Analysis Plan for Vision to Learn (VTL) Research Study
Final 06/06/2016

I.   Study Design

        The purpose of this study is to estimate the one- and two-year impacts of school-based vision services on student achievement and engagement outcomes. The study design is a cluster randomized controlled trial where elementary and middle schools in Baltimore City will be randomly assigned to one of three treatment conditions: treatment in the first year of the study (2016-17), treatment in the second year of the study (2017-18), or delayed treatment. Students in the delayed treatment group will serve as the control group, and they will ultimately receive vision services in the 2018-19 school year. There are approximately 141 elementary and middle schools in Baltimore City that have not already participated in a vision intervention, and we plan to include nearly all of them in the research study. The table below outlines the timeline and the number of schools in each treatment condition.

Table 1: Timeline and Number of Schools by Treatment Condition

	Cohort 1	**Cohort 2**	**Cohort 3**
Vision services implemented	2016-17 SY	2017-18 SY	2018-19 SY
Duration of treatment	Two years of treatment	One year of treatment	Delayed treatment (control group)
Impacts estimated	One and two year impacts of treatment	One year impact of treatment	NA
Number of schools in condition	44	44	44

II.   Research Questions

        This study addresses the following four research questions. The first research question addresses the one- and two-year impacts of the vision services on students' achievement in reading and mathematics. This research question will serve as the main or confirmatory research question. The second and third research questions will be exploratory. The fourth and final research question addresses the implementation of the vision services.

        1. What are the one- and two-year effects of providing eyeglasses and school-based interventions to promote eyeglass usage on the reading and math achievement of students with refractive errors (myopia, hyperopia, astigmatism)?

        2. How do the effects of receiving eyeglasses on achievement vary for students with different types and severities of refractive error? How do they vary for students with high, average, or low reading scores at pretest? For boys and girls?

        3. What are the one- and two-year effects of providing eyeglasses and school-based support for usage of eyeglasses on variables beyond achievement, such as retentions and disciplinary referrals?

        4. How can schools promote use of eyeglasses, develop strategies to reduce losses and breakage, and best provide replacement if glasses are lost?

III.   Study Sample

A total of 132 elementary, elementary/middle, and middle schools will be recruited from among 141 schools in Baltimore. The schools will be randomly assigned to receive the vision treatment in the 2016-17 (Cohort 1), 2017-18 (Cohort 2), or 2018-19 (Cohort 3) school year. Schools will be first be organized into groups of three by type (elementary, elementary/middle, middle), demographics (percent free lunch, racial/ethnic composition), prior achievement, and charter status, and then randomly assigned to one of the three treatment conditions (e.g., two-year experimental, one-year experimental, or control).

All students in grades Pre-K to 8 in all schools will be offered vision screens and services, but only students in grades 3 to 8 will be included in the study. In addition, only students diagnosed with a refractive error (i.e., myopia, hyperopia, astigmatism) will be included in the study. Assuming that 20% of all students will be diagnosed with a refractive error, the total number of students in the study will be approximately 6,500.

School rosters will be collected in 2016 prior to school random assignment, and only students who were enrolled in one of the 132 Baltimore City Schools prior to random assignment will be included in the study.[1] Thus, the study will track student outcomes for students who were in Baltimore City Schools in 2016 for a two-year period to understand the impacts of the school-based vision services. Students who are not enrolled in any of the 132 schools at the time of school random assignment, and who join a study school after school random assignment, will not be included in the study. Students will be retained in the cohort to which they were initially assigned for intent-to-treat analyses, even if they move to other BCPS schools after random assignment.

IV.   Data Sources

To estimate the impact of receiving school-based vision services on student achievement and engagement, we will collect individual student and school-level demographic, achievement, retention, and disciplinary data for the 2015-16 (baseline), 2016-17, and 2017-18 school years. Achievement outcomes will include student test scores on the PARCC English Language Arts/Literacy and Mathematics tests, which are administered each spring to all students in grades 3 through 8.[2] Other outcomes include measures such as disciplinary referrals and retentions in grade, which are important indicators of academic engagement.

Vision and medical history data will also be collected for individual students. Vision data include distance and near visual acuity, accommodative amplitudes, and strabismus, and medical history data include whether the child has ever received an eye exam and whether the child was prescribed glasses. Finally, we will carry out observations in a random sample of reading classes

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[1] We will use an intent-to-treat approach in which students will remain in their initially assigned treatment condition regardless of whether they transfer to another school in the study with a different treatment condition.

[2] Students' PARCC test scores in the 2015-16 school year (prior to school random assignment) will serve as the pretest. For third grade students, for whom there is no PARCC pretest, we will use scores from an assessment administered in the fall of students' third-grade year.

three times each school year (2016-17 and 2017-18) to determine how many students in experimental and control schools are wearing glasses.

V.   Methods

To address the confirmatory research question, we will use hierarchical linear modeling (HLM) to estimate the impact of school-based vision services on students' achievement in reading and mathematics. HLM accounts for the fact that students are clustered within schools. We will estimate differences in spring achievement for students in schools that have received vision services for one year and for students in control schools, and we will estimate differences in spring achievement for students in schools that have received vision services for two years and for students in control schools. We will also account for students' achievement prior to any vision services by including a pretest as a covariate in the models. The models will also include student grade level at the time of school random assignment and school-level blocking variables or covariates used in the random assignment process.

The second and third research exploratory research questions will also be addressed using HLM or hierarchical generalized linear modeling (HGLM). The second research question will be addressed by including interaction effects in the model and/or by analyzing the model for a specific subgroup of students (e.g., males). The third research question will be addressed by HGLM, which is an extension of HLM when the outcome variable is not continuous.

We conducted a power analysis to ensure that the study would be likely to detect a statistically significant impact of school-based vision services on student achievement outcomes, should one exist. The estimated minimally detectable effect sizes (MDESs) for the one-year impacts on mathematics and reading achievement are 0.15 and 0.14 standard deviations, respectively. For the two-year impacts on mathematics and reading achievement, the MDESs are 0.17 and 0.16 standard deviations, respectively.

A key assumption in the design is that children's vision will remain stable over the two-year experiment, so that vision testing carried out in 2018-2019 can be assumed to produce the same results as vision testing in 2016-2017. Ideally, we would want to obtain assessments of the vision of students in the two-year treatment sample in fall 2018, to establish this equivalence. This poses practical questions and requires permission from BCPS, BCHD, and Vision to Learn, but we are committed to seeking a way to do this. If we can obtain all necessary permissions we may request additional resources from the Arnold Foundation to add this component to our design.

VI.   Correspondence with Ethical Standards for Research

The research protocol will be reviewed by the Johns Hopkins School of Medicine Institutional Review Board (IRB) and by the Baltimore City Public Schools IRB. The research design ensures that students who have not yet received their vision treatment will receive at least the current standard of care, until they receive full services. Privacy of all data will be maintained

using code numbers, with a code sheet maintained only by the experimenters. Parent permission for vision assessment and use of existing data will be obtained as specified by the IRB.