" by proposal CMS 2249-P. The language proposed by CMS to define these settings is narrow, troubling and would jeopardize the individual's right to free choice and, in the end, severely limit highly-desirable options. It could eliminate funding under HCBS waivers for a number of wonderful communities - both existing and planned.

Thank you.

Mark Jackson
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