

## POSITION PAPER

# Innovative approaches to the provision of refractive error services

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IAPB adopts advisory positions in areas to assist in guiding the work of its members and their stakeholders. This position paper has been developed by inputs and advice from members of the Refractive Error Working Group based on their learnings, available published evidence, and existing position papers by IAPB. The paper focuses on introducing an innovative approach to refraction services in a country. It defines the minimum threshold for any new technology or innovation to be introduced. It provides further context specific recommendations to be considered during the introduction of innovative technology or processes.

This position paper is not intended to replace structured frameworks, guidance or tools provided by WHO to member states, nor to be used as a planning tool for national level programming. It is intended to guide thinking for IAPB members when they are considering the introduction of new innovative approaches during their strategic development and also through the implementation phase, pilot or scale up of the innovation.

This paper does not suggest that IAPB is responsible for the actions of its members nor responsible for ensuring its members follow these guidelines.

*IAPB Refractive Error Working Group September 2021*

### Definition of Innovation for the purpose of this paper

The World Health Organization (WHO) defines “health innovation is to develop new or improved health policies, systems, products and technologies, and services and delivery methods that improve people’s health, with a special focus on the needs of vulnerable populations”<sup>1</sup>. In the context of uncorrected refractive error (URE), innovative approaches are those that aim to yield scalable solutions that improve accessibility to and/or quality of URE detection, diagnosis, and correction for a defined population of people. Innovations can be classified as technological, organisational, social or financial.

Innovating to develop, test, deliver and finance refractive error (RE) services at scale will be critical to addressing the unmet need in the coming decade. This may include innovation on cost-effective and high impact refractive services and products, screening, health promotion, diagnosis and monitoring tools and efficient delivery mechanisms. Adopting innovative approaches to overcome the significant supply chain challenges that exist globally and within countries, that break down bottlenecks to supply services to the poorest and most vulnerable communities will also be important. Technology, such as 5G, artificial intelligence, digital health information systems, tele-ophthalmology, tele-optometry, mHealth, digital payment platforms, digital screening and self-screening devices, has the potential to transform the demand and supply of RE services.

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<sup>1</sup> World Health Organization. Health Innovation Group <https://www.who.int/life-course/about/who-health-innovation-group/en/>



The COVID-19 pandemic has also put a spotlight on the resilience of health and education systems. The long-term societal, health, education and economic impacts of the pandemic are not yet known. However, it has set the clock back on the attainment of universal eye health coverage and education goals and disproportionately affected the poorest and most marginalised people. There is a strong realisation that innovative approaches and technology-based solutions have a significant role to play to ensure that equitable and accessible refractive and optical services are available for all.

Patient safety is fundamental to delivering quality eye health services. To ensure successful implementation of patient safety strategies; clear policies, leadership capacity, data to drive safety improvements, skilled health care professionals and effective involvement of patients in their care, are all needed.<sup>2</sup>

Innovations may be context specific or have broad, multi-national applicability. However, the introduction of any RE innovation should be tailored to the political, legislative, economic, geographic, cultural, and technological context of a country or community. The introduction of any innovative approach should engage with relevant national and global stakeholders, practitioners, producers and communities to assess the relevance of the innovation, review against other available models and country need, validate interoperability and help establish processes to ensure that these will help achieve positive eye health outcomes and health systems benefit in the short and long term.

Innovative approaches for the purpose of this paper, include self-refraction, self-prescription systems, ready-to-wear or adaptive spectacles, autorefraction systems, rapid detection systems, and entrepreneurial service delivery models. Innovations in these areas will continue to emerge in the coming decade and the pace of innovation may mean that solutions fall outside existing policy and regulatory frameworks. In all circumstances, stakeholders need to ensure that new approaches deliver additional benefits in terms of improved access and quality and that all innovations are monitored to guard against unintended negative consequences.

### Scope and Thresholds

This paper is inclusive of both distance and near vision refractive needs. The seventy-fourth World Health Assembly, endorsed the global target for effective coverage of refractive errors (eREC).<sup>3</sup> After a series of WHO technical consultations, key considerations for eREC, were presented in the Health Policy paper published in *The Lancet Public Health*. 6/12 is the threshold used to define “met needs” vs “unmet needs” at individual level. In order to ensure consistency, the thresholds used to define eREC and eCSC have been aligned with the threshold for VI as defined in the ICD-11 (6/12). Thresholds in this paper have been aligned with the eREC VA levels as published. For distance vision the threshold of  $\geq 6/12$  is used. For near vision the threshold of  $\geq N6$  at 40cm is used.<sup>4</sup>

This paper is inclusive of both adults and children. The definition of a child used for this paper is 18 years and younger as defined by the United Nations Convention on the Rights of a Child<sup>5</sup>. It is acknowledged that there will be country context to be considered when referring to a child. It is

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<sup>2</sup> <https://www.who.int/news-room/fact-sheets/detail/patient-safety>

<sup>3</sup> [Integrated people-centred eye care, including preventable vision impairment and blindness \(who.int\)](https://www.who.int/news-room/fact-sheets/detail/patient-safety)

<sup>4</sup> Keel S et al Keeping an eye on eye care; monitoring progress to effective coverage. Published: July 05, 2021 DOI:[https://doi.org/10.1016/S2214-109X\(21\)00212-6](https://doi.org/10.1016/S2214-109X(21)00212-6)

<sup>5</sup> <https://www.unicef.org/child-rights-convention/convention-text>

further acknowledged that whilst the threshold VA is 6/12 for children, ideally, we would be striving for visual acuity outcomes of 6/9 or better for children as promoted in the IAPB School Eye Health Guidelines in consideration of classroom environment and contrast.<sup>6</sup>

## Sections

**Section 1** focuses on the technology assessment criteria. It summarises considerations relating to efficacy, performance and quality of the technology and looks at criteria for [Screening devices](#) and [Self-refraction and prescribing devices](#)

**Section 2** focuses on the contextual and operating environment for the new technology or other innovation. It summarises considerations on the introduction of technology into the health system and market of a country. Each of these considerations are situational dependent and should be informed by the specific country context. Section 2 considers criteria on [Policy environment](#), [Regulation of Human Resources](#), [Digital Health Technology](#), [Referral Systems](#), [Provision of Spectacles & Cosmesis](#), [Competitive Environment](#), [Equity](#), [Permanent Access](#)

The **appendices** provide contextual information that support the minimum criteria and further recommendations.

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<sup>6</sup> <https://www.iapb.org/learn/resources/school-eye-health-guidelines/>



Section 1 - Technology

Innovation	Minimum Criteria for Introduction	Recommendation for Introduction
<p><b>Screening devices</b></p>	<ol style="list-style-type: none"> <li>1. Screening devices consistently achieve minimum screening thresholds for detection of vision impairment validated against clinically trained screeners using traditional manual methods</li> <li>2. The devices have been tested and validated in country of introduction or a similar country context and data is published in a peer reviewed journal</li> <li>3. Devices are easy for screeners to understand and use</li> </ol>	<ol style="list-style-type: none"> <li>1. Mechanisms are in place to monitor and assess effectiveness of the screening innovation</li> </ol>
<p><b>Quality of refraction self-refracting and prescribing devices</b></p>	<ol style="list-style-type: none"> <li>1. The device has undergone testing that establishes a significant correlation between conventional refraction and the refraction received by the self-refraction testing device where 95% of patients achieve visual acuity of 6/12 and/or N6 or better using the device<sup>7</sup></li> <li>2. The devices have been tested and validated in country of introduction or a similar country context and data is published in a peer reviewed journal</li> <li>3. The implementor of the device is competent and active in conveying basic eye health information to the patients; including that this is not a substitute for a full eye examination, ensures the patient is aware of referral pathways and urged to comply with referral</li> </ol>	

<sup>7</sup> DA Goss, T Grosvenor, Reliability of refraction--a literature review. J Am Optom Assoc. 1996 Oct;67(10):619-30

<https://pubmed.ncbi.nlm.nih.gov/8942135/>



	4. Device maintenance, repair and replacement options are available locally or regionally	
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## Appendix 1 - Technology

### Quality of Screening Devices for Refractive Error

The ability to easily and economically screen communities for refractive disorders is a major step forward in the ability to reduce URE and detect and treat other eye health conditions. Non-digital methods of screening have been integrated into systems for many years such as the tumbling E Chart which has meant that non-health workers such as teachers, community workers and village volunteers are being trained to screen.

The introduction of tablet and smart phones devices has increased access to vision screening. There is the potential for self-screening opportunities that could digitally connect results up the referral chain and to patient’s digital health record. Accuracy in screening is still critical as an excess of false positives can overload clinical eye health at referral sites and reduce confidence in the system for the community. It can also lead to unnecessary expenditure by patients who are already facing challenges such as financial, time and availability of an escort to take them to appointments. Ensuring the accuracy of the devices and the competency of personnel trained to use them is critical.

#### Criteria & Considerations for Introduction:

1. Screening devices consistently achieve minimum screening thresholds for detection of vision impairment validated against clinically trained screeners using traditional manual methods
2. The devices have been tested and validated in country of introduction or a similar country context and data is published in a peer reviewed journal
3. Devices are easy for screeners to understand and use
4. Mechanisms are in place to monitor and assess effectiveness of the screening innovation

### Quality of Refraction using self-refracting and self-prescribing devices

Shortages of trained health workers to carry out refractions has led to some innovations in self-refraction via various adjustable spectacle designs or smart phones, increasing access for many communities. Current examples include devices based on the Badal optometer principle<sup>8</sup>, variable power lenses, fluid filled spectacles, spectacles that allow different prescriptions via snap together, slide in lenses etc. The quality of refraction using self-refraction devices should be measured by the visual acuity of the patient at the end of the consultation.

The supply of adjustable spectacles should, where possible occur in conjunction with the provision of a full eye examination by a suitably trained person. Caution should be used with self-refraction devices and adjustable spectacles for children aged 10 years and under as this has not been sufficiently studied to determine accuracy and efficacy.

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<sup>8</sup> [http://schorlab.berkeley.edu/passpro/oculomotor/html/chapter\\_18.html](http://schorlab.berkeley.edu/passpro/oculomotor/html/chapter_18.html) (Examples include Eg LVPEI Folding Forofter, Essilor’s ClickCheck)





**Criteria & Considerations for Introduction:**

1. The device has undergone testing that establishes a significant correlation between conventional refraction and the refraction received by the self-refraction testing device where 95% of patients achieve visual acuity of 6/12 and/or N6 or better using the device
2. The devices have been tested and validated in country of introduction or a similar country context and data is published in a peer reviewed journal
3. The implementor of the device is competent and active in conveying basic eye health information to the patients and aware of referral pathways
4. Device maintenance, repair and replacement options are available locally or regionally

Section 2 – Operating Environment

Factor	Minimum Criteria for Introduction	Recommendation for Introduction
<b>Policy Environment</b>	<ol style="list-style-type: none"> <li>1. Regulatory bodies aware of the introduction of the innovation</li> </ol>	<ol style="list-style-type: none"> <li>1. The innovation sits within an existing regulatory, security or policy framework</li> <li>2. If the innovation does not meet existing regulatory, security and policy guidelines/standards/frameworks, a mechanism exists for the innovation to be introduced to appropriate policies or regulations</li> </ol>
<b>Quality and Regulation of Human Resources</b>	<ol style="list-style-type: none"> <li>1. The device is being distributed under the guidance of a suitably trained health worker who has met recognised competencies (WHO)</li> <li>2. Personnel to implement are available to be trained and assessed as competent and fit within existing public or private sector HR systems</li> <li>3. The cadre performing the service meets minimum competency requirements for the task they are performing; particularly when refracting children</li> <li>4. The cadre can follow the clinically verified steps of use for the technology and identify patients that need to be referred for further treatment</li> </ol>	<ol style="list-style-type: none"> <li>1. Personnel and/or technology innovation can adequately refract children to the required standard</li> <li>2. Personnel can detect and refer patients with visible eye health pathologies or who cannot attain sufficient visual acuity of 6/12</li> <li>3. The task-shifting cadre fits within an existing human resources structure in the health system</li> <li>4. Relevant health professions councils or regulatory bodies and MoH supports the approach that there are limited health workers available for provision of services so utilising non-health workers is the only option</li> <li>5. Mechanisms are in place to regularly assess the competency and effectiveness of the cadre and provide refresher training</li> </ol>



<p><b>Digital Health Technology</b></p>	<ol style="list-style-type: none"> <li>1. Proposed solution aligns with existing in-country mHealth digital strategies and platforms</li> <li>2. Existing internet and mobile infrastructure support consistent access to the innovation</li> <li>3. Technology is affordable to service providers/ targeted users</li> <li>4. Technology can be integrated into the health systems for sustained use or regularly shared with government in a format easily integrated into their system</li> <li>5. Patient information, data and associated financial systems are secure and aligned with national regulations</li> </ol>	<ol style="list-style-type: none"> <li>1. Innovation has been tested in similar country environments and is robust enough to be used in rural and remote locations</li> <li>2. Technology and/ or digital platform is compatible with existing health systems for sustained use or regularly shared with government in a format easily integrated into their system</li> <li>3. Mechanisms are in place to monitor and assess the effectiveness of the innovation</li> </ol>
<p><b>Referral Systems</b></p>	<ol style="list-style-type: none"> <li>1. There are clearly defined accessible referral pathways for patients targeted by the innovation</li> <li>2. The patient has access to and is encouraged to have a basic eye examination to allow for referral of non-refractive causes of vision loss</li> <li>3. For digital referral and tracking systems, patient data is protected</li> </ol>	<ol style="list-style-type: none"> <li>1. Referral pathways are aligned to the public health referral system</li> <li>2. Proactive eye health messaging that is responsive to community needs is encouraged to accompany uncorrected refractive error policy and service provision.</li> </ol>
<p><b>Provision of Spectacles</b></p>	<ol style="list-style-type: none"> <li>1. The spectacles meet minimum quality (ISO) standards or local regulatory standards if higher</li> <li>2. The spectacles will have minimal negative environmental impacts</li> <li>3. The spectacles meet local regulatory standards</li> <li>4. The spectacles are affordable to the majority of the population in the local context</li> <li>5. The spectacles are equal to, or surpasses, the quality and style of currently available affordable spectacles</li> </ol>	<ol style="list-style-type: none"> <li>1. The cost of spectacles is reduced</li> <li>2. Accessibility of spectacles is increased</li> <li>3. Providing choice of frame style and colours for both adults and children that is comparable to spectacles offered to low-income consumers in high income markets.</li> <li>4. The spectacles improve upon existing environmental impacts of spectacle provision</li> <li>5. An understanding of product preference based on market testing of spectacles offered from the self-refracting and prescribing devices. These should be compared to eyewear commonly sold at</li> </ol>



		<p>low-cost retail outlets in high income countries</p> <p>6. Effectiveness of the introduction can be monitored and measured</p>
<b>Competitive Environment</b>	<ol style="list-style-type: none"> <li>1. The innovation leads to broader availability and reach of affordable services and products and does not negatively impact a market player that is currently providing this</li> <li>2. If selling subsidized spectacles, there is an ability and process to measure subsequent growth or changes in the local market.</li> </ol>	<ol style="list-style-type: none"> <li>1. A data driven understanding of how the innovation will bring down the cost of refractive services and spectacles in the marketplace over time, with metrics that track progress towards this goal</li> </ol>
<b>Equity, Safety &amp; Acceptability</b>	<ol style="list-style-type: none"> <li>1. Relevant disaggregated monitoring indicators in place to determine level and type of coverage</li> <li>2. Risk assessments and management protocols for patient safety must be in place</li> <li>3. Any service involving children must have safeguarding protocols in place and activated</li> </ol>	<ol style="list-style-type: none"> <li>1. An understanding of groups or individuals who may not be able to access the service</li> <li>2. URE equity plan is part of program and action plans of government policy</li> <li>3. Acceptability of services provided is measured</li> </ol>
<b>Permanent Access</b>	<ol style="list-style-type: none"> <li>1. A permanent access arrangement or a fixed point for referrals exists for the innovative service</li> <li>2. The innovator has assessed the fixed point they are referring to and can verify the availability of affordable, high-quality spectacles and quality refraction services if that service is not part of the innovation.</li> </ol>	<ol style="list-style-type: none"> <li>1. Community awareness of the fixed access referral point and the services available</li> <li>2. Complimentary programs are implemented to enable community awareness of the fixed access referral point and the services available</li> </ol>

## Appendix 2 – Operating Environment

### Policy Environment

Policy and regulatory frameworks provide the structures and processes to ensure health services are equitable, accessible and of a satisfactory level of quality. The introduction and scale-up of innovations needs to be within the context of government policies, legal and regulatory frameworks.



To further the appropriate regulation processes, it is critical that new approaches are underpinned by evidence, are affordable for service providers and patients, are robust and durable enough for the physical environment, ensure individual privacy is protected, are not open to use for fraudulent purposes, have a focus on patient safety and will not have a negative outcome for patients vision and eye health and are sustainable.

#### **Criteria & Considerations for Introduction:**

1. Regulatory bodies aware of the introduction of the innovation
2. The innovation sits within an existing regulatory or policy framework
3. If the innovation does not meet existing regulatory and policy guidelines/standards/frameworks, a mechanism exists for the innovation to be introduced to appropriate policies or regulations

#### **Quality & Regulation of Human Resources for Refraction**

The lack of trained optometrists has led to varying innovations in refraction provision. Examples include task shifting by training health workers, community level workers, or community members in short refraction courses, training people to use devices such as auto-refractors, tablets or other devices to do a simple refraction on a patient.

New cadres and existing personnel should be trained and assessed as competent to accurately use the innovation. The cadres should ideally be competent to refer patients whose vision does not improve with refraction, meet minimum VA results, or have a visible eye pathology not treatable by the issuance of spectacles (i.e. cataracts, conjunctivitis, pterygium, trachoma, strabismus). When task-shifting to community and primary health care workers, those workers should be recognised cadres within the health system or linked to the health system who fall under the guidance of a trained optometrist or ophthalmologist and with defined referral pathways.

Competency to refract children needs to be carefully considered as it is more complex due to their inability to control their accommodation. The recommended standard is that children under 11 years of age should have a cycloplegic refraction to control their accommodation.<sup>9</sup> In settings where the cycloplegic drops are not available or unable to be used then technology that meets the criteria outlined in this paper can be used to determine a patient's prescription, but this must be followed by subjective refraction.

Where national plans with eye health cadre development exists, projects to increase access to refractive care should look at task-shifting within existing structures rather than creating parallel cadres and systems which risk lowering quality of refraction, undermining confidence in eye health providers and potentially causing poor or worse vision outcomes for patients.

#### **Criteria & Considerations for Introduction:**

1. The device is being distributed under the guidance of a suitably trained health worker who has met recognised competencies (WHO)
2. Personnel to implement are available to be trained and assessed as competent and fit within existing public or private sector HR systems

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<sup>9</sup> Doherty SE, Doyle LA, McCullough SJ & Saunders KJ. Comparison of retinoscopy results with and without 1% cyclopentolate in school-aged children. *Ophthalmic Physiol Opt* 2019; 39: 272–281. <https://doi.org/10.1111/opo.12629>

3. The cadre performing the service meets minimum competency requirements for the task they are performing; particularly when refracting children
4. The cadre can follow the clinically verified steps of use for the technology and identify patients that need to be referred for further treatment
5. The task-shifting cadre fits within an existing HR for health system
6. Personnel and/or technology innovation can adequately refract children to the required standard
7. Personnel can detect and refer patients with visible eye health pathologies or who cannot attain sufficient visual acuity of 6/12
8. The task-shifting cadre fits within an existing human resources structure in the health system
9. Relevant health professions councils or regulatory bodies and MoH supports the approach that there are limited health workers available for provision of services so utilising non-health workers is the only option
10. Mechanisms are in place to regularly assess the competency and effectiveness of the cadre and provide refresher training

### Integration of Refractive Error health promotion or services in Digital Health Technology

An increasing proportion of the population is accessing health information and services through mobile telephones, and a vast array of mobile-based solutions – from SMS to complex “smartphone” applications – have been developed to improve health access, knowledge, and behaviours across a range of contexts and target groups. Despite the potentially wide applicability of digital health strategies and solutions to address the diversity of patients’ and populations’ needs, governments have found it challenging to assess, scale up and integrate such solutions. There are a number of contributing factors, including:

- multiplicity of pilot projects with no clear plan or process for scale;
- lack of interconnectedness between individual applications, and of integration with existing national eHealth strategies and health information architectures;
- absence of standards and tools for the comparative assessment of functionality, scalability and comparative value of fast-evolving digital health solutions, resulting in a lack of evidence to articulate normative guidance;
- lack of a multisectoral approach within government – and also among donor agencies – especially engagement between ministries of health and ministries of information and communication technologies and recommended rules of engagement with mobile network operators and the private sector<sup>10</sup>.

In 2018 WHO determined there were 121 countries with national eHealth strategies. It is therefore recommended that any RE digital health strategies should work with established national digital health strategies.

### Criteria & Considerations for Introduction:

1. Proposed solution aligns with existing in-country mHealth digital strategies and platforms
2. Existing internet and mobile infrastructure support consistent access to the innovation
3. Technology is affordable to service providers/ targeted users

<sup>10</sup> [https://apps.who.int/gb/ebwha/pdf\\_files/WHA71/A71\\_20-en.pdf?ua=1](https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_20-en.pdf?ua=1)



4. Technology can be integrated into the health systems for sustained use or regularly shared with government in a format easily integrated into their system
5. Patient information, data and associated financial systems are secure and aligned with national regulations
6. Innovation has been tested in similar country environments and is robust enough to be used in rural and remote locations
7. Technology can be integrated into the health systems for sustained use or regularly shared with government in a format easily integrated into their system
8. Mechanisms are in place to monitor and assess the effectiveness of the innovation

### Referral System

Innovations in URE detection, correction, management and spectacle design exist within the broader eye health and health context so well-defined referral criteria and pathways are fundamental to provision of care. Any innovation designed to increase access to RE services must ensure effective referral pathways for people with complex RE and/or eye disease.

Referral pathways can be via direct referrals to fixed health facilities or via mobile health consults or tele-optometry/ophthalmology or a combination. The same principles of patient data capture and confidentiality for patient health records apply with mobile and tele-health solutions and informal mechanisms such as WhatsApp for inter-clinician consults on patients. Systems used should also enable tracking of patient care and history across the referral pathway within eye health and health broadly, i.e. did those referred for more complex care attend the consult and get required treatment, are those requiring follow-up care receiving it.

Introduction of tele-health should consider the operating landscape, reliability and coverage of communication networks, security of the networks, cost of internet and mobile services. Innovations in referral systems should align with any existing public health systems or work with health departments in the introduction of systems.

### Criteria & Considerations for Introduction:

1. There are clearly defined accessible referral pathways for patients targeted by the innovation
2. The patient has access to and is encouraged to have a basic eye examination to allow for referral of non-refractive causes of vision loss
3. For digital referral and tracking systems, patient data is protected
4. Referral pathways are aligned to the public health referral system

### Provision of Spectacles & Cosmesis

Correcting refractive error with an eye examination and spectacles is a simple, cost-effective and high-impact intervention. WHO World Report of Vision 2019 recommends that spectacles should be provided within the context of comprehensive eye care and integrated within the healthcare system and national health plans.<sup>11</sup> Spectacles are also included on the WHO Priority Assistive Products List.

However, the provision and use of spectacles is severely affected by weak health systems with insufficient resources and infrastructure; the high cost of import duties; inefficient supply chains for

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<sup>11</sup> World Health Organization. World report on vision. 2019.

spectacles; the poor density and distribution of eye health workforce; and the lack of awareness and stigma associated with wearing spectacles.

The accuracy and quality of the prescription lenses and the quality, style and colour of the frames can impact the uptake and ongoing usage of spectacles. At a minimum, spectacles procured in a country should meet ISO quality standards or their equivalent, should match the person's prescription for each eye, be comfortable to look through, fit the face of the user, and be durable.<sup>12</sup>

Spectacles should also be acceptable in terms of style. The ability to choose from a range of sizes and fashionable styles has the potential to promote acceptance and compliance in new wearers since an unwillingness to wear spectacles is frequently attributed to the cosmetics of the spectacles. As noted in the Global Alliance for Assistive Technology's Product Narrative on Spectacles, "... (spectacle) compliance remains an issue due to style, cultural stigma, or misconceptions around spectacles. Among adults, a study in East Timor found that the primary reasons for unwillingness to use spectacles were cosmetic (41%) and embarrassment (38%)."<sup>13</sup> The effect is equally pronounced in children, a 2016 study reveals that 75% of children who were able to select the frames they preferred were still wearing their spectacles three-four months after the intervention.<sup>14</sup>

The proliferation of low cost spectacles in some settings enables organizations that were previously limited to a single style option or a product that would not be appropriate or accepted in high income countries, to offer more attractive options. Such proliferation removes cost of a new product as a barrier and it is recommended that innovators offer eyewear that is similar, or the equivalent, to the product offerings at the low-cost retail outlets in high income countries.

However, the cost of spectacles can vary greatly between settings, can involve large out-of-pocket expenditure and be unaffordable to many people. Reading or ready-made spectacles are less expensive, with prices ranging from approximately USD3 to approximately USD20.<sup>15</sup> In some countries there is an unregulated market of optical shops, some of which may sell poor quality spectacles.

Innovation in production techniques such as 3D printing of frames and of lenses, community level plastic recycling and new techniques in the pipeline have the potential to increase accessibility and decrease costs.

The environmental impact of innovations in spectacle production and delivery systems must also be considered. Innovation in spectacle production should also consider economic sustainability, including cost to end user, production and supply chain overheads and livelihood of local manufacturers and distributors.

### **Criteria & Considerations for Introduction:**

1. The spectacles meet minimum quality (ISO) standards

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<sup>12</sup> Lenses: ISO 8980 focuses on anti-reflective and anti-abrasion coating properties, lens optical power, positioning, geometric size, thickness tolerance and robustness, and luminous transmittance, among other aspects. Frames: ISO 12870 focuses on general frame construction (e.g. smooth surfaces, rounded edges), stability in elevated temperatures, and resistance to sweat and fire, among other aspects. Ready-made reading spectacles: ISO 16034 focuses on frame stability, resistance to sweat and fire, nickel release, lens surface quality and strength, optical power, and luminous transmittance, among other aspects.

<sup>13</sup> AT scale product narrative (citation)

<sup>14</sup> Morjaria, P. Murali, K. Evans, J. Gilbert, C. Spectacle wearing in children randomised to ready-made or custom spectacles, and potential cost savings to programmes: study protocol for a randomised controlled trial. *Trials*. 2016;17:36.

<sup>15</sup> ATscale. Product Narrative Spectacles.





2. The spectacles will have minimal negative environmental impacts
3. The spectacles meet local regulatory standards
4. The spectacles are affordable to the majority of the population in the local context
5. An understanding of product preference based on market testing of spectacles offered from the self-refracting and prescribing devices. These should be compared to eyewear commonly sold at low-cost retail outlets in high income countries
6. Providing choice of frame style and colours for both adults and children that is comparable to spectacles offered to low-income consumers in high income markets.
7. The spectacles is equal to, or surpasses, the quality and style of currently available affordable spectacles
8. The cost of spectacles is reduced
9. Accessibility of spectacles is increased
10. Effectiveness of the introduction can be monitored and measured
11. The spectacles improve upon existing environmental impacts of spectacle provision

### Competitive Environment

The Lancet Global Health Commission on Global Eye Health states “*given the magnitude of uncorrected refractive error globally, eye health cannot be addressed as part of universal health coverage without a major contribution from the private sector.*” The report also recommends supporting appropriate market conditions that will promote high quality, affordable, and equitable services.

In LMICs access to high-quality, affordable spectacles in the private sector is limited, with businesses concentrated in urban areas and price points often only appropriate for high income consumers. Low demand for spectacles in peri-urban and rural areas has created a perception that these are not viable markets for private sector providers. Projects that increase spectacle demand in these markets, and among the urban poor, by providing URE detection, diagnoses and affordable spectacles can demonstrate that these can be growth markets for spectacle and optometric service providers.

In areas where there is scope for a range of spectacle sales from high-end to low-cost, which supports cross-subsidisation principles making good quality spectacles available to low-income communities whilst still allowing entrepreneurs to earn a living. Similarly, a range of spectacle offerings catering to low and middle income consumers supports a tiered pricing structure where entrepreneurs determine optimal margins for each product category to ensure a profitable business model. Innovation can also be a significant driver in reducing production and distribution costs to enable this balance to be achieved. Greater demand for services also starts to drive bulk purchasing savings for frames, lenses and optometric equipment, it can lead to more service providers, creation of service provider networks allowing for group purchasing savings, co-investment in training and technology and attracting more service providers to expand the networks<sup>16</sup>.

It is recommended that organizations demonstrate how their innovations catalyse growth in local private sector spectacle and refractive service supply sector that provides affordable services to previously under-served communities. It is recognised that disruption to a market is often an important part of innovation. However, innovations and projects that under-cut existing affordable

<sup>16</sup> Odero, P. Sable, S. Cook, J. Udayakumar, K. (2016) Healthcare innovation in East Africa. SEAD at Duke University for Innovations in Health Care.  
<https://www.innovationsinhealthcare.org/East%20Africa%20Landscape%20Report%20-%20SEAD.pdf>



local market by providing heavily subsidized spectacles, and create a customer based that expects subsidized spectacles in perpetuity can put existing businesses at risk and inhibit the growth of market driven affordable services. An innovative model can, however, result in increased competition in local markets leading to lower price points and improved services and offerings for LMIC consumers.

**Criteria & Considerations for Introduction:**

1. The innovation leads to broader availability and reach of affordable services and products and does not negatively impact a market player that is currently providing this service
2. If selling subsidized spectacles, there is an ability and process to measure subsequent growth or changes in the local market.
3. A data driven understanding of how the innovation will bring down the cost of refractive services and spectacles in the marketplace over time, with metrics that track progress towards this goal

**Equity, Safety & Acceptability**

The WHO<sup>17</sup> defines health equity as the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically. Removing health inequities in URE is critical to achieving UHC.

Partners planning URE interventions should consider the coverage of their intervention, and individuals or communities in their target area that will not be able to or struggle to access URE services. This can include, but is not limited to exclusion based on, geographical distance, availability/cost of transport, gender, age, physical or mental disabilities, economic barriers, cultural or political barriers, language or literacy barriers, other infrastructure barriers, employment status, enrolment in school etc. For example, school enrolment/attendance can drop significantly for secondary school-aged children, a school-based intervention would not detect and treat a large number of children.

Identification of individuals who could be excluded and potential barriers should be done in consultation with community leaders, local government, and civil society groups. Understanding the acceptability of services will be critical to ensure uptake by those most disadvantaged.

Patient Safety is a key consideration in the delivery of any health services. It aims to prevent and reduce risks, errors and harm that occur to patients during provision of health care. A cornerstone of the discipline is continuous improvement based on learning from errors and adverse events. A particular focus needs to be given when providing services to children as it increases the potential risk to the welfare and safety of the child. Safeguarding practices must be developed and implemented with any introduction of innovative service or approach.

**Criteria & Considerations for Introduction:**

1. Relevant disaggregated monitoring indicators in place to determine level and type of coverage
2. Risk assessments and management protocols for patient safety must be in place

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<sup>17</sup> <https://www.who.int/healthsystems/topics/equity/en/>

3. Any service involving children must have safeguarding protocols in place and activated
4. An understanding of groups or individuals who may not be able to access the service
5. URE equity plan is part of program and action plans of government policy
6. Acceptability of services provided is measured

### Permanent Access

To achieve universal eye health, all individuals must have consistent access to reliable eye care detection, diagnostic and correction services. Research indicates that availability of a fixed facility offering eye care services is associated with higher uptake of the service by the district population.<sup>18</sup> In addition, a study published in 2010 reveals that the most common reason for discontinued spectacle use 6 and 12 months following vision campaigns was broken frames.<sup>19</sup> If an innovation involves on-site screening, refraction, and dispensing of spectacles outside of the public health sector it is recommended to either make those services available at the same site, at least every two years (or more frequently for children); or identify an appropriate fixed access point where individuals can be referred for a replacement pair of spectacles and / or a comprehensive eye exam if needed.

If the innovation is focused on the delivery of near spectacles outside of the public health system, individuals will be identified who will require a comprehensive eye exam and a pair of prescription spectacles. It is strongly recommended that an appropriately fixed access point is identified where individuals can be referred for a comprehensive eye exam and prescription spectacles.

### Criteria & Considerations for Introduction:

1. A permanent access arrangement or a fixed point for referrals exists for the innovative service
2. The innovator has assessed the fixed point they are referring to and can verify the availability of affordable, high-quality spectacles and quality refraction services if that service is not part of the innovation
3. Community awareness of the fixed access referral point and the services available

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<sup>18</sup> Wallen, S. Schmidt, E Jolley E, et al. Factors affecting cataract surgical coverage and outcomes: a retrospective cross-sectional study of eye health systems in sub-Saharan Africa. *BMC Ophthalmol.* 2015;15:67. Published 2015 Jun 30. doi:10.1186/s12886-015-0063-6

<sup>19</sup> Vincent, JE. Netek, S. Parry, A. Mladenovic, D Thein, NN. Amendola ,P. Reporting Wearing Compliance of Ready-Made Spectacles at 6 and 12 months. *Optometry and Vision Science.* 2010;87(12): 958-965.