The iD2: A Smart Eye Drop Cap Monitor for Eye Drop Adherence

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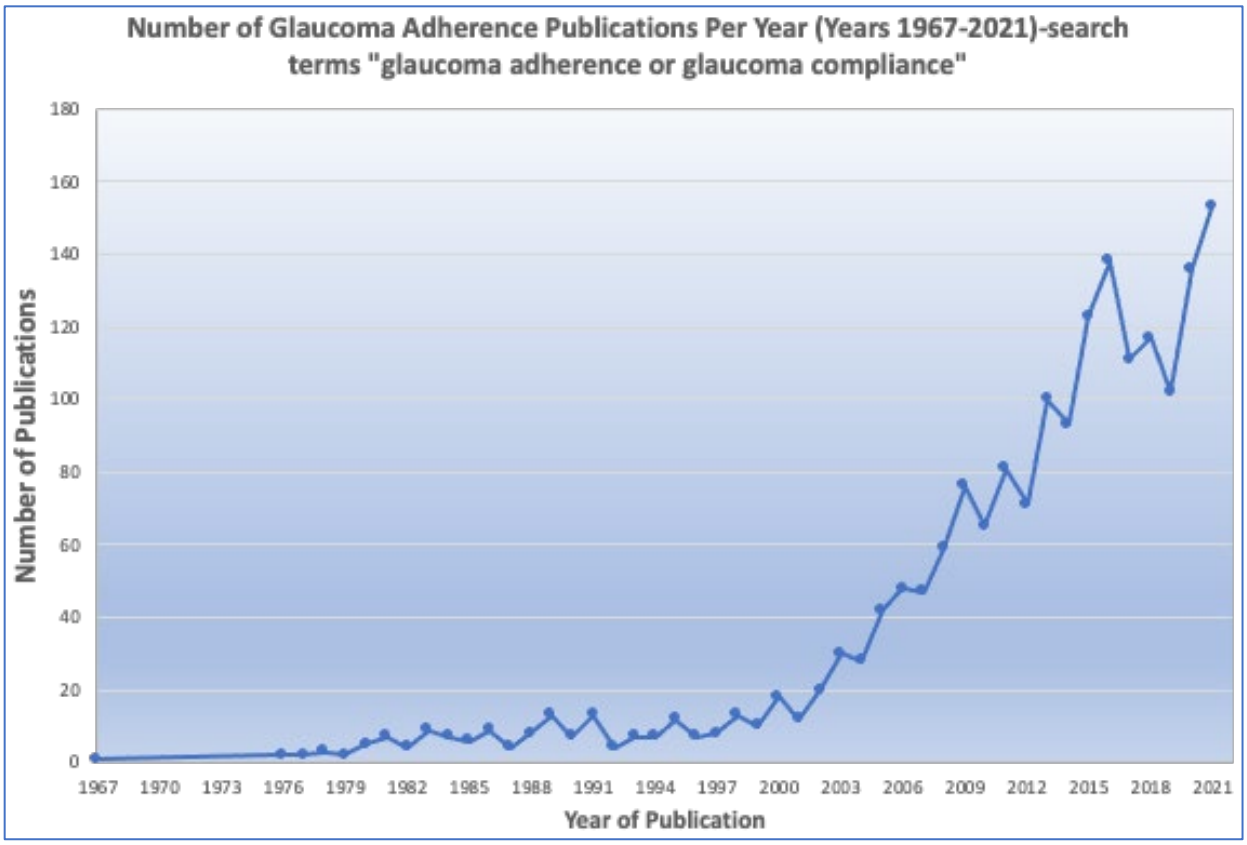
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Abstract:
Most patients with a diagnosis of glaucoma use eye drops to lower intraocular pressure. However, poor adherence to prescribed eye drop regimens can lead to significant loss of vision-related quality of life. This study will test the iDrop Device (iD2), a device-on-cap electronic platform designed to accurately track when a research participant removes an eye drop bottle cap, wirelessly communicate usage data to a database accessible to researchers, and send on-demand alerts when a medication is due. A device capable of tracking eye drop usage and sending dosage alerts will test the hypothesis that electronic reminders improve medication adherence and help research subjects improve their eye drop taking behavior. While our primary focus is on glaucoma adherence, this device could also benefit those with other chronic eye conditions requiring regular eye drop treatment, such as dry eyes, corneal endothelial disease, eye infections, and uveitis.

Background/Reference Literature:
Glaucoma is a chronic eye disease associated with visual field loss and optic disc cupping.[1] Glaucoma is the leading cause of global irreversible blindness and is expected to increase from 64.3 million people in 2013 to 111.8 million in 2040, which represents a 50% increase each

decade as the population becomes older.[2] Visual impairment is a devastating public health and medical issue for patients, their families, and their communities with a cost to the US government of $6.2 billion in 2011.[3–5]



Glaucoma eye drop medications are the most common treatment for glaucoma.[6] About 15 million people worldwide use these eye drops. Studies show that these drops can reduce the development or worsening of glaucoma by at least 60%.[7–9] However, to be effective, glaucoma eye drops must be taken daily. Despite this, adherence to prescribed glaucoma treatments is poor,[10–12] and is arguably the biggest barrier to preventing vision loss from glaucoma.[13,14] This issue is of great importance to researchers as evidenced by a steep increase in publications on glaucoma adherence (see Figure).

Poor adherence with glaucoma eye drop medications, defined as using less than 80% of expected doses, occurs in at least 50% of glaucoma patients.[15–18] Poor adherence results in vision field progression, increased surgery, and higher risk of blindness.[19–21] At least 3 million individuals worldwide lose vision from glaucoma each year due to poor adherence with eye drops.[19–21] Studies suggest that low adherence with eye drops is associated with multiple factors, which may include low self-efficacy, difficulty remembering, cognitive impairment, barriers (e.g. cost, side effects), low cues-to-action, depression, low health literacy, low dexterity as well as other associations.[17,21–30] In summary, eye drop taking behavior is complex and would benefit from an easy-to-use device to accurately and reliably measure adherence.

One of the tenets of epidemiology is measuring outcomes of interest as accurately and reliably as possible. Without accurate and reliable data, it is difficult to establish baselines, create goals,

track progress over time, nor understand the multidimensional constructs of adherence with eye drop medications. Researchers and eye care providers have difficulty measuring adherence with eye drops[12], which creates a large gap in knowledge. Patients routinely overstate their level of adherence using self-reporting[12], and pharmacy records may be incomplete, inaccurate, and difficult to obtain for individual patient.[31] Eye researchers have measured adherence to glaucoma medications using electronic oral pill bottle caps[21,29,30,32] that fits onto oral pill bottles. However, this eye drop "bottle within a bottle" mechanism requires that the patient remove the electronic cap, remove the eye drop bottle, remove the eye drop bottle's cap, dispense the eye drop, replace the bottle's cap, replace the bottle in the electronic cap container, and replace the electronic cap. This 7-step process is cumbersome and deviates from the usual process of administering eye drops. And it does not require that the eye drop bottle be replaced back within the oral pill monitor, which results in over- and underestimation of adherence. Researchers need a direct, reliable, and easy-to-use electronic method of monitoring adherence of ocular medications.[33]

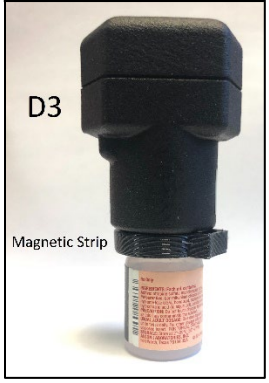
Monitoring adherence with the iDrop Device (iD2) may result in a direct increase in adherence because research subjects know that they are being monitored (Hawthorne Effect). As well, the device will improve adherence directly by providing on-demand reminders if the subject does not remove the device from the bottle within 45 minutes of the designated dosing time. Reminders have been shown to increase adherence by 18%.[34] We hypothesize that the iD2 will have higher improvement since the device will give reminders on-demand in contrast to the previous study[34] where reminders occurred even when the subject used the eye drop. On-demand reminders may increase self-efficacy, confidence and habit formation, and we will test these factors in the proposed clinical trial. In addition, treating non-adherence to eye drops for glaucoma has also been shown to be cost effective.[35]

The eye drop medication industry is far behind the oral pill industry in measuring adherence and encouraging medication refills. For example, pharmaceutical companies that sell oral medications lose billions of dollars each year due to infrequently filled prescriptions. In response, several companies have developed smart devices for oral pill bottles, such as GlowCap® (Vitality, Inc.), AdhereTech Smart Wireless Pill Bottle, and SMRxT Smart Bottle. Academic research departments, insurance companies, medical systems, and pharmaceutical companies are using these devices to improve oral pill adherence. Smart oral pill bottles have improved adherence rates, self-efficacy scores, and depression scores for depression in breast cancer survivors. With multiple myeloma, they have increased adherence and were cost-effective.[36,37] They have improved outcomes in many other medical conditions, but also show that nonadherence was more nuanced than simply missing pills and was the result of multiple factors.[38] We expect similar successes and findings in eye care when a suitable device to measure eye drop adherence is available.

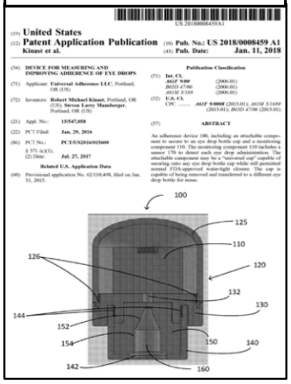
Figure 2: Older prototype versions



Figure 3: Current iD2 prototype

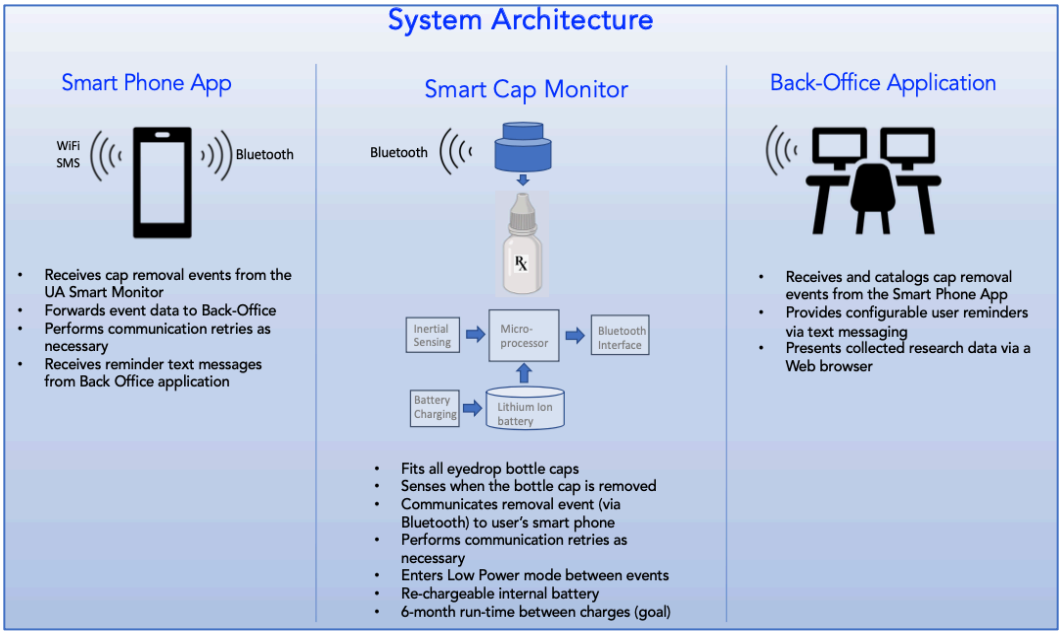


Universal Cap for measuring eye drop adherence



Preliminary Data: We tested the iD2 smart cap monitor in a clinical trial that included 50 research subjects with a diagnosis of glaucoma who were using latanoprost once per day. Over a 25-day period, the iD2 device remained attached to the eye drop bottle cap and collected adherence data for all patients. The mean adherence rate was high, averaging 90% (range: 32-100%). Additionally, 98% of participants agreed that "the device always stayed attached to the bottle cap," and 96% reported that "they were able to use the device to take the drops." If available commercially, participants would purchase the device for about $61 (range: $0-400).[39,44] This provided key insights and findings including accurate measurement of adherence using a smart eye drop bottle cap, high patient satisfaction, and willingness to pay. While this proof-of-concept device was successful, the trial highlighted several aspects to improve.

The iD2 connected directly to our research network using Wi-Fi with 100% success. However, only 52% of research subjects were able to connect the device to their home Wi-Fi using the Esptouch open-source smart phone App (Espressif Systems, Shanghai, China) and the device did not connect to public Wi-Fi. This made it difficult to collect adherence data in real-time. The battery required charging once a month, which required disassembly in a research office. Finally, the proximity sensor used a 2-part design with one part consisting of the magnetic sensor within the smart cap, and a second part including a magnetic strip that was manually attached to the neck of the eye drop bottle (see Figure 3). The magnetic strip requires removal and transfer to subsequent eye drop bottles that would be difficult for research subjects. We concluded that the device requires additional improvements.



Objectives:

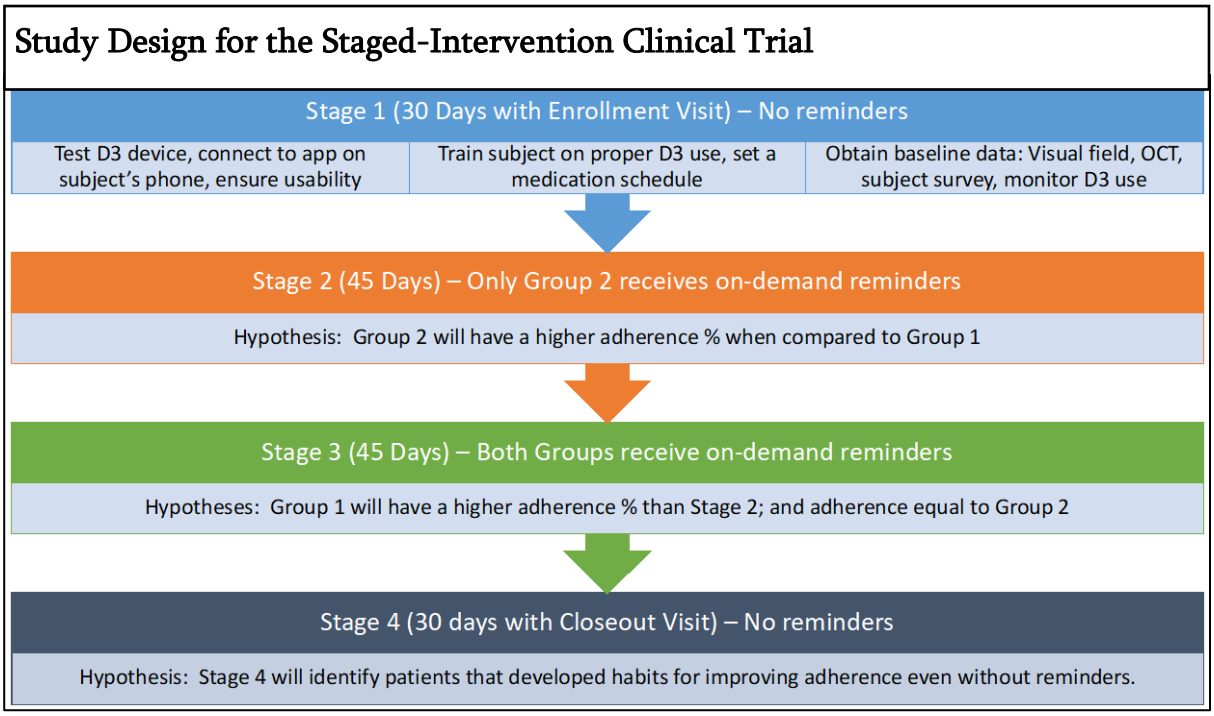
Through this study, we seek to test the effectiveness of the iD2 in improving medication adherence and eye drop taking behavior.

Hypothesis:

We will test the hypothesis that electronic reminders given through the iD2 will improve medication adherence and help research subjects improve their eye drop taking behavior.

Study Design:

This study is a randomized interventional clinical trial. We will register the clinical trial with clinicaltrials.gov and test the iDrop Device (iD2) in a clinical research environment with research subjects with self-reported poor adherence to their glaucoma medications. Legacy Devers Eye Institute (Legacy Health, Portland, Oregon) will conduct the clinical trial with oversight by the Legacy Health Institutional Review Board (IRB). The trial will also collect feedback regarding the patient/customer requirements from the perspective of functional, physical, and sensory performance.



The trial includes 4 stages: Stage 1) a 30-day run-in period using the ID2 without any reminders; Stage 2) a 45-day period with 1:1 random assignment to determine the effect of no reminders vs. smart cap reminders if the drop is not used within the designated time window; Stage 3) A 45-day period in which all participants receive the reminders using the smart-monitor; and Stage 4) A 30-day period using the iD2 without any reminders.

Stage 1 (Enrollment visit with 30-day run-in period): This *run-in period without any reminders* will allow all participants to become comfortable with the iD2 and decrease the risk of bias from increased adherence that occurs soon after a clinic or research visit.[48] We will also be able to troubleshoot any connection issues or device issues. On day 1 ('Enrollment Visit'), the RA will: 1) use the App to connect the iD2 to the participant's smart phone and test its ability to send information to the smartphone App and database; 2) test the ability for the App to control the reminders; 3) train the research subject how to charge the device, and how to remove it and transfer it to a subsequent eye drop bottle cap when the first bottle runs out; 4) determine the research subject's preferred time to schedule their dosing (e.g. 8 pm, 8 am and 10 pm, etc.); 5) measure function and structure in glaucoma using the Zeiss-Humphrey Field Analyzer (24-2 Sita Standard visual field test, HFA III, Carl Zeiss Meditech, Half Moon Bay, CA) and the Spectralis Optical Coherence Tomograph II (nerve fiber layer thickness of the optic nerve and macula,

Heidelberg Engineering, Heidelberg, Germany), respectively; 6) administer a 20 minute survey (see survey description below); and 7) monitor and educate the subject to administer their eye drops using the device according to clinical guidelines.[49] The RA will instruct subjects to use their eye drop per their usual routine and provide one device per participant. If the participant uses more than 1 eye drop medication, they will attach the device to the most frequently dosed medication. If both eye drops have a similar dosing schedule, they will assign the device to the eye drop medication randomly. The iD2 device will track when the bottle cap is removed as a measure of medication adherence. This stage will not include any electronic notifications and will allow us to determine baseline adherence in all participants using remote monitoring. The research physician will prescribe a 90-day supply of ocular hypotensive medications with 3 refills. The participants will also be given a diary to note any difficulties with the device during the clinical trial.

Stage 2 (45-day duration): A 45-day period has been shown to have high diagnostic precision for determining baseline adherence,[12,15,50] since patients usually revert to their normal dosing pattern about 4 weeks after their last clinic visit.[50] The total duration of Stage 1 (30-day duration) and Stage 2 (45-day duration) helps to avoid enrollment bias and the Hawthorne effect, which are improvement in behavior from enrolling in a study or being monitored, respectively, The research assistant will use a random number generator to randomize subjects to either *Group 1 "no reminder", which is usual care and the most common clinical situation, or Group 2 "the integrated daily smart reminder" using the iD2 App*. They will turn on the functionality of the App remotely and enter the research subject's preferred dosing time(s), which will allow the App to send visual, audio, and text message alerts to Group 2. If the subject does not remove the iD2 from the bottle within 45 minutes after the subject's scheduled dosing time, the App will send reminders and will continue them every 15 minutes until the research subject removes the iD2 from the eye drop bottle. The device will not send a reminder if the subject uses the drop within an appropriate time window, which we define as removing the eye drop bottle cap 3 hours before, or 45 minutes after the subject's scheduled dosing time. We will consider drops that occurred after the reminders started as 'rescue doses'. The number of rescue doses will help to determine the benefits of reminders with an integrated smart eye drop cap monitor and provide additional data to adherence percentage. For example, a higher number of rescue doses may suggest a greater value of a dose monitor for a person requiring regular eye drops. Exploring the date/time of rescue doses may provide personalized interventions such as cues to action to improve eye drop taking behavior.

Stage 3 (45-day duration): *All subjects will have the benefit of eye drop reminders*. This period will allow those in the original Group 1 "no reminder" to have the potential advantage of the technology. The staged-interventional design will also maximize safety in a group with self-identified poor adherence and allow us to examine the improvement in adherence using all participants. We hypothesize that Group 1's adherence will improve with the benefit of eye drop reminders and match Group 2 by the end of this stage. Dr. Mansberger has used this staged-interventional design previously[51,52] and the extended period of monitoring for both groups will help us understand long-term effects of electronic remote patient monitoring. For those participants without a change in adherence with reminders or those who give up the device, this would suggest that an eye drop monitor may not be useful. These individuals may require a different intervention; for example, eye surgery or an intervention centered on social determinants of health, motivational interviewing, health literacy, or a health behavior model.

Stage 4 (30-day duration with Closeout Visit): This period *without any reminders* will allow us to determine whether the device creates 'habits' for using eye drops. If a participant with a history of poor adherence remains adherent, this suggests that the device created changes in eye drop taking behavior and is not needed long-term. In contrast, a participant whose adherence

percentage decreases during this stage suggests that on-demand reminders are important for long-term adherence. This will provide a personalized approach to treating poor adherence. At the end of this stage, the subjects will return to the research clinic for the 'Study Close Out' visit. At this visit, the research assistant will collect the devices and conduct a short survey (see below).

The time period of the study is clinically relevant and similar to the 3- to 6-month interval that eye care providers commonly use to schedule a return visit for a treated patient with a diagnosis of glaucoma. We will use the methods from a previous study[53] to calculate adherence where adherence percentage is the number of days with dosing within 3 hours of the prescribed time by the number of days in the study stage.[16] Thus, a participant who misses 10 days out of 45-day stage will be considered 77.8% (35/45) adherent. The study diary given at the enrollment visit will allow them to record difficulties, device suggestions, and any other inputs they may have during the study.

Subject Surveys: The main goal of this study is to develop an eye drop cap monitor to measure eye drop adherence. Additionally, we will use univariate and multivariate regression to analyze the relationship between adherence percentage (during usual care without reminders) and various factors, including:

- Health behavior (Glaucoma Treatment Compliance Assessment Tool (GTCAT))[17,22–25]
- Health literacy (Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF))
- Vision-related quality of life (National Eye Institute-Visual Function Questionnaire (NEI-VFQ-28))[56]
- Cognition (Montreal Cognitive Assessment (MoCA)).[58–60]
- Depression (Center for Epidemiologic Studies Depression Scale Revised (CESD-R-10)[57]
- Social determinants of health (SDOH)[61]
- General health (Short Form-12 (SF-12)) questionnaire[62]
- Glaucoma severity (measured by visual field mean deviation)

We will also collect demographic and medical information at the subject level. We will use the Legacy Health electronic medical record system (EPIC and Care Everywhere, EPIC Systems, Verona WI) to collect data on social determinants of health (SDOH) in all adults. Health belief model data will be gathered at two time points to assess whether an electronic dose monitor alters the score of a health belief factor, such as self-efficacy.

Data Components	Item(s) measured	Visit administered
National Eye Institute-Visual Function Questionnaire (NEI-VFQ-28)[56]	Vision-related quality of life	Enrollment visit

Glaucoma Treatment Compliance Assessment Tool (GTCAT) [17,22–25]	health belief model (susceptibility, cues to action, severity, barriers, etc..), socioeconomic status, patient-provider satisfaction	Enrollment and Closeout visit
Short Form–12 (SF-12) questionnaire[62]	General health	Enrollment visit
Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF[63])	Health literacy	Enrollment visit
Center for Epidemiologic Studies Depression Scale Revised (CESD-R-10)[57]	Depression	Enrollment visit
Montreal Cognitive Assessment (MoCA) [58–60]	Cognition	Enrollment visit
Social determinants of health (SDOH)[61]	Social and environmental factors	Enrollment visit
EPIC data abstraction	Demographic, medical, and socioeconomic information	Enrollment visit
Study close out visit questionnaire	Patient satisfaction, willingness-to-pay, self-reported adherence, eye drop dexterity, self-reported reasons for poor adherence	Closeout visit

Methods, Interventions and Procedures:

This study will consist of four stages and lasts a total of 150 days. Subjects will be asked to come into clinic twice at the beginning and end of this duration.

Enrollment Visit/Stage 1 (in-person): Day 1

The first stage will last 30 days (including enrollment visit). In order to measure a baseline for eye drop adherence, the subject will not receive any reminders during this stage. Prior to receiving the iD2, the subject will come to clinic and the following procedures will be performed:

- Consent: Before any research activities, the subject will be asked to sign the informed consent form. This will be done in accordance with the Legacy standard operating procedure for consenting subjects.
- Demographic data collection,
- Comprehensive Medical History, including current/past medications and surgical history.
- All subjects will complete the following questionnaires:
    - MOCA (Montreal Cognitive Assessment)
    - GTCAT (Glaucoma Treatment Compliance Assessment Tool)
    - CESD-R-10 (Center for Epidemiologic Studies Depression Scale Revised)
    - NEI VFQ-25 (National Eye Institute-Visual Function Questionnaire)
    - REALM-SF (Rapid Estimate of Adult Literacy in Medicine-Short Form)
    - SDOH (Social determinants of health)
    - SF-12 (Short Form-12)
- Comprehensive eye exam, performed according to clinical standards of care
- Gonioscopy
- Pachymetry
- Visual field
- SD OCT of optic nerve and macula
- Device dispensation: Subject will be given the iD2 device and instructed in its use. We will also test the device to ensure app connectivity and usability.

Stage 2:

This stage will last 45 days. Researchers will remotely reprogram the device to follow stage 2 procedures. This includes a 1:1 randomization of participants into two groups: Group 1 will not receive reminders while Group 2 will receive on-demand reminders.

Stage 3:

This stage will last 45 days. Researchers will remotely reprogram the device so that both Group 1 and Group 2 will receive on-demand reminders.

Stage 4/Closeout Visit (in-person):

This stage will last 30 days. Researchers will remotely reprogram the device so that neither Group 1 nor Group 2 will receive any reminders. At the end of the 30 day duration, the subject will return to the clinic. The following procedures will be performed:

- Satisfaction questionnaire
- GTCAT (Glaucoma Treatment Compliance Assessment Tool)
- Researchers will collect the iD2

Data/Statistical Analysis:

Power Analysis: A recent paper suggested a minimal clinically important difference (MCID) of 15% for an intervention in glaucoma adherence.[26] A study using a simple calendar reminder noted an improvement of 18%.[34] Two recent studies[54,55] using electronic oral pill bottles and reminders suggest a mean average improvement in adherence of 22.5% (22 and 23%) with a standard deviation of approximately 20%. Other studies show an indirect relationship where higher change in adherence is associated with those with worse baseline adherence. Using a conservative 20% change in improvement, a standard deviation of 20, an alpha of 0.05, and power (beta) of 0.80, the table suggests a sample size of 74 persons. We will recruit a higher number, 100 persons to accommodate attrition. This proposal will include those with self-identified poor adherence using a validated question in a similar clinical trial.[27] However, we may recruit a cohort with better adherence than expected with a lower change in adherence. We will perform a mid-study analysis to compare differences between the groups and increase sample size as necessary.

Table: Power Analysis

% Change in Adherence	Standard Deviation	Total Sample Size
15	15	70
15	20	126
20	15	42
20	20	74
25	15	28
25	20	50

Sample Size Considerations: The NEI-VFQ-28 requires 21 subjects per case to detect a 20-point difference in vision-related quality of life ($\alpha = 0.05$, power = 0.80).[56] The MoCA is scored from 0 to 30, with >26 considered normal, and requires 35 subjects per case to detect a 2-point difference.[59] The GTCAT has a mean score of 73.8% (SD = 21.0%) and requires 93 patients to detect a 20% difference in adherence.[22] The SF-12 has a mean score of 50 (SD=10) and an effect size of 5 units requires 22 subjects.[62] We plan to recruit 100 participants, which will allow us to investigate many of these factors associated with adherence as well as provide a robust preliminary dataset for future proposals regarding eye drop adherence.

Estimated Duration of Project:

We estimate that this study will last a total of 13 months. Total estimated duration of a subject's study is 150 days (~5 months). We estimate the end of all data collection to be 12 months after recruitment commences. We plan to finish data analysis one month after all data has been collected.

Study Population:

This study will enroll 100 participants with a diagnosis of glaucoma and who have a self-reported history of poor eye drop adherence. We will not enroll the following vulnerable populations: Children, Neonates of uncertain viability or nonviable neonates (up to 28 days post birth), Pregnant women, Prisoners, or Cognitively Impaired Adults.

Eligibility Criteria:

The inclusion criteria will include the following: adults aged 18 years and older with self-reported poor adherence (≤80% self-reported adherence) with eye drops, use of at least one glaucoma eye drop daily, and own a functioning smart phone (Apple iOS, or Android) with Bluetooth and cellular connectivity. To identify those with poor adherence, we will screen all glaucoma patients with a single question validated by Cho and colleagues[27], "Over the past month, what percentage of your drops do you think you took correctly?" The study tested several other measures and this question has the highest association (r=.47, AUC=0.76, sensitivity=84%, specificity= 59%, positive predictive value 67%, and accuracy=71%) with adherence when using an 80% level as a cut-off for adherence.[27] We will exclude patients with severe cognitive impairment. However, we will include participants who live independently and have decision making ability but may have mild and moderate cognitive impairment since these conditions are common in older adults[47] and the proposed device may be an important tool to enhance self-efficacy and self-administration of their eye drops.

Inclusion/Exclusion Criteria:

Subjects Legacy health records will be reviewed prior to proceeding with enrollment in the study to ensure that patients meet the enrollment criteria. Criteria will be confirmed during the first visit.

Inclusion Criteria:

- Age ≥ 18
- Taking at least one glaucoma drop daily
- A history of poor adherence when taking glaucoma eye drops.
    - This is determined as an answer of 80% or less for the following question: "Over the past month, what percentage of your drops do you think you took correctly?"
- Owns a functioning smart phone with Bluetooth and cellular connectivity

Exclusion Criteria:

- Advanced cognitive impairment
- Current or expected pregnancy during the study.

Vulnerable Populations:

This study will not enroll patients that belong to the following vulnerable populations:

- Children
- Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)
- Pregnant women
- Prisoners
- Cognitively Impaired Adults: These are subjects that cannot consent for themselves and need a surrogate to consent.

Consent Process:

A Legacy Devers research assistant (RA) will enroll 100 participants into a prospective trial with duration of 150 days (~5 months). Upon notice of approval, the RA will create a database of possible participants using referrals from ophthalmologists and optometrists from the Legacy Devers Schnitzer Glaucoma Center (Portland, OR) and the surrounding metropolitan area. The RA will also solicit participants through electronic searches of the Legacy Health electronic medical record called EPIC. The RA will also use electronic print and social media advertising (e.g. Facebook) to enable self-referral. These methods have previously been successful in recruiting research subjects with different racial and socioeconomic backgrounds, which are generalizable to the community at large. Legacy Devers has successfully recruited for over 40 clinical trials for the NIH and industry using similar methods.

During the first visit and prior to any research activities, researchers will discuss the study and provide a consent form. The investigator will be available for questions. Patients will have time available to read and consider the consent form in clinic or the preoperative area, and if they require more time we will allow them at least 48 hours to take the consent form home for discussion and consideration. Technical language in the consent form will be explained by trained coordinators and by the investigator.

Use of PHI:

The informed consent form used in this study will contain a section authorizing appropriate research use of HIPAA data. Subject data will not be transmitted to a person or office not associated with this institution.

Waiver of consent for all subjects:

No waiver of consent will be available.

Human Subject Ethics:

Study subjects will be recruited and approached for participation and will be allowed adequate time to review the written consent form, have their questions answered by the PI or study staff, and will be advised about the research in a private setting where confidentiality is maintained. All data will be deidentified prior to analysis and publication.

Risks:

We do not expect participation in this study to add any additional risk beyond those present during typical clinical procedures.

Benefits:

Subjects may benefit from improved medication adherence, and thus improved efficacy of glaucoma treatment. Subjects stipend for this study is $300, split between $150 given at the enrollment and exit visits.

Adverse Event Assessment:

Participation in this study poses minimal risk. Should an adverse event occur, the event will be reported to the Legacy Institutional Review Board in accordance with their reporting guidelines.

Costs/Budget:

All costs for this study will be covered by its sponsor, Universal Adherence LLC. Costs for this study include the iD2 devices, researcher effort, access to testing equipment, and patient reimbursement. Participants will not incur any cost for participating in this study.

Sharing of Results with Subjects:

The results of this study will not be shared directly with the participants.

Data and Specimen Banking:

Subject demographics will be stored along with their survey results. Specimens will not be collected during this study.

Subject Materials:

During this study, subjects will complete the following surveys:

- MOCA (Montreal Cognitive Assessment)
- GTCAT (Glaucoma Treatment Compliance Assessment Tool)
- CESD-R-10 (Center for Epidemiologic Studies Depression Scale Revised)
- NEI VFQ-25 (National Eye Institute-Visual Function Questionnaire)
- REALM-SF (Rapid Estimate of Adult Literacy in Medicine-Short Form)
- SDOH (Social determinants of health)
- SF-12 (Short Form-12)
- Subject Satisfaction Questionnaire

QUESTIONS?

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