

# Qualitative Research Exploring the Patient Experience of Symptoms and Health-Related Quality of Life Impacts in Chronic Ocular Surface Pain

POSC371

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## Introduction

- Chronic Ocular Surface Pain (COSP) originates at the ocular surface and can cause persistent eye-pain related symptoms for at least three months, and in some cases years, despite treatments for the underlying causes and conditions.<sup>1,2</sup>
- COSP is under-recognized, with no formal diagnostic criteria. It is reported in relation to ophthalmic conditions or trauma, but also manifests as a standalone pain condition.<sup>1,2</sup>
- Key symptoms of COSP include unbearable eye pain, eye itch, burning in the eye, eye dryness, chronic eye irritation, eye fatigue and sensitivity to light which can significantly impact the patients' Health-Related Quality of Life (HRQoL).<sup>3-6</sup>

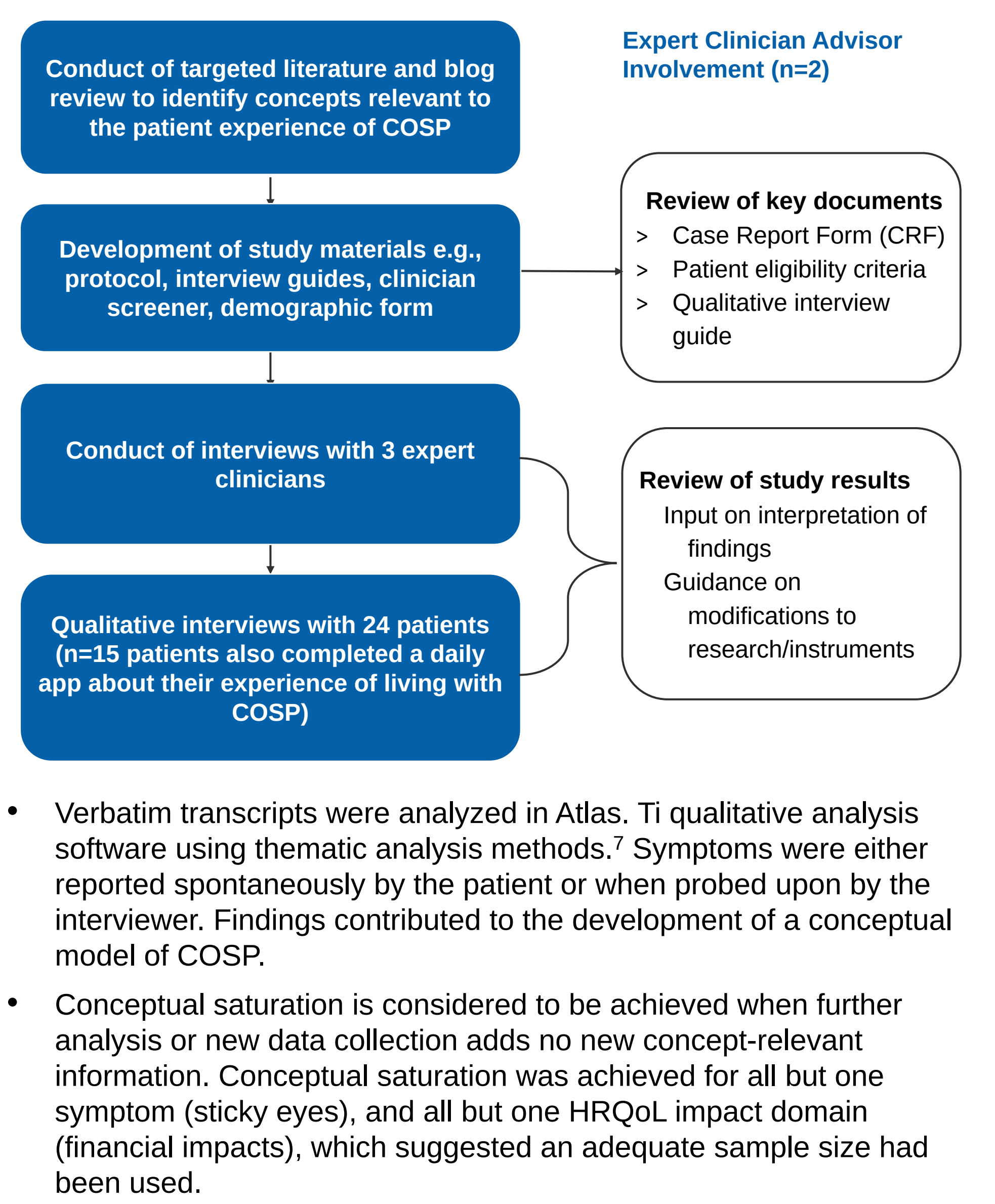
## Objective

- To perform qualitative research to obtain insights into the symptoms and HRQoL impacts associated with COSP.

## Methods

- Qualitative, semi-structured, 25-minute concept elicitation telephone interviews were conducted with US patients experiencing symptoms of COSP as confirmed by their healthcare professional (HCP, N=24; conducted in two rounds) and with expert clinicians (N=3) [Figure 1].
- Patients [N=15] also completed a real-time daily diary app task about their experience of COSP over seven days. Two patients completed the real-time daily diary app only.

Figure 1. Study methodology



## Results

### Participant Characteristics

- A diverse sample of COSP patients were interviewed; ages ranging from 28 to 79 years (mean age of 56 years), slightly more females (61.5%) compared to males (38.5%), and a range of racial, educational, and socio-economic backgrounds [Table 1].
- Patients recruited had varying clinical characteristics and underlying causes of COSP including corneal erosions/dystrophies (n=8/24), refractive eye surgery (n=7/24), and dry eye disease (n=7/24) [Table 2].
- The three expert clinicians (n=1 US, n=1 Canada, n=1 France) each had over 11 years of experience treating patients with symptoms of COSP.

Table 1. Patient Demographic Characteristics

| Demographics                                         |                                | Total n (%) (N=26) ^ |
|------------------------------------------------------|--------------------------------|----------------------|
| Age (mean, range)                                    |                                | 56, 28-79            |
| Gender (n)                                           |                                |                      |
|                                                      | Female                         | 16 (61.5)            |
|                                                      | Male                           | 10 (38.5)            |
| Race (n)                                             |                                |                      |
|                                                      | Caucasian                      | 16 (61.5)            |
|                                                      | Black/African/American         | 5 (19.2)             |
|                                                      | Multi-racial                   | 4 (15.4)             |
|                                                      | Hispanic                       | 1 (3.8)              |
|                                                      | More than high school          | 16 (61.5)            |
|                                                      | High school or less            | 10 (38.5)            |
| Level of education (n)                               |                                |                      |
|                                                      | Retired                        | 10 (38.5)            |
|                                                      | Working full time              | 5 (19.2)             |
|                                                      | Working part time              | 4 (15.4)             |
|                                                      | Looking for work               | 3 (11.5)             |
|                                                      | Homemaker                      | 2 (7.7)              |
|                                                      | Student                        | 1 (3.8)              |
|                                                      | Not working due to ocular pain | 1 (3.8)              |
| Working Status                                       |                                |                      |
| Frequency of eye pain per week (n)                   |                                |                      |
|                                                      | 4-6 days                       | 19 (73.1)            |
|                                                      | Every day                      | 7 (26.9)             |
|                                                      | 4                              | 2 (7.7)              |
| Eye pain severity* on average in the past 7 days (n) |                                |                      |
|                                                      | 5                              | 8 (30.8)             |
|                                                      | 6                              | 1 (3.8)              |
|                                                      | 7                              | 10 (38.5)            |
|                                                      | 8                              | 5 (19.2)             |

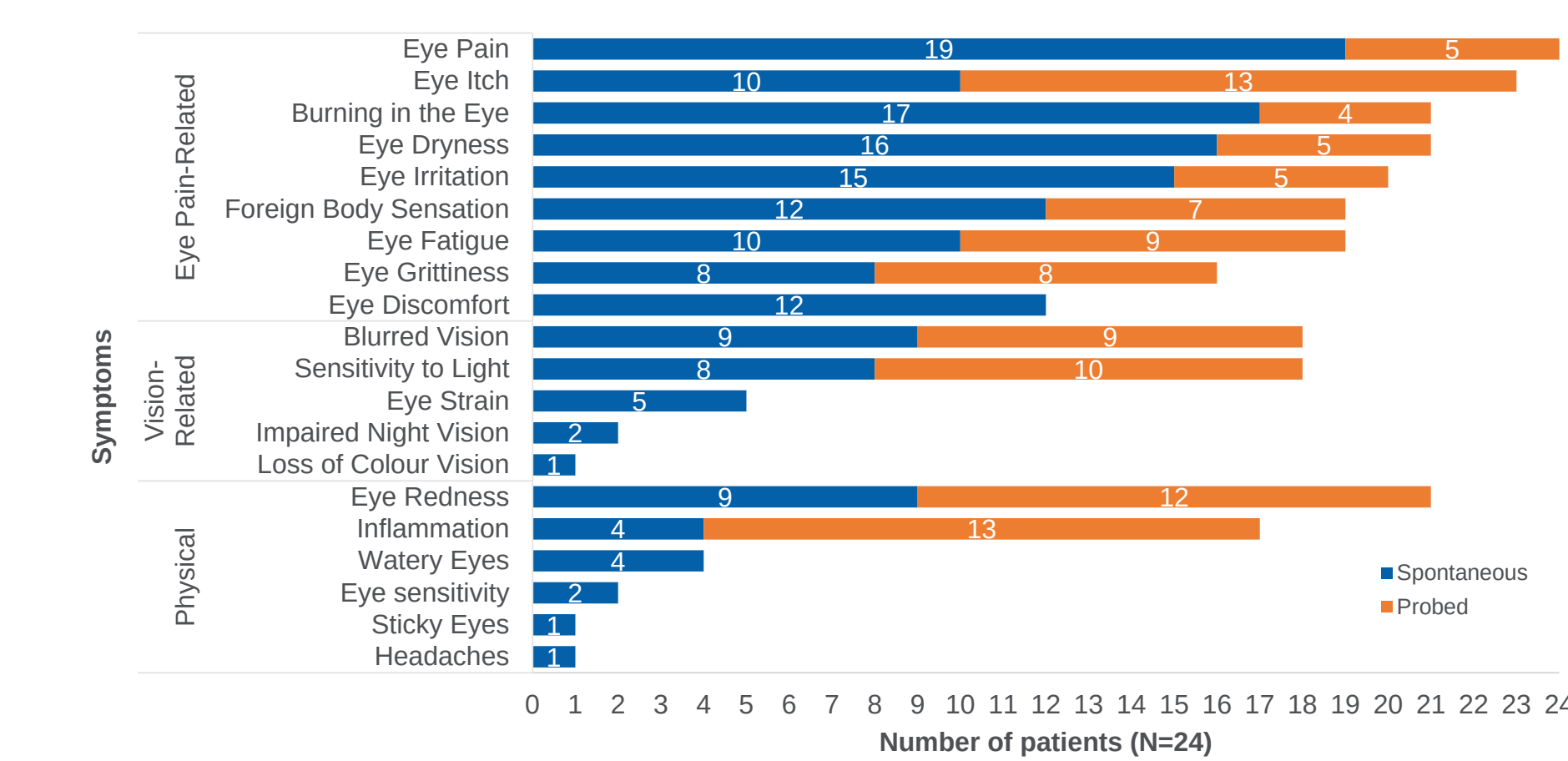
^ Includes n=2 patients who participated in the app task only  
\* Based on patient's response to 0=no eye pain to 10=worst possible eye pain numerical response scale (NRS)

Table 2. Patient Clinical Characteristics

| Clinical Characteristics                         |                                     | Total n (%) (N=26) ^ |
|--------------------------------------------------|-------------------------------------|----------------------|
| Severity of COSP as assessed by HCP (n)          |                                     |                      |
|                                                  | Very severe                         | 1 (3.8)              |
|                                                  | Severe                              | 4 (15.4)             |
|                                                  | Moderate                            | 19 (73.0)            |
|                                                  | Mild                                | 2 (7.7)              |
| Diagnosed with ophthalmological condition (n)    |                                     | 19 (73.1)            |
| Has had refractive eye surgery (LASIK, PRK)^ (n) |                                     | 7 (26.9)             |
|                                                  | Dry Eye Disease (DED)               | 7 (26.9)             |
|                                                  | Sjogren's syndrome                  | 5 (19.2)             |
|                                                  | Corneal erosions                    | 5 (19.2)             |
|                                                  | Corneal dystrophies                 | 3 (11.5)             |
|                                                  | Post-surgical corneal neuropathy    | 2 (7.7)              |
|                                                  | Post-herpetic neuralgia             | 2 (7.7)              |
|                                                  | Conjunctivochalasis                 | 1 (3.8)              |
|                                                  | Blepharitis/meibomitis              | 1 (3.8)              |
|                                                  | Scleritis                           | 1 (3.8)              |
|                                                  | No other ophthalmological condition | 4 (15.4)             |
| Ophthalmological conditions (n)*                 |                                     |                      |
| Severity of dry eye disease (n)**                |                                     |                      |
|                                                  | Severe                              | 6 (23.1)             |
|                                                  | Moderate                            | 1 (3.8)              |

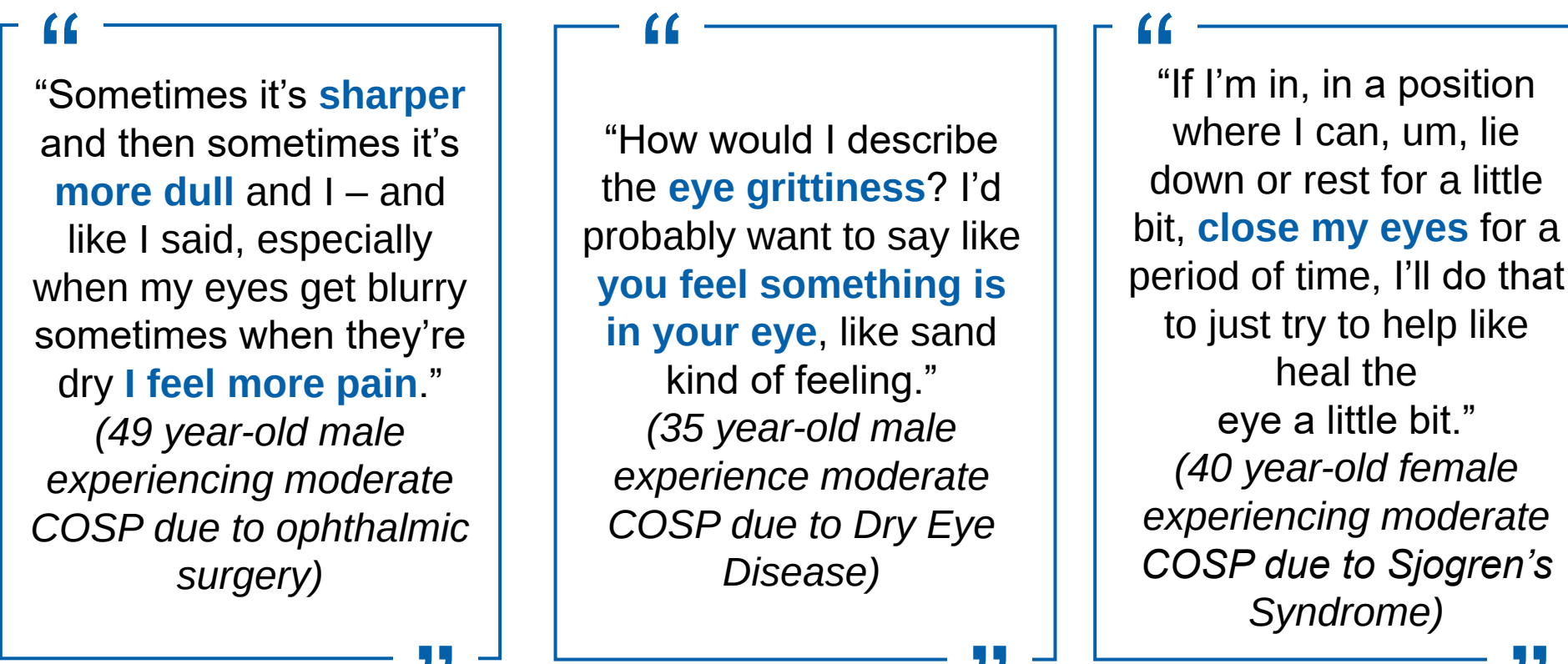
^ Includes n=2 patients who participated in the app task only  
^^ Laser-Assisted In-Situ Keratomileusis (LASIK), Photorefractive Keratectomy (PRK)  
\* Some participants selected more than one option  
\*\* Out of those diagnosed with dry eye disease (DED)

Figure 2. Key Symptoms



\*This graph only presents participants who completed an interview (n=24), Table 1 & 2 presents information for all participants (n=26) including those who only took part in the app task (N=2).

Figure 3. COSP symptoms as directly reported by patients



### Impact Overview

- Patients experienced impacts to HRQoL, with all patients reporting impacts on daily living, including reading (n=24/24) and use of digital devices (n=23/24).
- The most common emotional impacts were anger/frustration (n=15/24) and depression/sadness (n=8/24).
- All but three patients experienced an impact on their ability to partake in their hobbies and leisure activities (n=21/24); the most commonly reported activity was attending events e.g., sports games (n=18/24).
- Impact on social functioning was reported by 18 of the 24 patients (n=18/24) and included negative interpersonal interactions (n=9/18), disruption to group activities/events (n=8/18), and effects on family life/events (n=5/18).
- Fifteen patients (n=15/24) indicated that their work was impacted by their COSP. Key work impacts reported included needing to take breaks while working (n=8/15), reduced productivity (n=2/15), and difficulty concentrating (n=2/15).
- Sleep impacts were reported by 12 patients (n=12/24), with poor quality sleep due to COSP (n=7/12) being the most commonly reported impact on sleep.
- There were no notable differences when comparing impact experience with underlying condition. No conclusions could be drawn for COSP severity given most patients (n=18) had moderate COSP.
- The symptoms and impact concepts reported during interviews with patients align with those reported during the expert clinician interviews. The most commonly reported symptoms of COSP described by all three expert clinicians were foreign body sensation, deep pain, sensitivity to light and eye dryness.
- The most frequently reported impacts described by all three expert clinicians included impacts on household activities, ability to work, physical functioning, and social life.

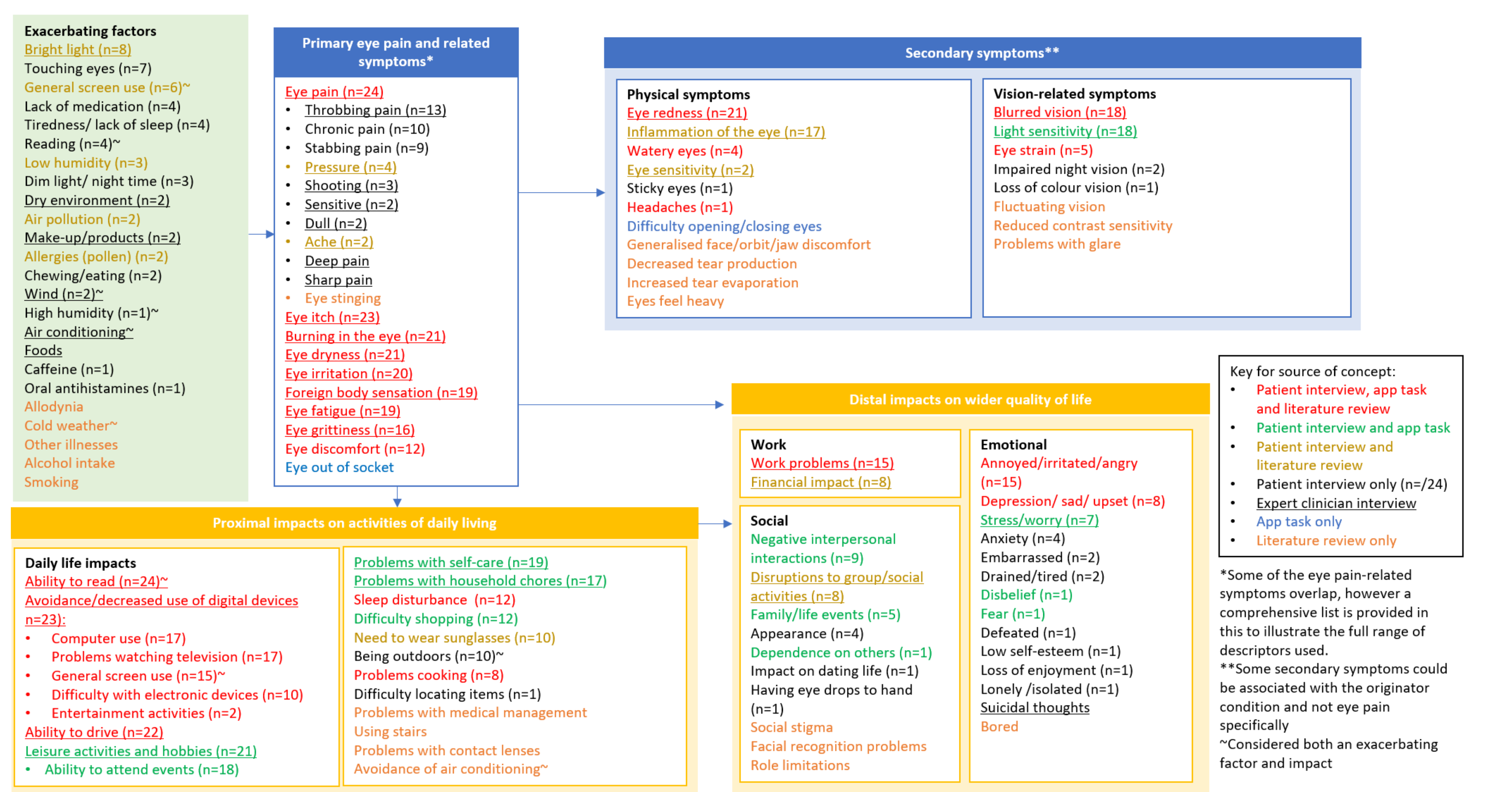
### Symptom Variation During App Task

- During the daily diary app task patients (n=15) were asked each day to rate the severity of their pain over the previous 24 hours using a 0-10 numerical rating scale (NRS; 0=no eye pain, 10=worst possible eye pain). The findings from this task showed that fluctuation in severity varied across the sample.
- One patient remained 'stable' across the seven days (change of <2 points; n=1), most experienced small fluctuations (between 2 and 4 points; n=11) while others experienced somewhat substantial changes across the seven days (up to 8 points from day to day; n=2). Over a 24-hour period (Day 4), most patients stayed stable (n=6), whereas others experienced small fluctuations (n=3).

### Conceptual model in COSP

- The evidence generated from the targeted literature review, patient interviews and patient daily diary app task informed the development of a conceptual model reflecting the most relevant and important symptoms and impacts of COSP for patients [Figure 4]

Figure 4. Conceptual Model



## Conclusion

- This research provides an in-depth understanding of the patient experience of COSP.
- Findings contributed to the development of a patient-reported outcome measure which assesses eye-pain and related symptoms, impact on visual functioning and wider HRQoL impact concepts for use in clinical programs.

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