Review Article

# Quality assurance in ophthalmic imaging

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Quality assurance (QA) is the maintenance of a desired level of quality in a service, by means of attention to every stage of process of delivery. Correct image acquisition along with accurate and reproducible quantification of ophthalmic imaging is crucial for evaluating disease progression/stabilization, response to therapy, and planning proper management of these cases. QA includes development of standard operating procedures for the collection of data for ophthalmic imaging, proper functioning of the ophthalmic imaging equipment, and intensive training of technicians/doctors for the same. QA can be obtained during ophthalmic imaging by not only calibration and setting up of the instrument as per the manufacturer's specifications but also giving proper instructions to the patients in a language which they understand and by acquisition of good quality images. This review article will highlight on how to achieve QA in imaging which is commonly being used in ophthalmic practice.

**Key words:** B-scan, optical coherence tomography, ophthalmic imaging, Pentacam, quality, quality assurance, slit-lamp photography

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Ophthalmic imaging is essential for diagnosis, treatment, and long-term monitoring of many ocular conditions. In addition, it plays a central role in ophthalmic disease screening, teaching, clinical trials, and in virtual clinics and telemedicine.[1] Ocular imaging devices have been incorporated into clinical management after their diagnostic capabilities have been documented in a wide range of ocular diseases.[2] Ophthalmic imaging is now an integral part of work in all ophthalmic departments. It allows the clinician to record the findings from clinical examination in an objective, reproducible, transmissible, and durable manner. Many ophthalmic imaging devices also facilitate identification of anatomical and disease features that are not readily visible with standard examination techniques, and thus enabling quantitative analysis.

Quality assurance (QA) is the maintenance of a desired level of quality in a service, by means of attention to every stage of process of delivery.[3] QA ensures accurate and reliable collection as well as documentation of data. Correct image acquisition along with accurate and reproducible quantification of ophthalmic imaging is crucial for evaluating disease progression/stabilization, response to therapy, and planning proper management of these cases. QA includes development of standard operating procedures (SOPs) for the collection of data for ophthalmic imaging, quality of imaging, proper functioning of the ophthalmic imaging equipment, intensive training and work instructions for technicians/doctors for the same, reporting, quality indicators, and audit of the imaging tests done periodically. It also necessitates calibration and setting up of the instrument as per the manufacturer's specifications for acquisition of good quality images and proper instructions to the patients in a language which they understand. A literature search was conducted using MEDLINE, Cochrane Library, and PubMed for studies published on the topic of QA in ophthalmic imaging and individual imaging modalities, but only a limited studies pertaining to the topic could be found out.

QA activities of imaging services include the following:

1) Quality and validation of imaging services
   - Display imaging safety signage boards for entry restriction in rooms where ultrasound B-scan and fundus fluorescein angiography (FFA) are done
   - Display Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994 (amended in 2003) signage board declaring No Sex Determination near B-scan area
   - Display caution for pregnant women in the radiation zones
   - Display fire exits.
2) Verification and validation of imaging methods
   - Evaluate the patient and the procedure to identify variances that may affect the expected outcome
   - Complete the evaluation process in a timely, accurate, and comprehensive manner
   - Measure the procedure against established policies, protocols, and benchmarks
   - Identify and document exceptions to the expected outcome

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- Develop a revised action plan, if necessary, to achieve the intended outcome
- Communicate revised action plan to appropriate team members
- Notify appropriate consultant when immediate clinical response is necessary based on procedural findings and patient condition
- Initiate additional scanning techniques for further investigation of area of interest
- Collect additional images and patient data requested by interpreting ophthalmologist. Adjust imaging parameters, patient procedure, or computer-generated information to improve the outcome.

3) Verification and validation of outcome measurement
The treating ophthalmologist performs the following duties:
- Reviews and evaluates the outcome of the procedure to evaluate the quality of care
- Compares the actual outcome with the expected outcome
- Reviews all diagnostic or therapeutic data for completeness and accuracy
- Determine whether the actual outcome is within established criteria
- Evaluate the process and recognize opportunities for future changes
- Assess the patient's condition/status prior to discharge from the hospital.

Validation of test result is to be done by the consultant, if the test is taken by a technician or optometrist. Validation of examination procedure (technically and clinically) should also be done by the consultant. The number of reporting errors and redo investigations are to be monitored every month. Comparison of data by a number of experienced treating physicians is to be done at regular intervals, to see whether their interpretation on the basis of imaging is comparable.

4) Surveillance of imaging result
The imaging results to be audited for accuracy and quality of reporting, by the head of the department (HOD) and other technician within the radiology department and documented in the surveillance register. Correlation of imaging diagnosis with clinical diagnosis is to be done by the HOD for randomly selected patients.

### Quality indicators for imaging studies

Indicators provide quantitative basis for the clinicians to achieve improvement in quality of care. The following indicators can be monitored on a regular basis for improving the quality:

1. Percentage of reporting errors
2. Percentage of redo of imaging study
3. Percentage of ophthalmic imaging findings correlating with clinical diagnosis
4. Safety deviations while performing imaging procedures
5. Waiting time for each diagnostic/imaging study.

A *safety committee* should be constituted to periodically assess these quality indicators. The committee should consist of the healthcare officer (HCO), HOD, experienced ophthalmologists, optometrists, and head technician.

The HCO should provide information to the Safety Committee on the following:

- Operator training
- Type of communication between operator and surveillance personnel
- Emergency procedures
- Safety procedures
- Briefing of personnel for hazards associated with equipment/lasers
- Detailed description of each effect
- Distance of separation of beams from other staff/audience
- Alignment checks between procedures
- Alignment procedures and recommendations.

Common work instructions for imaging procedures are given in Table 1. A checklist common for all the ophthalmic imaging procedures is given in Table 2.

### Critical report

Critical results are defined as those that require immediate attention of the treating physician. It is the duty of the attending doctor or of the technician performing the test in the absence of the duty doctor to report critical results immediately either personally or on the phone. Such a file needs to be marked critical/emergency and immediately delivered to the concerned physician. The following are generally considered critical and need immediate reporting in eye care:

1. A-scan with extremes of reading such as beyond 26 mm and less than 18 mm
2. B-scan suggesting endophthalmitis
3. Lacrimal syringing revealing a block in the nasolacrimal duct in a patient undergoing the procedure as a part of preoperative assessment for surgeries other than that for the patency of the lacrimal drainage system itself or that with microbial keratitis or endophthalmitis
4. Other results that may need reporting immediately are the ones that are specifically requested for by the physician or are considered critical at the discretion of the duty doctor
5. Fundus photograph showing arterial plaques/blocks, disc edema, papilledema.

## Consent for Ophthalmic Imaging Procedures

- Consent needs to be obtained for imaging as for any examination, but usually this will take the form of either implied or verbal consent, as one would do, for example, when instilling drops or measuring intraocular pressure in clinic
- Written consent is not required to obtain images performed for clinical care or to use these images for quality and administration purposes (e.g., to access for clinical audit)
  However, for publication (e.g., in a scientific journal), to show other patients (for leaflets, or for pre- and postop comparisons for other patients considering a procedure) and even, strictly speaking, to use a patient's images for teaching colleagues, consent is required and this should be written formal consent
  Some hospitals use a consent form specific for imaging purposes and this is particularly important when the patient might be identifiable from the image[1]
- Clinical staff who are permitted under Medical council of India (MCI)/ Indian Nursing Council (NCI) as per their credentials to instill medications to achieve mydriasis must be aware of contraindications to the use of certain mydriatics and be able to warn patients, and/or their guardians and

**Table 1: Common work instructions to be followed while acquiring images using imaging procedures**

| |
|---|
| Ensure calibration of the imaging units is as per the specification by the manufacturer. If any problem occurs with the equipment, notify the chief technician.[4] |
| Ensure and encourage thorough reading and understanding of the operating manuals of the imaging units by technicians/doctors. They should be well versed with the machine and its operation. |
| Ensure maintenance of the front objective lens to prevent any imaging artifacts due to debris/scratches/fingerprints/eyelash/nose prints on the lens. The measures to maintain the front objective lens are as follows:<br>Inspect lens with a penlight and an air bulb<br>Use brush to remove any debris<br>Clean the lens from the center outward using lens wipes wrapped around a cotton tipped applicator dampened with lens cleaner (diluted acetone or lens cleaning solution). Wipe the lens with one pass in one direction. Discard the used lens wipes.<br>Clean the lens daily or as per requirement even if required multiple number of times per day<br>Do not touch lens by hands/nose/forehead of the patient/technician/doctor[1] |
| Cover imaging units by dust covers which are to be removed and replaced at the end of each session[4] |
| Keep the lens cover for the objective lens in place until just prior to each examination[4] |
| Position the patient comfortably by adequate adjustment of forehead and chin rests. Chin rest should be adjusted so that the eyes are approximately level with the height adjustment mark on the face rest pole.<br>Take assistant's help with head fixation and support in cognitively impaired and physically disabled patients. Test can be performed with the patient in the wheelchair for physically disabled patients.[1] |
| Ensure if the procedure is being performed on the correct patient and correct site by cross checking the file details with the patient/guardian |
| Ensure that the patient/guardian understands the procedure and signs on the consent form (if required as in before performing FFA) |
| Enter the data into the system in a prescribed format |
| Enter the details of the patient, procedure, result, and time are in the procedure register |
| Carry out the test as per SOP) |
| Undertake aseptic measures to prevent cross infection |
| Dispose biomedical waste properly as per Biomedical Waste disposal Guidelines (BMW) |
| Give proper instructions to the patients about the procedure in a language which they understand to increase their cooperation |
| Acquire images when the eyes are most still for the longest increment of time. In nystagmus patients, time acquisition of images to a null point in nystagmus can patch the fellow eye to improve patient fixation and reduce distraction in imaging techniques which acquire images of one eye at a time.[4] |
| Instruct the patient to blink once/twice just before the image is taken to ensure a moist cornea and to safeguard unwanted blinks at the moment of image acquisition. Lids/lashes can be held open to prevent artifacts. Use lubricating eye drops in patients with dry eyes.[4] |
| Store the images and data in a retrievable format<br>Ensure that the reported results are complete in all aspects including description, clinical correlation, probable diagnosis, laterality, date, and time. The report is to be signed by the technician and doctor on duty after verification. |

FFA=Fundus fluorescein angiography; SOP=Standard operating procedure

**Table 2: Checklist for ascertaining quality for ophthalmic images**

| Question | Answer |
|---|---|
| Is the calibration of the imaging unit up to date? | Yes/No |
| Is the technician/doctor thoroughly acquainted with the operating manual of the imaging unit? | Yes/No |
| Is the procedure properly explained to the patient/patient's guardian in a language that he/she understands? | Yes/No |
| Is the consent taken? | Yes/No |
| Is the patient comfortably positioned for imaging? | Yes/No |
| Is the patient's identity and intended procedure checked? | Yes/No |
| Are proper details of the patient entered in the software? | Yes/No |
| Is the laterality of the eye checked? | Yes/No |
| Is the test being carried out as per the SOP? | Yes/No |
| Is the report duly signed with the results by the technician/treating ophthalmologist? | Yes/No |

SOP=Standard operating procedure

caregivers, of the effects and dangers of dilated pupils after imaging procedures.

### Manuals/SOPs/work instructions

Ophthalmic imaging is a rapidly changing field and practitioners will need to keep up to date with the changes. It is expected that the technicians and the users be completely familiar with the operation and functions of the particular ophthalmic equipment used in their practice. For "Step by Step" technical instructions, one should check the manufacturer guidelines/work instructions/manual and the SOP of the HCO.

### Equipment and room setup checks

The equipment, room supplies, and room setup need to be checked on a regular basis. Some checks are completed daily and others need to only be completed on a weekly basis or at the beginning of each procedure/session. These checks include equipment inspection, calibration checks, and maintenance inspection of equipment as well as supplies necessary for the procedure and preparation of the room and equipment for the session examinations.

### Quality control log-on box/documentation

Each time a technician logs on to the equipment/software, the system will remind you to do quality control check, if the checks have not been completed for that time period. The quality

checks are to be completed daily, weekly, and/or at every session or procedure. Once you have completed the checks and entered this in the register/system, the message box with the reminder will not be displayed again until the appropriate time period has passed.

### Networking

- All medical imaging devices must be networkable and have the ability to save data to a network storage location. It is no longer acceptable to have patient data saved locally on the personal computer (PC) of the capture device, as this presents as an information governance risk. Most devices and PCs will connect to the hospital network through an Ethernet cable. It is often common to have viewer software supplied by the manufacturer of the medical device to enable clinicians to use Trust PCs to view patient data saved to the application patient database
- Connectivity and Digital Imaging and Communications in Medicine (DICOM): The common format for digital imaging files is DICOM. Having a common format aids connectivity of different modalities and manufacturers' devices. All new medical devices need to be able to output files in a DICOM format to ensure interoperability and help with data storage
- Data storage, picture archiving and communication system (PACS): With continued advancements in imaging technology, this often means that the volume of patient data being captured and stored is ever increasing in size. Most instrument suppliers will provide software that includes a patient database that will be hosted on a server and a data folder that will be located on a storage device (Storage Area Network "SAN" or similar)
- When planning storage requirements one needs to consider storage space in multiple terabytes (TBs) taking into consideration patient data file sizes and patient throughput. Remember that for all the live data being stored, there is the same amount again being stored on a data backup drive
- The best way to ensure connectivity between multiple modalities, and to enable the clinician to consider the data from multiple modalities in a single report, is by way of a PACS system. PACS will enable the end user to access all patient data from one system, significantly speeding up patient throughput and promoting a paperless environment.[2-4]

### Electronic medical records (EMR)

EMR systems are now common in most hospitals and are used to replace paper records and for automatic reminders, e-prescribing, medication tracking, and procedure coding. It is essential that the EMR system and PACS system are linked together to ensure that patient demographics are only entered once, thus saving time and reducing the risk of clerical errors.

QA procedures are required for the following imaging modalities in ophthalmology:

- External photographs and anterior segment imaging
- Fundus camera
- Optical coherence tomography (OCT)
- FFA
- Corneal topography
- Ultrasound B-scan.

## External Photograph and Anterior Segment Imaging

Conventional macro photography equipment and techniques are used to document the external appearance of the eyes, surrounding lid, and facial tissues. External imaging is an essential tool to evaluate progression of ocular and adnexal disease and to record surgical outcomes. It is essential that the pictures are standardized to ensure internal consistency between serial images. This requires exposure, ambient lighting to remain constant, and adequate training of the staff.[1,5,6]

Digital single-lens-reflex (DSLR) cameras are the best tool for high-quality external photography. DSLRs avoid parallax between lens and viewfinders as well as they offer a variety of compatible lens and electronic flash choices. Magnification for routine external ocular photography ranges from full-face up to life-size 1×.

**Standard:** In digital imaging, the 24 mm × 36 mm format with DSLR camera is standard format. For example: Canon EOS 5D camera (Canon EOS 23.9 mm × 35.8 mm); Nikon D3 camera (Nikon FX digital format 23.9 mm × 36 mm).

Lens settings are based on those marked on the Nikon 60 mm and 105 mm Micro Nikkor lenses (other lenses must be calibrated to meet these standards). As lenses are not marked for the digital ratios, it is common practice to achieve standardization using the closest lens focus as marked on the lens barrel.

**Reproduction ratios:** While lens focal lengths have been specified, lenses ±10 mm of the stated focal lengths would conform, provided the appropriate "reproduction ratios" and "lens to subject distances" are maintained.

**Lenses:** For 24 mm × 36 mm imaging format, a 105-mm focal length lens is used for all views and should adhere to the established "Westminster" reproduction ratios. Variable focal length (zoom) lenses should be avoided unless "reproduction ratios" and "lens focus settings" are comparable to the parameters in these guidelines.

**Lighting:** Lighting must be simple and reproducible; large, multiple conflicting reflections, and shadows must be avoided. The aim is to produce a single, small corneal, or conjunctival reflex with minimal reflections from the cornea, conjunctiva, and lid margins. However, reflections must not be totally eliminated. Ideally, the head should be restrained to prevent compensatory head movement with the secondary and tertiary positions.

**Primary position:** The direction of gaze is straight ahead into the camera lens.

**Secondary positions:** The patient is directed to look

- Straight up as far as possible
- Straight down as far as possible
- Straight over to the right as far as possible, and
- Straight over to the left as far as possible.

**Tertiary positions:** The patient is directed to look

- Up and to the right as far as possible
- Up and to the left as far as possible
- Down and to the right as far as possible
- Down to the left as far as possible.

Upper eyelids must be retracted for the secondary and tertiary inferior positions.

**Facial views**
- Anterior full face
- Right lateral face
- Left lateral face
- Right and/or left oblique face may be indicated
  Camera axis is directed to the point where the median plane meets the interpupillary line at the level of the orbito-helix line.

**Single eye with adnexa**
- Anterior
- Right lateral
- Left lateral
- Additionally, oblique, superior (bird's eye view) or inferior (worms' eye view) may also be indicated.

The specific area of interest, that is, lids; internal (medial) or external (lateral) canthus; lacrimal punctum, and so on can be focused.[1,5,6]

## Anterior Segment Imaging Guidelines

The use of a dedicated ophthalmic photo slit-lamp microscope is preferred. Conventional lenses and cameras together with careful lightning techniques can be used to image some conditions in the anterior segment. In addition, a retinal camera in the anterior segment setting can be used for imaging corneal and conditions using fundus reflex or general views of the iris, conjunctiva, and cornea, provided the annular light reflex is positioned away from the pathology.

Because of the very varied pathology and locations, accurate standardization is difficult to achieve with the normal "photo slit lamp." Most instruments, however, have a means of standardizing image magnification, slit width, slit height, slit angle, light intensity, and background light intensity, allowing intrapatient standardization. Interpatient standardization can be specified provided that the anatomical structure and the exact pathology have been defined.

### Image magnification

In most cases, high image magnifications must be sacrificed to achieve a greater "depth of field" (typical depth of field values range from 0.2 to 0.8 mm at 1.6 × magnification at the imaging plane). This is a workable compromise between magnification and depth of field bearing in mind the light available for recording a sharp image. Generally, magnification at the imaging plane has been standardized at 1.0/1.6 × unless otherwise indicated. Illumination and lighting angles are adjusted appropriately for modeling with minimal reflections and to ensure reflections do not obscure important details. **Position of gaze:** The eye is normally in the primary position of gaze. The direction of gaze is used to bring off-center lesions such as pterygia to the center of the field of view. This should conform to one of the nine defined positions of gaze. However, variations and reproducibility for "follow-up" images must be considered for lesions which do not conform to any of the nine positions. Upper and lower eye lids must be retracted where indicated and upper lids must be everted for lesions on the tarsal conjunctiva.

### Application standards

*Anterior chamber*
- Slit-lamp beam set to a diameter of 0.1–1.0 mm projected at 45°–90° through the anterior chamber with the microscope at 90° to the light beam, background illumination set at low intensity or turned off. For example: narrow angle glaucoma, iris lesions extending into the angle
- Direct focal coaxial illumination with gonioscopy lens
- Slit-lamp beam set to maximum opening, maximum depth of field. For example: anterior chamber intraocular lenses.

*Conjunctivitis, gross corneal lesions, pterygia, eye lid lesions*
- Widefield general view – diffuse illumination
- Defined field view – direct focal illumination
- Slit-lamp beam set to maximum opening and positioned with the background illuminator to provide widefield illumination. Modeling of lesions can be introduced by varying the intensity ratio between the slit-lamp beam and the background illuminator. Dark field illumination may be required
- Slit-lamp beam centered, set to 0.1–0.2 slit width, angled 30°–45° across the lesion. Magnification at the imaging plane – 1.0×/1.6×.

*Cataract, intraocular lens implants, anterior vitreous*
- Slit lamp with diffusion filter, slit beam set to maximum opening at 30° to the microscope axis, background illuminator. Direct focal illumination: wide to medium beam.
- Slit-lamp beam set to 2.0–4.0 mm, positioned at 30°–45°, background illuminator. Direct focal illumination slit beam. The beam is required to show the degree of convexity of the lens.[1,5,6]

## QA for Ophthalmic Images by Fundus Camera

Additional work instructions for the ophthalmic images acquired by the fundus camera are given in Table 3 and an example of the same is given in Fig. 1. The pointers are in addition to the common work instructions highlighted in Table 1.

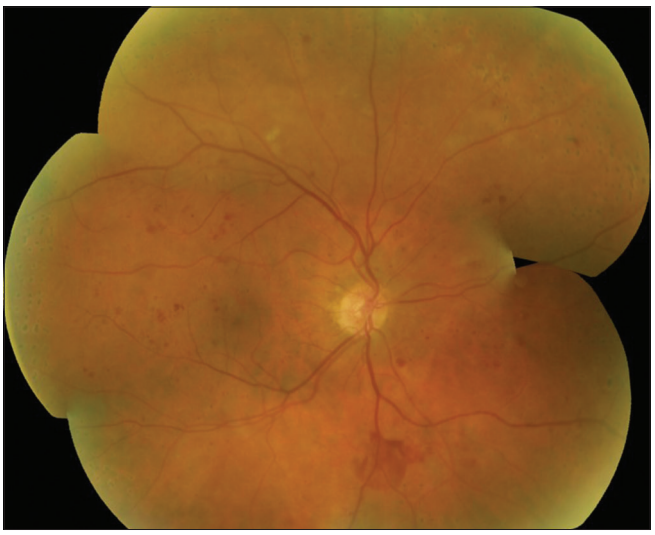

**Figure 1:** Montage of the fundus of right eye acquired by a fundus camera after using all standard work instructions as highlighted in the text

**Table 3: Work instructions for ophthalmic images acquired by fundus camera**

| |
|---|
| Assure proper date and time on the imaging printouts. Change the date manually if the clock has failed or if the camera has been left unplugged for a long period of time. |
| Enter the laterality of the eye which is to be tested correctly |
| Darken the room to improve contrast and to allow pupils to dilate physiologically[4] |
| Dilate the pupil in cases with media opacity and when peripheral fundus photographs are to be recorded. Photography through small (<4 mm) pupils will be difficult because some of the camera light does not enter the smaller pupil thus resulting in uneven illumination seen as dark shadows on the monitor.[4] |
| Acquire multiple images until sharper, clearer images are acquired. |
| Take the images when centered on disc, macula, and peripheral images of any peripheral pathology |
| Ensure alignment, focus, and proper fixation of fundus photographs (there are fine and coarse adjustment knobs, coarse adjustment brings the image in focus, whereas fine adjustment fin focuses the image). Constantly adjust and position the camera to maintain alignment and fixation which may be required multiple times during the examination of a single patient.[4] |
| Unacceptable images which warrant imaging to be repeated can be<br>Overexposed images (too light)<br>Underexposed images (too dark)<br>Obvious shadow on macula/disc<br>Shadows covering over 40% of the image<br>Out of focus/blurred image<br>Incorrect field of fundus which has been acquired<br>Image captured during blink<br>Incomplete acquisition of pathology<br>Green/white/partial halo[4] |
| Various modes are available in fundus camera for photography:<br>Color, where the retina is illuminated by white light and examined in full color.<br>Red-free fundus photography uses a green filter of 540-570 nm to block out red wavelengths of light. This allows a better contrast for viewing retinal blood vessels and associated hemorrhages, pale lesions such as drusen and exudates, and subtle characteristics such as nerve fiber layer defects and epiretinal membranes.<br>Angiography records vascular flow within the retina and surrounding tissue by injecting a fluorescent dye into the blood stream (fundus fluorescein angiography and indocyanine green angiography) |

The following standard fields while acquiring images by fundus camera have been set up in a protocol by Network UK[7]:

1. Calibration field (CF) – whole of the optic disc and macula must be visible in the field
2. Field 1M (optic disc) – center the temporal edge of the optic disc at the intersection of the cross hairs; the optic disc will be off center providing a partial view of the macula
3. Field 2 (macula) – center the macula at the intersection of the cross hairs
4. Field 3M (temporal to macula) – position the intersection of cross hairs 1–1.5 DD temporal to the center of macula.

Modified 7 field capture has also been specified in their protocol when acquiring images on a Spectralis system.[7]

1. Field 1M (optic disc)
2. Field 2 (macula)
3. Field 3 (temporal to macula)
4. Field 4 (superotemporal field) – center the optic disc in frame, tilt the camera downward until the disc is at 6o'clock position, pivot the camera toward the temporal area to position the disc in the lower right corner of field
5. Field 5 (inferotemporal field) – center the optic disc in frame, tilt the camera upward until the disc is at 12o'clock position, pivot the camera toward the temporal area to position the disc in the upper right corner of field
6. Field 6 (superonasal field) – center the optic disc in frame, tilt the camera downward until the disc is at 6o'clock position, pivot the camera toward the nasal area to position the disc in the lower left corner of field
7. Field 7 (inferonasal field) – center the optic disc in frame, tilt the camera upward until the disc is at 12o'clock position, pivot the camera toward the nasal area to position the disc in the upper left corner of field.[7]

## QA for Ophthalmic Images by OCT

The work instructions for the ophthalmic images acquired by OCT are given in Table 4 and an example of the same is given in Fig. 2. The pointers are in addition to the common instructions As highlighted in Table 4, signal strength assessment tool along

with their recommended values of various machines for acquisition of OCT is enumerated in Table 5.

## QA for Ophthalmic Images by FFA

The instructions for the ophthalmic images acquired by FFA are given in Table 6 and an example of the same is given in Fig. 3. The pointers in this list are in addition to the common instructions highlighted in Table 1.

## QA for Ophthalmic Images for Corneal Topography by Pentacam

The instructions for the ophthalmic images acquired by Pentacam are given in Table 7 and an example of the same is given in Fig. 4. The pointers in this list are in addition to the common instructions highlighted in Table 1.

## QA for Ophthalmic Images by Ultrasound B-Scan

Ultrasound is acoustic energy with frequencies above the audible limit. Very high-frequency, low-energy, and short-duration ultrasonic pulses are transmitted into the ocular and orbital structures from a "probe" through a coupling agent. In the time intervals between pulse transmissions, reflections from tissues are received by the same probe and the signals can be used to produce various types of detailed images of the eye and orbit. During ultrasonographic examination, the following systemic approach is universally recommended:

- Screening for lesion detection: A- + B-scan
- Topographic examination for shape, borders, location, and extension (if possible) of the lesion: B-scan
- Quantitative echography to know reflectivity, sound attenuation, and internal structure of lesion. It helps in determining the texture of lesion: A-scan
- Kinetic echography provides information about mobility, after movements (checked by performing valsalva maneuver and or ocular movements) on B-scan. It is performed by moving the eye but not the probe.[10]

B-scan probes have a mark which indicates the beam orientation so that the area toward which the mark is directed appears at the top of the echogram on display screen.[10]

During the procedure, the probe is moved from limbus to fornix in different clock hours and the picture seen is of diagonally opposite meridian as depicted in Table 8.[10]

Scan is done as per the suspected area and type of lesion:

Axial section: The patient fixates in the primary gaze and the probe is placed on the globe and directed axially. These sections demonstrate lesions at the posterior pole and ONH.

**Table 4: Work instructions for ophthalmic images acquired by OCT**

| |
|---|
| Enter the correct date of birth of the patient |
| Select scan protocol or pattern as per the required image/area which is to be examined[8] |
| Ensure proper alignment of the pupil with the center of scan. The centering line is helpful to center the scan over fovea, optic nerve head, or any other area of interest.[8] |
| Select dark or light according to patient's iris color to optimize illumination, brightness, and contrast settings. If neither eye color is selected, then the default protocol which is the average of the respective values of illumination, brightness, and contrast for the dark and light eye is selected.[8] |
| Ensure polarization adjustment (P motor) to optimize the OCT image signal strength which results in a clearer image. It must be done before and repeated during a scanning session.[8] |
| Adjust OCT image noise for best visualization of retinal tissue. For the line and cross line scan, select the option of averaging multiple scans to achieve final averaged image. To obtain the final averaged image in either the line or cross line scans, move the rectangle on or over the region of interest.[8] |
| Ensure optimum placement of the scan between the red dashed lines. If the lines are horizontal, the scan should be in the upper part of the target area (3 diopter disc area will have some of the scan image which will fall below the lower line which is acceptable).[8] |
| Ensure an even signal strength across the entire scan with no section of any weak signal (signal strength assessment tool along with their recommended values is enumerated in Table 5) |
| Minimize missed or dropped scans which are due to blinking/weak signals/eyelash obstruction/iris clipping. The missed or dropped scans are indicated in gray instead of white scan indicator lines. More missing scans equate to more interpolation in the map values. These scans should be repeated.[8] |
| Select the option of follow-up if this visit is a follow-up scan to allow the comparison in between the two visits[6] |

OCT=Optical coherence tomography

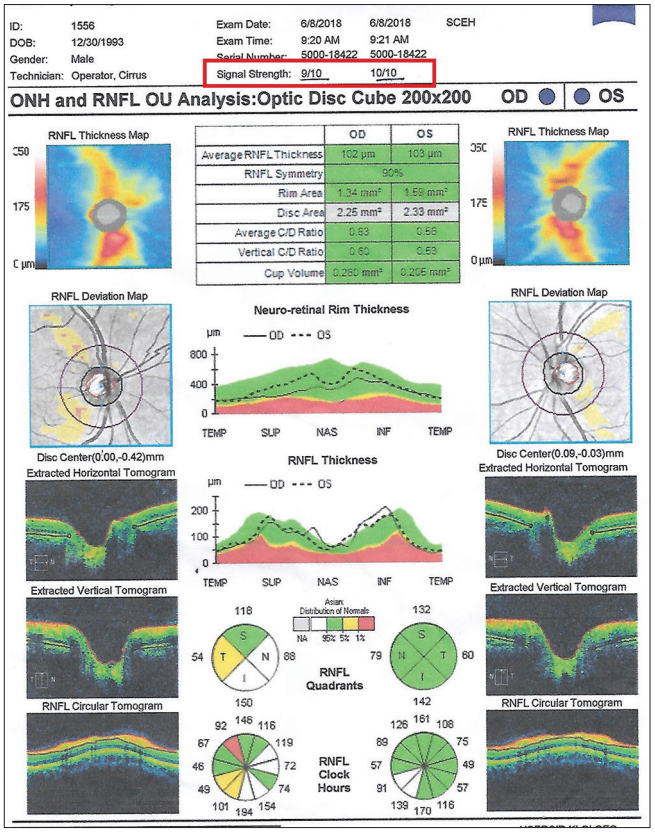


**Figure 2:** Optical coherence tomography (OCT) of the patient acquired after using all standard work instructions as highlighted in the text showing good signal strength (red box)

**Table 5: Signal strength assessment tools in various machines of OCT**

| OCT machine | Cirrus | RTvue | Spectralis | 3D-OCT 1000 |
|---|---|---|---|---|
| Signal strength assessment tool | SS | SSI | Quality | Image quality metric |
| Range of indicator | 0-10 | 0-100 | 0-40 | 0-100 |
| Recommended threshold value | 6 | 39 | 15 | 45 |

OCT=Optical coherence tomography; SS=Signal strength; SSI=Signal strength index. Signal strength assessment score is based on the total amount of the retinal signal received by OCT

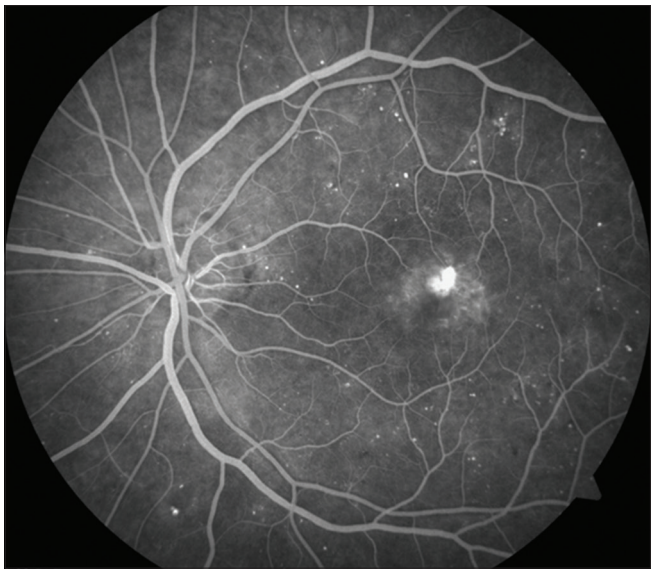

**Figure 3:** Fundus fluoroscein angiography (FFA) of the patient acquired after using all standard work instructions as highlighted in the text

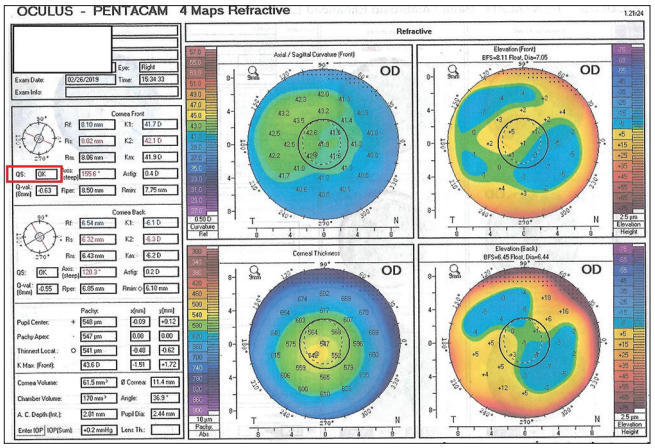


**Figure 4:** Pentacam of the patient acquired after using all standard work instructions as highlighted in the text showing quality specification (QS) to be OK (red box)

Transverse section: The mark is kept parallel to the limbus and probe is shifted from limbus to the fornix and also sideways. This scan gives the lateral extent of the lesion.

Longitudinal section: The mark is kept at right angle to the limbus to determine the anteroposterior limit of the lesion.

With contact type of scanning, there is a dead zone of about 7.5 mm adjacent to the probe, so that the lesions in this region are missed. To visualize this area, one can keep the probe on the opposite side at right angle or use immersion scan technique.[10]

The instructions for the ophthalmic images as acquired by ultrasound B-scan are given in Table 9 and an example of the same is given in Fig. 5.

The alignment of *A-scan* is vitally important. If the alignment is incorrect, the length of the eye will be underestimated. Most systems rely on the patient fixing on a target – usually a light in the probe. Patients with poor vision, whether from cataract or from some other pathology, are less likely to fix accurately and are more prone to biometry errors.

Work instructions (apart from the regular instructions) should include the following:

- Ensure the machine is calibrated and set for the correct velocity setting (e.g., cataract, aphakia, pseudophakia)
- The echoes from cornea, anterior lens, posterior lens, and retina should be present and of good amplitude (misalignment along the optic nerve is recognized by an absent of scleral spike)
- The gain should be set at the lowest level at which a good reading is obtained
- Take care with axial alignment, especially with a handheld probe and a moving patient
- Do not push too hard – corneal compression commonly causes errors
- Average the 5–10 most consistent results giving the lowest standard deviation (ideally <0.06 mm) errors
- Take note of eyes that are very short (less than 22 mm) or very long (more than 25 mm). Axial length errors are more significant in short eyes and a posterior staphyloma may be present in a long eye

**Table 6: Work instructions for ophthalmic images acquired by FFA**

| |
|---|
| Ensure adequate pupillary dilatation before starting procedure |
| Ensure proper positioning of illumination beam within pupil using joystick |
| Focus on the area of interest and maintain fixation by repeated and precise instructions to patients |
| Acquire good quality control images of both eyes before injection of fluorescein dye |
| Follow preplanned photographic sequence to prevent any missing of relevant photographs in between |
| Ensure adequate illumination of photographs to prevent too bright/too dim image quality |

FFA=Fundus fluorescein angiography

**Table 7: Work instructions for ophthalmic images acquired by Pentacam**

| | |
|---|---|
| Ensure that QS, which specifies the quality of the topographic capture, is displayed as "OK." If not done, the software tends to extrapolate the missing information[9] | |
| Check corneal form factor asphericity (Q) | |
| Q <0 | Untreated prolate cornea |
| Q >1 | Treated oblate cornea (post LASIK/PRK/PK) |
| Q=0 | Spherical cornea |
| Normal cornea is prolate and has a Q-value of −0.26[9] | |
| Avoid the following artifacts: | |
| Shadows on cornea from long eye lashes/trichiatic lashes | |
| Ptosis or insufficient eye opening | |
| Irregularities of tear film (dry eye/mucinous/greasy film) | |
| Incomplete/distorted image (due to corneal pathology)[6] | |
| Ensure proper centering of the scan. Can use automatic release option which decreases the chances of the patient blinking during the scan.[5] | |
| No eye drops should be applied to the patient's eye prior to examination which may interfere with tear film and affect the measurements in corneal topography scans[9] | |

QS=Quality specification

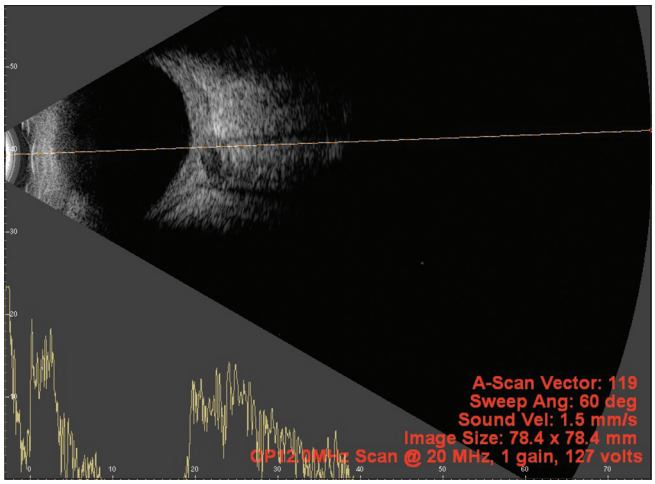


**Figure 5:** Ultrasound B-scan along with A-scan (below) of the patient acquired after using all standard work instructions as highlighted in the text

**Table 8: The area of the retina screened on the basis of the position of the B-scan probe**

| Clock hour - probe position | Clock hour - area screened |
|---|---|
| 3-Limbus | 9-Posterior |
| 3-Equator | 9-Equator |
| 3-Fornix | 9-Anterior |
| 6-Limbus | 12-Posterior |
| 6-Equator | 12-Equator |
| 6-Fornix | 12-Anterior |

**Table 9: Work instructions for ophthalmic images acquired by ultrasound B-scan**

| |
|---|
| Ensure lesions are placed in the center of the scanning beam |
| Instruct the patient to fix the gaze so that the probe or beam is perpendicular to the interfaces at the area of interest |
| Ensure the lowest possible decibel gain should be used to optimize the resolution of images[10] |
| Higher gain increases the sensitivity of the instrument in displaying weak echoes such as vitreous opacities. |
| Lower gain only allows display of strong echoes such as retina and sclera |

- Look out for the unexpected result, for example, an axial length of 27 mm in a patient with a +4.00 D refractive error
- Always measure both eyes and repeat if the difference between eyes is greater than 0.3 mm, or if consecutive measurements differ by more than 0.2 mm.

Some common mistakes while doing A-scans

- Wrong A-constant selected
- Wrong formula used
- Wrong K-readings entered by hand (90° out)
- Biometry print-out stuck in wrong patient's notes.

Quality indicators include the below:

1. Number of errors while doing A-scan/100 patients
2. Number of redo's per 100 patients
3. Percentage of cases of postoperative prescription within one diopter range
4. Percentage of patient with refractive surprises.

A QA system has been adopted by the *Network of Ophthalmic Reading Centers* (networcuk.com), United Kingdom, for acquisition of ophthalmic images using FFA and fundus camera which provides an example of a perfect model. All the graders within NETWORK UK initially undertake an extensive 3-month training program. Central Angiographic Resource Facility (CARF) provides a framework for grader training for acquiring basic knowledge, skills, and resources needed to perform grading to the required standards and to ensure consistency in intragrader, intracenter, and intercenter grading. Each reading center is responsible for training of its graders in accordance with the grader training plan. Structured concordance exercises take place on a biannual basis involving all NETWORK UK graders to test concordance with a grader's past performance and between graders. CARF director and clinical advisors select the ophthalmic images for the concordance exercises; statistical analysis is performed on the results and kappa values are measured. Feedback is provided to graders on the issues raised during these sessions to help maintain and improve their performance. QA grading is performed on a randomly selected set of study images. CARF also has an in house photographic manager who can review the photography procedures at clinical study sites to ensure optimal photographic quality is consistently obtained.[7] This model can be adopted in clinical practice for acquiring ophthalmic images using fundus camera and FFA.

## Conclusion

QA in ophthalmic imaging is not only essential for proper functioning of the devise but also for image acquisition and accuracy of results. SOPs should be institutionalized for all the imaging equipment and should be strictly adhered to. Proper documentation, data capturing, and monitoring can go a long way in achieving the best possible outcomes.

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### Conflicts of interest

There are no conflicts of interest.

## References

1. The Royal College of ophthalmologists. Ophthalmic Services Guidance: Ophthalmic Imaging. November 2016. Available from: contact@rcophth.ac.uk. [Last accessed on 2019 Apr 21].
2. Nadler Z, Wollstein G, Ishikawa H, Schuman JS. Clinical application of ocular imaging. Optom Vis Sci 2012;85:E543-53.
3. Available from: https://en.oxforddictionaries.com/definition/quality%20assurance. [Last accessed on 2019 Apr 21].
4. National Health and Nutrition Examination Survey (NHANES): Ophthalmology procedures manual. September 2005.
5. Young S. Maintaining standard scales of reproduction in patient photography using digital cameras. J Audiov Media Med 2001;24:162-5.
6. Fogla R, Rao SK. Ophthalmic photography using a digital camera. Indian J Ophthalmol 2003;51:269-72.
7. Available from: https://www.networcuk.com. [Last accessed on 2019 Apr 21].
8. RTVue Model RT100 user's manual version 3.0, PN 500-42929 Rev. C 11/2006.
9. Ambrosio R. Simplifying ectasia screening with Pentacam corneal tomography. Highlights Ophthalmol J 2010;38:12-20.
10. Kumar S, Goel R. AIOS CME Series (no. 24): Diagnostic ultrasonography of the eye 2011:1-37.