

DROPS

DRY EYE OUTCOME AND PRESCRIPTION STUDY

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CONTENTS

- BACKGROUND AND GOALS
- WHY GET INVOLVED?
- OVERVIEW
- DRY EYE EXAMINATION (THE GOLD STANDARD)
- HOW TO START

DRY EYE DISEASE (DED)

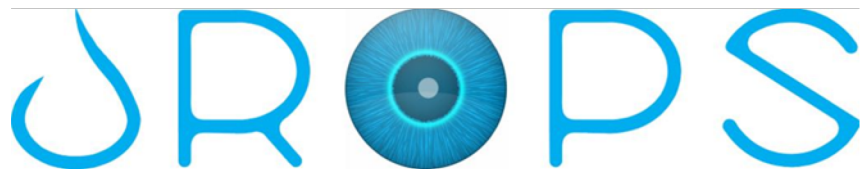
- PREVALENT (5-50%)
 - INVOLVED IN 30% OF OPHTHALMOLOGICAL CONSULTATIONS
- INTERFERES SIGNIFICANTLY WITH HEALTHY AGEING
 - QOL SIMILAR TO PATIENTS WITH ANGINA

ARTIFICIAL TEARS



- CORNERSTONE OF TREATMENT
 - WIDE VARIETY OF DROPS
- COCHRANE REVIEW: LACK OF KNOWLEDGE OF OVERALL EFFECTIVENESS*
- NO PUBLISHED STUDIES ON THE EFFECTIVENESS OF ARTIFICIAL TEARS IN THE 'REAL WORLD'

* van der Westhuizen L, Pucker AD. Over the counter (OTC) artificial tear drops for dry eye syndrome: A Cochrane review summary. 2017



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DROPS STUDY



- **DRY EYE OUTCOME AND PRESCRIPTION STUDY**
 - RUN BY THE LONDON OCTN
 - FUNDED BY RCOPHTH AND FIGHT FOR SIGHT
 - HRA/REC APPROVED
- **OBSERVATIONAL**
 - LOOKING AT THE EFFECTIVENESS OF ARTIFICIAL TEARS ON DRY EYE SYMPTOMS IN THE REAL WORLD
 - ...AND AT DETERMINANTS OF EFFECTIVENESS
 - NO CHANGE FROM NORMAL PRACTICE



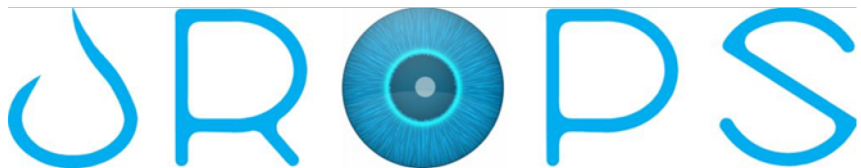
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FIGHT FOR SIGHT
The Eye Research Charity

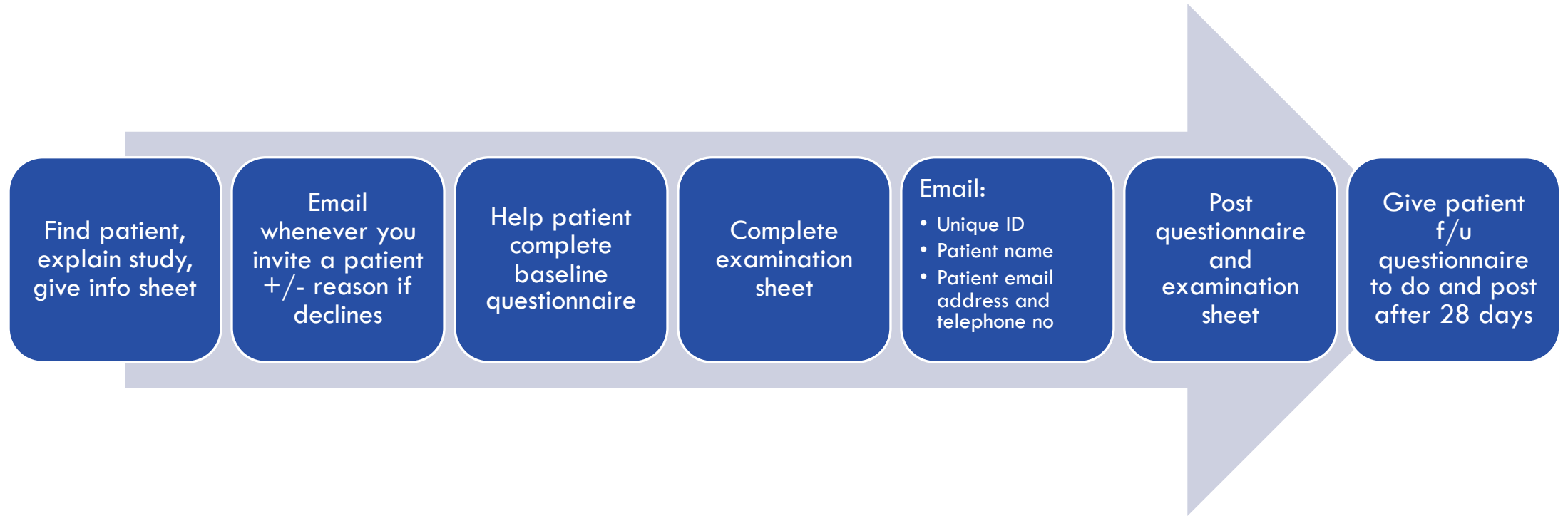
PATIENT QUESTIONNAIRES

- AT BASELINE & AFTER 4 WEEKS
- SYMPTOMS:
 - OCULAR SURFACE DISEASE INDEX (OSDI)
 - SYMPTOM ASSESSMENT IN DRY EYE (SANDE)
- QUESTIONS ABOUT COMORBIDITIES, RISK FACTORS AND ADHERENCE
- TAKES <5 MIN; NO SEPARATE CONSENT FORM



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OVERVIEW

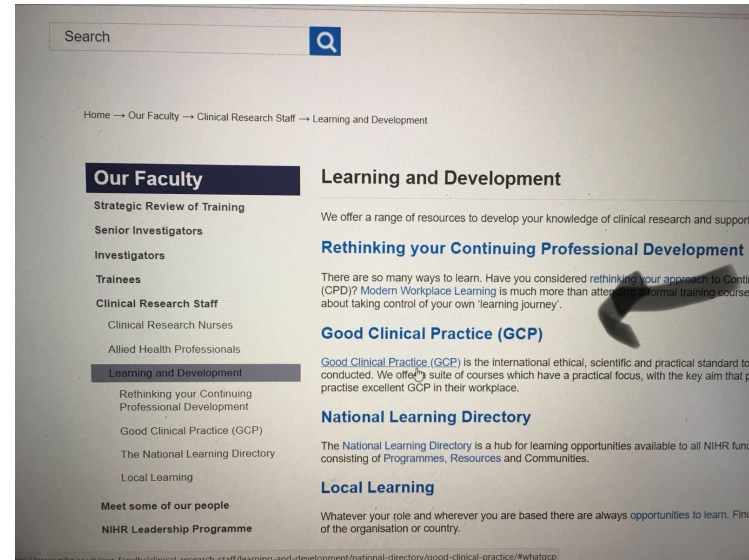
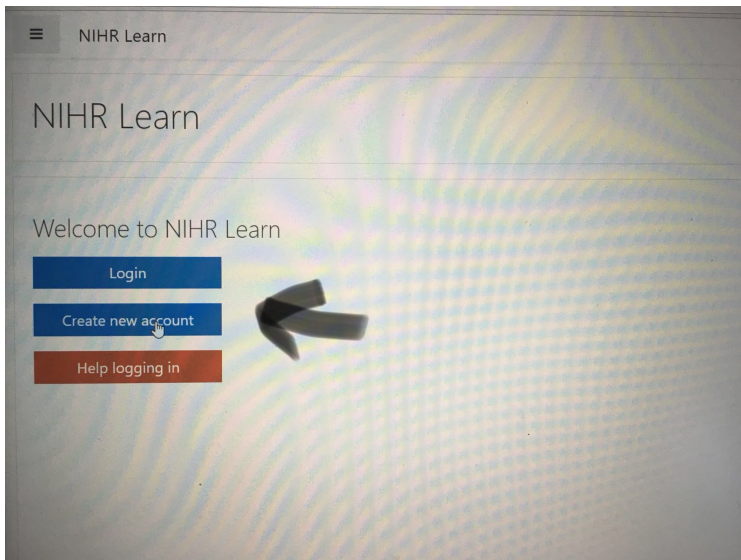


KEEN TO START?

- SEND US YOUR FULL NAME +/- MIDDLE INITIALS AS YOU WANT IT TO APPEAR ON YOUR CERTIFICATE +/- PUBLICATIONS (SEE 'RECOGNITION')
- TELL US WHAT HOSPITAL AND TRUST YOU ARE AT
- YOU NEED AN NHS.NET EMAIL ADDRESS
- SEND COPY OF GCP CERTIFICATE & CV TO YOUR LOCAL PI

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TO OBTAIN/RENEW YOUR GCP VISIT [HTTPS://LEARN.NIHR.AC.UK/](https://learn.nihr.ac.uk/)



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RECOGNITION

- A CERTIFICATE FOR EVERY COLLABORATOR WHO ENROLS 5 OR MORE PATIENTS (ENROLLED BUT DOESN'T RETURN F/U QUESTIONNAIRE = 0.5 POINTS, ENROLLED AND RETURNS F/U QUESTIONNAIRE = 1 POINT).
- COLLABORATORS WHO ENROL 10 OR MORE PATIENTS WHO COMPLETED BOTH QUESTIONNAIRES (OR 10 POINTS) WILL BE PUBMED-CITABLE COLLABORATORS ON ALL RESULTING PUBLICATIONS.
- COLLABORATORS WHO ENROL 20 OR MORE PATIENTS WHO COMPLETED BOTH QUESTIONNAIRES (OR 20 POINTS) WILL BE INVITED TO HELP WRITE UP RESULTS (I.E. BECOME AUTHORS).
- IF ≥ 40 PATIENTS ARE ENROL COLLABORATORS WILL BE INVITED TO CONTRIBUTE TO TWO PUBLICATIONS AND ≥ 60 TO THREE ETC.

LONDON OCTN WEBSITE UPDATED WITH RESULTS SO COLLABORATORS CAN TRACK PROGRESS

COLLABORATORS WHO MEET CRITERIA FOR AUTHORSHIP WILL NEED TO REVIEW MANUSCRIPT(S) PRIOR TO SUBMISSION, BUT NOT CITABLE COLLABORATORS.

INCLUSION CRITERIA

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- RE PRESENT, SYMPTOMS OF VISUAL DISTURBANCE SUCH AS POOR VISION AND BLURRED
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EXCLUSION CRITERIA

- NO CONSENT, NO CAPACITY (E.G. DEMENTIA) OR POOR ENGLISH.
- BEST-CORRECTED VA $<6/12$.
- ACTIVE OCULAR SURFACE DISEASE INCLUDING CONJUNCTIVITIS, ABRASION, RES, EPISCLERITIS, INFLAMED PINGUECULUM/PTERYGIUM, TUMOUR, INFECTIOUS KERATITIS.
- IMMUNE OCULAR PATHOLOGY INCLUDING SCLERITIS AND UVEITIS.
- RECENT (WITHIN 3/12) OR PLANNED OCULAR SURGERY OR IVT
- CURRENT USE OF OTHER OCULAR MEDICATION, E.G. ANTIGLAUCOMA DROPS, G CICLOSPORINE.
- LID ABNORMALITIES, INCLUDING SIGNIFICANT ECTROPION OR ENTROPION; FACIAL NERVE PALSY; THYROID EYE DISEASE; TRICHIASIS.
- USE OF ARTIFICIAL TEARS OR OINTMENT IN THE LAST 1/12

PACKAGE PER PATIENT

- COLLABORATOR INSTRUCTIONS
- PATIENT INFORMATION LEAFLET
- BASELINE QUESTIONNAIRE
- EXAMINATION SHEET
- FOLLOW-UP QUESTIONNAIRE
- 2 PREPAID ENVELOPES
- CONSENT FORM FOR NOTES

DRY EYE TESTS

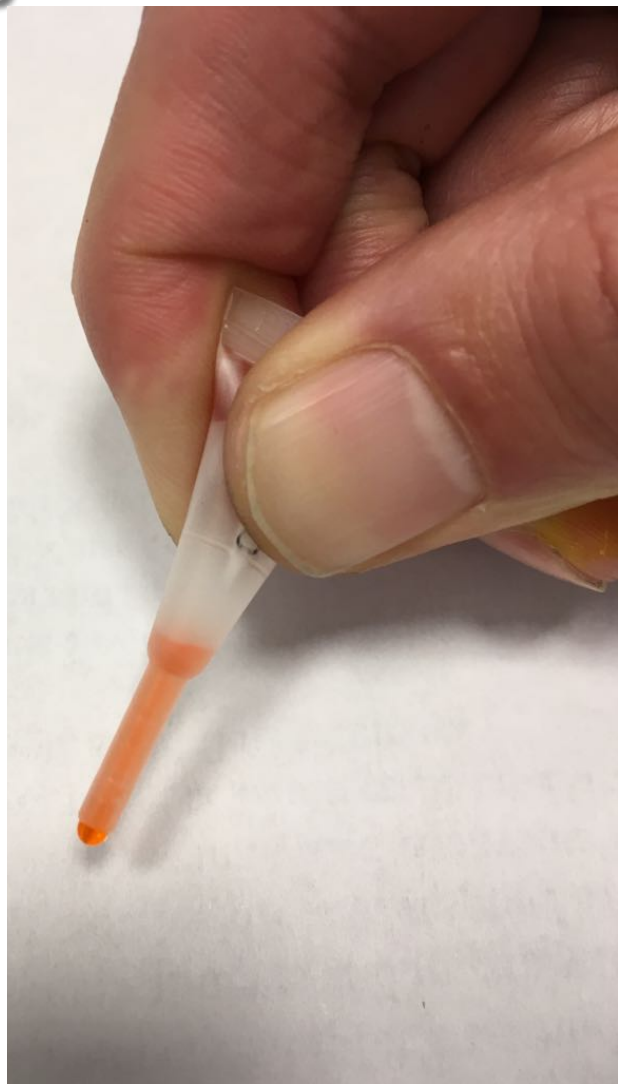
- PLEASE FOLLOW THE DEVS GUIDELINES FOR EVERY PATIENT TO STANDARDISE RESULTS BETWEEN COLLABORATORS
- IN THIS ORDER:
 - TBUT
 - CORNEAL STAINING (USING OXFORD GRADING)
 - MEIBOMIAN GLAND DYSFUNCTION
 - BLEPHARITIS ANTERIOR

TBUT

1. INSTIL SMALLEST POSSIBLE AMOUNT OF 2% FLUORESCEIN MINIM TO TEMPORAL CANTHAL LID MARGIN AREA WHILE PATIENT LOOKS UP, RE THEN LE
2. ASK PATIENT TO BLINK NATURALLY, WITHOUT SQUEEZING, X3
3. AFTER 1 MIN, ASK PATIENT TO STARE STRAIGHT AHEAD WITHOUT BLINKING
4. SLIT-LAMP MAGNIFICATION 10X, CONSTANT ILLUMINATION INTENSITY: COBALT BLUE
5. FOR EACH EYE SEPARATELY COUNT IN SECONDS UNTIL 10 BETWEEN LAST COMPLETE BLINK AND FIRST APPEARANCE OF GROWING MICELLE; DO THIS X3 AND NOTE MEDIAN VALUE

[HTTP://WWW.TEARFILM.ORG/DETTCONFERENCES-DIAGNOSTIC_VIDEOS/5582_5581/ENG/](http://www.tearfilm.org/dettconferences-diagnostic_videos/5582_5581/eng/)

(TEAR STABILITY VIDEO, FROM 1:50)



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CORNEAL STAINING


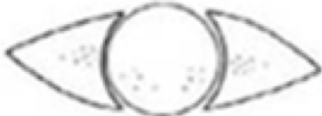



- ASSESS STAINING RAPIDLY AFTER TBUT, IN SEQUENCE, RE THEN LE
- STAINING IS REPRESENTED BY PUNCTATE DOTS ON A SERIES OF PANELS (A-E)
- CONDUCT OF TEST:
 - 1. DYE HAS ALREADY BEEN INSTILLED DURING THE TBUT TEST.
 - 2. SLIT-LAMP IS SET (EG, 16 MAGNIFICATION WITH X10 OCULARS WITH HAAG-STREIT).
 - 3. CORNEA: THE UPPER EYELID IS LIFTED SLIGHTLY TO GRADE THE WHOLE CORNEAL SURFACE FOLLOWING SCHEME BELOW:

NB THE PANEL REPRESENTS THE *MAXIMUM* PUNCTATE DOTS PER GRADE

[HTTP://WWW.TEARFILM.ORG/DETTCONFERENCES-DIAGNOSTIC_VIDEOS/5582_5581/ENG/](http://www.tearfilm.org/dettconferences-diagnostic_videos/5582_5581/eng/)

(OCULAR SURFACE DAMAGE VIDEO, FROM START)

HOW TO PERFORM CORNEAL STAINING

PANEL	Grade	Criteria
A 	0	Equal to or less than panel A
B 	I	Equal to or less than panel B, greater than A
C 	II	Equal to or less than panel C, greater than B
D 	III	Equal to or less than panel D, greater than C
E 	IV	Equal to or less than panel E, greater than D
>E	V	Greater than panel E

HOW TO ASSESS MEIBOMIAN GLAND DYSFUNCTION (BLEPHARITIS POSTERIOR)

- ASSESS BOTH THE **EXPRESSIBILITY** AND **QUALITY OF THE MEIBUM**
- BY PRESSING ON THE MEIBOMIAN GLANDS OF THE **CENTRAL** UPPER AND LOWER EYE LIDS WITH **A COTTON BUD OR MINIM.**
- USE THE FOLLOWING GRADATION TO SCORE THE AVERAGE EXPRESSIBILITY AND QUALITY OF THE MEIBOMIAN GLANDS OF BOTH EYES:
 - EXPRESSIBILITY: 0 LIGHT; 1 MODERATE; 2 HEAVY PRESSURE; 3 CAN'T EXPRESS; N/A
 - QUALITY: 0 CLEAR; 1 CLOUDY; 2 GRANULAR; 3 TOOTHPASTE; N/A

HOW TO ASSESS BLEPHARITIS ANTERIOR

- CRUSTING AND/OR SCALES AROUND THE EYE LASHES WITH OR WITHOUT LASH LOSS
- [HTTP://WWW.TEARFILM.ORG/DETTCONFERENCES-DIAGNOSTIC_VIDEOS/5582_5581/ENG/](http://www.tearfilm.org/dettconferences-diagnostic_videos/5582_5581/eng/)
(LID EVALUATION & DGE VIDEO, FROM START)

CAN I START NOW?

- LOCAL APPROVAL SECURED AT MOORFIELDS EYE HOSPITAL, INCLUDING ALL MEH PERIPHERAL SITES

IF YOUR TRUST IS A NEW SITE

1. IDENTIFY SUITABLE PI (NEEDS TO BE PERMANENT MEMBER OF STAFF)
2. IF INTERESTED, INVITE SOMEONE FROM YOUR DEPT:
 - ✓ STUDY IS ON NIHR PORTFOLIO
 - ✓ NO COSTS FOR DEPARTMENT
 - ✓ HRA/REC APPROVAL ALREADY SECUREDSEND US DETAILS OF PI AND R&D CONTACT AT YOUR TRUST
3. COLLABORATOR SENDS EMAIL TO PI (TEMPLATE ON WEBSITE)
4. WE WILL SEND A STATEMENT OF ACTIVITIES FOR THEM TO SIGN
5. CONTACT R&D TO HELP LOCALISE DOCUMENTS AND SECURE LOCAL APPROVALS
6. SITE INITIATION VISIT AND DELEGATION LOG

THE TEAM

- PROF CHRIS HAMMOND, GSTT PI & OVERALL SENIOR LEAD FOR STUDY
- JELLE VEHOF, CHIEF INVESTIGATOR
- VICTORIA NOWAK, INVESTIGATOR
- DAREN HANUMUNTHADU, INVESTIGATOR
- CRISTINA SOARE, INVESTIGATOR
- ROXANNE CROSBY-NWAObI, MEH PI
- CATEY BUNCE, STATISTICIAN
- GEETA GHADIALI, MEH PORTFOLIO MANAGER
- MINAK BHALLA, WEBMASTER

WITH THANKS TO OUR SPONSOR, KCL AND OUR
FUNDER – RCOPHTH/FIGHT FOR SIGHT