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H_2O: GET THE LEAD OUT

Contents

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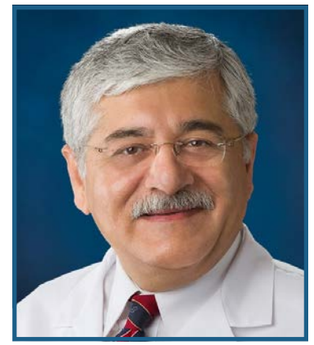
Editor's Note



Happy New Year Colleagues!!

As we start a new year we need to renew our efforts for advocacy for children. Advocacy for children has never been more important. Changes are happening nationally and at the state level that will require child advocates to stand up even taller and make sure that our children do not lose the many gains they have made over decades.

Your Chapter continues advocacy efforts in Tallahassee. Our legislative team and lobbyists led by Doug Bell, Esq., are tracking all child related bills. We are supporting child friendly bills and opposing anti-child bills. We have already achieved several successes in committee deliberations. However, we remain active throughout the legislative session. We will need your support and you may be called upon to reach out to your legislators, ask for your expert opinion, and may even be asked to testify in front of the legislature. We appreciate your support in these efforts.

Children's Health Insurance Program (CHIP) is under assault we must make efforts to make CHIP permanent. Periodical renewal means that our children are again and again at the mercy of politics and politicians. We need a law similar to the Vaccine for Children (VFC) law. Under VFC legislation every time a new vaccine is approved for use in children and is recommended by Advisory Committee on Immunization Practice (ACIP) it is automatically covered by VFC. A CHIP legislation that does not require renewal from time to time and pays for health insurance for all eligible children would stop making our children hostage to politics.

Florida's renowned Children's Medical Services (CMS) programs has been a national model for decades on how to best serve children with special health care needs (CSHNs). Major changes are also afoot in the CMS program. One hopes that these changes will enhance services for CSHNs and not decrease services for these vulnerable children. However, hope is not a strategy. Child advocates must keep a close eye on these changes and be vigilant that these most vulnerable children receive all the services they need. Your Florida Chapter of the American Academy of Pediatrics (FCAAP) has advocated for increased access to healthcare for all children. Our successes in these efforts of advocacy and legal action were the result of support by you, our members. We need to closely monitor the changes and speak up if we see that children are being shortchanged.

In addition to advocating for improved access to healthcare for children, your Chapter has also teamed up with the Florida Department of Health to organize four webinars about Zika Virus infection to keep our members up to date on the latest science and guidance on testing, evaluating, and managing congenital Zika virus infection. These webinars were recorded and are available for viewing, with CME and CEU credits. You can access the webinars at: http://fcaap.org/members/cme/

Finally, I want to end with the epidemic of our time. The opioid epidemic is hitting the country hard and Florida has been particularly hit hard. The littlest victims of this crisis are the infants born to mothers abusing opioids (and other substances of abuse). Unfortunately, these children have not received the due attention they need. This is something we will be talking about in the future; however, we cannot lose sight of this issue.

Best of luck to all of you in the New Year.

Mobeen H. Rathore, MD, FAAP

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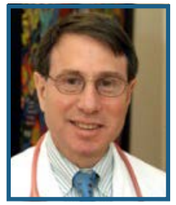

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Florida Chapter
American Academy of Pediatrics

REVIEW ARTICLE

Lead Levels In Drinking Water In Elementary Schools In Tallahassee Florida; Recommendations For Lead Exposure Reduction; Pediatricians' Role

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ABSTRACT

In recent times the issue of lead in drinking water has drawn national attention and concern. On that basis we sampled for lead in drinking water in 16 elementary schools in Tallahassee Florida - water fountains and cafeteria water taps - which revealed that lead concentrations in 30 of 32 samples exceeded the American Academy of Pediatrics 1 part per billion lead recommendation. The school system responded by flushing water pipes daily thus reducing lead levels in drinking water. We recommend further remedial action, namely installation of point-of-use NSF/ANSI Standard 53 water filters certified to reduce lead, on drinking water sources in the schools. This is an inexpensive option that can rapidly be implemented and offers greater certainty that lead levels - both dissolved and particulate lead - will be appropriately reduced. Given that allowable lead levels in potable water plumbing - pipes and fittings - was relatively high in the US until 2014, the use of lead-removal certified water filters should be considered broadly for drinking water sources used by young children – in schools, daycares and residences. Pediatricians have an important role in reducing their patients' exposure to lead, by assessing and educating their patients, and via advocating for protective policies.

LEAD IN DRINKING WATER IN FLINT MICHIGAN PROMPTS CONCERNS

Last year we read with alarm of the public health crisis in Flint Michigan resulting from elevated levels of the neurotoxic heavy metal lead in that City's drinking water [1, 2]. In 2014, as a cost-saving measure, the City of Flint had changed its drinking water supply source from Lake Huron to the Flint River. This almost immediately resulted in discolored, unpalatable and malodorous drinking water, and consequent apprehension on the part of Flint's residents.

City and state officials and staff initially dismissed citizens' concerns, and attempted to placate residents by for example providing photo ops showing city officials drinking Flint River water from the Flint Water Treatment Plant, while the mayor tweeted "*(My) family and I drink and use the Flint water everyday (sic), at home, work, and schools*."

Later, city and state officials and staff disputed findings of elevated lead levels in the drinking water and in Flint children's blood as reported by US Environmental Protection Agency (US EPA) and Virginia Tech scientists, and by a pediatrician from Flint's Hurley Medical Center, respectively. Public pressure and science finally prevailed; after 18 months, Flint went back to using Lake Huron as their drinking water source.

The cause of the elevated lead levels in Flint's drinking water was that Flint River water was more corrosive than Lake Huron water[1], and city staff failed to require that corrosion-control chemicals be added to the water. Consequently, corrosion of lead water pipes and household lead-bearing plumbing fittings contributed dissolved and particulate lead to the water, and exposed 8,000 children under the age of six to lead-contaminated drinking water. Subsequently, the proportion of young children in Flint with elevated blood lead levels - above the Centers for Disease Control and Prevention's (CDC) lead reference level of 5 µg/dL (micrograms per deciliter) - rose from 2.4% to 4.9%[2]. To date, 15 current or former state or city officials have been indicted for their actions, or lack of actions, regarding this water quality disaster.

THE CITY OF TALLAHASSEE'S MESSAGING ON LEAD IN DRINKING WATER

Elevated levels of lead in drinking water is a national problem; not one just limited to Flint, Michigan[3, 4, 5]. With this in mind, we noted that an article last year in a Tallahassee Florida newspaper reporting on interviews with City of Tallahassee water utility staff, stated, "*Leon County (Tallahassee) residents reading of lead-laced water in Flint Michigan, need not worry about their water at home*[6]." We felt that this might not be the full story.

In fact, the City of Tallahassee wrote in their water utility's annual drinking water quality report for 2016, that "*in Tallahassee, our water source is the Floridan Aquifer and there is not naturally occurring lead in the water*", but then warned many pages later that "*lead can get into drinking water by corrosion of older pipe and plumbing components that contain lead*[7]".

The City further wrote "*our community is fortunate in that our water supply is naturally non-corrosive*"; that "*laboratory testing results confirm that the water delivered to our customers does not contain lead, and samples taken from older homes routinely show that lead corrosion, and the consequent addition of lead from pipes, plumbing fittings and solder to drinking water is not a problem*[7]."

Following that information the City wrote: "*However, if a customer is still concerned that their own plumbing may be contributing to lead in their drinking water…*" "*Have your drinking water tested*", *and/or "Flush your household plumbing before using the water*[7]". This messaging might confuse some citizens, and is not authoritative guidance about the safety of drinking water, nor the means of ensuring safe drinking water as regards lead contamination.

This is not to fault Tallahassee in particular. Inadequate messaging from water utilities regarding lead in drinking water appears to be common[5] and in part may stem from the fact that water utilities generally do not have the benefit of regular communications with toxicologists and physicians regarding research updates on lead exposure and toxicity.

Adding to the messaging problem, the US EPA's 15 ppb (parts per billion) lead-in-drinking-water "action level" as in the US EPA Lead and Copper Rule[8] and as generally used by water utilities to define acceptable human lead exposure, is in fact not a public health standard. It is instead a "technology based" standard which indicates when a water utility should take actions including adding corrosion-control chemicals to drinking water to reduce lead contamination from corroding water pipes and plumbing fittings. As well, the 15 ppb standard, which is defined as a 90th percentile concentration, by statistical definition could allow 10% of the population to be exposed to very elevated lead concentrations in drinking water[8].

Rather than supporting the widely used 15 ppb lead action level for protection of public health, the US EPA has stated that the health-based "maximum contaminant level goal" for lead concentration in drinking water is 0 ppb[8]; that there is no safe level of lead exposure[9]. That latter guidance from the US EPA does not seem to be recognized by many water utilities nor school systems.

As a consequence of confused messaging regarding lead, among other factors, about half of Americans polled are not very confident in the safety of their tap water and believe drinking-water contamination is a widespread problem[10].

Causing us to question the City's assessment of drinking water as consumed by Tallahassee residents was a 2016 article in USA Today which stated that excessive lead levels have been found in almost 2,000 water systems across all 50 states[5]. As well, testing for lead in drinking water by water utilities is often not conducted according to US EPA protocols, and thus may produce results that are biased low[4]. These realities prompted the current study in which we assessed whether 16 elementary schools in the City of Tallahassee had acceptably low levels of lead in drinking water.

DECISION TO SAMPLE ELEMENTARY SCHOOLS

The decision to sample Tallahassee elementary schools' drinking water for lead was based on the fact that lead is well known to increase young children's risk for neurodevelopmental disorders[11]. As well, water consumption in schools is characterized by periods of little or no water usage - over night, weekends, holidays, and summer - resulting in long stagnation periods of water in water pipes where ongoing corrosion can increase lead levels in drinking water[12].

Further, because schools, unlike homes, are not covered under the US EPA's 1991 Lead and Copper Rule[13], there is no requirement to sample drinking water in schools for lead levels, unless the school has its own drinking water well. For the approximately 90% of the US schools that receive their water from local utilities, no local, state, or federal entity is required to ensure that lead levels in drinking water are acceptably low and the water safe to drink.

Finally, as indicated, many of the water utilities and schools that do sample to determine lead levels in water, do not follow the US EPA Lead and Copper Rule[8] nor the "3Ts" drinking water sampling protocols[13] and so may miss signs of lead corrosion of pipes and plumbing fittings and consequent lead contamination of drinking water. The 3T's are "Training, Testing and Telling", with the intended purpose of this comprehensive US EPA manual being to help schools minimize their students' and staff's exposure to lead in drinking water.

SAMPLING SCHOOLS

Upon our request to sample to determine lead levels in schools' drinking water, the Leon County (Tallahassee) Superintendent of Schools' enthusiastically granted approval and offered us the assistance of school staff, in order for us to sample for lead in water fountains and cafeteria taps (one in each school) in sixteen of the systems' elementary schools.

Older elementary schools were selected because these were more likely to have plumbing fittings which contained lead. Sampling of drinking water was conducted in August 2016 in accordance to the US EPAs 3Ts methodology[13]. This sampling protocol maximizes the likelihood that lead will be detected in drinking water because samples are collected after overnight stagnation of water in drinking water pipes - a worst case scenario.

FINDINGS ON LEAD IN DRINKING WATER IN SCHOOLS

This study represents the first independent scientific evaluation of lead in drinking water in a Florida school system. The results were surprising - while only 2 of the 32 water samples had lead levels above the US EPA action level of 15 ppb (18 and 25 ppb) - 30 of the 32 samples from the 16 schools had lead levels above the American Academy of Pediatrics (AAP) 1 ppb recommendation[14].

Data on lead levels in the Floridan aquifer suggest that the elevated lead levels in Tallahassee's schools' drinking water were due to corrosion of water supply lines and/or plumbing fixtures, not from the aquifer (groundwater). Tallahassee's water supply is in fact not "*naturally non-corrosive*", though it is of low corrosivity.

Our data on lead in schools' drinking water made front-page news in the local press and was picked up by approximately 100 newspapers nationwide. As is common, the newspaper coverage was more sensationalist than aimed at offering explanations, suggesting solutions, or extrapolating to the broader problem of lead in water in schools in Florida- or nationwide. It is important to note that the lead levels in Tallahassee's schools' drinking water were far lower than those in drinking water in Flint Michigan.

Regarding the two water samples that tested above the US EPA action level, the Leon County school system took quick action to reduce those lead levels via flushing water lines and cleaning screens at the end of water spouts. The Leon County school system continues to flush water pipes daily before schools open to insure fresh (non-stagnant) water is introduced into the water lines thus reducing lead levels in drinking water.

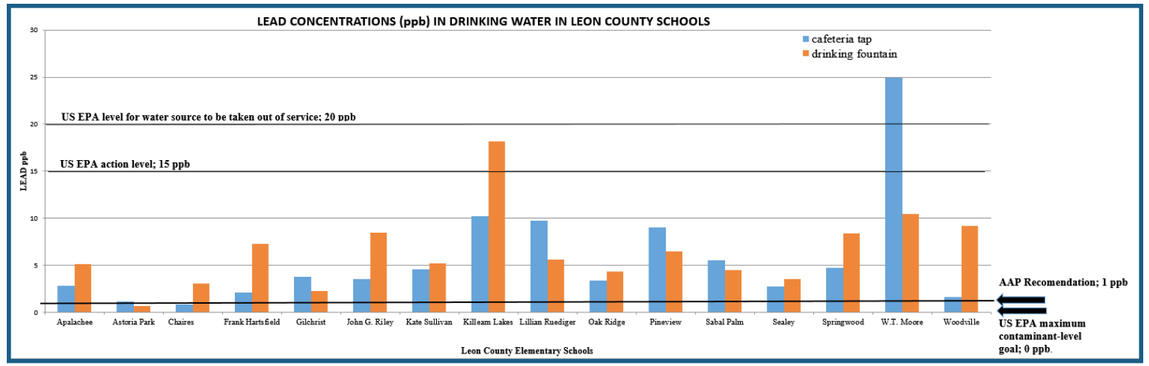

Figure 1:
Lead concentrations as measured in Leon County schools' drinking water from one drinking fountain and one cafeteria water tap in each of 16 elementary schools, August 2016; overnight stagnation samples. Measured values in schools are compared to: the "US EPA level for water source to be taken out of service"; the "US EPA action level"; the "American Academy of Pediatrics (AAP) Recommendation"; and the "US EPA maximum contaminant-level goal".

HEALTH IMPACTS OF LEAD EXPOSURE

Lead exposure is a widespread problem in the US that most seriously affects children. Approximately 500,000 US children ages 1-5 are presently at or above the CDC lead reference level of 5 µg/dL in blood, putting them at risk of IQ deficits, attention and learning disorders, slowed growth and development, ADHD, and later, juvenile delinquency, and criminal behavior[15, 16, 17].

Each year in the US there are approximately 90,000 new lead exposures above the CDC lead reference level in this age group[18]. It has been established that there is no safe level of lead exposure for children[5]. Developmental neurotoxicity has been associated with the lowest levels of lead exposure reported[1]. Thus the CDC lead reference level of 5 µg/dL in blood, does not represent a safe lead exposure; in fact children with a blood lead concentration greater than 5 µg/dL suffer an average IQ-score deficit of about 6 points[17].

The cost of dealing with children with intellectual impairment and maladaptive behaviors requiring expensive remedial educational programs or even leading later to imprisonment due to lead exposure effects, places a heavy financial and social burden on communities, children and families[19]. On average, in the US it costs twice as much to educate a child with developmental disabilities as compared to one without[20]. No treatments have been shown to be effective in ameliorating the permanent developmental effects of lead toxicity[21]. Further, childhood lead exposures have long-term ramifications, being associated with lower IQ, cognitive function and socioeconomic status in adults[22].

Lead exposure reduction has cost-benefit ratio comparable to that for childhood vaccines[1]. An enormous gain to society could be made by monitoring for lead in tap water; this can be conducted for as little as $8 a sample. Further, remediation of lead levels in water is inexpensive and can be rapidly implemented relative to reducing other lead exposure sources, such as lead-based paint in homes and lead-contaminated soil.

Rosner and Markowitz summarized the issue of children's lead exposure clearly: "*The ongoing tragedy of lead poisoning rarely provokes the outrage one might expect*"... "*If this were meningitis - or even an outbreak of measles - lead poisoning would be the focus of national outrage and action.*[23]" "Lead poisoning is a wholly preventable disease[24]."

THE SCOPE OF THE LEAD-IN-WATER PROBLEM

The lead-in-water problem spans all 50 states. A "USA Today" report found levels of lead exceeding the US EPA action level of 15 ppb in 80 public water supplies throughout Florida, and 2,000 drinking water systems nationwide[5]. Nationally, 15 to 22 million Americans are serviced by lead water pipes connecting household plumbing to the water main in the street. Homes and schools constructed before 1986 may well have plumbing fixtures containing very high levels of lead. In 1986 the Safe Drinking Water Act was revised to limit lead in plumbing materials used for potable water to 8.0%; a concentration still almost 10 million times higher than that the AAP recommends for lead in drinking water. This limit was in effect until January 2014 when allowable lead concentrations in plumbing materials were reduced to not more than 0.25% lead as a weighted average [24].

Our present concern is that a significant number of Florida school children, including those attending pre-school and day

care centers, may be exposed to excessive levels of lead from drinking water. Under-reporting of elevated blood lead levels in children is a concern. For Florida, for the period 1999-2010, CDC National Health and Nutrition Examination Survey (NHANES) data on children's blood lead levels were compared to data from CDC's Childhood Lead Poisoning Prevention Program. On that basis it was estimated that 85% of the Florida children with elevated blood lead levels (then defined by the CDC as10 µg/dL) were either not tested for lead by their pediatricians or local health departments, or that these medical providers do not report the results to the CDC Childhood Lead Poisoning Prevention Program. Only 15% of Florida children with elevated blood lead levels were reported to the CDC[25].

WHAT CAN BE DONE

The State of Florida should consider passing a law mandating that lead levels be checked in drinking water sources in schools, pre-schools and day-care centers' (just as drinking water in homes is monitored for lead by water utilities). Children covered by Medicaid are required to be checked for blood lead levels at ages 1 and 2, and such testing should be expanded to cover all children. The American Medical Association (AMA) recently recommended that drinking water in all US schools and daycares be tested for lead levels[26]. New York and New Jersey have already passed laws requiring lead testing in schools, but despite the headlines of elevated lead levels in Florida's school systems, no state legislator has called for similar legislation in Florida.

SUCCESSES IN TALLAHASSEE

This limited scientific program of lead testing of drinking water in a school system represents the first independent such evaluation ever performed in Florida. Following reporting of elevated lead level results, immediate action was taken by school maintenance personnel via flushing of water lines to reduce lead levels. Parents were informed of the problem and a website was set up to keep the public informed; a consultant was contacted to develop permanent remedies - beyond flushing of water lines - to the issue of elevated lead levels in drinking water. Water sampling for lead in these 16 Leon County elementary schools followed by flushing of water lines to reduce lead levels represents a public health success story – though we recommend further remediation actions. To protect children, more school systems and communities in Florida should monitor for lead in drinking water and take remedial action where needed.

RECOMMENDATIONS FOR TALLAHASSEE SCHOOLS

For Tallahassee schools, we recommend additional action regarding elevated lead levels in drinking water, beyond the present practice of daily flushing of schools' water lines. While remedial flushing did cause reductions in water lead levels for schools in Seattle and Los Angeles, the predicted reduction in the proportion of students with elevated blood lead levels resulting from flushing of water lines pipes was only about 30%; more active remediation measures such as replacement of water fountains/plumbing fixtures/piping, and installation of filters were more effective[27].

Further, standard sampling of lead in drinking water - including our own sampling - does not adequately quantify particulate lead (lead particles) in water. Mobilization of particulate lead from corroded lead-soldered water pipes, lead pipes, galvanized steel pipes and lead-bearing plumbing fixtures occurs at irregular and unpredictable intervals[28]. This means that if flushing of water pipes is used to reduce water lead levels, repeated testing of water taps is necessary to assess the contribution of particulate lead to children's lead exposure; a practice that is both uncommon and costly[12]. Further, standard sampling and analysis for lead in drinking water may not fully solubilize particulate lead, resulting in underestimation of children's lead exposure[29].

There is abundant evidence that point-of-use water filters, which filter water as it is drawn from the tap, are effective in producing drinking water with acceptably low dissolved and particulate lead levels. NSF/ANSI Standard 53 establishes the minimum requirements for the certification of point of use filtration systems designed to reduce specific health-related contaminants including lead. The CDC and the US EPA concur that use of NSF/ANSI 53 certified, properly installed and maintained water filters, which are often solid carbon block filters, will produce safe drinking water as regards lead concentrations. For Flint, where lead concentrations in water were substantially higher than those in Tallahassee, average filtered water lead concentration were less than 0.3 ppb – well under the AAP 1 ppb recommendation. Such filters provide water that is safe for "*pregnant women, nursing and bottle-fed children, and children under six*", and may produce low enough lead concentrations such that they do not result in significantly increased blood lead levels[30].

In fact, data from Flint Michigan schools indicate that point-of-use NSF/ANSI 53 certified water filters are more effective than is replacement of lead-containing drinking water plumbing fittings, at reducing lead levels in drinking water – and at far less expense[31].

On this basis, we recommend the installation of NSF/ANSI Standard 53 point-of-use water filters in Tallahassee schools.

LOOMING CHALLENGES

The data collected suggest that lead in water is a problem which could be widespread particularly in older buildings - not because lead is present in the aquifer, but due to lead in plumbing fittings and pipes. The amount of lead allowable in plumbing materials has been reduced by federal regulation over time, but until January 2014, pipes, pipe fittings, plumbing fittings and fixtures could legally contain up to 8% lead; a level high enough to be of concern.

Pediatricians in Florida as well as the broader medical community should be particularly alarmed since the neurotoxic risks of lead exposure are well known to the health care community. Physicians can use their medical knowledge - knowledge that may not be readily available to water utilities and schools - to explain lead risks to them, and to the public and legislators, and to promote a state law to mandate lead testing in schools, pre-schools and daycare centers, as has been advocated by the American Medical Association (AMA)[26].

In 1991, the CDC recommended universal blood lead testing for all children[14], but in practice the degree of testing varies widely from state to state, and city to city. Although lead screening is included in the AAP/Bright Futures recommendations for preventative pediatric health care, for many children, clinician discretion is the determinant of which children are tested for elevated blood lead levels. This matter should be revisited with our new understanding of lead exposure and toxicity. Without mandatory testing and remediation, the lead-in-water problem will possibly worsen because as lead-bearing plumbing materials age, they may release more lead.

WHAT THE INDIVIDUAL PEDIATRICIAN CAN DO: PRACTICE AND PUBLIC POLICY

- The American Academy of Pediatrics calls for pediatricians to advocate for the promulgation and enforcement of strict legal standards that regulate allowable levels of lead in water and other sources[14]. The AMA is advocating for laws that require all schools and registered daycare sites to receive routine municipal water quality assurance testing[26]. Consider that the AAP recommended limit of 1 ppb lead in water is a safe concentration and suggest that schools abide by this public health standard rather than the widely-used US EPA action level of 15 ppb, which is not health based.
- Advocate for installing point-of-use NSF/ANSI 53-certified lead removal water filters on drinking water sources used by young children, given the uncertainty regarding sources of lead contamination of drinking water, and the sporadic nature of contamination. Because of the "hit and miss" nature of lead contamination of drinking water, water testing cannot, and should not be relied upon to determine if water from a tap is safe regarding lead levels. Point-of-use NSF/ANSI 53 lead-certified water filters on drinking water sources in schools may be the least costly, quickest and best option[4]. Support their installation in Florida schools.
- Advocate to your Congressperson in favor of "proactive" primary prevention - prevention of children's lead exposure - as preferential to "reactive" secondary prevention, treating of children's lead poisoning.
- Support universal blood lead level testing for children ages 1 and 2. Testing for lead can be conducted using point of care technologies and finger-stick (capillary) blood. Testing is completed in the office laboratory and results are available in less than 10 minutes. In the past, the test required a venous blood sample which was invasive, time-consuming and costly. Insurance plans didn't always cover it, however now it is a billable service.
- Assess pregnant women for lead exposure using a risk assessment questionnaire at the initial prenatal visit, blood lead testing for women identified as being at risk for lead exposure.
- Assess all children under six years of age annually for lead exposure using a risk assessment questionnaire, and suggest blood lead testing for children identified as being at risk for lead exposure.
- Ensure that where children's blood lead levels are determined to be above the CDC reference value (5 µg/dL), that these results are reported to local and state health departments and the CDC.
- Support case management support for all children with blood lead levels greater than 5 µg/dL.
- Write letters to the editor of your local newspaper, urge your local medical society and the AAP – Florida Chapter, to support legislation to mandate lead testing in Florida schools.
- Write your Congressperson urging that non-essential uses of lead be phased out - starting with the use of lead in plumbing fixtures and water lines including galvanized water pipes.
- As a physician, educate yourself and assume a primary role in assessing children's lead exposures and educating

families about preventing lead exposures.

- If lead concentrations in water are high, infants consuming reconstituted formula or baby food are at special risk. Recommend to mothers that these foods be prepared using filtered or bottled water.
- Ensure that pregnant patients and young children are replete in essential nutrients - dietary deficiencies in calcium, iron and vitamin C in particular may result in higher blood lead levels[32]. Communicate to patients that fasting increases the absorption of lead in drinking water.
- Inform patients that they should drink only cold water from the tap, and if a home water tap has not been used for several hours (e.g. overnight), to run the tap for at least 30 seconds before filling a drinking glass.
- Consider sampling drinking water at your child's school and having the samples tested for lead. These should be overnight stagnation samples (e.g. sampling of water first thing in the morning before the water is used by students or school staff). If such drinking water samples test at 1 ppb lead or less - the AAP recommendation - this is a good sign. Higher lead levels indicate that lead-bearing plumbing fittings/pipes may be present and the water is at least somewhat corrosive. This might indicate that particulate lead could occur sporadically in the drinking water, and further investigation of lead sources to the water, or installation of water filters, is warranted.

Contact the authors if you want additional advice on testing for lead in drinking water, or for sampling bottles. The testing can be relatively inexpensive at around $8 per lead test.

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REVIEW ARTICLE

Childhood Obesity and Cardiovascular Risks

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Obesity, defined as a body mass index (BMI) greater than 97th percentile for age and sex, is a major public health issue. Over the past 30 years, the prevalence of obesity has increased among children of all ages (1). Although the prevalence has trended down in children between the ages of 2-5 and leveled off in children between 6-11 years of age, the number of obese adolescents has increased in the last decade (2). Between 2011-14, the overall prevalence of obesity was 17% with extreme obesity rate of 5.8% (2), (extreme obesity is a BMI at or above 120% of sex specific 95th percentile). This is particularly worrisome as the obese children are more likely to become obese adults compared to non-obese children (3). Approximately 80% of the children who were overweight at 10-15 years of age were obese by the age of 25 years (3). Also 25% of obese adults were overweight or obese as children (4).

The primary etiology of obesity is an imbalance between excessive calorie intake and decreased expenditure over time. Genetic susceptibility, parenting styles (child feeding practices, foods available in house, etc.), as well as community, social (presence or absence of a school lunch program),and demographic factors (race, ethnicity, socioeconomic status etc.) all play a role in the development of obesity. Sedentary behavior often caused by increase time spent watching television, playing video games, engaging in social media and excessive cellphone use is associated with development of obesity (5,6).Additionally, studies have shown that infants exposed to secondhand smoking, maternal gestational diabetes and short periods of breastfeeding are at higher risk of developing obesity later in life. Infants born to diabetic mother tend to deposit more body fat in first few months of life. There are many medications such as corticosteroids used for the treatment of chronic lung disease or chronic inflammatory process, which may cause weight gain. In patients on these regimens, their obesity may be considered iatrogenic, or secondary to the treatment of a medical condition.

Obese and overweight children are at risk for development of a wide range of health problems (7). Obesity is a risk factor for the development of pulmonary disorders such as obstructive sleep apnea(OSA)due to increased fat deposition in the upper airway, and it continues to asthma due to decreased functional residual capacity and expiratory reserve volume (8). They are also prone to acquire cardiovascular diseases (CVD) such as hypertension, dyslipidemia, and coronary artery disease (CAD) later in life. Obese children are also at risk of developing endocrine disorders including type II Diabetes Mellitus (DM) and polycystic ovarian syndrome due to increased insulin resistance. Obese and overweight children are at risk for genitourinary carcinomas due to altered hormonal profile, hepatic steatosis, and pancreatitis. There is also increased incidence of osteoarthritis due to increased wear and tear of the joints and pseudotumorcerebri syndrome secondary to neuroendocrine effects leading to increased cerebrospinal fluid production, which subsequently leads to increased intracranial pressure (9) in obese and overweight patients.Additionally, those diseases typically seen in adults, like Type II diabetes mellitus, are now increasingly diagnosed in obese and overweight children and adolescents.Obesity is strongly associated with co-morbid risk factors for cardiovascular diseases like dyslipidemia, and elevated blood pressure in addition to insulin resistance (10).

METABOLIC SYNDROME:

Metabolic syndrome (MetS) is a major public health problem (11) and is defined in adults as presence of three or more of the following CVD risk factors: 1. Elevated waist circumference, 2. Increased triglyceride levels, 3. High BP, 4. Persistently elevated fasting glucose level and 5. Reduced HDL cholesterol level. Despite the fact that multiple attempts were made to define the MetS in pediatric population, we still lack a meaningful definition. The fact that there is not a consistent definition is affected by: 1. Lack of accepted normal range for serum insulin concentration across childhood; 2.The normal physiological increase in insulin resistance during puberty; 3. Lack of central obesity cut points; 4. Variability in baseline lipid levels across the race and sex. There is emerging evidence to support that chronic inflammation and insulin resistance play a pivotal role in the manifestation of this condition. We are experiencing an epidemic of MetS with approximately 34%-39% of adults are affected in the United States. As per National Health and Nutrition Examination survey data (1999-2002), the prevalence of MetS was 2% to 9.4% among teenagers and was as high as 12.4% to 44.2% among obese adolescents (12, 13). There is a strong association between obesity, physical inactivity and hypertension in early childhood and subsequent development of MetS. An important strategy in lowering the prevalence of MetS is to prevent childhood obesity,as there is clear evidence that prevention of obesity in childhood reduces the prevalence of MetS in adulthood (13). Obese and overweight patients should be evaluated for cardiovascular risk factors which include family history of premature CVD, hypertension, dyslipidemia, DM,left ventricular hypertrophy (LVH), and OSA and positive findings should be properly addressed (13). Maintaining fewer cardiovascular risk factors starting in childhood is associated with a lower prevalence of CVD and increased longevity in adult life.At risk patients should be referred to intense weight reduction programs, along with the management of individual cardiovascular risk factors, including pharmacological treatment if needed, to prevent the consequences of the MetS.

ATHEROSCLEROTIC CARDIOVASCULAR DISEASE:

Atherosclerotic CVD is the leading cause of death worldwide - including the United States. Atherosclerosis leading to CAD is a complex pathophysiological process. With this disease, fatty streaks form on the walls of blood vessels beginning in childhood. The formation is directly related to increased level of serum low density lipoprotein (LDL) cholesterol (14). Berenson GS et al.demonstrated that the extent of atherosclerotic plaques in the blood vessels of young people is also related to the cardiovascular co-morbid factors such as high BMI, high blood pressure, dyslipidemia, and insulin resistance (15). In the Bogalusa Heart Study, a cohort of children was followed for 30 years and cardiovascular co-morbid risk factors were monitored, which included total cholesterol, very low density lipoproteins (VLDL), LDL, high density lipoprotein (HDL), systolic and diastolic blood pressure, and obesity. Investigators of this study demonstrated that the extent of arterial intimal surfaces covered with fatty streaks and fibrous plaques increased with age and the severity of these plaques is positively correlated to the number of co-morbid risk factors present. It is also observed that obesity independently influences the severity of atherosclerotic disease (15). The progression of the disease process relates not only to the number of risk factors but also to persistence of risk factors over time (16).

In addition to extent of atherosclerotic disease, left ventricular hypertrophy (LVH) is an independent risk factor for cardiovascular morbidity and mortality. Levy D et al. demonstrated that an increase in the left ventricular mass is associated with an increase in cardiovascular events - including death (17). Obesity and HTN, important determinants of LVH, frequently coexist and have an additive effect on left ventricular remodeling. Obesity induced metabolic, hemodynamic and inflammatory changes lead to LVH. The investigators of Bogalusa study and Lai et al. (18) demonstrated adverse effects of obesity and HTN on left ventricular geometry begins in childhood. In this longitudinal study by Lai et al, investigators followed 1,061 subjects with a mean follow-up of 28 years. Starting in childhood, subjects were examined four or more times for BMI and blood pressure (BP). All the subjects underwent cardiac evaluation with an echocardiogram in early adulthood and had the left ventricular dimensions measured in parasternal long-axis and short-axis views. Higher values for BMI and BP during childhood were associated with higher left ventricular mass index. Even though routine echocardiogram is not recommended, it is important not to overlook the adverse effects of obesity on the heart.

Importance of Risk Stratification for Atherosclerotic Disease:

The extent and severity of the atherosclerotic disease is related to the presence of co-morbid factors over time. Therefore, it is important to identify the children at high risk for atherosclerotic CVD. The major modifiable risk factors for the CVD include: Obesity, HTN, DM, and Dyslipidemia (increased LDL cholesterol and Triglycerides). In 2009, Dawson J et al. showed that triglycerides, diastolic blood pressure, obesity, and waist/hip ratio have a strong-association with aortic intima media thickness - an indicator of early atherosclerotic disease (19). Raitakari OT et al. demonstrated linear association between number of risk factors and the severity of atherosclerotic disease (20). Therefore, a comprehensive risk assessment plays a pivotal role in predicting and modifying the risk for atherosclerotic disease in the future. The CVD risk assessment includes age, sex, family history, BMI, blood pressure, glucose, and cholesterol.

In 2007, American Academy of Pediatrics endorsed the scientific statement issued by American Heart Association in 2006 on "Cardiovascular Risk Reduction in High-Risk Pediatric Patients" (21). In this statement, patients were stratified into high risk, moderate risk and at risk groups by the disease process *(Fig1)*. The risk stratification helps us in providing appropriate care and establishing treatment goals for each individual patient.

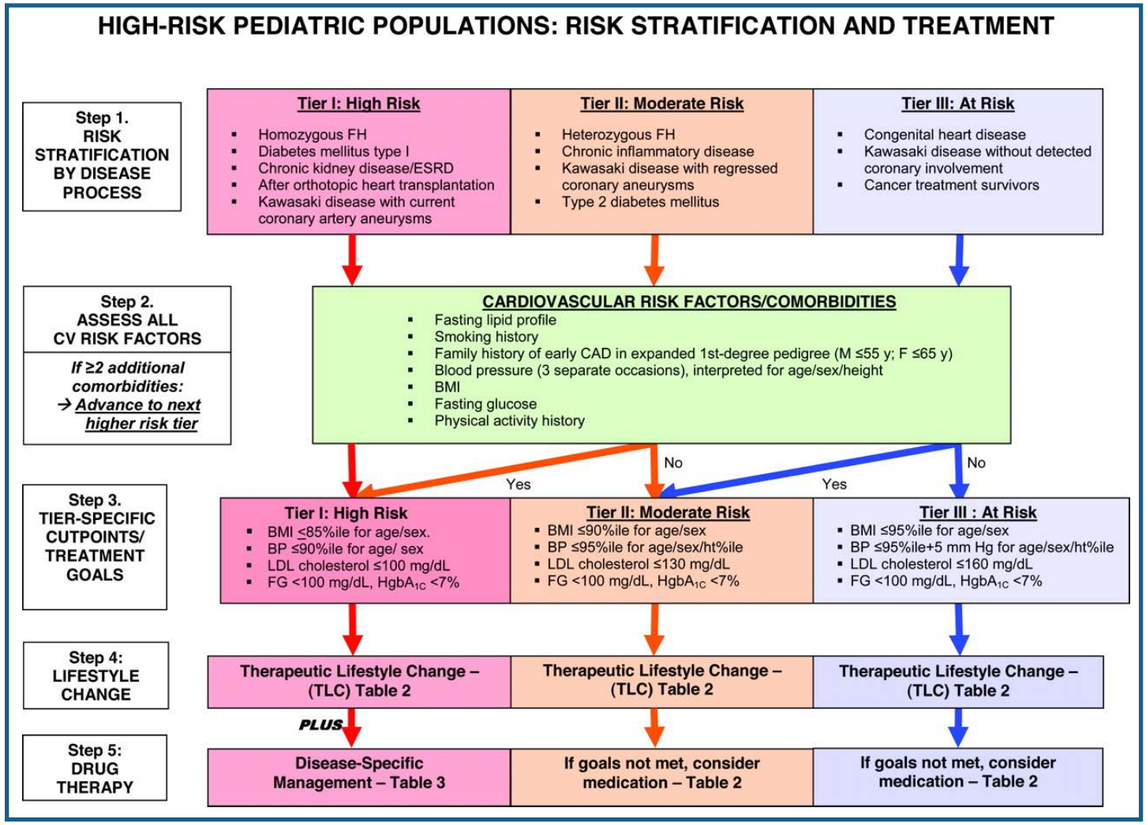

Figure 1: Risk stratification and treatment algorithm for high risk pediatric population (see full article for further information). "Cardiovascular Risk Reduction in High-Risk Pediatric Patients; Circulation. 2006 Dec 12; 114(24):2710-38. Permission granted by Wolters Kluwer Health Inc Licensed content publisher of the above mentioned statement to replicate the figure.

SCREENING FOR DYSLIPIDEMIA:

Dyslipidemia characterized by increased triglycerides, LDL cholesterol, and decreased HDL cholesterol is associated with atherosclerotic disease. As obesity is increasing, as is dyslipidemia.Evidence supports that early identification and treatment of lipid disorder during childhood and early adolescence substantially reduces the CVD risk in adult life (13). In 2011, an expert panel in Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents released evidence based recommendations for lipid screening in children (13). According to these guidelines there is no need to screen for dyslipidemia in children less than 2 years of age. The expert panel recommended for universal screening with a non-fasting lipid panel in children between 9-11 and 17-21 years of age. Lipid screening is not recommended for those ages 12-16 years because of significantly decreased sensitivity and specificity for predicting adult LDL-C levels and significantly increased false-negative results in this age group (13).The panel also recommended early screening for dyslipidemia with a fasting lipid panel twice and averaged in high risk children between 2-8 and 12-16 years of age.

HOW TO COMBAT OBESITY:

Obesity with the associated cardiovascular morbidity is a recognized public health priority because of the burden imposed on health care cost. The prevention and treatment of obesity is the key to the reduction of CVD. Pediatricians are in a unique position in that they can work closely with families to address the needs for proper nutrition, physical activity and lifestyle changes which are key in prevention and treatment of obesity. The AAP published a clinical report in 2008 on "The Role of Pediatrician in Primary Prevention of Obesity" (22). Pediatricians should be educated about factors and mechanisms leading to weight gain, which will enable them to provide appropriate counseling and recommendations to patients and their families. The pediatricians should also be aware of community based interventional programs and encourage patients and families to participate. The pediatricians should also take an active role in the community to encourage the need for parks, school infrastructure and programs to promote adequate physical activities and supporting healthy food in the schools.

An increase in physical activity, healthy diet, and reduction of screen-time are key factors in fighting the obesity (23). According to the physical activity guidelines released by Department of Health and Human Services, children and adolescents should be involved in 60 minutes or more of age-appropriate physical activity each day which should include a combination of aerobic exercise and musculoskeletal-strengthening exercises (24). The home environment should evolve to limit the opportunities for sedentary entertainment and screen time should be limited to less than two hours per day (22). This can be achieved by limiting the availability of television, video games, computers at home, especially in child's bedroom.

Nutrition plays an equally important role in maintenance of healthy weight.Optimal nutrition includes having a well-balanced diet, and reducing the number of empty calories from sugary drinks, pizza, and fast food. Family should be educated on the importance of decreasing the consumption of high calorie foods and replacing them with healthy alternatives like fruits, vegetables and water. Changing the environment to increase access to healthier foods will improve the choices children make about what they eat. It may also be helpful to decrease the size of serving dishes, plates, bowls and glasses for high-calorie foods and increasing them for low-calorie foods.

Community based health and wellness programs focusing on physical activity and nutritional education for families are powerful resource for pediatricians involved in the care of obese patients (25).Inspired by former First Lady Mrs. Obama's "Let's Move" campaign, Miami-Dade County Parks, Recreation and Open Spaces Parks Department started the "Fit-2-Play" after school program. For several years Miami-Dade County has been running this program: a fully supervised evidence/ outcome-based, interactive, fun and educational wellness program, which incorporates physical activity, sports, play and homework. This program fosters the development of healthier lifestyles with interactive learning. The program is available in 31 Miami-Dade park locations. Family-centered interventions targeting parents as healthy lifestyle role models for their children have shown encouraging results in preventing obesity among preschool children,suggesting a model that could be implemented statewide (26).

CONCLUSIONS:

Obesity is a complex and multifactorial disease affecting an increasing number of children around the world. Obesity affects the physical and social aspects of a child's life and most of all, it increases the likelihood of developing precursors of cardiovascular disease such as hypertension, diabetes and dyslipidemia. If the obesity epidemic we are facing is not controlled, it will lead to an increase in premature deaths from cardiovascular disease.

Obesity is the product of an imbalance between energy expenditure and food/calorie intake.

The etiology is multifactorial including genetics,child's characteristics, parenting style, socio-economic status, and environment along with a decrease in physical and an increase in sedentary activities.

Fighting obesity means a concerted effort to address each of these factors at different phases of life, from pregnancy through adulthood and modifying the environment which allows obesity to flourish.

Fighting obesity in children should start during pregnancy addressing hyperglycemia and hypertension and monitoring appropriate gestational weight gain. Education about healthy food and lifestyle should be initiated here. Throughout growth, the child should be educated to choose healthy foods rich in nutrients and the reduction of saturated fats and food with empty calories such as sugary drinks and fast food. Promoting physical activities and limiting screen time is essential. The education of children and parents is essential but the interventions at a higher level is essential, which means changing the infrastructure of the community with schools providing healthy meals and facilities promoting a healthy lifestyle through physical activity. Cities and communities will need to provide adequate areas such as parks and recreational spaces where children are encouraged to be involved in physical rather than sedentary activities.

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REVIEW ARTICLE

So You Want to Make it Better: Common Pitfalls in Quality Improvement

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INTRODUCTION

Something is bugging you, I guarantee it. There is at least one thing in your clinical domain that if you could fix, life would be OK. All right, maybe something doesn't bug you, but if not, I'm willing to bet there's something big that bugs your colleagues, nurses, front office staff, or even patients and their families.

Board-certified Pediatricians are required to improve professional practice as part 4 of their Maintenance of Certification (MOC) through the American Board of Pediatrics (ABP). Historically, many pediatricians have completed this requirement through Performance Improvement Modules (PIMS) rather than practice-developed quality improvement (QI) activities (Arvanitis, et al., 2017). However, the ABP has increasingly promoted the idea of gaining these MOC points through national QI efforts and practice-developed QI activities. Among the current processes of receiving MOC Part 4 credit, for $75, any group of 1-10 pediatricians can submit a QI project at abp.mymocam.com. By utilizing this route, you both fix one of those nagging problems *and* get your MOC requirements completed.

In order to get MOC credit, however, a QI project must follow the Institute for Healthcare Improvement's (IHI) model for improvement. Specifically, an application must: a) identify a "problem (gap in quality) that was addressed," b) have an aim statement that states "a clear, quantified goal set within a specific time frame," c) list "measures used to evaluate progress" with at least 3 points of measurement and d) list "interventions or changes that were made."

The following article seeks to familiarize the reader with the IHI Model of improvement on which these requirements are based, and to identify and solve three common pitfalls: a) focusing on a solution, not the underlying problem, b) not having the data you need to assess how you are doing, and c) planning too far ahead without learning as you go.

THE IHI MODEL FOR IMPROVEMENT

IHI (www.ihi.org) has multiple free resources for healthcare practitioners interested in learning more about QI. The basis for the QI taught by IHI is the Model for Improvement (Langley, et al., 2009) as shown in Figure 1. The Model for Improvement itself consists of three sequential questions followed by a series of Plan-Do-Study-Act cycles. Practicum Forms are available publicly at (http://www.ihi.org/education/ihiopenschool/Courses/Pages/PracticumForms.aspx).

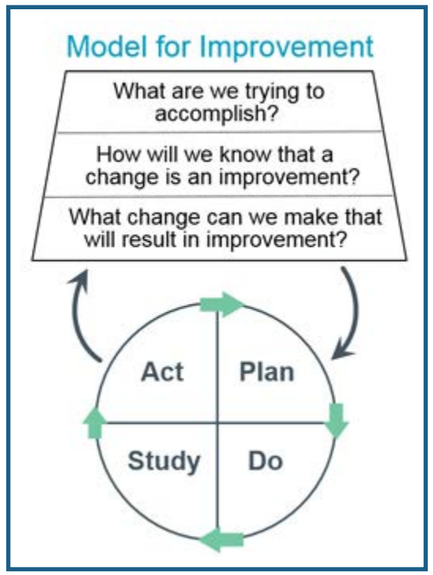

Figure 1. The Model for Improvement contains three sequential questions followed by a series of Plan-Do-Study-Act Cycles (Institute for Healthcare improvement, n.d.)

What are we trying to accomplish?

The first question seeks to clarify the aims of a quality improvement project. The aim is intended to be SMART, standing for specific, measureable, action oriented, reasonable, and time-bound. See Figure 2 for explanations and examples of each of these elements. It is often helpful to ask the question, "Assuming we don't interrupt any other processes, what is the one thing that, if true, we would consider a success?"

	EXPLANATION	GOOD EXAMPLE	BAD EXAMPLE
Specific	Needs to be objective. At the end of the project, there should be no doubt if you have succeeded or not	Lose 10 lbs in weight	Lose weight
Measureable	Related to attainable data with pre-set cutoffs	Lose 10 lbs in weight	Feel better looking in mirror
Action-oriented	Must be something over which you have control. If you cannot affect the outcomes, then it is pointless to try	Lose 10 lbs in weight	Gain 3 inches in height
Reasonable	Aim to have a 50-70% chance of succeeding in your goal. Not too easy that you don't push yourself, not too hard that you are destined to fail	Lose 10 lbs in weight	Lose 150 lbs in weight
Time-bound	Set a deadline by which you aim to succeed. This can be by a particular date or over a set amount of time	Lose 10 lbs in weight over the next 2 months (by June 21)	Lose 10 lbs in weight

Figure 2. Explanations and examples of SMART mnemonic for goal setting

How will we know that a change is an improvement?

"It is sometimes easier to make the world a better place than to prove you have made the world a better place" (Lewis, 2016). The second question of the Model of Improvement surrounds data gathering. Data can be collected informally for some simple projects, but formal data can allow the project's participants to create a vivid visual story of their success over time, as seen in run charts. Various metrics serve different purposes in the improvement measurement, including outcome measures (typically a reflection of the specific aim(s) from the first question), process measures (the things we do to try to get a better outcome), and balancing measures (the things we might mess up by fixing one part of the system.)

What change can we make that will result in an improvement?

Remember that "all improvement requires change, but not every change is improvement" (Langley, et al., 2009). When trying to brainstorm solutions, it is often best to look deeply into understanding the problem. Multiple tools such as key driver diagrams, fishbone (or Ishikawa) diagrams, and "five whys" can help with this phase. Five approaches are suggested for developing fundamental change: 1) logical thinking about the current system, 2) benchmarking or learning from others, 3) using technology, 4) creative thinking, and 5) using one or more of the 72 change concepts (for example, "change the order of process steps") (Langley, et al., 2009).

PDSA Cycles

PDSA cycles are where the work gets done. The cycle itself includes four stages: Plan what you are going to do, do the action, study the results of the action and act on the results by choosing the content of the next PDSA cycle. There exist four types of PDSA cycles, which are typically performed sequentially for a given proposed solution: Plan an intervention, test an intervention, implement an intervention, and spread an intervention.

Common QI Pitfalls: (Personal note: these cases are based on personal experiences as a pediatric hospitalist, but similar problems could just as easily arise in the outpatient or subspecialty setting.)

Pitfall 1: Focusing on a solution, not the underlying problem

Case: A group of physicians is hoping to decrease the delay that families have waiting for medications to be delivered prior to discharge. The initial proposed solution is to ask parents to complete a questionnaire at the time of admission to determine which medications will need to be prescribed to facilitate the timely fill and delivery of necessary prescriptions. They quickly determine that the families are too busy to complete this questionnaire and attempt multiple methods to get the prescriptions written at the time of admission, all of which fail.

Eventual solution: The physicians eventually return to their SMART aim statement, which reads, "To decrease the time between eligible patients being ready for discharge and having a discharge order from 150 minutes to 75 minutes within 6 months." They then consider the amount of time it takes for prescriptions to be filled by the delivering pharmacy and realized that there will be no delay in discharge as long as the prescriptions are written at least 2 hours prior to the patient being ready for discharge. They change their focus to increasing the proportion of prescriptions written more than 4 hours prior to the patient becoming ready for discharge. The project is successful and succeeds in reaching its SMART aim.

Commentary: Most physicians are problem solvers. When we see something that is wrong, our minds flood with potential solutions. In addition, people are more likely to value something they have created. Problem solvers can lose track of the problem they are trying to solve and instead spend inordinate time and energy fixing their solution. Having a prominent aims statement and using one of the techniques (key driver diagrams, fishbone diagrams, "five whys") to brainstorm root causes and potential solutions can help to keep the focus on the problem. Consistently returning to that statement can help to unstick projects that seem to be stalled.

Pitfall 2: Not having the data you need to assess how you are doing

Case: A team of physicians is appalled at how infrequently other physicians clean their white coats. To get a sense of the problem, they survey a number of physicians about when the last time was that they had their white coat washed. The results show that most white coats have not been washed in months. They then provide education to the physicians about how often they should be washing their white coats and resurvey. The survey results are pristine! Every physician reports having their white coat washed within the last 3-4 days. The team does not believe the results and feels like they have not made a significant improvement.

Eventual solution: The team discovers that the vast majority of local physicians use a particular laundry service through the hospital. They team up with the laundry service and get a weekly report of physician white coats laundered. Over the next

3 months, they show that on average, the number of white coats cleaned increases from 0.05 coats per physician per week to 0.5 coats per physician per week.

Commentary: Having a robust data plan is key to assessing the success of a quality improvement project. Ideally, the data collected should come in regular intervals, be objective, and match the project's specific aim. The closer that the data represents the actual processes or outcomes the better. In the case above, there were multiple problems. First, the initial data was subjective and survey-based. It probably represented people's knowledge of what they should do, but not necessarily what their actual behavior. The solution improved upon this problem by getting data that tracked actual physician behavior. Second, the pre-test/post-test nature of two surveys makes it very difficult to tell a story over time. By getting weekly data, the team was able to show exactly when the increase occurred and that it was sustained over time. They also will be able to identify future changes in laundering practices.

Pitfall 3: Planning too far ahead without learning as you go

Case: A group of physicians are putting in place a new checklist for discharge of inpatients. They have met multiple times, refined the checklist, and are now planning to implement it on one of the pediatric floors. They plan to rollout the checklist itself for 3 months, followed by additional re-education of staff and a second phase of interventions. When the checklist is implemented, there is immediate pushback from the nurses that is takes too much time and no one is doing it. The physicians decide to wait the full 3 months in order to get good data for their implementation.

Eventual solution: The physicians eventually realize that the qualitative information they are receiving from the nurses is more powerful than any numerical data they might gather over the next 3 months. They remove the checklist from the floor. They then meet with the nurses, refine the checklist and test it with a single discharge. After 3 attempts, they find a version that works well and expand it until they feel comfortable implementing this version on the unit as a whole.

Commentary: While quantitative data is important, it is even more important to remember that we get multiple types of information in quality improvement. In addition, when possible, it is often helpful to move through the develop, test, implement, and spread stages in order, without skipping the testing stage. You never know what will or will not work in the real world until you try, and the subjective response you get from those who attempt to use your solution will speak volumes. One piece of advice is to start with "one patient, one provider, on one day" until that succeeds and then increase one of those numbers by a factor of five. For example, you could try five consecutive patients by a single provider on a single day to scale up. By studying the information you receive during the "do" phase of the PDSA, it can be quicker and easier to redirect when a project veers off-course.

CONCLUSIONS

While the cases presented may seem far-fetched, they are each based on real problems I have encountered in trying to improve quality as a pediatric hospitalist (most of which I have caused). In each of these cases, there was a common lesson to learn: taking the time to go through the steps of the Model for Improvement in order will usually speed up the overall progress of a quality improvement project.

Preparation and thought up front will grease the wheels down the line. And, almost as importantly, they will ensure that the project is eligible for much needed MOC part 4 credit!

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RESIDENT ARTICLE

Ceftriaxone Use in Neonates

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Both Ceftriaxone and Cefotaxime have been used to treat infections in children since the 1980s. These two antibiotics have been the mainstay for the management of sepsis in children. However, most experts recommend that only cefotaxime should be used in the neonatal age group. This is in large part because of concerns about the risk of hyperbilirubinemia associated with ceftriaxone use in neonates. Despite this concern some centers used ceftriaxone for treatment of neonatal sepsis in those neonates in whom hyperbilirubinemia was not a concern.

With the recent shortage of cefotaxime there has been a renewed interest in the possible ceftriaxone use in the neonates. More recently, an additional serious adverse effect of the use of ceftriaxone with calcium has raised concerns.

In this review, we discuss the potential risks of ceftriaxone use in neonates and offer suggestions when ceftriaxone may be considered for use in neonates, especially when cefotaxime is not available.

CEFTRIAXONE SAFETY IN NEWBORNS:

Ceftriaxone is an attractive medication to use in children given its long half-life, excellent CSF penetration, wide spectrum of activity against microorganisms, and good safety profile. Ceftriaxone has been used in the neonates since its approval in 1984, however, the limitation to use was in premature neonates with hyperbilirubinemia.

In neonates, ceftriaxone given at a dose of 50 mg/kg intravenously or intramuscularly reaches a similar maximum plasma concentration level[1]. A loading dose of 100 mg/kg/day and subsequent doses of 80 mg/kg/day to treat meningitis has been suggested by some[2]. However, a dose of 50 mg/kg/day is sufficient to reach bactericidal levels in CSF[2,3]. Almost 60% of ceftriaxone is eliminated in the urine and the rest in the gastrointestinal tract through the hepatobiliary system. Ceftriaxone clearance increases with the increase of postnatal age and decreases with worsening kidney function.

CARDIORESPIRATORY ADVERSE EVENTS:

In 2006 a fatal neonatal case associated with ceftriaxone use was reported to the French regulatory agency. This resulted in ultimately updating the ceftriaxone label in 2007[4]. After the initial French report, an additional nine cases of cardiorespiratory arrest in neonates were also reported to the FDA. These cases were associated with the concurrent use of ceftriaxone with calcium containing fluids. Bradly et al 4 reviewed eight of these nine cases. Seven of the eight infants died. A dose of 200 mg/kg either once daily or divided every 12 hours was used in two neonates. This dose was much higher than the recommended dose of ceftriaxone. In addition, ceftriaxone was administered as a fast push over 2-4 minutes instead of the recommended 30 minutes infusion in two other cases. In four neonates who had autopsies done, arterial crystalline thrombi were found in all of them.

A follow-up study showed that, in vitro, the presence of calcium and ceftriaxone together can result in precipitations in both neonatal and adult plasma. For unknown reasons, the affinity of ceftriaxone to make insoluble calcium ceftriaxone salts was significantly higher in neonates. This study added to the concerns about ceftriaxone use in neonates[5].

INDIRECT HYPERBILIRUBINEMIA:

Hyperbilirubinemia associated with ceftriaxone use has been a concern since the approval of this drug. The major risk of hyperbilirubinemia is kernicterus. Kapitulnik at el found that the bilirubin-binding affinity to albumin in full term infants increases as early as the third day of life and gradually reaches the adult level by 5 months of ages[6,7]. However, a prolonged bilirubin binding defect in sick premature infants is seen8. That could be explained by a significant albumin decrease in sick infants after birth9. Consequently, the effect of ceftriaxone-albumin affinity would be less hazardous if the drug is used after 5 days of age in full term babies since their bilirubin binding capacity recovers as early as 5 days of life[9]. Ceftriaxone competes with bilirubin on the albumin binding sites. In vitro, ceftriaxone at a dose of 50 mg/kg over 30 minutes has a maximal displacement factor (MDF) of 2. The MDF defines a numeric estimate of the effect of the drug in displacing bilirubin from albumin binding sites and MDF of ≥1.2 is considered a potential risk for all jaundice infants[9,10]. In neonatal studies, the MDF dropped with a prolonged infusion of ceftriaxone over a 60-minute period[11].

BILIARY SLUDGE:

Ceftriaxone calcium salt was identified as a major component of the biliary sludge associated with ceftriaxone use[12]. Transient and asymptomatic pseudolithiasis with ceftriaxone use has been seen in infants up to 24 months of age[13,14]. Biliary sludge has been reported more frequently in children older than 24 months of age in whom ceftriaxone was dosed more than 2 grams. Other risk factors of biliary sludge with ceftriaxone use include, a course longer than 4 days, decreased biliary flow and increased ceftriaxone excretion though the biliary tract[15]. A recent study has suggested that a possible genetic predisposition to developing pseudolithiasis[16]. It appears that infants as opposed to older children tend to develop pseudolithiasis after 2-4 days of use[14,17]. Like older children, neonates rarely have clinical or laboratory evidence of cholelithiasis.

NEPHROLITHIASIS:

The association between ceftriaxone use and obstructive kidney stones was first reported in 1988[18]. Similar to biliary pseudolithiasis, small, asymptomatic and transit urinary stones can be formed in the first 10 days of treatment[19,20]. There are conflicting reports about hypercalciuria associated with ceftriaxone use[19,20 21,22]. The incidence of ceftriaxone induced nephrolithiasis in children is reported to be 1.4% and is less than biliary pseudolithiasis[19]. Risk factors that can result in large obstructing stones include dehydration, fluid restriction and nephrotoxic medication[20,23]. To the best of our knowledge there are no reports of nephrolithiasis in the neonatal period.

ALLERGIC REACTIONS:

Anaphylactic reactions with cephalosporin use are rare with frequency of 0.0001 to 0.1%[24]. There are two reports of anaphylactic reactions in neonates with ceftriaxone use. A 3-day old newborn experienced classical symptom including skin manifestations with the very first dose of ceftriaxone. A repeated dose in controlled environment revealed the same presentation which was immediately reversed with epinephren[25]. The second case is of a 10-day old male who had a sudden cardiorespiratory collapse immediately after the fifth dose of ceftriaxone[26]. Anaphylactic reactions with ceftriaxone use have also been reported in older children[27].

Type 3 immune complex hypersensitivity linked to ceftriaxone has also been reported in the pediatric population. A total of 23 cases of acute intravascular hemolytic anemia have been reported in children ≥ 2 years old[28]. Almost all the cases had either a hematological disorder or chronic or recurrent infections. To our knowledge there are no similar adverse events reported in neonates.

OTHER ADVERSE EVENTS:

Ceftriaxone induced hepatitis is observed rarely. Two cases in adolescents have been reported in the literature. Elevated hepatic enzymes with direct hyperbilirubinemia has also been seen. Hepatitis was the result of either a delayed ceftriaxone hypersensitivity[29] or a severe immune complex hypersensitivity reaction with acute hemolytic disease[30]. Other possible causes of ceftriaxone induced hepatitis could be cholestatic reaction, direct toxicity or idiosyncratic drug injury[29]. Ceftriaxone induced reversible pancreatitis has been reported in a two-year-old child[31].

CONCLUSION:

Although ceftriaxone has not commonly been used in neonates, the recent shortage of cefotaxime has allowed an opportunity to re-evaluate this practice. There may be a place for use of ceftriaxone as an alternative in a selected group of neonates who are not premature and do not have hyperbilirubinemia or a risk for developing hyperbilirubinemia. In addition, ceftriaxone should not be used in neonates receiving calcium containing fluids. Ceftriaxone use should be considered in term, previously healthy neonates as a definitive antimicrobial therapy for neonatal sepsis if cefotaxime is not available.

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STUDENT ARTICLE

Caregiving Youth in the United States: A Policy Perspective

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Sophia's family lives in a small apartment in West Palm Beach. She is 13 years old, has one younger sister who has autism, and a younger brother who has anger issues. Sophia's mother is overwhelmed with having two younger children with behavioral issues; she is experiencing depression. Mom's family lives in the Dominican Republic and Dad's family lives in Costa Rica. Dad is not living in the home as mom has asked him to leave due to adultery. Mom is seeking a divorce and leans a lot on Sophia for a listening ear. Sophia, like many other children in our community and beyond, serves as a caregiver to her family. This is one of countless examples of youth caregivers in the United States.

The National Alliance for Caregiving 2015 Report estimates that approximately 43.5 million adults in the United States have served in a caregiving role within the past year (1). While adults may be classically represented in this group, a population of caregiving youth exists in the United States; they are not included in this data. Caregiving youth are younger than 18 years old and provide significant assistance to relatives or household members who have a physical or mental illness, disability, frailties of aging, or substance misuse (2). Because children are often perceived as the receivers of caregiving, the term "caregiving youth" seems quite dichotomous, but the literature indicates that 1.3 to 1.4 million children between the age of 8 and 18 years serve as caregivers, as estimated in 2005 in the first national survey of youth caregivers in America (3). Twelve years have passed since this estimate was published; it is probable that this number has increased.

The AARP Public Policy Institute has calculated that the economic value of family caregivers in the US is $470 billion based on 2013 data, up from an estimated $450 billion in 2009 and $375 billion in 2007. An additional $8.5 billion dollars is the estimated value of youth caregivers in the United States, and this has not been updated with the most recent data (4). As evidenced by these numbers, caregiving by adults and youth is an invaluable service with tangible worth.

Most frequently, youth caregivers aid in the care of a grandparent or parent, and sometimes to a sibling with a health condition. Caregiving responsibilities include activities of daily living such as bathing, dressing, feeding, and toileting as well as instrumental activities of daily living such as meal preparation, shopping, household tasks, and even giving and

managing medication. These caregiving tasks can come at a price, especially for children whose primary task is supposed to be education along with age appropriate play and recreation.

From increased risk of anxiety and depression to poorer function in school, studies indicate that youth caregivers do not always fare as well as their non-caregiving counterparts mentally and physically (5). This difference is magnified in minority and financially insecure households with caregiving youth. For example, studies in caregiving minority populations have shown decreased utilization of coping strategies and lower life satisfaction in comparison to Caucasian counterparts (6).

While most pediatric health care providers have interacted with caregiving youth while in practice, many have not had the awareness to identify them as "caregiving youth", in need of specific supportive services. Some may have even considered this concept as objectionable, labeling the family's circumstances as unacceptable for a child. However, pediatric health care providers must recognize that both societal determinants and personal motivations thrust children into this role. Necessity, love and a sense of obligation all contribute to this phenomenon. Rather than impugning families who rely on children as caregivers, it is the responsibility of health care providers to advocate for their support.

Multiple bills pertaining to the provision of support services for adult caregivers have been enacted to law on both the federal and state levels in recent years (7,8). While the US government recognizes adult caregivers, caregiving youth are ignored in this arena and excluded from these benefits. There is no policy in the US that either acknowledges or provides an avenue for respite or support for these children.

This starkly contrasts with other countries, such as the UK, Australia, and Ireland, where caregiving youth encompass about 2% to 4% of the total childhood population are legally recognized as caregivers (9). Such legislation is aligned with the spirit of The United Nations Convention on the Rights of the Child (UNCRC), passed by the UN in 1989 as a comprehensive safeguard for children's rights. The UNCRC provides a framework for the protection of political, economic, social, health, and cultural rights of children of all participating UN entities (10). While 195 countries have ratified the Convention on the Rights of the Child (CRC), only one UN country has not: the United States (11). With similar economic development to that of the US, the UK and Australia provide case studies for comparison.

The UK provides a brilliant model of a policy framework inclusive of caregiving youth. Largely since the Children's Act of 1989, "young carers" have been recognized in the eyes of the government (12). A national network of services exists for young carers, and they are recognized in various governmental policy and guidance documents (13).

They are afforded the right to appropriate support services, involving formal assessment of their needs and ability to care for another person under the 2014 Children and Families Act and Care Act (14).

In Australia, stemming from policies that originated in the mid-1990s, the government has provided support to regional Carers Associations and Carers Groups to provide support services such as camps, mentoring programs, and counseling services, to name a few. Young carers in every region through age 25 years can rest assured that they will be provided support, as all Australian states have organizations and initiatives dedicated to this special population. Additionally, Through the Department of Families, Housing, Community Services, and Indigenous Affairs, Australia provides the Carer Payment and Carer Allowance programs, which give monetary supplementation to adult and youth caregivers in the country (15).

While the Carer Payment provides pension-like income support for those providing constant care for another person, the Carer Allowance is a supplementary payment for those who provide daily care at home, and the payment most often utilized by youth caregivers. While young carers still encompass only a small portion of recipients of these financial support programs, utilization marks the need for support. Additionally, utilization among this group has steadily increased in the years since the policy's inception (16).

Despite examples of policy changes in other developed countries, legislators in the US have been slow to adopt any changes to benefit this group. Youth caregivers in the United States have no specific legal rights. Why is the United States lagging so far behind other countries on this important issue?

Chief among the advocates for caregiving youth is the American Association of Caregiving Youth® (AACY). The AACY is a private, nonprofit organization in Palm Beach County, Florida (www.aacy.org). It works among the domains of education, community, and healthcare. In 2006, AACY launched the Caregiving Youth Project, and partners with The School District of Palm Beach County to identify caregivers among middle and high school students and provide services in and out of school as well as at home. It fills an important gap in delivery of support services for this special population. AACY stands alone in the US, compared to the multitude of similar organizations in other parts of the world.

In countries previously mentioned, non-governmental organizations have advocated to move policy forward throughout their lands. In contrast, numerous young lives in the US lack support services and are at risk for school dropout. In the absence of policy infrastructure bolstering the efforts of AACY, and without further expansion, these young people will stay unrecognized and unsupported. An integrated system with components similar to those offered through the Caregiving Youth Project, should be established throughout the US.

In addition, much more can be done for youth caregivers on the local level. Pediatric health professionals should play an important role in providing support by identifying youth caregivers, recognizing their strengths, and understanding their unique role with its challenges including physical and emotional health risks. For example, in practice and in clinics, pediatric health professionals can raise awareness of issues facing caregiving youth among associates and staff as well as document family health situations and youth caregiving responsibilities. Additionally, resources that already exist, such as the AACY, can be utilized along with advocating on their behalf among legislators, religious and business leaders, and in educational and professional groups.

Since her enrollment in the Caregiving Youth Project, Sophia continues with Skills Building groups in school where she has learned she is no longer alone, has made new friends, and has even gone on a CYP fishing trip. She is managing her stress better and more willingly helps mom with her siblings. Sophia is being supported through her transition into high school. Mom now attends an autism support group and has gotten help through Legal Aid. She is also now enrolled in college. The future is beginning to look bright for what once seemed bleak.

Remember the faces of youth caregivers in everyday practice along with strong advocacy for reform on the policy level.

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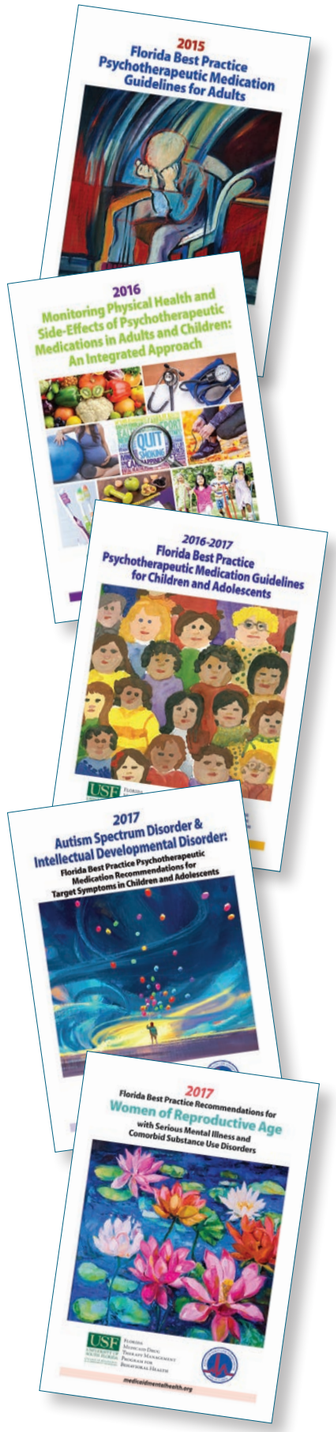

Florida Medicaid Drug Therapy Management Program for Behavioral Health

Working with Medicaid health plans and providers to:

- Improve behavioral health prescribing practices
- Improve patient adherence to medication
- Reduce clinical risks and medication side effects
- Improve behavioral and physical health outcomes

The following treatment guidelines are available on our website at medicaidmentalhealth.org.

- Autism Spectrum Disorder & Intellectual Developmental Disorder: Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents
- Best Practice Psychotherapeutic Medication Guidelines for Adults
- Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach
- Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents
- Florida Best Practice Recommendations for Women of Reproductive Age with Severe Mental Illness and Comorbid Substance Use Disorders

The Florida Clozapine Hotline and **The Florida Pediatric Psychiatry Hotline** are free services that provide consultation about medication management.

Florida Clozapine Hotline 1-727-562-6762

Florida Pediatric Psychiatry Hotline 1-866-487-9507

If you would like hard copies of any of our guidelines mailed to you, please contact

Sabrina Singh at sabrinasingh@usf.edu.

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For more information, visit us at **medicaidmentalhealth.org**