Demonstrating Feasibility of Color Vision Deficient Provider Use of EnChroma Products in the Emergency Department

(Short title: EnChroma in the ED)

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1. Title Page

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Short study title: EnChroma in the ED

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2. External Collaborators: None

3. Abstract

Color vision deficiency is common among males and can impact medical care in a number of ways, including limiting a provider's ability to note certain physical signs, interpret stool guaiac or urine dipstick tests, and to identify colors under a microscope. While this deficiency does not preclude a career in medicine, many such providers will develop "work-arounds" such as involving colleagues with normal color vision to care for their patients. This study seeks to understand whether products made by EnChroma to improve color vision will have a positive impact on patient care. Color vision deficient (CVD) providers in the emergency department will be identified using a screening test and then formal vision testing. These CVD providers will receive EnChroma products to utilize during patient care and will be surveyed on their experience.

4. Introduction and Background

Color discrimination is important in many careers but is particularly important in medical fields where decisions may be based on the ability to rapidly detect deviations in blood color, pallor or other important clinical signs. Color vision deficiency is the inability to distinguish certain shades of color and can range in severity from mild to severe. The most common form is red-green (representing both deutan and protan defects) which has an X-linked recessive inheritance pattern,[1] thus affecting mostly males. Red-green color vision deficiency affects approximately 1 in 12 men and 1 in 200 women in the world.[2] There are other more rare and more severe forms such as blue-yellow defects (also called tritan defects) and blue cone monochromacy which results in poor visual acuity and extremely reduced color vision. As red-green CVD is by far the most common form, research has primarily focused on subjects with this form.

Prior work has demonstrated that medical students and physicians are affected by CVD. This has a number of effects on the practice of medicine by CVD individuals, including: impaired ability to recognize abnormalities in stool guaiac tests, blood tests, urine tests,[3] histologic stains,[4] and ophthalmoscope exams,[5] as well as impaired ability to detect skin color changes due to cyanosis, jaundice or erythema, and rashes. There have also been case reports of providers with CVD failing to identify rectal bleeding resulting in a delay in treatment.[6] However, anecdotal reports demonstrate multiple "work-arounds" that CVD providers employ to minimize direct effects on patient care.[7] The vast majority of "work-arounds" reported involve peer corroboration in areas where color differentiation is important.[5] There is a lack of evidence regarding the effect of provider CVD on patient outcomes.

In addition to impacting patient care, CVD can also impact medical students' education by increasing difficulty with pathology and slide identification as well as anatomy as it impairs one's ability to distinguish certain tissues during dissections. Prior studies have also demonstrated that CVD impairs medical students' ability to detect color differences in the fundus during retinal exams. Standardized exams during medical school also include color identification on histological stains on pathology slides. These difficulties as well as others have led some students to avoid certain medical specialties.[8] In

addition to improving patient care, it may also be possible to reduce disparities in medical school performance and choice of specialty caused by CVD.

EnChroma (Berkeley, CA) has developed multiple products which improve brightness and color purity of primary colors for CVD people. While the manufacturer has reported the effectiveness of these products in aiding color vision, they have not yet been shown to cure color vision deficiency, and there is individual variation in the response to the glasses given varying degrees of severity and type of CVD.[9] However, they have not been evaluated yet in a clinical setting to assess their impact on patient care by CVD healthcare providers. Even an incremental increase in a physician's ability to detect a subtle difference may improve that provider's ability to identify a critical examination finding. Thus, the long term goal of the present study is to improve patient care by mitigating the deleterious effects of CVD in a clinical setting.

5. Study Aims and Outcomes:

Aim: Evaluate the feasibility of using EnChroma glasses in a patient care environment, as well as subjective reflections on the effects of the product on patient care. CVD providers will wear the glasses for 2 weeks. Providers and patients will be surveyed on the comfort of the product, any subjective influence on color vision overall, specific examples of improvements or hindrances to patient care, and overall impression providing evidence for safety and effectiveness of the product in the patient care setting.

Hypothesis: CVD providers will consider EnChroma products to be unobstructive to their daily work and without adverse effect on patient care.

6. Study Design and Methods

Study Population:

Study participants will be solicited by emails sent to faculty, residents, nurse practitioners, physician assistants, and registered nurses in Emory and CHOA's Department of Emergency Medicine. Providers from other departments providing care in the emergency department may also be recruited.

Students at Emory and Morehouse will be recruited using electronic and paper flyers posted at pre-approved locations on campus as well as through email to the emergency medicine interest groups at both schools.

In addition, members of the medical community outside of Emory will be recruited via the EnChroma website. A link reading "Emory University Seeks Color Blind ER Health Care Providers for Research Study, READ ON" will be on the main company website taking users to a page with the language in the attached document (Recruitment Language – EnChroma).

Volunteer subjects will first participate in the online screening test. Subjects who test positive for CVD or who know themselves to have a prior diagnosis of CVD will then undergo confirmatory color vision testing with the Farnsworth D15 test and HRR, both with and without EnChroma glasses. This will be performed by study personnel using personal equipment, not during or within Emory Clinic

resources. Visual acuity will also be obtained in addition to subject self-report of their ophthalmologic and medical history. They may also supply previously obtained refraction prescription for use in making their EnChroma glasses.

We will not be entering subjects' medical records to obtain health information at any time.

We do not expect to recruit tritan deficiencies, both because they are rare and because the glasses are not expected to be of benefit to this population. Of note, we expect a gender disparity in this study because CVD disproportionately affects males, though we will enroll both CVD males and females.

Study Participant Risk

The devices proposed for testing from EnChroma meet the FDA criteria for non-significant risk devices. The glasses pose no serious risk to the health, safety, or welfare of a subject, and they are not of substantial importance in diagnosing or treating disease. Healthcare providers are free to remove or discontinue use of these devices while performing patient care if they are hindering patient care in any way, reverting to their usual care. Furthermore, the glasses are currently available to the public without prescription and providers are able to purchase and wear them during patient care without approval. As such, we do not anticipate any substantive risk to patients while these are worn during patient care. We will encourage participants to remove the glasses if they feel their medical care is being hindered in any way. Of note, the indoor Enchroma glasses do diminish total light transmission somewhat (50% visible light transmission) and a key question in this study is whether that has a significant effect on providers' comfort and ability to deliver care without removing the glasses.

There is a risk of breach of confidentiality, albeit low. No personal identifying information will be collected about the patients examined as part of this study. Data will be aggregated before analysis.

Records of any ophthalmologic examinations performed on entry into the study will be maintained by study staff and destroyed at the end of data analysis. Any new pathologic conditions discovered during that examination will be reported to the subjects so that they may seek medical care as needed.

Consent:

CVD subjects will sign informed consent at the time of optometrist evaluation. They may discontinue participation in the study at any time.

METHODS

Each participant with CVD (other than medical students) will be provided EnChroma products to use indoors over the course of two weeks in the emergency department, educational settings, and in their personal life. They will be encouraged to wear the glasses for at least 10 hours over 1-2 weeks prior to wearing them in a clinical setting to adjust to their use, and for 10 minutes before beginning patient care as per manufacturer instructions. They will be encouraged to take specific note of clinical scenarios that require the use of color vision (e.g., - rashes, tympanic membrane erythema, stool guaiac

testing, etc.). Placebo glasses will not be provided given that subjects will not be able to be blinded to the difference, and subjects are unlikely to tolerate red tinted glasses which do not provide benefit. The participant will then complete a survey regarding their baseline experience of having CVD, and the participant's reflections on how CVD has affected his/her clinical practice and education in the past, including any "work-arounds" they have employed previously. The survey will also ask them to reflect on the impact of the glasses on patient care as well as a 100mm scale in addition to open ended questions.

Data will be analyzed both quantitatively (improvement on 100mm visual analog scale and any change in patient survey responses) as well as qualitatively, using thematic analysis of open ended survey data within the grounded theory paradigm.

In the event of substantial missing data, data will be imputed using a multiple imputation procedure. The type of procedure and the number of imputed data sets will be determined by the amount of missing data and the pattern of missingness. However, we do not expect significant missing data in this study. No data will be sent to the FDA.

7. Participant Selection

- **Sample Size Calculation**. Given the number of male providers in Emory's department of Emergency Medicine, and the prevalence of CVD in the general populations, the maximum achievable sample size is expected to be approximately 50 participants. A sample size of 50 will provide sufficient power (80%) to detect a within-group standardized difference (Cohen's d) of 0.44 between the glasses-on and glasses-off conditions.
- Inclusion/Exclusion Criteria
  Inclusion Criteria:

  - Age 18-65
  - Red-Green color vision deficiency

  Exclusion Criteria

  - Age>65
  - Chronic eye conditions limiting color vision including:
    - Achromatopsia
    - Cataracts
    - Glaucoma
    - Legal Blindness
    - Macular Degeneration
    - Retinitis Pigmentosa

- Subject Recruitment Plan
  - Faculty, Residents, and Nurses in the Department of Emergency Medicine will be recruited using email to listserves as well as announcements at department and faculty meetings.
  - Students will be recruited through flyers posted on campus and through emails to the EM Interest Group.

    - CVD subjects will receive EnChroma products to use for the duration of the study and may keep them at the end. EnChroma will be providing all products necessary for the purposes of the study.

- Screening for eligibility
    - Screening will be self-guided by subjects taking an online color vision test at home on the internet (publicly accessible site). They will share those results with the study investigators prior to enrollment.
- Subject withdrawal
    - Subjects who choose to withdraw will be permitted to keep any EnChroma products which have been provided to them.

8. Informed Consent Process

The optometrist co-I will obtain written informed consent at the time of optometrist evaluation. Given that all subjects will be local healthcare providers, we expect all will be proficient in English and able to consent for themselves.

We recognize that residents can be considered vulnerable groups in this study. All participation will be voluntary and consent will be obtained by the co-I from Ophthalmology instead of the PI (who is faculty in the School of Medicine, and an Associate Residency Program Director). Permission has already been requested and granted to recruit medical students at Emory from Dr. [redacted], Associate Dean for Medical Education and Dr. [redacted], Assistant Dean for Medical Education Research. Permission to recruit Morehouse students is pending from that school, awaiting Emory IRB approval of Morehouse as a research site.

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