International Pilot Survey of Childhood Glaucoma (IPSOCG)

Investigator's Manual

Database URL: http://c.glaucoma-research.net/

A. Inclusion & Exclusion Criteria

Inclusion criteria:

1. **Any child with newly diagnosed glaucoma in at least one eye with no previous glaucoma laser or surgical procedures**
2. Fulfils the CGRN definition of childhood glaucoma (Appendix A)
3. Includes children seen as both public and private patients

Exclusion criteria:

1. **previous glaucoma laser or incisional surgery**
2. currently children with glaucoma under your care
3. glaucoma suspects
4. availability of follow up outcome data unlikely even by referring outside source

B. Data entry will occur at time of:

1. **Diagnosis**
2. **Any Management action from the time you meet the patient, including:**
    a. **Medical treatment:** commencement or addition of meds prior to surgery
    b. **Laser or Surgical procedures as they occur both glaucoma or non glaucoma related** ie lens, corneal, vitreoretinal surgery.
    c. **Complications** as they occur
3. **6, 12 and 18 months after enrollment (IOP and VA outcomes)**
    - within a month of the 3 intervals is acceptable
    - double check UUID to ensure correct patient
    - **with each update entry please review notes to confirm that any complications or surgical episodes were not omitted in the preceding 6 months**

Data entry

Please complete all fields otherwise you will not be able to save the entry

If entering data, moving to another page on the website may result in loss of data

Universally unique identifier (UUID)

A UUID will be generated for each patient with a unique barcode which can be printed and placed in the patient's hospital notes or recorded in the EMR

- **This will be the only link between the UUID and the patient**
- The UUID will allow the entry of follow up data for the appropriate patient
- Only the unique ID identifies patient data.

Only one username will be connected to each patient.

- Therefore, each user will be able to update only the set of records they have entered.
- **And, multiple users from the same centre will not be able to see the same set of records**
- If two people have logged on with the identical username to update the same patient's entry at the same time, then the last of the two users to save the data will overwrite the changes made by the previous user.

If a single coordinator is entering patients for more than one PI, then they will need separate usernames for each PI.

Smartphone barcode app

QRReader app can be used for scanning the UUID patient's barcode to take you automatically to the patient's file for further data entry.

C. Database

i) Patient

Date of birth (DOB):

To avoid confusion, YYYY-MM-DD, the international standard date notation is used

The fields you complete will depend on your IRB approval

Postcode/Zipcode:

UK: postcode prefix (3/4 numbers & letters)
US – first 3 numbers
Germany – first 3 numbers
Australia - 4 numbers
India – 5 numbers
Saudi Arabia – 5 numbers

Unknown postcode insert '00000' (India & S Arabia)

Ethnic group / Race definitions (Appendix B)

ii) Baseline Assessment

Date

Refers to the date you are best able to complete all the requested findings.

If an Examination under Anaesthesia (EUA) is required to do so, the correct date to enter, is the date of the EUA.

If your visual acuity data is within 3 weeks of the EUA date, that is acceptable and the baseline assessment date will still be that of the EUA.

In all other cases, it will be the date of first presentation to you.

To avoid confusion, YYYY-MM-DD, the international standard date notation is used.

Diagnosis

As pre CGRN classification (Appendix C)

PCG subclassification into neonatal, infantile, late is determined by date of onset of symptoms not date of presentation.

Change the original diagnosis:

- if on presentation the diagnosis is not obvious and you choose 'Unknown'
- or if you subsequently realize you have chosen the wrong diagnosis
- by entering the patient's dataset, click 'Update' in the bottom right hand corner and proceed to enter the correct diagnosis in the same manner as original entry
- **any changes made will be tracked**

VA

Select 'Not recorded' if VAs not possible or not performed.

IOP

Record the IOPs (average of 3) that <u>you</u> have taken and feel are the <u>most accurate</u> (ie calm, relaxed child without a speculum and prior to dilation)

Do not record the referring doctor's IOPs

Must document medications

- remember to record combination drops as 2 separate medications

<u>iii) Management</u>

Record all of your management actions from the time you meet the patient:

Medical treatment including the commencement or addition of meds prior to surgery (remember to record combination drops as 2 separate medications)

any Laser or Surgical procedures (glaucoma or non glaucoma related) as they occur

any complication including any surgery if necessary

iv) Outcome

Regarding IOP control - your assessment of IOP control is determined not just be the pressure but by the whole clinical scenario taking into account optic disc appearance, corneal diameter, axial length, refraction, visual field stability etc.

Remember to record combination drops as 2 separate medications

We allow outcomes data measurements recorded from reliable referring outside source, as long as ALL outcomes data are complete. We will request that you record it as your own data or as data from a reliable outside source.

Record outcomes measurements at 6, 12 and 18 months post diagnosis. We allow a +/- 1 month window to record IOP and VA outcomes. Example Scenario – if you do a procedure at 5 months post diagnosis, you should record BOTH this procedure and the 6 month outcomes at this visit.

APPENDIX A

Definitions

Definition of Childhood

US: < 18 years of age
UK & Europe: <16 years of age

CGRN Definition of Glaucoma – 2 or more required

- IOP > 21mmHg (investigator discretion if EUA data alone*),
- Optic disc cupping: a progressive increase in cup-disc ratio, cup-disc asymmetry of ≥ 0.2 in optic nerves of equal size, or focal rim thinning,
- Corneal findings: Haab striae or diameter ≥ 11mm in newborn, > 12 mm in child < 1 year of age, > 13 mm any age,
- Progressive myopia or myopic shift coupled with an increase in ocular dimensions out of keeping with normal growth,
- A reproducible visual field defect consistent with glaucomatous optic neuropathy with no other observable reason for defect

***** Investigator discretion takes into account anesthesia related reduction in intraocular pressure leading to a reading < 21 mm Hg with all other clinical signs suggesting glaucoma (ocular enlargement, Haab striae, enlarged cup-disc)

CGRN Definition of Glaucoma Suspect – at least 1

- IOP > 21mmHg on two separate occasions, or
- Suspicious optic disc appearance for glaucoma, i.e. increased cup-disc ratio for size of optic disc, or
- Suspicious visual field for glaucoma, or
- Increased corneal diameter or axial length in setting of normal IOP

APPENDIX B

Ethnic group / Race definitions

White: a person having origins in any of the original peoples of Europe

Black: a person having origins in any of the black racial groups of Africa

Asian: a person having origins in any of the original peoples of the FarEast, Southeast Asia, or the Indian Subcontinent.

Middle Eastern: a person having origins in any of the original peoples of the Middle East, or North Africa

Hispanic or Latino: a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish origin

American Indian or Alaska Native: a person having origins in any of the original peoples of North and South America (including Central America)

Pacific Islander or Native Hawaiian: a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

APPENDIX C

CGRN Classification

Primary Childhood Glaucoma

- Á Á Primary Congenital Glaucoma (PCG)
- Á Á Juvenile Open Angle Glaucoma (JOAG)

Secondary Childhood Glaucoma

- Á Á Glaucoma Associated with Non-acquired Ocular Anomalies
- Á Á Glaucoma Associated with Non-acquired Systemic Disease or Syndrome
- Á Á Glaucoma Associated with Acquired Condition
- Á Á Glaucoma Following Cataract Surgery

Primary Congenital Glaucoma (PCG)

Isolated angle anomalies (+/- mild congenital iris anomalies)

Meets glaucoma definition (usually with ocular enlargement)

Subcategories based on age of onset

(1) Neonatal or newborn onset (0-1 month)

(2) Infantile onset (>1-24 months)

(3) Late onset or late-recognized (>2 years)

Spontaneously arrested cases with normal IOP but typical signs of PCG may be classified as PCG.

Juvenile Open Angle Glaucoma (JOAG)

No ocular enlargement

No congenital ocular anomalies or syndromes

Open angle (normal appearance)

Meets glaucoma definition

Glaucoma Associated with Non-acquired Ocular Anomalies

Includes conditions of predominantly ocular anomalies present at birth which may or may not be associated with systemic signs

Meets glaucoma definition

List common ocular anomalies (see Table 1)

Glaucoma Associated with Non-acquired Systemic Disease or Syndrome

Includes conditions predominantly of systemic disease present at birth which may be associated with ocular signs

Meets glaucoma definition

List common systemic syndrome or disease (see Table 2)

Glaucoma Associated with Acquired Condition

Meets glaucoma definition after the acquired condition is recognized. An acquired condition is one that is not inherited or present at birth but which develops after birth.

Glaucoma developing after cataract surgery is excluded from this category to highlight its' frequency and differences from other conditions in the acquired condition category.

List common acquired conditions (see Table 3)

Based on gonioscopy results:

(1) Open angle glaucoma (> / = 50% open) or
(2) Angle closure glaucoma (< 50% open or acute angle closure).

Glaucoma Following Cataract Surgery

Meets glaucoma definition **after** cataract surgery is performed and sub-divided into three categories:

(1) Congenital idiopathic cataract

(2) Congenital cataract associated with ocular anomalies / systemic disease (no previous glaucoma)

(3) Acquired cataract (no previous glaucoma)

Based on gonioscopy results:

(1) Open angle glaucoma (> / = 50% open) or
(2) Angle closure glaucoma (< 50% open or acute angle closure)