Potentiating Rural Investment in Children’s Eyecare (PRICE):

Manual of Procedures

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I. Study Aim

The aim of the project is to create, study and advocate for a model that can be adopted by the Chinese government to provide spectacles for all children sustainably.

II. Executive summary

Uncorrected refractive error (URE) is the leading cause of visual impairment among Chinese children, accounting for 90% or more of poor vision, and Chinese children have among the highest rates of myopia in the world. Despite the fact that the problem of URE is safely and inexpensively treated with glasses, only 15-40% of children needing them own and wear glasses sufficient to provide good vision in rural China. Major barriers include cost and lack of good quality glasses, as well as a widespread misconception that wearing glasses will harm children’s eyes.

The large majority of rural eye care is provided by government facilities in China, and coverage of the new rural health insurance scheme (NCMS) is > 95%. Providing free glasses to children through NCMS is a sustainable solution to the problem of URE in China, and in fact a small number of localities have begun to experiment with this approach. A recent randomized trial by our group of collaborators, Zhongshan Ophthalmic Center, ORBIS International and Stanford University's REAP, showed for the first time that providing free glasses significantly improves children’s educational outcomes, and further demonstrated that glasses wear actually protects against rather than promoting vision decline in children. These findings provide a strong impetus for the government to take on responsibility for glasses distribution. However, proven, sustainable models of how to achieve this are needed.

PRICE (Potentiating Rural Investment in Children's Eyesight) will use a randomized, controlled design across five groups of 25 schools in Yunnan (one of China’s poorest provinces) and Guangdong (one of the richest) to optimize the model of "free glasses for all with an optional upgrade." The selection of free spectacles and cost of the "upgrade" options will be varied between groups in order to find the optimal balance between high rates of purchase of upgrade glasses on the one hand and good acceptance and wear of free spectacles among those selecting these on the other. Outcomes of the trial will be:

1. Main trial outcome: Proportion of children in each group requiring glasses whose families elect to purchase them

2. Secondary outcome: Proportion of children receiving spectacles who are wearing them in each group at un-announced school visits 6-12 weeks after distribution of vouchers and prescriptions

At the heart of PRICE is the collaboration between county-level rural government hospitals (the main providers of rural healthcare) and private optical shops. In many regions of China, government hospitals are not permitted to sell spectacles. Thus, this collaboration, which will be supported by our industry partners, Luxottica and Essilor, will help the hospitals to earn the profit needed to sustain outreach screening, while bringing the quality control needed to improve optical shop service delivery.
The idea underpinning the PRICE model is that sufficient cost recovery will be available from the sale of upgrade glasses to sustain the continued costs of school-based outreach screening, while meeting the refractive needs of even the poorest children. The main trial hypothesis is that offering free spectacles will not decrease purchase rates. The glasses needed to drive this model will be provided initially by industry, but the fundamental aim of this project will be to create successful advocacy whereby the Chinese government will take on the responsibility to prove access to glasses for all children needing them.

III. Situation Analysis

Under-corrected refractive error (URE) accounts for 90% of visual disability among rural Chinese children (He et al, Ophthalmology 2007). Among the 13 million children in the world blind from URE, some half live in China (Resnikoff Bull eHO 200f). While Chinese children have among the highest rates of myopia in the world, a recent large survey in rural western China found that only 1 out of 6 children needing glasses had them (Ma et al, in press, 2014), including less than half of those with visually disabling myopia of 4 diopters or greater.

Recent studies by our group and others have shed light on the reasons for this situation. Many stakeholders including children, families and teachers believe incorrectly that wearing glasses will harm children's eyes (Li, Congdon et al, Arch Ophthalmol 200f). The quality of available glasses is poor: fully half of children in rural China wearing glasses have a power inaccurate by > 1 diopter (Zhang, Congdon et al, IOVS 2009), while two-thirds of rural refractionists have a high school education or less (Zhou, Congdon et al, IOVS 2014). This problem of poor quality is exacerbated by the fact that government hospitals, which may have the expertise to provide good refraction, are forbidden in many areas from selling glasses, while community optical shops are not permitted to use cycloplegia (dilating) drops necessary to provide accurate refraction in children. A collaboration between government hospitals and private optical shops is needed to solve the problem.

Ultimately, cost of glasses also remains a critical barrier: providing free spectacles more than doubled the rates of use 6 months later, compared to providing prescriptions alone. (Ma et al, in press, 2014). It seems unlikely that interventions short of free spectacle provision on a large scale will lead to major increases in use (Congdon N, Ophthalmology 2011), and yet providing free glasses alone may not be sustainable. Not only is there the problem of sustaining the school vision screening programs which are needed to identify children requiring glasses, but also a large-scale program providing free glasses would be likely to drive existing practitioners out of business. A model combining the advantages of free glasses (lack of financial barriers) and glasses sales (sustainability) is needed. We propose the PRICE model: "Free glasses for all with an optional upgrade."

Recently completed a trial showing the significant educational impact of providing children free glasses in rural China (Ma et al, in press, 2014), underscoring the need to find a practical solution now to remove the barriers to good vision for all Chinese children. China's rural health insurance covers > 95% of rural dwellers, and has recently begun small, local experiments with covering free glasses. In order to make a compelling case to the Chinese government to provide access to glasses
for all children through insurance, sharing new evidence of the educational benefits to children is only the first step. A proven, sustainable model is needed, that clearly demonstrates the appropriate pricing structures and selection range which can make the PRICE model a success, by assuring good uptake of purchased spectacles at the same time as making free glasses attractive to those families who select them.

IV. Partners and Roles

The principal investigator, Nathan Congdon, will be responsible for coordination across study centers. ORBIS International (Guangdong), Brien Holden Vision Institute (BHVI, Guangdong) and Fred Hollows (FHF, Yunnan) have built capacity for refractive service delivery in the provinces, and will coordinate local activities including training in refraction and optical dispensing. Outreach and refraction will be coordinated by tertiary hospitals currently leading NGO-supported children's eyecare networks in Guangdong (Zhongshan Ophthalmic Center hZOCl), and Yunnan (Yunnan Red Cross Hospital hYRCHI). Stanford's Rural Education Action Project (REAP) will assist in designing and implementing the randomized controlled trial. Spectacles and marketing training will be provided by Luxottica/OneSight and Essilor. Financial accounting support will be provided by the operations controller in the ORBIS N Asia office, gu Yang.

V. Timeline

The project will be implemented in 5 counties in Guangdong Province (XXX, XXX, XXX, XXX and XXX) and 5 counties in Yunnan Province (XXX, XXX, XXX, XXX and XXX). A county hospital (or county hospital paired with an optical shop) will carry out refraction of 12-13 elementary schools in each county, for a total of 125 schools.

A. Experimental Design

Schools will be randomized to one of 5 groups (25 schools each):

1. Provision of glasses prescription only (Pure Control)
2. Free glasses for all, no upgrade glasses offered
3. Free glasses for all, optional purchase from range of spectacles, cheapest RMB 100 (Mean price paid for glasses by Control families in Seeing is Learning I, subtracting one SD)
4. Free glasses for all, optional purchase from range of spectacles, cheapest RMB 150 (Mean price paid for glasses by Control families in Seeing is Learning I)
5. Free glasses for all, optional purchase from range of spectacles, cheapest RMB 200 (Mean price paid for glasses by Control families in Seeing is Learning I, adding one SD)

Children in groups receiving free glasses who need them (VA ≤ 6/12 in either eye) will receive vouchers to fill at the participating county hospitals (Groups 2-5), where they will be offered "upgrade" spectacles as above. Children in group 1 will be told if glasses are needed and receive a prescription only.

B. Power Calculation

125 schools (25 per arm), with a minimum of f0 children per school, is sufficient to detect a 10% difference in spectacle purchase between groups, with a power of f0% and Type 1 error of 5%, correcting for within-school clustering (ICC k 0.10, cluster level covariate k 0.50). (Calculations based on purchase rate of 30% in control schools in Seeing is Learning I).

C. Planning Prior to Fieldwork

1. Selection of schools
   - The regional coordinator (Guangdong: Dr Xiao Baixiang; Yunnan, Ms Ni Ming) will provide the Data Center at ZOC with a list of all elementary schools in the 5 selected counties, indicating the number of students at each school and any logistical issues (inaccessibility, etc).
   - A total of 15 schools will be selected at random in each county, one in prefecture (xiang) and each with no fewer than a projected f0 students in grades 3, 4 and 5.
   - For any counties with an insufficient number of schools meeting the size criteria, and which are accessible to screening teams, will have additional schools filled in from a neighboring county.
   - The lists will be forwarded to the regional coordinators to discuss any potential logistical problems with partner hospitals

2. Selection of spectacle designs and distribution of sale income
   - Frames will be selected with Luxottica/OneSight based on their experience and our research on desirability to children of certain frame design elements
   - OneSight’s new glasses will be used for all Free spectacles
   - The selection of upgrade glasses in groups 3-5 will all be the same. The only difference between the groups will be the price of glasses
   - The initial expectation is for 6000 pairs of free glasses and 4000 pairs of upgrade glasses, though this will be refined based on the pilot studies in Yunnan and Guangdong
   - The money gained from sales of upgrade glasses will be distributed as follows:
     - Group 3: RMB100/pair total cost, 25% (RMB25) to OneSight, 25% (RMB 25) to Essilor, 50% (RMB 50) to the hospital/optical shop
• Group 4: RMB150/pair total cost, 25% (RMB37.5) to OneSight, 25% (RMB37.5) to Essilor, 50% (RMB75 to hospital/optical shop)
• Group 5: RMB200/pair total cost, 25% (RMB50) to OneSight, 25% (RMB50) to Essilor, 50% (RMB100 to hospital/optical shop)

3. Plan for provision of spectacles

• Some county hospitals already have optical dispensing capability and some do not all have refraction capability
• A goal of the project will be to provide equipment and training for all centers in optical dispensing
• Workflow will be as follows:

1) Each hospital will have an inventory of frames of all styles. Luxottica will send the frames to YRCH in Yunnan and ZOC in Guangdong by 1 August (Lux to pay shipping), and we are responsible to get the frames to the hospitals (we pay shipping).

2) Essilor will send all lenses to the edger in Yunnan and in Guangdong by 1 August.

3) Sept 7-12, REAP will do vision screening.

4) They will enter and analyze data, and have the school lists with randomization allocation to ZOC by Oct 8.

5) We will give hospital lists of schools with group allocation, names of kids, and time schedules by Monday 13 October

6) Hospitals will screen 2 schools per week. They will give out the vouchers at each schools and make it clear that families must show up WITHIN 3 WEEKS to choose their glasses and frames at the hospital.

7) Each week, each hospital will send the edger a set of prescriptions and glasses frames (project will pay shipping). There will be pre-printed barcode labels stuck on each prescription and frame to match them to each other. The edger will send the completed glasses back to the hospital.

8) The edging takes 3 weeks. Thus, including the 3 weeks to complete glasses choice and 3 weeks for edging, a school will receive their glasses about 6 weeks after the initial refraction.

9) The hospitals will return to the schools to give out the glasses at each school 6 weeks after screening. An optometrist must come to help make sure the glasses are properly fit, but this will not take long. Glasses can be given out at 3-4 schools/day. Those families who came AFTER the 3 week period to pick out their glasses will have to go to the hospital to pick them up.

10) If the power of the glasses is wrong:

   If they are free glasses, project pays shipping cost
If they are upgrade, and hospital at fault, they will have to pay 25% of cost of glasses (Essilor’s fee for the upgrades), assuming the frames can still be used.

If Edger is at fault, edger must redo the edging for free.

11) Need a contract with Edger!

12) Timing should be such that at 2 schools per week, total of 13 schools, hospitals begin 13 October and finish by 28 November with refraction at schools. Adding 6 weeks for families to choose frames and for edging, the last school should receive their glasses by mid January, well before Han Jia.

4. Training

5. Pilot study

- Pilot will be hold in GD to test the forms, and ZOC will be responsible.

D. Phase I: Vision screening and administration of child and parent surveys (see appendix)

**Responsible groups:** REAP, ZOC, YRCH

**Purpose:** Identify student and parent financial information and attitudes towards glasses. Detect potential myopia using distance visual acuity test.

**Forms:** Baseline Parent Form, Baseline Child Form, Vision Form (See Appendix)

**Teams:** There will be 13 teams, each responsible for screening 10 schools in September. Each team will consist of 2 visions screeners and 5 enumerators and a team captain. A total of 65 enumerators (recruited by REAP), 26 volunteer screeners (recruited by ZOC/YCRH) and 13 team captains (recruited by REAP) will be needed. Screeners/enumerators will be paid 70 RMB/day + room and board, but ONLY if the screening is completed. The total screening, including one day of training (ZOC/YCRH responsible) and administration of forms (REAP to train) will be approximately 8 days. With trained screeners and appropriate responders, the acuity test component should require one minute per student on average.

**Grades:** 3rd, 4th and 5th grade students in rural elementary schools selected in the 5 counties in Yunnan and the 5 counties in Guangdong. On average, there are 30-60 3rd, 4th and 5th grade students in each school, 20% of them are myopic.

**Equipment:**

1) ETDRS test chart (at a distance of 4 meters)

2) Occluder (paper cup or paper patch are also considered); long tape (at least 4 meters);

3) Stick;

4) Sticky tape;

5) Visual acuity screening form (Provided below, collects the information of name, whether or not wears glasses, uncorrected vision acuity for both eyes, whether or not needs refraction test);

6) At least one pen per team member.
Pre-test preparation: One day before the screening, the team captain contacts the school principal to assign a classroom (or office) with at least 4 meters length and ask the school principal to remind the students who have glasses to bring their glasses to school.

Procedure:
A. Setting up (see picture 1)

The team enters the classroom/office and place the visual chart in the area with subdued ambient room lighting and maximum natural lighting (sunlight). All glare must be eliminated from the chart surface. Use the sticky tape to fix the visual chart on the wall (or blackboard). Make sure the chart is straight and the height is parallel to student’s eye level. Mark a line on the floor 4 meters away from the chart. Put a chair for the student being tested. Place one table and one chair next to the student chair for registration. Before the screening starts, Screener 1 works with head teacher to call the students in a line. The team stands in front of all students, and Screener 2 makes a brief announcement:
1) This is not a score test. Don’t be nervous. Try your best to see it if you can see it. Do not squint. Do not lean your head. If you cannot see it, just say you cannot;
2) You will see a chart with all kinds of E's. You will be asked to tell me the way the legs of E are pointing. You should also show me with your fingers how the E is pointing.
3) When you enter the classroom, report your name to me (Screener 2);
4) Stand next to the line. Be straight, not to lean your torso or head;
5) First cover your left eye, and then cover your right eye.
6) If you wear eyeglasses, please put them on now. If you didn't bring them with you, and if you have them at school, please to and get them now.

After the announcement, Screener 1, Screener 2 or older student enter the classroom, leaving the teacher in the waiting area.

B. Waiting Area (see picture 2)

Teacher supervises this area that is critical to maintain proper traffic control. Screener 2 must be here to direct students that are waiting in line outside the classroom before being called to enter the classroom to the registration table. Make sure all students are waiting outside quietly, and no one is sneaking or helping other student being tested.

C. Registration (see picture 3)

Screener 1 will be sitting in the registration table calling students to enter the classroom for visual acuity test. When one student enters the room reporting his/her name, Screener 1 will check it with the information on his/her student visual acuity screening form.
D. Visual Acuity Test (see picture 4)

After checking the name of the student, Screener 1 asks the student whether he/she wears glasses and then ask them bring the glasses now if they are at school. Then tell them to stand in the line. Screener 1 and Screener 2 work together to start conducting the visual acuity test.

1) Screener 2 will stand next to the chart and direct the student sitting on the chair 4 meters away from the E chart and covering his/her eye. Screener 1 will sit next to the student make sure the student does not lean the torso or head and does not squint.

2) Screener 2 asks the student to occlude his/her left eye with an occluder (while being certain not to compress the eye with the occluder) and starts testing the right eye by pointing the letters with the stick. Screener 2 should put the stick below the lines of the E chart, and not touch the bottom the letters in order to make sure the student can see well which letter is being pointed.

3) Screener 2 starts testing visual acuity at a distance of 4 meters with the student’s attention directed toward the top line (6/60 h0.1i). If the orientation of at least four of the five optotypes is correctly identified the student is re-examined on line 4 (6/30 h0.2i). If one or no optotypes are missed on line 4 the testing resumes at line 7 (6/15 h0.4i), continuing to line 11 (6/6 h1.0i). A failure is defined as an inability to correctly identify the orientation of at least four of the five optotypes in a given line. The line immediately above the failed line should be tested until the student identifies at least four of the five optotypes in a line. The lowest line read successfully is assigned as the visual acuity for the eye undergoing testing (i.e. 6/6 h1.0i). If the top line is missed at 4 meters, the student should be advanced to 1 meter with progression down the chart as described above, and the visual acuity should be recorded divided by 4. For example, if the lowest line read successfully is the top line (6/60 h0.1i) at 1 meter, the visual acuity should be recorded as (6/240 h0.025i). And if the top line is still missed at 1 meters, the visual acuity should be recorded as (j6/240 hj0.025i).

4) When finishing the test of right eye, Screener 2 reads the vision score to Screener 1, Screener 1 must repeat it before writing down the vision score in the student vision form in order to make sure the score is documented correctly.

5) Before switching the test of the other eye, Screener 2 should ask the student to rest a few seconds in order to make sure his/her left eye feels ready to be tested. Then Screener 2 repeats the procedure above and test his/her left eye.

6) Screener 2 must be consistent in testing the right eye first to avoid recording errors.

7) During the testing process, Screener 1 should supervise that the occluder covers students’ eyes completely, but not to press the eye ball. Make sure the student does not squint or peek.

8) If the student undergoing test has glasses, Screener 2 should measure the vision with and without glasses.

9) After finishing all the steps above, Screener 1 calls the next student to enter the classroom and repeat the procedures above.

10) After recording all the students being screened, Screener 1 marks those needing refraction tests.

Inclusion criterion: uncorrected VA ≤ 6/12 (0.5) in either eye.
Note: No smoking and phone calls during the whole process of vision screening. No judging language such as “Yes, correct; oh, you are wrong; you vision is really not good, etc” are allowed to use.

Personnel Duties and Responsibilities:

Screener 1

1) One day before the screening, contact the school principal for assigning the classroom/office and reminding the students who have glasses to bring the glasses to school.
2) Cooperate with Screener 2 to set up the screening room (measure the room illumination with the light meter, and place the chart in the area with appropriate lighting condition; fix the chart on the wall/blackboard with sticky tape; adjust the height of the chart; mark the 4 meter line on the floor and set a chair on the line; put one table and one chair next to the student chair for registration);
3) Before the screening starts, explain to all students about what is expected to happen in the screening;
4) Ask student to enter the screening classroom and check his/her name on the student eye visual acuity screening form;
5) Make sure the student sit straight, not lean the torso or head;
6) Make sure the student not squint;
7) Make sure the student cover his/her eye completely, but not press the eye ball;
8) Double checks the vision score with Screener 2 and record it.
9) Calls the next student when one student finishes his/her screening test;
10) After testing all the students, mark those need refraction test and give the list of students needing refraction to the school principal or head teacher.

Screener 2

1) Cooperate with Screener 1 to set up the screening (same as above);
2) Direct student to use occluder and start pointing to the vision chart;
3) First test the right eye and then the left eye; and be consistent of the screening sequence;
4) Before the student switches to test the other eye, ask him/her to rest both eyes for seconds;
5) Report the vision score to the Screener 1 and wait her to repeat in order to make sure it is documented correctly;

Head teacher

1) Coordinate with the screeners to bring all students to the screening station;
2) Supervise the waiting area.
Before the screening starts, Nurse 1 explains what is expected to happen.

Make sure all students are waiting outside quietly, and no one is sneaking or helping other student being tested.
Picture 3: Registration. When one student enters the room reporting his/her name, Nurse 1 checks it with the information on his/her student vision screening form.
**WRONG:** Not allow to lean the torso or head forward.

**WRONG 1.** Must use occluder. 2. Must cover the eye COMPLETELY, but not press the eye ball.

5. **CORRECT:** Make sure the student sit straight, not lean the torso or head forward; Make sure the student not squint; Make sure the student cover his/her eye completely, but not press the eye ball.
E. Phase II: Refraction and distribution of vouchers/prescriptions

Purpose: This refraction test is performed following the vision screening in order to give the student a prescription for eyeglasses.

Responsible parties: County hospitals, with oversight by ZOC and RYCH.

Forms: Refraction form; refraction quality check form

Preparation:

- Based on vision screening above, the schools will be randomized to one of the 5 groups, and a list for each school, and the group assignment of that school, will be provided by REAP to ZOC/YRCH and then by them to the county hospitals
- YRCH/ZOC will carry out 2 days of training and checking on refraction in September for all the county hospital refractionists
- Vouchers must be printed
- Forms must be printed

Team: one trained local optometrist, two trained nurses. All the three members must attend the training camp above.

Quality checks: Teams from ZOC and YRCH will check the accuracy of refraction on a random 10% sample of children by going to schools and re-refracting them without dilation.

Testing subjects: 3rd, 4th and 5th grade students in rural elementary schools in 5 counties in Yunnan and 5 counties in Guangdong. Children are selected to take part according to their visual acuity at the time of the vision screening exam: all children with uncorrected VA ≤ 6/12 (0.5) in either eye and 25% of the students with uncorrected VA > 6/12 (0.5) in both eyes. There are expected to be about 1f-30 students per schools needing to be refracted. With trained refraction test team and appropriate responders, the refraction test (auto-refraction and trial lens) component should require less than 20 minute per student on average.

Equipment (see picture 1):
1) Proparacaine 0.5% topical anesthesia;
2) Cyclopentolate 1% eye drop;
3) Timer for dilation (cell phone also can be used);
4) Face tissues;
5) Auto refractor;
6) Motorized table;
7) Glue;
8) 2 sets patch board with 10 meter multi-plus extension cord;
9) Trial lens box and trial frames (with different pupil distance);
10) ETDRS test chart (at a distance of 4 meters)
11) 2 or more occluder (paper cup or paper patch are also considered);  
12) Stick;  
13) Sticky tape;  
14) Long tape (at least 4 meters);  
15) Ruler for measuring pupil distance to make glasses;  
16) All types of frames with type number attached on the frame temple;  
17) Mirror for frame trying;  
18) Refraction form (See below, collects the information of name, whether or not wears glasses, uncorrected vision acuity for both eyes, whether or not needs refraction test; the process of each dilation drop; results of auto-refraction of both eyes; results of subjective refraction of both eyes; trial lens prescription of both eyes; frame type preferred);  
19) At least one pen per team member.

Pre-test preparation: One day before the screening, Nurse 1 contacts the school principal to assign a classroom (or office), preferably the room where the screening took place. Also, a list of all students with VA less than ≤ 6/12(0.5) in either eye and a random 25% sample of children with normal vision in both eyes should be made up for the school.

Procedure:  
A. setting up (see picture 2)

The team enters the classroom/office and place the visual chart in the area with subdued ambient room lighting and maximum natural lighting (sunlight). Use the sticky tape to fix the visual chart on the wall (or blackboard). Make sure the chart is straight and the height is parallel to student’s eye level. Mark a line on the floor 4 meters away from the chart. Put a chair for the student being tested. Place one desk and one chair next to the student chair for trial lens test. Put the trial lens box on the desk. Place the motorized table next to the trial lens desk. Put the auto-refractor on the motorized table and make sure it is firm and flat. Connect the auto-refractor and the motorized table, and plug the motorized table. One chair can be put on the top of plug line, in order to prevent from tripping the students. Put a set of 20 chairs at the other side of the room as dilation area. Then place another set of desk and chair next to the trial lens desk, and put the frames and the mirror on the desk. Before the refraction starts, Nurse 1 works with the head teacher to ask the students stand in a line. The team stands in front of all students, and the nurse makes a brief announcement:

1) We will give you some dilating drops. Dilation will take for one hour. Because of the drops used, your eyes may be sensitive to light and the vision may be blurred for a few hours. So go to bathroom first;  
2) Don’t be nervous then, these drops are for relaxing your eyes, so we can give you a more accurate refraction test;  
3) If you feel anything uncomfortable, just tell us.  
4) If you wear glasses, please put them on now. If you don’t have the glasses with you, please go to the classroom to get them now.
B. Dilation (see picture 3)

This part is conducted by Nurse 2. Nurse 1 will assist by timing the dilation process. The dilation process will take about 40 minutes with two-three rounds of dropping. One drop of Proparacaine 0.5% is administered in each eye, followed 15 seconds later by 1 drop of 1% cyclopentolate in each eye. **Children should shut their eyes tightly after the drops for at least 5 minutes. This decreases the chances of systemic absorption and side effects (explain to the children why they should shut their eyes tightly in order to improve the effect of the drops).** Five minutes later, a second drop of cyclopentolate 1% is given in each eye (the Proparacaine need not be repeated at this time, as the anesthetic is still working). After an additional 30 minutes, if the pupillary light reflex is still present (the pupil grows smaller when a bright torch light is shined in the eye), a third round of both Proparacaine and cyclopentolate is administered. After a further 15-20 minutes interval, pupils are considered fully dilated if they are ≥6 mm in diameter and the pupillary light reflex is absent. The nurses should test the cycloplegia outcome for both eyes and record these on the form.

1) Nurse 1 checks their names on their student visual refraction forms and directs them sitting down on the dilation chairs;

2) Nurse 1 give 1st round of dilating drops to them, and tells them:

   a) Don’t be nervous. This is for relaxing your eyes, so we can give you a more accurate refraction test;

   b) Close your eyes until we ask you open to have another round of drop;

   c) After finishing the dilation, it is possible that you feel dizzy when you open your eye;

   d) If you feel anything uncomfortable, just tell us.

   e) Remember, your vision will be blurry for several hours, and bright lights may be uncomfortable. You will need to be careful about PE class and riding your bike home. You may have some trouble reading until these drops wear off.

3) Nurse 2 times for 5 minutes and record the starting time of dilation on students’ visual refraction forms. Also give each of the students a piece of face tissue;

4) After 5 minutes, the nurse ask the student to open their eyes and give them 2nd round of dilating drops;

5) Nurse 2 records the time of the 2nd drop on the visual refraction form;

6) After another 15 minutes, the nurse gives the 3rd drop if the pupil still gets small when light is shined in it, record the time of the 3rd drop on the visual refraction form;
7) After another 15-20 minutes, the nurse tests the cycloplegia outcome for both eyes and record these on the form;

8) During the whole dilation process, make sure that all students close their eye unless they are told to open.

D. Auto-refraction Dilation (see picture 4)

After finishing the dilation, the local optometrist gives the students auto-refraction test.  
1) The local optometrist explains to the student how to place chin and forehead in cup, and then help him/her to the right position.

2) The local optometrist explains where to look and that he/she should not blink or move his/her eyes or head during the exam.

3) Five separate measurements are made with the machine for each eye. The mean of these five values for each eye (which the machine should automatically compute) is considered the final result of auto-refraction.

4) After this testing component is complete, the local optometrist prints the results and writes them down on the visual refraction form, then attaches them to the form.

E. Trial lens (see picture 5)

Then the local optometrist and Nurse 2 conduct the trial lens test, the nurse help to walk with the student when he/she is adjust his/her trial lens.  
1) The local optometrist uses the trial lens to refine the prescription according to his/her auto-refraction result;

2) The local optometrist explains to the student how to respond during the process of switching lenses. The local optometrist will ask questions like “is your vision better or worsen with this lens, or this lens? How about that?”

3) Nurse 2 stands next the visual chart and starts pointing;

4) The local optometrist tries different lenses until s/he finds the lens with the least minus power which gives the student the best possible vision in each eye.

5) Criteria of giving glasses is as following:
Myopia ≤-0.75 diopters (D)

Hyperopia ≥+2.00 D or

Astigmatism (Non-spherical refractive error) ≥ 1.00 D

6) Students whose vision cannot be improved to > 6/12 (0.5) in both eyes will be referred to the local hospital for further examination.

7) In the cases of students with >2.5D lens power difference between the two eyes, the values will be recorded for either of his eyes with best-corrected vision > 6/12, but the student will be referred to the local hospital for further examination, and glasses will not be given. (This difference in power is too great for children to tolerate).

f) Then the local optometrist asks the student to go out of the classroom to adapt to the trial lens with the company of the nurse for 10 minutes. During this period, the nurse asks the student these questions:

Do you have any of the following with the trial lens?
  a) Blurred vision
  b) Distorted vision
  c) Headache
  d) Disorientation
  e) Dizziness
  f) Eyestrain
  g) Nausea

9) The nurse will assess if any of the children are having flushing of the face, confusion, dizziness, difficulty walking, difficulty breathing, disorientation or slurred speech. These systemic side effects are very rare, but if they occur, the child should be sent to the doctor from the Local Health Center (one van will be ready during the refraction test). The appropriate management for these conditions is calm reassurance and rest, except in the very rare event of difficulty breathing, in which case the child should go to the health center.

10) When the student is adapting to the trial lens, the local optometrist can continue doing trial lens test for the next student;

11) When the student finishes his/her 10-min adaption and comes back to the classroom, if the student does not report any bad feeling, the local optometrist can write down his/her trial lens prescription on his/her visual refraction form.

If there is any bad feeling reported, the local optometrist will refine the prescription and
the students will adapt to the trial lens for another 10 minutes;

12) For the students in the treatment groups 2-5, hands out a voucher of the appropriate color and the prescription:
   • Group 2: Green
   • Group 3: Yellow
   • Group 4: Blue
   • Group 5: Red

13) For the students in the control group 1, gives a letter writing down the result of uncorrected vision acuity and the eyeglass prescription to the parents of the students;

14) Before letting the student go, the nurse should mention one more time “Remember, you should be careful about going to PE class or riding a bike until the medication wears off. Also you will have trouble reading before the medication wears off. You’d better drink more water. Make sure you tell your teacher and parents about that.”

Note: Not all students attending refraction test need eyeglasses. No smoking and phone calls during the whole process of refraction test.

**Personnel Duties and Responsibilities:**

**The Local optometrist**

1) Cooperates with the nurses to set up the refraction room (place the chart in the area with appropriate lighting condition; fix the chart on the wall/blackboard with sticky tape; adjust the height of the chart; mark the 4 meter line on the floor and set a chair on the line; put one table and one chair next to the student chair for trial lens test; place the motorized table and connect it with the auto-refractor; plug the motorized table and put a chair on the line of the plug line, in order to prevent students from stumbling; put one set of 20 chairs as dilation areal place another set of desk and chair next to the trial lens desk, and put the frames as well as the mirror on the desk)

2) Before the dilation, conduct the vision acuity double check for those uncorrected VA ≤ 6/12 (0.5) in either eye and 25% of the students whose uncorrected VA > 6/12 (0.5) in both eyes with Nurse 2.

3) Conducts the auto-refraction test, writes down and attaches the auto-refraction prescriptions on the students’ refraction forms;

4) Conducts the trial lens test until students feel the best vision with, and records the trial lens prescription.

5) Give final prescription after the student finish his/her 10-min adjusting walk and report no bad feeling; if the student reports any bad feeling, the optometrist need to refine the prescription until no bad feeling is reported.

**Nurse 2**

1) One day before the refraction test, contact the school principal for assigning the
classroom/office;
2) Cooperates with the local optometrist and nurse 1 to set up the refraction test room (same as above);
3) Cooperate with the optometrist to conduct double check of visual screening test for those uncorrected VA $\leq 6/12$ (0.5) in either eye and 25% of the students whose uncorrected VA $> 6/12$ (0.5) in both eyes with the optometrist;
4) Times the dilation process and makes checks on students’ visual refraction forms;
5) Makes sure that all students close their eyes unless they are told to open during the dilation;
6) For the students in the treatment groups 2-5, hands out a voucher of the appropriate color and the prescription:
   • Group 2: Green
   • Group 3: Yellow
   • Group 4: Blue
   • Group 5: Red
7) For the students in the control group 1, gives a letter writing down the result of uncorrected vision acuity and the eyeglass prescription to the parents of the students;

Nurse 1
1) Cooperates with the local optometrist and Nurse 1 to set up the refraction test room (same as above);
2) Before the refraction starts, explain to students about the dilation process;
3) Give two-three rounds of dilating drops and record the cycloplegia outcomes;
4) Makes sure that all students close their eyes unless they are told to open during the dilation;
5) Walk with the student and ask him/her questions when he/she are adapting to his/her trial lens;
6) Before the student leaves, reminds him/her that “Remember, you should be careful about going to PE class or riding a bike until the medication wears off. Also you will have trouble reading before the medication wears off. You’d better drink more water. Make sure you tell your teacher and parents about that.”
Picture 2: Setting up

Before the refraction test starts, the nurse explains what will happen in dilation.
Picture 3: Dilation

WRONG: No smoking.

Make sure every student close their eyes until the nurse tells them to open.
Picture 4: Auto-refraction

The local optometrist explains to the student how to place chin and forehead in cup, then help him/her to the right position and tells the student where to look and that he/she should not blink or move his/her eyes or head during the exam.
Picture 5: trial lens

After the local optometrist sets the trial lens which makes the student feel the best vision with, the nurse asks him/her if he/she experiences any of the following with the trial lens?

a) Blurred vision
b) Distorted vision
c) Headache
d) Disorientation
e) Dizziness
f) Eyestrain
g) Nausea
F. Phase III: Fulfillment of spectacle orders at county hospitals

Responsible groups: County hospitals

Forms: Glasses distribution form

The biggest challenge in this project for the partner hospital/optical shops will be identifying patients in the study from among their usual patients, and then distinguishing the groups from each other. This will be accomplished with a set of color-coded vouchers for groups 2-5 as follows:

- Group 2: Green
- Group 3: Yellow
- Group 4: Blue
- Group 5: Red

Each of these colors will correspond to a color-coded sheet explaining what the patients should be shown, and what prices will be offered. Patients in Group 2 will be offered only Free Glasses, and will be permitted to choose from 2 colors. Groups 3-5 will be shown the Free Glasses and also a case of sample upgrade glasses, which will be the same for all groups, though the pricing will be different as described above.

The selection of frame will be recorded for each child, and the family will be asked to return in two weeks to receive their glasses and undergo fitting. The outcome of receiving glasses, and having purchased upgrade glasses, will be recorded at the county hospital/optical shops for Groups 2-5 on the Glasses Order Form. Since patients in Group 1 will not be referred to any specific hospital, and would have no particular motivation to present to the partner hospital/optical shop (as there is no offer of free glasses), their outcome of having purchased glasses will be recorded at the time of follow-up (see below), based on self-report.

As a quality check on whether partner hospitals/optical shops correctly allocated children to the different groups, a 5-10% sample of families will be contacted by investigators at YRCH and ZOC to confirm whether they were offered upgrade glasses, and the price they were quoted. Additionally, all parents will be asked to sign a section on the Glasses Order Form which indicates the amount they have been asked to pay. Hospitals will be warned that any deviation from protocol will be grounds for being dropped from the study, with withholding of all payments for glasses sales.

G. Phase V: Follow-up and assessment of wear
Responsible Groups: REAP, YRCH, ZOC

Forms: Follow up glasses wear and attitudes form

An un-announced visit to all schools will be made by the same teams that carried out vision screening. These teams will observe children’s wear of glasses, and will also ask for the child’s self-report of glasses. Additionally, all children will be asked if they purchased or obtained glasses or not. Finally, as a further quality check, the glasses children are wearing will be identified as free or upgrade, and the result checked with that reported by the hospital. All this information will be recorded on the Follow Up Form.

There will be a monitoring trip of optometry and optical quality inspection, and the specific time and arrangements still pending.

The end line investigation will be hold in 2015, around May. It includes vision screening, questionnaire and glasses wearing survey. REAP will be responsible for this.

VI. Analytic plan

Main outcomes will be:

1. Main trial outcome: The proportion of children requiring spectacles whose families elect to purchase them in each group (Recorded at the hospital and through follow-up at school)

2. Secondary outcome: Proportion of children in each group receiving spectacles who are wearing them at un-announced school visits 6-12 weeks after distribution of vouchers and prescriptions

Data analysis: The primary trial analysis will be to compare the proportion of children whose families elect to purchase spectacles between Group 1 on the one hand and Groups 3, 4 and 5 on the other, in order to determine the effect of providing “free glasses with an optional upgrade” on glasses purchase. The study hypothesis is that providing free spectacles will not reduce the proportion who choose to purchase them. We will also compare the rates of purchase between groups 3, 4 and 5 in order to determine the demand curve for spectacles, to set optimal pricing. Rates of wear between group 1 and 2 will be compared to assess the impact of providing free glasses on wear. As an observational (non-trial) outcome, we will also compare the proportion of children wearing spectacles at follow-up between those with free and purchased glasses.