Headache Action Plan Project for Youth (HAPPY): System Change through School-Facilitated Intervention

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Abstract:

Migraine is one of the top five health problems experienced by youth and can become increasingly disabling if not treated early with evidence-based approaches. School nurses and primary care physicians are optimally positioned to facilitate treatment before the risk of worsening disability is created but typically have limited training in migraine management. Our project goal is to establish a generalizable framework for system change in which community schools become a vehicle for the early identification of migraine and facilitation of optimal primary care management. To achieve this goal, an innovative education plan centered on use of an evidence-based migraine management template ("Headache Action Plan") will be implemented in a target community. School nurses will be trained to screen students for migraine in need of improved management and to facilitate a process for Headache Action Plans to be implemented during primary care visits for headache. Primary care providers in the targeted community will be educated through a series of live sessions on migraine management and use of the Headache Action Plans to help prevent worsening migraine-related disability. A dedicated web portal will supplement live education through assisting in implementation of Headache Action Plans and furnishing useful resources to school nurses, PCPs, and students and their parents. Feasibility and system level outcomes (i.e., changes in prescription patterns, changes in patient disability, and changes in healthcare utilization) will be evaluated over time and between the target and control regions of a community served by the applicant pediatric hospital to determine project impact.

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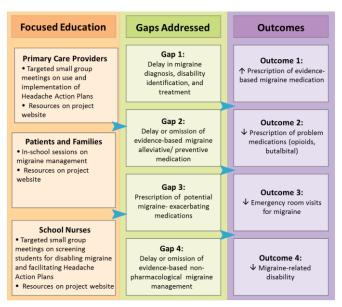
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1. Overall Goal & Objectives

1.1 Goals. Migraines are among the top ten most disabling medical conditions worldwide (Vos et al., 2012) and for the majority of individuals first develop in childhood (Stewart et al., 1992), with migraine being one of the top five health problems experienced by youth (Hershey & Winner, 2005). Compelling cumulative evidence from the basic sciences and clinical research suggests that in most cases <u>migraines will become increasingly frequent, severe, and disabling if not identified and appropriately treated with evidence-based treatment approaches soon after first development (Bigal & Lipton, 2011; Charles et al., 2009; Monastero et al., 2006). By inference, therefore, migraine can be prevented as a leading cause of worldwide disability assuming that the known gaps to identifying and appropriately treating migraine in youth can be overcome.</u>

The long-term goal of the headache program at the applicant institution is to reduce the risk of enduring disability in youth with migraine through evidence-informed, patient-tailored multimodal treatment and prevention strategies. Our <u>specific goal</u> for the proposed project <u>is to establish a sustainable, scalable, and generalizable framework for system change in which community schools become a vehicle for early recognition of students with migraines in need of <u>improved care and facilitation of evidence-based primary care management.</u> To achieve this goal, we plan to implement and evaluate a multi-layer system change approach that will unite the applicant organization, community schools, and primary care providers in addressing the critical gaps in pediatric migraine care that contribute to headache refractoriness, repeated</u>

emergent care, and increasingly worsening impairment in physical, social, academic, and emotional functioning. In particular, our planned novel approach to system change (discussed in Section 2.2 and outlined graphically in the figure to the right) aims to reduce delays in migraine diagnosis, deficiencies in the prescription of evidence-based migraine medications in primary care, inappropriate prescription of ineffective medications in primary care, and delay or omission of evidence-based nonpharmacological migraine management strategies. In so doing, our interdisciplinary project team seeks to



create a tangible and sustainable impact on the community of children with migraine whose lives might otherwise be marked by progressively worsening disability. <u>The project therefore is directly aligned with several foci of the Pfizer RFP</u>, including the need to: (a) increase the role and the involvement of primary care providers in the management of pediatric migraine; (b) design and implement comprehensive learning and system change strategies that facilitate improving the diagnosis and management of pediatric migraine; and (c) achieve long-term goals of migraine management through professional training, patient (and parent) education, and appropriate medical and non-pharmacological treatment. Similarly, <u>the project goal also is</u>

<u>aligned with the vision of the applicant organization to advance pediatric health and deliver</u> optimal health outcomes through innovation and a high-value, integrated system of care.

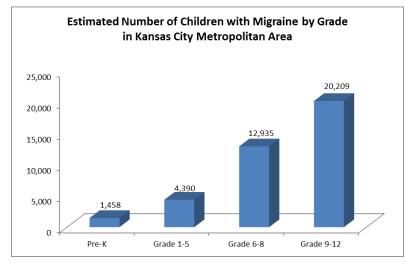
- **1.2 Objectives.** Through the provision of education and straightforward evidence-based management tools, the proposed project seeks to mobilize the "front line" clinicians in the community that are fundamental to positively changing the trajectory of children with migraine soon after symptoms first develop: school nurses and primary care physicians. The specific overall objective of the project is to assess the feasibility and impact on clinically relevant system-level outcomes of implementing a migraine recognition and care plan strategy in local school districts. The specific aims related to this overall objective are to:
- (a) equip school nurses through focused education with the ability to recognize symptoms of migraine in students, assess the need for improved management based on headache-related disability, and facilitate evidence-based primary care management;
- (b) expedite and optimize evidence-based medical treatment of pediatric migraine in primary care through school nurse-facilitated identification of youth in need of enhanced care, provider education, and provision of evidence-based treatment guidelines (i.e., "Headache Action Plans"); and
- (c) equip students with migraine, their parents, their schools, and their primary care providers with specific information and tools for reducing migraine-related disability.

These objectives will be accomplished through a series of focused face-to-face educational sessions supplemented with web-based migraine education and management tools designed for school nurses, children identified at schools as in need of enhanced migraine management and their parents, and community-based primary care providers. Through this initial project, we hope to establish a viable framework and the tools necessary for system change in pediatric migraine care. With these project outcomes, we will be positioned to broadly disseminate a system change approach that we hope ultimately has the capacity to positively transform pediatric migraine care in our region, nationally, and beyond.

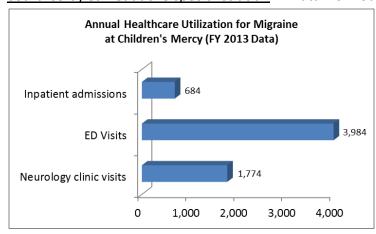
2. Technical Approach

2.1 Current assessment of need in target area. Based on estimates of migraine prevalence in youth (Abu-Arafeh et al., 2010) and the age distribution of the general catchment

area served by the applicant pediatric medical center (Children's Mercy, Kansas City, MO), the expected number of individuals under 18 years old having migraine in the region of the applicant organization is approximately 165,000 (Annie E. Casey Foundation, 2014). Estimates of migraine prevalence by grade level in just the immediate Kansas City region are shown graphically in the figure to the right.



Children's Mercy provides healthcare services to over 90% of those in the pediatric age range seeking specialty care in the Kansas City and surrounding region. Thus, if all children in the region received specialty care for migraine, the headache program at Children's Mercy would need to manage over 140,000 children with migraine. Although the number of children actually seen at Children's Mercy for migraine treatment is considerably less, nevertheless the demand for services is particularly high given that the <u>surrounding states are among those with the worst ratio of headache specialists to children with migraine, with the state of Kansas having no board-certified headache specialist at all.³ Data from our institution in the 2013 calendar year</u>



show that pediatric migraine constituted 20% of the 8,874 outpatient Neurology clinic visits, 6% of the 66,405 Emergency Department visits, and 5% of the 13,692 inpatient visits (see figure to the left). Taken together, there is clear evidence of a significant need for pediatric migraine care in our community that cannot be tenably met at the level of subspecialty care.

The disparity in demand for pediatric migraine care and the supply of specialty providers in our region has significant implications for community healthcare providers. Due to limited availability of headache specialists, the evaluation and management of treatment-seeking children with migraine typically is done through primary care. Even when children are referred for specialty evaluation and management of headache, primary care management often must continue for several months while families are awaiting an appointment. Primary care providers, however, rarely receive any training in the diagnosis and evidence-based management of pediatric migraine (Gallagher et al., 2005; Sivaswamy & Pawlik, 2013). The resulting knowledge gaps often result in delayed or incorrect diagnosis, delay in treatment, omission of evidence-based migraine medications early on, and prescription of inappropriate medications (e.g., opioids and butalbital), all of which have been consistently shown to lead to worse headache outcomes and greater healthcare utilization (Charles et al., 2009; Bigal et al., 2008; Langer-Gould et al., 2013).

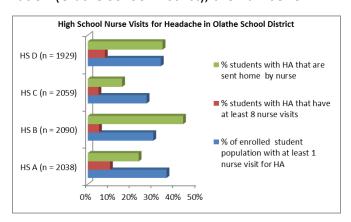
With regard to local data on indicators of knowledge gaps affecting migraine management in primary care, a review of 2014 electronic medical record data at our institution revealed that only 30% of patients referred to Neurology that were ultimately diagnosed with migraine had any medications prescribed in primary care, of which 21% of patients had been prescribed opioids or butalbital. These data dovetail with findings from a survey study of community pediatricians that revealed rare use of any preventive medication or triptan therapy for migraine management (Sivaswamy & Pawlik, 2013). Deficiencies in primary care knowledge of pediatric migraine thus has generated a system which inherently contains preventable risk factors for migraine chronification, worsening disability, and greater healthcare resource utilization. Improving such a system in part requires equipping primary care providers with knowledge of evidence-based migraine care. Indeed, data suggest that simply increasing the

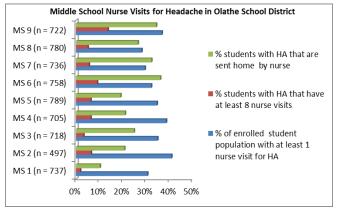
use of appropriate migraine preventive and abortive medication significantly reduces emergency room visits, hospital admissions, physician visits, and unnecessary diagnostic procedures (Silberstein et al., 2003, 2007).

Improving the migraine care system through education of primary care practitioners, however, assumes that most families consult a medical professional for headaches. Yet data suggest that the majority of patients with migraine do *not* see a healthcare provider for treatment (Lipton et al., 2013). Any successful effort to change the current system of migraine care in the community therefore must also find a way to reach children who have not yet sought medical treatment. One unique avenue for doing so is to partner with school nurses in system change efforts. School nurses frequently encounter children with headaches in their daily work. For example, based on 2013 school year data we collected from one of the largest school districts served by the applicant organization (Olathe School District), the number of

visits to the school nurse for headache amounted to 33% of the enrolled student population, with 7% of students having at least 8 school nurse visits related to headache (see figures to the right). Data suggest that fewer than half of these children likely had ever seen a primary care physician or headache specialist (Lipton et al. 2011, 2013). As in the case with primary care physicians, however, school nurses rarely have training in recognition or management of migraine in children and adolescents. As a result, they may not identify whether children are getting appropriate care for migraine. Moreover, school nurses often send children home from school with migraine symptoms (see figures to the right), which if repeated over time can establish a system in which migraines and school-related disability progressively worsen without children ever receiving evidence-based care (Kernick &

Campbell, 2009; Rees & Sabia, 2011).





Based on data we collected in 2014 on newly referred patients to the Division of Neurology at the applicant organization, youth missed up to 60 days of school per year for migraine (\underline{M} = 4.5 days/year, range = 0-60). Headache also was responsible for 18% of the students who were on medical homebound in the Olathe School District. Interestingly, those prescribed evidence-based preventive medicine for migraine in primary care before referral to Children's Mercy missed 50% less school days than those who were not. <u>Our plan of educating school nurses to recognize children with migraine in need of improved management, facilitate primary care treatment plans, and implement strategies capable of preventing long-term</u>

<u>disability therefore hold great promise for optimally transforming the system of pediatric</u> migraine care.

In summary, left as is, the system of pediatric migraine management in the region will continue to facilitate a pathway toward school-related disability, healthcare burden and adverse public health outcomes. <u>To change the system, education and collaboration is needed with school nurses and primary care physicians given their fundamental role in positively changing the trajectory of children with migraine</u>.

2.2 Project Design and Methods.

2.2.1 Overview of Project Procedures. The proposed project seeks to change the current system of migraine care in the community beginning with one region served by the applicant organization (i.e., USD No. 233 - Olathe School District) and then generalizing findings and methods to other districts. Based on our assessment of need as outlined in Section 2.1 above, our proposed project will target both school nurses and primary care physicians as the principal agents of initiating system change in migraine management. Research on effective continuing education strategies for healthcare providers has demonstrated that practice is more likely to be changed with multiple exposure to the content, use of multiple media (versus, for example, written educational materials alone), interactive small group-based sessions, and provision of specific tools to use in practice (Marinopoulos et al., 2007; Davis et al., 1995, 1999; Tian et al., 2007; Cauffman et al., 2002); didactic sessions alone have not consistently shown efficacy in changing healthcare provider practices (Davis et al., 1999). Rather than exclusively relying on less effective generic education on pediatric migraine to generate changes in behavior of the target audience, therefore, our education plan (described in more detail in section 2.2.5 below) is principally designed to support the initiation of straightforward evidencebased migraine management plans ("Headache Action Plans") for those students identified by school nurses as in need of enhanced migraine management based on school-related disability. We plan to also supplement live migraine education and facilitate the initiation of Headache Action Plans through the use of an educational web portal that will be custom-designed to meet the needs of our project (described in more detail in section 2.2.6 below). The web-based system will help support implementation and coordination of the Headache Action Plans across those involved (school nurses, primary care physicians, and children and families) and will assist in the collection of outcomes data.

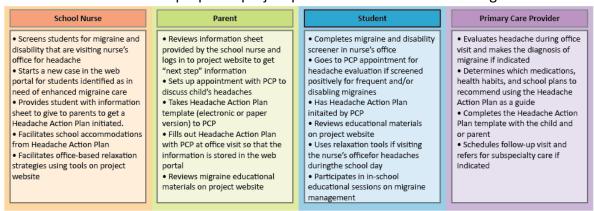
As part of the proposed education plan, school nurses will learn to administer brief migraine and migraine-related disability screening tools to middle school and high school students in a targeted school district that visit the school nurse's office for headache. The screening tools will include the ID Migraine – a three-item tool having fair sensitivity, specificity, and validity for diagnosing migraine in adults and adolescents (Lipton et al., 2003; Zarifoğlu et al., 2008), and an adapted version of the PedMIDAS – a six-item questionnaire that assesses migraine-related disability over the past month; the one-month time frame was found to improve accuracy over the three-month time frame used in the original PedMIDAS (Heyer et al., 2014). Eligibility criteria for initiating the Headache Action Plan process will include a positive ID Migraine screen and either (a) headaches occurring at least four times per month, or (b) clinically relevant disability indicated by a score of >10 (corresponding to the lower end of moderate disability) on the adapted PedMIDAS. If students are found to be in need of a

Headache Action Plan by the school nurse, an information sheet about the Headache Action Plan project will be given to the student to take home to parents along with information on accessing the project website with a given username and password.

Parents accessing the project website will receive further information on the project, educational information on migraine management, and recommended "next steps." In the "next steps" section, parents will be instructed to set up an appointment with a primary care provider *specifically for headaches* (as is recommended based on findings from the American Migraine Communication Study; Lipton et al., 2008) and will be given information on how to prepare for the visit. Parents with smartphones will be encouraged to bring a mobile version of the student's Headache Action Plan template from the web portal to be completed together with the primary care provider during the office visit. Alternatively, web portal login information also can be given to the primary care provider to complete the student's Headache Action Plan from an internet-connected computer at the time of the visit, or parents without smartphones can enter information from a paper version of the Headache Action Plan into the web portal from a computer following the visit. Community primary care physicians will be educated in the use and completion of Headache Action Plan templates so that they can effectively work with families on discussing and completing the plan templates during office visits.

Once a Headache Action Plan has been entered for a student by the physician or parent into the project website, the student's name will be added to a list that is accessible by the student's school nurse. As such, the school nurses will be able to look up whether or not a Headache Action Plan has been initiated for a student visiting his/her office for headaches and can continue to encourage a visit in primary care if not. School nurses also will be able to electronically access the recommendations for school provided on the student's Headache Action Plan once it is initiated and help implement these. Further, school nurses will be trained in facilitating self-guided web-based relaxation-training tools that students on Headache Action Plans can use if they are taking a rest break in the nurse's office. The intent of these tools is to help nurses give students options for managing headaches at school rather than sending them home each time, thereby reducing the risk of worsening disability.

An overview of the proposed project procedures is outlined in the figure below:



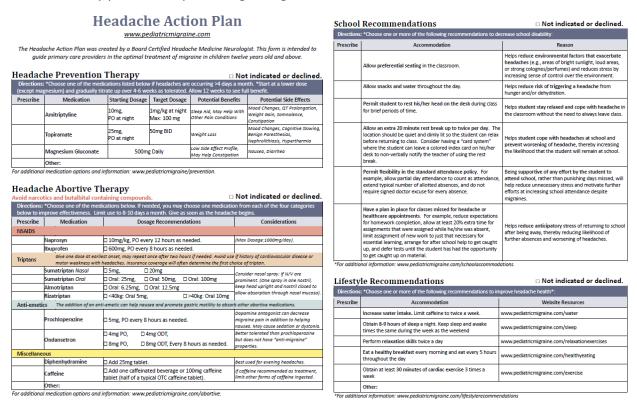
In order to establish the feasibility and impact of the proposed system change approach, we plan to first implement the project procedures in one of the largest school districts in the region (USD No. 233 – Olathe School District) and compare values on the selected outcome

variables both over time (within the targeted school district) and with school districts for which no targeted educational intervention was done. Per recommendations for evaluation of continuing medical education efforts (Tian et al., 2007), the primary project outcomes to be evaluated include changes in practice (i.e., increased prescription of evidence-based preventive and abortive medication when indicated and decreased prescription of opioids and butalbital), changes in patient health (i.e., improved headache-related disability), and changes in healthcare utilization (i.e., reduced emergency room visits). In the subsequent school year we will then repeat implementation of the project procedures in another school district (USD No. 512 – Shawnee Mission School District) to demonstrate generalizability and reliability of findings from the year prior. We anticipate that by empowering local school nurses and PCPs with migraine education and concrete tools for evidence-based pediatric migraine management, the proposed project will offer benefits to children, families, healthcare providers, schools, and the community and healthcare system at large.

2.2.2 Overview of Participants and Setting. Participants in the educational and procedural aspects of the proposed work include primary care providers servicing children from a targeted school district (Olathe School District in Project Year 1 and Shawnee Mission School District in Project Year 2), school nurses in the targeted school district, and students in middle school or high school with migraine and their families. These school districts were selected for the project since we have existing collaborative relationships with physicians and community leaders in these districts, they are two of the largest school districts serviced by the applicant organization (29,171 and 27,444 students, respectively), they reside in a state with no boardcertified headache specialists, and they have a school nurse dedicated to every school. There are 25 school nurses (for middle and high schools) and 34 primary care providers serving the targeted school districts that are expected to participate in educational sessions and project procedures. The median household income of families residing in these school districts is approximately \$72,000, and 81% of families in the state of Kansas report access to the internet from home (www.census.gov/hhes/computer/publications/2012.html); thus, we anticipate most families in these school districts will be able to use the planned web portal for implementing Headache Action Plans and for reviewing educational materials on migraine.

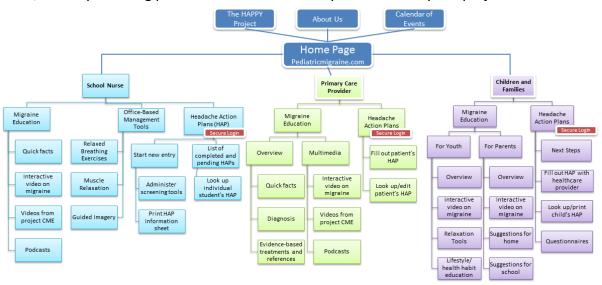
2.2.3 Headache Action Plan. Traditional continuing medical education efforts often fail to change practice by virtue of omitting practice-based clinical decision tools for implementing the information being taught. The intent of the Headache Action Plan is to equip primary care providers with specific guidelines and recommended options for treating pediatric migraine based on the state of the science; the plans will provide a tangible means of translating migraine education into practice. The proposed Headache Action Plans are designed to be relatively self-explanatory and to guide primary care providers in discussing and selecting evidence-based abortive, preventive, and adjunctive medications to initiate with pediatric patients in primary care. Additionally, the plans contain a list of research-supported patient self-care strategies and school recommendations to discuss and consider recommending for the patient to help prevent worsening of migraine and associated disability. A current draft of a Headache Action Plan template is shown in the graphic below. Drafts have been distributed for

comment from colleagues at the applicant institution and from community pediatricians, with an extremely positive response regarding ease and likeliness of use.



2.2.4 Web portal overview. A project website (www.pediatricmigraine.com) will be developed for the proposed project both for housing the educational information/tools developed as part of the work and for electronically recording Headache Action Plan information. A draft website skeleton is provided in the figure below. The site will be divided into sections for access by school nurses, primary care providers, and patients/families. School nurses will have access to continuing education on pediatric migraine (e.g., video recordings from the project's didactic sessions, podcasts developed previously by the project team, interactive video explaining migraine) as well as management tools that can be used with students that visit the office for headache; the latter are an extension of previously developed computer-based tools by the project team for facilitating use of evidence-based relaxation training for headache management (diaphragmatic breathing, progressive muscle relaxation, and guided imagery). School nurses also will use the website to administer screening tools to determine if a Headache Action Plan is indicated and to initiate a new Headache Action Plan template if so (or look up if a Headache Action Plan has already been filled out for the student). Scores from the student's disability (PedMIDAS) screen completed in the school nurse's office will automatically be transferred to the top of the student's electronic Headache Action Plan template, given evidence that disability information positively influences physician perception of treatment needs yet often is not discussed (Holmes et al., 2001). PCPs similarly will have access to continuing education on pediatric migraine (e.g., overview information on diagnosis and evidence-based treatment, video recordings from the project's didactic sessions) and will be able to fill out a Headache Action Plan template that was initiated by the school nurse.

The patient/family portion of the site will contain tailored education on migraine, relaxation tools that can be used at home or school, and recommendations for health habits (i.e., water intake, sleep and eating habits, and exercise). Youth also will be asked to sign up for e-mail or text reminders to complete a brief questionnaire on their headache status (frequency, intensity, duration) and disability (30-day PedMIDAS; Heyer et al., 2014) on a monthly basis as part of outcomes tracking. Parents will have access to "next step" recommendations for starting Headache Action Plans with their child's PCP as well as evidencebased suggestions for helping children manage migraines at home and school. Parents also will be able to login to the site and access the child's Headache Action Plan template so that it can be printed out on paper or filled out on a parent's mobile device (if applicable) by a primary care provider at the time of a visit. Portions of the site containing the Headache Action Plans and questionnaire data will have security measures implemented (e.g., password protection and encrypted communication via Secure Hyper Text Transmission Protocol) to ensure the protection of health information. A deidentified dataset containing Headache Action Plan and questionnaire data will be stored on the project site for review and analyses by the project team, thereby ensuring patients are not individually identifiable by the project team.



2.2.5 Education Plan. The proposed migraine education plan comprises a multi-tiered approach that seeks to influence the knowledge and behavior of school nurses, community primary care providers, and students and families. *In order to maximize the likelihood of changing the system of migraine care through education, our proposed education plan combines traditional didactic continuing medical education on pediatric migraine with practical instruction for using evidence-based treatment quidelines (Headache Action Plans) and migraine management tools.* In so doing, we are adhering to what has been found through research to be the most effective approach to continuing medical education, including repeated exposure to content and provision of specific tools to use in practice (Marinopoulos et al., 2007; Davis et al., 1995, 1999; Tian et al., 2007; Cauffman et al., 2002). In order to also incorporate children with migraine and their families into the proposed education plan, students and families also will be educated on migraine care through information and tools on the project website and through a series of school-based education sessions within the targeted school district.

(a) **School nurse education.** Education of school nurses will proceed sequentially from more general education on pediatric headache to specific training on identifying candidate students for Headache Action Plans and implementation of the plans. With regard to more general education, Dr. Bickel will present a one-hour didactic talk at the Annual School Health Conference in the fall of each project year. This conference is held at the applicant organization and primarily is attended by school nurses from school districts within the immediate catchment area of Children's Mercy; it has been a standing conference for the past 36 years. The meeting recurs annually and Dr. Bickel has been a regularly invited speaker on pediatric neurology topics. The planned content of the presentations during the project period will focus on pediatric headache symptoms and diagnosis, general principles of medical management of headache, and school-based management of headache.

Following the Annual School Health Conference, focused small group educational sessions will be provided by project team members to school nurses within the targeted school district each fall. The Director of Health Services for the initial targeted school district (project team member Cindy Galemore, RN, MSEd, NCSN) will help coordinate these sessions to occur with other school nurse meetings to maximize the likelihood of full attendance from school nurses within the targeted school district. These educational sessions are planned for 2 hours in length. The first half will be dedicated to teaching the school nurses about recognizing migraine based on the International Headache Classification diagnostic criteria, the basic pathophysiology of migraine, medical management of migraine (evidence-based abortive and preventive medications), and school-based strategies for limiting school-related disability (i.e., basic school accommodations, facilitation of relaxation skill training). The second half will then review procedures for screening students for migraine (ID Migraine tool), identifying students in need of improved migraine management based on headache frequency and/or level of disability (PedMIDAS tool), and the process for initiating Headache Action Plans. During these sessions we will emphasize the expected benefits for students, schools, and the community associated with implementing Headache Action Plans in order to recruit active engagement of the district's school nurses.

Additionally, focused interactive educational sessions at standing school nurse meetings throughout the year will be conducted by the medical project team members. The intent of these sessions is to provide school nurses within the targeted school district with ongoing guidance in using the proposed web portal to initiate Headache Action Plans and to solicit ongoing project feedback so that modifications can be made as needed. These sessions also will provide education and support for implementing in-office relaxation-based tools to students with headache who visit the school nurse.

(b) **Primary care provider education.** Education of community primary care providers similarly will proceed sequentially from more general education on pediatric headache to targeted education in smaller groups on implementing Headache Action Plans for migraine in the community. For general education, Dr. Bickel will present a one-hour continuing medical education talk at the Clinical Advances in Pediatrics Symposium (CAPS) in the fall of each project year. This conference is held at the applicant organization annually and primarily is attended by primary care providers within the catchment area of Children's Mercy. This educational presentation will focus on evidenced-based guidelines for migraine management, including appropriate use of abortive medications, preventive medications, and health habit

modification. A specific focus will be made on discouraging the use of narcotics/butalbital-containing compounds and on increasing provider comfort in prescribing triptans to the pediatric population.

Following the Clinical Advances in Pediatrics Symposium, project team members will give recurring presentations on the Headache Action Plan program specifically to primary care providers serving the targeted school district. Dr. James Wetzel, Vice-President of Physician Services for the medical group for which most primary care physicians in the targeted school district are affiliated, will help facilitate these meetings with community physicians. The initial meeting will focus on increasing the awareness of headache-related disability in children, reviewing use of the Headache Action Plan as a means of improving the evidence-based management of pediatric migraine, and discussing indications for subspecialty referral for migraine management (e.g., continuing to miss school for >4 days/month after initiating a preventive medication). A draft of the Headache Action Plan will be presented during the initial meeting for additional comment from the community pediatricians prior to finalizing procedures. After the project web portal is completed, project team members also will schedule meetings with primary care providers serving the targeted school district to demonstrate use and ensure active stakeholder engagement throughout the project.

(c) **Student education.** Estimates suggest that as many as 90% of students with headaches have never had any form of education about headaches (Tonini & Frediani, 2012). In addition to clinician education, therefore, the proposed project will offer migraine management education directly to students at schools in the targeted district. The intent of these sessions is to provide guidelines for preventing migraines and disability to students with recurrent headaches that may have not previously visited the school nurse office (and therefore would have been otherwise overlooked by the proposed project). Beginning in the winter, nurse practitioners on the project team will provide one hour in-school educational sessions at 5 middle schools and 5 high schools in the targeted school district each year. The talks will be coordinated with the Director of Health Services for the district and will be offered as part of a wellness curriculum. Students who indicate having recurrent headaches and who obtain signed permission of their parents will be eligible to participate in the session. During the educational sessions, the selected children will receive information on the basic pathophysiology of migraine, how to identify headache triggers/aggravating factors (e.g., stress, sleep deprivation), and basic relaxation and stress management tools for use at school and in daily life.

2.2.6 Innovation and Preliminary Work. The proposed project represents a vertical departure from extant work in pediatric migraine that primarily has centered on comparative efficacy and reactive care rather than improving a system of care that tends to facilitate delayed diagnosis/treatment and progressive disability. To our knowledge, leveraging a community system change approach that specifically targets preventable risk factors for worsening health outcomes in pediatric migraine has not been done to date. Moreover, the planned approach to provider education on pediatric migraine is novel in that it integrates a practical tool for primary care providers to use in order to translate education into practice.

The project is led by the interdisciplinary directors of one of the few dedicated pediatric headache programs in the U.S. and builds logically on foundational work by project team members, including: (a) an established physician and school nursing education program in

pediatric neurology and specifically pediatric headache management, from which we identified gaps in migraine recognition and care that provided the impetus for the proposed project; (b) an established program of research on pediatric headache and specifically using e-Learning/e-Health tools to improve headache assessment and outcomes in children; and (c) established collaborative partnerships with physicians, school nurses, and community leaders in the regions being targeted for system change. The applicant institution also has a well-established web-based provider portal (www.childrensmercy.org/Providers/) used by most community physicians, as well as a school health portal that is accessed on average by 40 school nurses in the region per month. Thus, we are able to capitalize on our existing preliminary work and relationships to ensure the successful implementation of the proposed project in the community.

- **2.3 Evaluation Design.** The overall objective of the project is to assess the feasibility and impact on clinically relevant system-level outcomes of implementing a migraine recognition and care plan strategy in local school districts. We hypothesize that our planned educational approach will be feasible, that the selected outcomes in a targeted region will be significantly improved over time (relative to baseline), and that outcomes in a targeted region will be significantly better than outcomes from control regions.
- **2.3.1 System impact outcomes.** In order to determine if our education plan and project procedures influences the current system of managing pediatric migraine in the community, we have selected pragmatic outcomes to track that are most relevant to patients, families and the healthcare system (see table below). Changes in these outcomes will be compared both within the targeted school district region (over time since baseline) and relative to school districts for which no targeted educational initiative was done (to control for the influence on outcomes of variables that are not associated with the planned education, such as seasonal trends). We will use multilevel growth models to analyze these data (Singer & Willett, 2003). These models permit us to statistically evaluate overall changes in outcomes that are serially measured over time and further enable a determination of the extent to which changes in outcomes are predicted by a particular intervention implemented at a given time; thus, we can explore what components of the planned education approach add benefit when they are implemented (e.g., targeted small group sessions for primary care providers). Further, these models will allow us to statistically control for demographic differences between the targeted and control regions when comparing changes in outcomes between regions.

OUTCOME	RATIONALE	DATA SOURCE	TARGET
Prescription of Preventive Migraine Medication	Use of migraine preventive medication, when indicated, reduces healthcare utilization and headache-related disability (Silberstein et al., 2003, 2007; Brown et al., 2005)	Monthly electronic medical record query for proportion of children seen in Neurology Clinic at Children's Mercy for migraine who are on a preventive, as a function of school district	30% increase over baseline* in prescription of migraine preventive medication by PCPs in targeted region, and statistically reliable difference from control regions

OUTCOME	RATIONALE	DATA SOURCE	TARGET
Prescription of Abortive Migraine Medication	Use of recommended migraine abortive medication when indicated reduces healthcare utlization and headache-related disability (Silberstein et al., 2003, 2007)	Monthly electronic medical record query for proportion of children seen in Neurology Clinic at Children's Mercy for migraine who are on a triptan, as a function of school district	20% increase over baseline* in prescription of triptan medication, and statistically reliable difference from control regions
Prescription of Opioids or Butalbital- Containing Compounds	Avoiding use of opioids and butalbital-containing compounds prevents migraine chronification (Charles et al., 2009; Loder et al., 2013)	Monthly electronic medical record query for proportion of children seen in Neurology Clinic at Children's Mercy for migraine who have been prescribed an opiod or butalbital, as a function of school district	50% decrease over baseline* in prescription of opioids or butalbital by primary care providers in targeted region, and statistically reliable difference from control regions
Headache-Related Disability	Reducing headache- related disability reduces healthcare utilization and costs (Mennini et al., 2008)	PedMIDAS Score	20% decrease over baseline** in PedMIDAS Score for children on Headache Action Plan
Emergency Room Visits for Migraine	Reducing emergent care for migraine reduces healthcare burden and costs (Insinga et al., 2011).	Monthly electronic medical record query for proportion of children seen in ED for migraine at Children's Mercy as a function of school district	20% decrease over baseline* in ED visits for migraine, and statistically reliable difference from control regions

^{*} Baseline = average over prior calendar year from the date the project begins

2.3.2 Feasibility Outcomes. Although we have taken measures to ensure the planned project will be well-received by the target audience of school nurses and primary care providers in the community (e.g., soliciting feedback on the project concept from community physician and school nurse leaders), one of the project objectives is to systematically evaluate feasibility of the planned approach to system change. In order to establish feasibility of the approach, we will evaluate project outcomes according to the RE-AIM framework (Glasgow et al., 1999). RE-AIM (Reach, Efficacy, Adoption, Implementation, and Maintenance) is a recommended method for evaluating the feasibility of efforts to translate evidence-based interventions into practice (Bakken & Rulen, 2009). Table 1 provides definitions of the RE-AIM domains and lists the descriptive outcome data to be collected as part of the planned work for the proposed project.

^{**} Baseline = PedMIDAS score from the initial school nurse screening

DOMAIN	DEFINITION	OUTCOME MEASURE
Reach	The number, propotion, and/or representativeness of individuals who are willing to participate	Number of individual nurses who initiated a Headache Action Plan; number of individual doctors who completed a Headace Action Plan for a patient; number of families who had a Headache Action Plan completed
Effectiveness	The impact of an intervention on important outcomes	{Same as System Impact Outcomes from Section 2.3.1}
Adoption	The number, proportion, and representativeness of settings who are willing to participate	Number of schools with nurses that initiated a Headache Action Plan; number of primary care practices with providers that initiated a Headache Action Plan
Implementation	Consistency of program delivery as intended and/or the time and cost of the intervention	Personnel time and project expenditures associated with education plan and tools
Maintenance	The extent to which a program becomes part of routine organizational practices, and/or the long-term effects of a program on individual outcomes	Consistency of Headache Action Plan use over the duration of the project

2.3.3 Other outcomes. In addition to system impact and feasibility outcomes, we will collect data on school nurse and primary care provider satisfaction with the education sessions and use of Headache Action Plans. Education evaluation forms will be provided to participants to complete after education sessions; these forms are standard forms used by the applicant organization for continuing medical education and inquire about satisfaction with the session and perceived utility for practice. In addition, brief questionnaires will be distributed via e-mail lists to school nurses and primary care providers in the spring of each project year to assess satisfaction and perceived utility of using Headache Action Plans.

2.3.4 Dissemination and next steps. The proposed project has been designed in such a way as to facilitate easy dissemination of the procedures to other school districts, regions, settings, and professionals. We have planned the project to inherently test generalizability of the procedures to another school district during the second project year. We also have garnered significant initial support for implementation of the Headache Action Plan project from stakeholders that are critical to widespread regional dissemination of project findings and methods, including education board members and members of local government (see included Letters of Support). The approach of training clinicians to screen for the need for optimized migraine management and facilitating concrete treatment plans through primary care also has applicability in emergency department settings, where we plan to adapt and implement project procedures in the future. Findings from the project will be disseminated both locally (through local school district and medical community websites and newsletters) and more broadly (e.g., presentations at scientific meetings such as the American Academy of Pediatrics meeting and National Association of School Nurses conference). Additionally, the basic structure of the

project website will be scalable to permit use in other regions and settings, and associated electronic resources developed as part of this project will be available for widespread use following project completion.

3. Detailed Workplan and Deliverables

A Gantt chart listing project tasks and completion timelines in detail is provided with the grant application materials. During the first several weeks of project Year 1, we plan to complete the Headache Action Plan template following final vetting from specialist and primary care colleagues in the community. We also plan to ensure all written education materials needed for the project website are updated with the most recent evidence-based or consensusbased information. Completion of the project website, including the multimedia tools (i.e., relaxation tools for use at home or in a school nurse's office and interactive migraine education video) and structure for completing and viewing Headache Action Plan templates, will be completed within an estimated 14 weeks from project start. During development time, the general education sessions with school nurses and community primary care providers will be completed and the smaller-group focused sessions will be scheduled. The targeted education sessions on use of the Headache Action Plans by school nurses and primary care providers then will occur following completion of the project website. Data on the feasibility and system impact outcomes will be prospectively collected and reviewed for trends on a monthly basis, with final analysis for Project Year 1 outcomes occurring during the final 3 months of the project year. Materials and methods then will be modified as necessary based on these data and accumulated feedback from Year 1 experiences. Subsequently, we will repeat the education and data collection and analysis process in the second targeted school district during Year 2 (10/1/15 to 9/30/16). The final months of the project will be reserved for final data analyses and dissemination efforts.

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PROJECT SCHEDULE Academic Year Two - 2016 to 2017 Academic Year One - 2015 to 2016 Academic Year Three - 2016 to 2017 H.A.P.P.Y. Headache Action Plan Project for Youth Calendar Year One - 2014 Quarter Three Quarter Two COMPONENTS/ACTIVITIES WHO Academic Year One Finalize Headache Action Plan (HAP) Templates Patient Health Habit Guidelines Assemble Information Design and Approve Guidelines Assemble Information Design and Approve Guidelines School Recommendations Assemble Information 6 NPs, Pls Design and Approve Guidelines A. Complete Web Portal 5 Project Manager, Pls Create Portal Create Portal Skeleton and Pages 4 Web Designer Bulid Individual Pages with Content Test System and Fix Issues 4 Web Designer 3 Web Designer Final Approval and Launch Assemble Nurse/Provider Education Content 2 Web Designer Design and Complete Content Complete Instructions for Use ssemble Parent/Children Education Content 8 NPs, Pls, Programmer 8 NPs, Pls 8 NPs, Pls, Programmer 8 NPs, Pls Design and Complete Content Complete Instructions for Use B. Complete Education Sessions 2 Project Manager 3 Project Manager 2 Project Manager 2 NPs, PIs Contact Schools and PCP Groups for Dates/Times Setup Talks and Organize Schedules Print Educational Handouts for Talks Obtain Approvals Obtain Approvals Complete Analyses of Outcomes Data A Refine Materials and Methods Finel Approval and Re-Launch Refine Patient Health Habit Guidelines on HAP Refine Information and Design Approvals and Reprints Refine Information and Design Approvals and Reprints Refine Information and Design Approvals and Reprints Refine School Recommendations on HAP Refine Information and Design Approvals and Reprints Refine School Recommendations on HAP Refine Information and Design Approvals and Reprints Refine School Recommendations on HAP Refine Information and Design Approvals and Reprints Before School Recommendations on HAP Refine Information and Design Approvals and Reprints Conduct PCP, Nurse, and Student education sessions 4 Pls 4 Pl, Data Analyst 2 Web Designer 1 Web Designer 1 Web Designer 1 NPs, PIs 1 Project Manager Academic Year Two 8. Complete Education Sessions Contact for potential dates and times Setup talks and organize schedules Pritt Educational Handbus to Talks Conduct PCP: nurse, and student education sessions C. Collect. Publicate and Publish Data 2 Project Manager 3 Project Manager 4 Project Manager NPs, Pls 26 4 Pls 5 Pl, Data Analyst 16 Pls 4 Pls Obtain Approvals Complete Analyses of Outcomes Data Write Papers Disseminate Outcomes