Quality of Refractive Error Care (Q.REC) Study Protocol Template

Protocol Information

- Protocol Title: Quality of Refractive Error Care Study in *[Location]*
- Protocol Version*: [Number]*
- Date: *[Date]*
- Principal Investigator: *[Name and Institution]*
- Co-Investigators: *[Names and Institutions]*

Section 1. Research Aims & Questions

The aim of this study is to determine the quality of refractive error care provided by optical services in *[Location]* by assessing the proportion of spectacles that meet optimal and/or adequate quality standards.

The research questions/hypotheses that this study seeks to address is: What proportion of optical services produce spectacles that are 'optimal quality' in *[Location].*

The study will also seek to:

1. Investigate the relationship between service delivery characteristics and spectacle quality.
2. Assess adherence to professional standards and guidelines in refractive care delivery. This assessment will highlight areas where current practice aligns with or deviates from established standards.
3. Generate evidence to inform policy development and quality improvement initiatives in the optical sector. This evidence will support decision-making about professional training, service delivery standards, and regulatory frameworks.

Section 2: Lay Summary & Background Literature Review

Global burden of uncorrected refractive error

Uncorrected refractive errors represent the leading cause of vision impairment globally, affecting approximately 161 million people with distance vision impairment and an additional 510 million people with near vision impairment. Despite being easily correctable with appropriate spectacles, these conditions

continue to impact quality of life, economic productivity, and educational outcomes worldwide. In 2021, the United Nations General Assembly adopted a resolution committing the international community to provide eye health for all people living with vision impairment by 2030, emphasizing the urgent need for quality vision care services.

Local context and significance

[In this section, describe:

- *Current prevalence of refractive error in your setting*
- *Existing eye care service provision*
- *Known challenges or gaps in service delivery*
- *Relevant policies or regulations governing optical services*
- *Previous quality assessment efforts, if any]*

Quality Assessment in Refractive Care

Traditional methods of assessing refractive care quality often fail to capture real-world service delivery. While cross-sectional studies can provide information about the prevalence of uncorrected refractive error, they do not adequately assess service quality or identify specific areas for improvement. The World Health Organization has emphasized that quality eye care services must be provided according to population needs, highlighting the importance of measuring and monitoring service quality.

Study Rationale

This study employs the Quality of Refractive Error Care (Q.REC) methodology, which uses unannounced standardized patients (USPs) to evaluate service quality. USPs are considered the gold standard for assessing clinical practice as they minimize observation bias – providers maintain their typical behaviour patterns when unaware they are being assessed. This approach enables the collection of objective data about real-world service delivery and patient experiences.

This study is important/significant because it will identify the proportion of people that are prescribed and dispensed spectacles that were appropriate for their refractive error needs. These results can be used to identify particular aspects of clinical practice that require improvement, or further training.

Section 3. Research Design and Methodology

Study Type

This research employs a cross-sectional observational design using unannounced standardized patients to assess the quality of refractive care services.

The methodology follows the standardized Q.REC protocol developed by the Fred Hollows Foundation, which enables systematic evaluation of both technical and interpersonal aspects of refractive error care.

Study Setting

The study will be conducted in *[describe specific geographic region],* encompassing both urban and urban areas where optical services are available.

The optical service landscape in this region includes *[describe types of providers]* operating under *[describe regulatory framework].* These services represent the primary access points for refractive error correction in the community.

Study Timeline

The study will be conducted over a *[XX]* month period, according to the following timeline:

- Ethics approval: *[Month/s]*
- Partnerships with relevant stakeholders: *[Month/s]*
- Stakeholder/Community Consultation: *[*Month/s]
- Recruitment of Participants: *[Month/s]*
- Training: *[Month/s]*
- Notification of optical services*: [Month/s]*
- Data Collection: *[Month/s]*
- Analysis of Data: *[Month/s]*
- Dissemination: *[Month/s]*
- Publication of Research: *[Month/s]*

Data Collection

The data will be collected in the following way:

Data Collection Method 1: *Clinical Observation [USP Baseline Refraction]*

- The purpose of this data collection method is to identify an accurate baseline of each USPs prescription
- The data will be collected by the Study Optometrist, who will perform three individual clinical refractions on each Study USP, in order to establish the USPs average baseline prescription.

- Each individual baseline refraction is anticipated to take approximately 20-30 minutes and will be repeated twice (three times in total).
- Data collection will take place at *[locations]:*
- In each country, the project team has consulted with the Ministry of Health and the relevant optical council to obtain support for the project.
- The data will be recorded on a mobile data collection instrument (REDCap) using FORM A: Q.REC Record Forms *[Version].*

Data Collection Method 2 *Clinical Observation [USP Post-Training Assessment]*

- The purpose of the USP Post-Training Assessment is to identify whether the study USPs can accurately identify elements of a refraction.
- The data collection will be administered by observation of the study USPs ability to accurately identify elements of a refraction.
- The data will be collected by the Study Optometrist by observing USPs.
- The data will be recorded by the Study Optometrists.
- Data collection will take approximately 1 hour and will occur at the end of USP training.
- Data collection will take place at the following *[locations]:*
- The data will be recorded on a mobile data collection instrument (REDCap) using FORM B: Q.REC Record Forms *[Version].*

Data Collection Method 3 *Clinical Observation [Optical Service Visit Checklist*]

- The purpose of this data collection method is to identify whether optical services have prescribed and dispensed spectacles that are appropriate for the refractive error needs of each USP.
- The data will be collected by the USPs, who will visit individual optical services, undergo a refraction, purchase spectacles (if recommended) and record observations about which elements of a refraction were conducted.
- Optical services will be identified through a list requested from the *[Relevant authority].* The visits will be coordinated by the local research team (i.e. investigators).
- All known optical services in each location will be sent the Participant Information Statement and Withdrawal Form at least one month in advance advising that the services might be visited for research purposes. During this time, the optical service owner/manager will be asked to read

the form, assess whether they meet the inclusion/exclusion criteria, have the opportunity to opt-out and identify whether study feedback is desired.

- If the randomly selected services do not return the Form for Withdrawal of Participation and the first USP attending says they are unlikely to be detected, they are considered successfully enrolled.
- Although a schedule will be developed for each USP to attend selected optical services, no prior appointment will be made unless it is standard practice for specified optical service.
- The USP will attend the optical services and request an eye examination.
- The USP will follow the lead of the staff member(s) and respond accordingly. During this time, the USP will observe and remember as many/all the details as outlined in REDCap mobile data collection FORM B: Q.REC Record Forms *[Version].*
- Once the eye examination is complete, the USP will place an order for new spectacles/lenses
- Once the USP leaves the optical service, he/she shall find a suitable location out of view from the optical service and staff to complete the checklist on a mobile phone survey form (or a paper record form if mobile phones are not available/working).
- Payment will be made at the time of ordering or at collection. A receipt is to be collected with payment.
- Upon spectacle collection, a spectacle prescription will be requested.
- The spectacles are to be labelled with the unique ID number provided out of sight from the participating service.
- Each optical service visit is anticipated to take approximately 30-45 minutes. Each Study USP will attend [*10-20]* individual optical services.
- Data collection will take place at the following *[locations].*
- The data will be recorded on a mobile data collection instrument (REDCap) using FORM C: Q.REC Record Forms *[Version].*

Data Collection Method 4 Clinical Observation [Spectacle Quality]

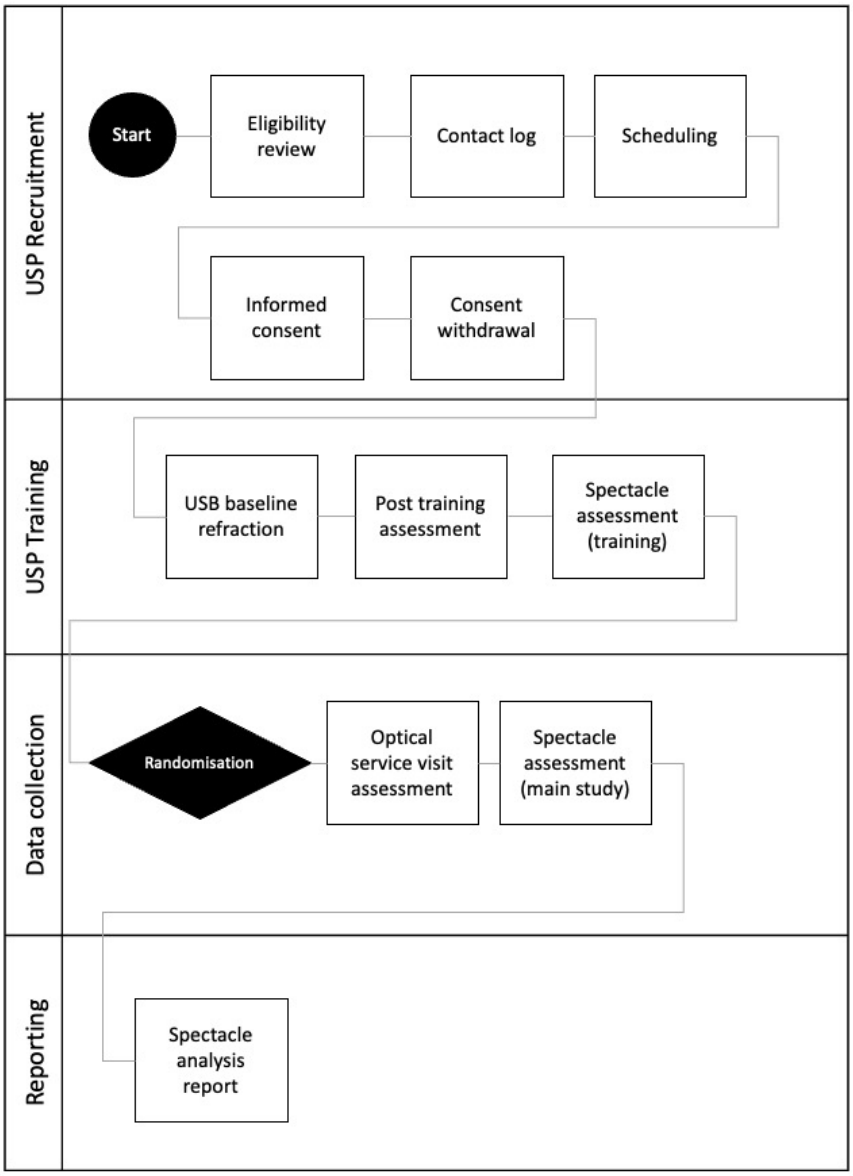
- The purpose of this data collection method is to identify whether spectacles that have been dispensed by optical services are appropriate for the refractive error needs of each USP.

- The data will be collected by the Study Optometrists, who will assess every pair of spectacles that have been dispensed.
- The data collected on whether each pair of dispensed spectacles are appropriate for the refractive error needs of each USP (includes visual acuity, and focimetry).
- The Study optometrist will collect the data by assessing the appropriateness of each pair of spectacles
- Each spectacle quality assessment is anticipated to take 5 to 10 minutes.
- Data collection will take place at the following *[locations].*
- The data will be recorded on a mobile data collection instrument (REDCap) using FORM D: Q.REC Record Forms *[Version].*

[The Q.REC Record Form will be translated into local languages by the local research team].

Study Flow Chart

The following flow chart describes how an individual participant will progress through the phases of the research process:



Sample Size

The total sample size for the project is *[number]* spectacles from *[number]* optical services.

The sample size has been calculated using the Q.REC Sample Size Calculator, which accounts for clustering effects at both the service and USP levels. Based on an anticipated proportion of *[X%]* of spectacles meeting *[optimal/adequate]* quality standards, an intraclass correlation coefficient of *[Y]*, and a desired margin of error of *[Z%]*, the study requires *[number]* spectacle assessments from *[number]* optical services.

The calculated sample size has been increased by 10% to account for potential service withdrawals and data loss. This adjustment ensures adequate statistical power even if some services opt out during the study or if some USP visits result in unusable data due to detection or other complications.

Sampling Strategy

Service Selection

The selection of optical services will employ a stratified random sampling approach. The sampling frame will first be stratified by *[relevant characteristics such as geographic location, service type, or provider qualification].* Services within each stratum will then be randomly selected using a computer-generated sequence to ensure unbiased representation.

USP Distribution

The study requires *[number]* USPs representing different refractive error profiles. These profiles will include myopia, hyperopia, astigmatism, presbyopia and emmetropia to assess service quality across a range of common refractive conditions. Each USP will be assigned to visit multiple services according to a predetermined schedule designed.

Research Participants

The study encompasses two distinct populations: optical services that will be evaluated and unannounced standardized patients who will conduct the evaluations.

Optical Services

The study will include optical services located within *[geographical region]* that provide both refraction and dispensing services. These services may include privately owned stores, franchises, vision centers, and eye care facilities within healthcare institutions. The sampling frame will be developed using comprehensive service mapping in collaboration with local health authorities and professional organizations.

To be eligible for inclusion, services must provide refractive error examinations and spectacle dispensing as part of their routine operations. They must also maintain regular operating hours and serve a minimum of three new patients per week. This threshold ensures sufficient patient flow to minimize the risk of USP detection.

Inclusion criteria for Optical Services:

- Optical stores that have at least three new patients attending per week

Exclusion criteria for Optical Services:

- If the optical store is owned by the same person or has the same staff members as another optical store that will be/or has already been visited
- If the optical store is personally known to the USP

Services will be excluded if they share ownership or staff members with another participating service, as this could compromise the independence of observations. Additionally, services personally known to any of the USPs will be excluded to maintain the integrity of the unannounced visits.

Recruitment of Optical Services:

A list of optical stores within the sampling frame will be compiled by requesting a list of optical stores from the *[relevant Ministry of Health/Commerce and relevant optical associations].* All optical stores identified will be sent a letter of invitation accompanied with the Participant Information Statement and Withdrawal Form to introduce the research. Optical stores will then be chosen at random for USPs to visit.

The Participant Information Statement Form requests that optical stores notify the researchers if they do not meet the inclusion/exclusion criteria or choose to opt-out of the study. The first USP attending the optical store will assess whether there are enough patients attending to not be exposed.

[The Optical Store Letter of Invitation will be translated into local languages by the local research team.]

No screening process is required because the inclusion and exclusion are such that participants can determine their own eligibility to participate.

Optical Service Reimbursement

Optical services will not be reimbursed for their participation, nor will their participation incur any expenses.

Risks to Optical Services

Involvement in the research carries no risk to participating services

Unannounced Standardized Patients

USPs will be recruited from the local community through appropriate advertising channels. Candidates must be adults aged 18 years or above who are fluent in the primary language(s) used in the study area. Each USP must demonstrate

good ocular health and possess refractive errors that align with the study's predetermined profiles.

The study will exclude individuals who have undergone refractive surgery or other recent eye procedures. Those with conditions that could affect refractive stability, such as keratoconus, uncontrolled diabetes, or significant ocular surface disease, will also be excluded. Furthermore, individuals with prior training in refraction or current employment in eye care will not be eligible to serve as USPs.

Inclusion/Exclusion criteria for USPs:

- Adults aged 18 years or above
- Has healthy eyes
- Has the refractive error profile we are looking for (myopia, hyperopia, astigmatism, presbyopia and/or emmetropia)
- Never had refractive eye surgery
- Has not had any other eye surgery in the past 3 months

Recruitment of USPs:

- The research team will identify participants for this project by advertising via posting recruitment advertisements in *[locations].*
- *[Advertisements will be translated into local languages by the local research team.]*
- The research team will make initial contact with potential participants by posting recruitment advertisements in suitable locations. If participants do not respond to this initial contact, no further contact will be made.
- Potential participants can indicate their interest in participating by contacting the research team directly *[via email/phone]* using the contact details available on the recruitment invitation.
- Once a potential participant has indicated their interest in participating in the study, the researcher(s) will determine their eligibility by conducting a brief screening ocular health assessment to determine whether the potential USP meets the inclusion and exclusion criteria.
- Once a potential participant is determined to be eligible, the researcher will undertake the consent process and will schedule/organising training by advising the USP when and where to attend training.

USP Reimbursement

Participants will be reimbursed for their participation by means of a daily stipend and reimbursement of travel, food, accommodation expenses. Participating

USPs will be reimbursed *[$XXUSD per day]* (plus any travel, accommodation or meal expenses).

Risks to UPSs

USPs may experience the following discomforts/harms:

- Anxiety may be induced due to the "undercover" nature of the USPs role.

To minimise the risk of these discomforts/harms, the researchers will adopt the following processes:

- All USPs will be briefed on the tasks involved and will be allowed sufficient time to practice acting as a patient.
- Training packages have been developed to provide USPs with a 'script' that they can use during optical service visits. It is anticipated that this training will increase the confidence of the USPs and reduce anxiety.
- All USPs will be offered the opportunities to withdraw from the study prior to and after training, if USPs anticipate that they are likely to experience anxiety.
- All USPs shall have access to emotional support services at all times through the recommendations of the local research team and partner organisations.
- A COVID-19 Safety Protocol has been developed to ensure that hygiene, social distancing and personal protective equipment standards are maintained.

The benefits outweigh these potential risks of discomfort/harm because the concealed nature of the research is essential for eliminating the effects of observational bias in a clinical setting.

Participant Consent

Optical Services: OPT-OUT approach

An opt-out approach will be used because explicit consent is not practical, as the aim of the study is to determine the quality of spectacles. If optical services are aware that they are being observed, then this is likely to induce optical staff to modify their behaviour.

Optical services will be provided with the PISCF at least one month prior to the start of data collection. The PISCF will ask optical service owners/operators to read it through. If they choose to participate, then no further action is needed. If they chose to not participate and opt-out, then they will be asked to contact the researchers *[via, phone, email, sms, WhatsApp or mail].*

[The Optical Services PISCF will be translated into local languages by the local research team.]

Participants will have sufficient time to consider their participation because the letter will be delivered to the optical service at least one month before the study commences

This opt-out consent approach is appropriate for the data collection method and participant group because:

- Involvement in the research carries no risk to participating services, as USPs will attend the store as if they were a regular patient and will receive typical care,
- The public (potential optical service clients/patients) have a right to understand the quality of the services that they might be expect to receive in each location, although the quality of each individual store will not be published in any way so the privacy of each store will be maintained,
- The research is likely to be compromised if optical stores are aware that they are providing optical services to a USP due to the Hawthorne effect (where clinicians modify their behaviour in response to being observed).,
- All prospective participants will be provided with a plain language information (PISCF) explaining the nature of the information to be collected, the purpose of collecting it and the proceed to decline participation of withdraw from the research,
- A reasonable time period (one month) will be provided to prospective optical service owners/operators to decline to participate,
- Multiple mechanisms will be provided for prospective participants to obtain further information and decline to participate. The study team will provide *[email, sms, phone, WhatsApp and mail]* contact details for optical stores to request further information or opt-out,
- The data collected will be managed and maintained in accordance with relevant security standards,
- The project has a data management plan and data sharing arrangements are clearly defined in collaborator agreements for the appropriate management of data.

USPs: Written Consent

- Participants will be provided with the PISCF in person when they contact the research team about taking part.

- Participants will be asked to read the PISCF and will have sufficient time to consider their participation because they will have at minimum 24 hours between being asked to read the PISCF and when training commences.
- Participants will be advised to contact the researcher(s) if they have any questions, and once they are comfortable providing their consent to participate, will be asked to sign the consent form and bringing it to the site where training will be conducted, on the date that training commences.
- *[The USP PISCF will be translated into local languages by the local research team.]*

Section 5: Study Procedures

Training Procedures

Study Optometrist Training

The study will begin with comprehensive training for all study optometrists. This training encompasses protocol familiarization, standardized refraction procedures, and quality control measures. Each study optometrist will receive detailed instruction in the Q.REC methodology, including proper documentation requirements and data collection procedures. The training will include practical sessions to ensure consistency in baseline refraction techniques and spectacle assessment methods.

USP Training Program

The USP training program consists of both theoretical and practical components delivered over five days. The first component involves online modules covering basic concepts of refractive error, examination procedures, and observation techniques. Following the online preparation, USPs participate in intensive in-person training at the designated study facility.

During in-person training, USPs learn to recognize and document different examination procedures, maintain cover during visits, and accurately record their observations. The training includes practical exercises, role-playing scenarios, and supervised practice visits. Each USP must demonstrate competency through written assessments and practical evaluations before beginning actual service visits.

Baseline Data Collection

USP Baseline Refraction

Each USP undergoes three independent baseline refractions conducted by different study optometrists. These refractions establish the reference standard against which service-provided spectacles will be evaluated. The process follows a standardized protocol including both objective and subjective refraction techniques. If significant variation exists between the three refractions, a fourth refraction will be performed to ensure accuracy.

Documentation Requirements

All baseline data is recorded using standardized forms in the REDCap database. This includes detailed refraction measurements, pupillary distances, and recommended spectacle types for each USP. The documentation also captures relevant clinical observations and any specific considerations for individual USPs that might affect their participation.

Service Visit Procedures

Visit Scheduling

Service visits are carefully scheduled to minimize detection risk. Each USP receives a specific schedule of visits with adequate time between appointments to prevent fatigue and maintain data quality. The schedule considers factors such as service operating hours, travel time, and local conditions that might affect visit timing.

Visit Protocol

During each visit, USPs follow a standardized protocol while maintaining natural patient behavior. They present with consistent symptoms and history as established during training. USPs undergo whatever examination procedures the service provider initiates, excluding those identified during training as potentially harmful or unnecessary. Following the examination, USPs order spectacles according to the provider's recommendations.

Data Recording

Immediately after leaving each service, USPs complete the standardized visit checklist using the mobile REDCap application. This documentation captures all aspects of the visit, including examination procedures performed, communication quality, and recommendations received. USPs also collect any written prescriptions provided and maintain records of all expenses incurred.

Spectacle Assessment

Collection Procedures

When collecting dispensed spectacles, USPs request written prescriptions if not previously provided. They transport the spectacles to the study facility without wearing them unless absolutely necessary to maintain cover. Each pair of spectacles is labeled with a unique identifier corresponding to the visit documentation.

Technical Assessment

Study optometrists perform comprehensive assessment of all dispensed spectacles. This includes measurement of sphere and cylinder powers, axis orientation, and prismatic effects using calibrated equipment. Visual acuity testing and comfort assessment are conducted under standardized conditions. All measurements are recorded in the REDCap database using Form D: Assessment of Glasses.

Quality Control Procedures

Data Quality Monitoring

The study coordinator conducts regular reviews of submitted data to ensure completeness and consistency. This includes daily checks of visit documentation, weekly review of spectacle measurements, and monthly analysis of data patterns that might indicate protocol deviations or USP detection.

USP Performance Monitoring

Regular meetings with USPs allow for discussion of challenges encountered and reinforcement of protocol requirements. Random checks of visit documentation and occasional supervised visits help maintain consistency in data collection. Additional training is provided as needed based on quality control findings.

Safety and Ethics Procedures

USP Safety Protocols

Clear procedures are established for managing any safety concerns that arise during service visits. USPs have immediate access to study team support through designated communication channels. The protocol includes specific guidance for situations such as service provider suspicion or requests for procedures outside the study scope.

Data Protection Measures

All study data is managed according to institutional privacy requirements and ethical guidelines. Personal identifiers are removed from service visit records, and all electronic data is stored in secure, password-protected systems. Access to study data is restricted to authorized team members based on their roles and responsibilities.

Section 6: Data Management

The data will be collected as online survey and online data record form in a REDCap database. The data will be retained for a minimum of 7 years after completion of the project.

All research documentation will be labelled with a unique person number as an identifier and stripped of any potentially identifiable information. Identifiers will automatically be removed from all printed or exported materials generated by REDCap where the user has not been given access to identifiers.

The REDCap application was chosen as it enables multisite users to contribute via the internet to a secure database and allows the study coordinator to oversee all data entry. Access to the REDCap database is restricted and password protected. The study coordinator will assign different levels of access to the REDCap database to ensure confidentiality of all sources of data. The study coordinator will have full access to all data using independent password codes. Co-investigators will have access to their site-specific data only, enabling local data entry and reporting specific to their site.