

NCLE Basic Exam Review

Domain VI: Dispensing;

Domain VII: Follow-up;

Domain VIII: Regulatory/Regulations



Developed by the National Federation of
Opticianry Schools

Professor Robert J. Russo has no financial
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NCLE Basic Exam Review

Domain VI: Dispensing; Domain VII: Follow-up; Domain VIII: Regulatory (45 questions)

a. Lens Delivery, Solutions and Aftercare

Importance of Patient Management:

- Besides the proper fitting of any contact lens, lens success is based on:
 - Training
 - Hygiene
 - Proper use of solutions
 - Proper techniques for inserting and removing contact lenses
 - Proper cleaning and disinfection
 - Importance of follow-up

Preparing a Soft Contact Lens for Wearing:

- Instruct your patients to always wash their hands with a mild soap, rinse completely and dry their hands with a lint-free towel
- Instruct patients to avoid soaps containing cold cream, lotion, and oily cosmetics
- Instruct patients to handle their lenses with their fingertips and avoid using their fingernails
- Fingernails should be kept short and smooth
- Have patients start off using proper hygienic procedures from the beginning

Lens Packaging:

- Instruct patients that prior to opening an individual lens package, shake the lens package to see if the contact lens is floating in the solution
- Patients should peel back the foil to reveal the lens
- Have the patient remove or pour the contact lens in the palm of their hand and rinse prior to inserting the lens in their eye
- Prior to insertion, have the patient check the lens for surface defects, nicks, or tears
- If the lens is damaged, instruct the patient to use another lens
- Remind patients that sometimes lenses maybe damaged or missing from lens packages
- Patient should be instructed to verify that the contact lens is not inverted or turned inside out
- Taco Test

Soft Lens Application:

- Lay out supplies, open contacts and solutions
- Wash your hands
- Have patient wash their hands
- Place lens on patient's index finger
- Middle finger of hand that patient usually uses holds down the lower lid
- Place lens over cornea/iris(for direction you may need to say colored portion as the patient may not know parts of the eye)
- Direct patient slowly and calmly
- If lens is not centered have patient turn eye toward location of lens. Lens will self-center
- After application is complete let patient rest and explain cleaning technique with the solution you want them to use.

Removal:

- a) Have patient open lids as they did with insertion.
- b) Use index finger and thumb to reach into the eye and gently pinch and pull lens from eye
- c) Repeat instructions until job is complete.

Insertion:

- a) Technique 1 - One Hand Placement
- b) Technique 2 – Two-Finger Placement

After Insertion:

- a) Have the patient close their eyelids and gently massage the lens into place through the closed eyelids or
- b) Have patient gently manipulate the off-centered lens onto to the cornea, using finger pressure on the edge of the upper or lower lid
- c) Never use fingernails to manipulate the lens in place

Removal:

- a) Two Finger Method
- b) One Hand Method

The Role of Contact Lens Products:

- To remove surface deposits
- To disinfect microorganisms
- To improve surface wettability

Considerations for Topical Application:

- Osmotic Pressure: .9% - 1% NaCl Equivalent
- PH: Tears 7.0 – 7.4 Range
- Comfort Range 6.6 – 7.8
- 7.0 - or < is acidic or 7.0 or > is alkaline
- Buffers help balance the PH in solutions
- Solutions should be non-abrasive and non-irritating
- Solutions should be sterile when placed in the eye
- Preservatives allow for the reuse of a solution

For Use with Rigid Lenses

- Cleaning (surfactant cleaner) – removes surface deposits from contact lens surfaces
- Wetting – acts as a cushioning agent when a contact lens is placed on the eye
- Disinfection – kills germs and microorganisms that can cause eye infections (Multipurpose solution)
- Lubricant – formulated to rewet lenses in the eye from dryness
- Artificial tears – an additive for patients with marginal dry eye. Not to be used with contact lenses in the eye.
- Decongestants – are used to reduce redness in the eye
- For rigid lenses, there are usually three steps, cleaning, rinsing and disinfection. This can involve two solutions, surfactant cleaner and disinfecting solution for storage
- Many rigid solutions today use a one step method that cleans, rinses and disinfects in one solution today

Soft Contact Lens Disinfection:

- Thermal Disinfection (Heat) No longer used because of high water contents of 55% or greater
- Chemical Disinfection
- Peroxide or Oxidation Disinfection
- UV Disinfection

For Use with Soft Lenses

- Surfactant cleaner – removes surface deposits from contact lenses
- Rinsing – after using a surfactant cleaner on lenses, the lenses should be rinsed with saline or a multi-purpose solution before disinfecting
- Multipurpose solutions for soft lenses today clean, rinse and disinfect with one solution
- Enzymatic cleaner – breaks down tear protein deposits on the contact lens that surfactant cleaners leave behind. Frequency depends on patients tear chemistry and the type of lens being fitted. Some enzyme cleaners are used separately before disinfection or used during the disinfection process.
 - **Papain**, an enzyme derived from papaya; **pancreatin** an enzyme derived from pig pancreatic tissue
 - **Subtilisin**, derived from beneficial bacteria
- Both are available in liquid and tablet form
- Lubricant – formulated to rewet lenses in the eye from dryness

Preservatives:

A preservative is added to a solution to ensure that the solution remains sterile under normal conditions of use by destroying or inhibiting the multiplication of microorganisms

The following preservatives are found in rigid lens solutions, BAK should not be used with soft lenses

Benzalkonium Chloride (BAK)

- Chlorobutanol
- Thimerosal
- Chlorhexidine

The following preservatives are found in soft lens solutions:

- Sorbic Acid
- Potassium sorbate
- Dymed
- Polyquad
- Alexidine
- Polyhexanide

Surfactants: are cleaners that combined with rubbing remove surface deposits from the anterior surface of the contact lens.

- Poloxamine
- Miranol

Additives:

- Hydroxypropyl methylcellulose – cushions lens material
- Dexpant-5 – “Hydrolock” – prevents evaporation

Demulcents:

Enhances comfortable contact lens application

- Propylene glycol

Wetting Agents:

Decreases the wetting angle to make the lens more hydrophilic

- Polyvinyl Alcohol
- Plysorbate
- Absorbobase
- Polyvinyl pyrrolidone

Viscosity Builders:

Found in Artificial Tears to add substance to the tear film and prevent increase evaporation

- Methylcellulose
- Hydroxyethyl Cellulose

Buffers and Osmolarity Control:

Keep the pH of the solution as close to natural tears

- Sodium Borate
- Sodium Chloride
- Sodium Phosphate
- Sodium Bicarbonate

Lubricants

Agents that attract moisture and prevent the lens material from drying up when used with contact lenses in the eye

- Hydroxypropyl Methylcellulose
- Poloxamine

Decongestants

- Phenylephrine HCL
- Naphazoline HCL
- Epinephrine HCL
- Tetrahydrozoline HCL

Disinfection

- antimicrobial agents
- protect a care solution's bottle contents from contamination

Solution Guidelines

- Follow directions for your lens care system
- Wash hands dry before handling lenses
- Dispose of disinfecting solution after use
- Air-dry storage cases
- Never use tap water to store or wash lens cases
- Replace storage cases every three months

Heat Sterilization

- Not used anymore because most lenses are available in 55% water and these lenses cannot be heat disinfected
- Advantages- Simplicity and reduce cost
- Disadvantages- Cannot be used with water contents above 55%
- Requires an electrical outlet

Chemical Disinfection

- a) **MPS** – Multi-purpose solution – requires rubbing, rinsing and soaking to achieve disinfection
- b) **MPDS** – Multi-purpose-disinfecting solution- must achieve a higher kill rate of bacteria and fungi during the labeled soak time without rubbing or rinsing
- c) All MPS systems contain preservatives that disinfect and surfactants and protein removers that help keep the lenses clean
- d) Most MPS systems also contain ingredients that may help improve comfort by decreasing dryness
- e) All MPS solutions are approved for NO RUB however, the traditional rub and rinse is still highly recommended
- f) Advantages- Simplicity and reduced cost, used with any lens
- g) Disadvantages- Higher risk of patient hypersensitivity

Hydrogen Peroxide (Oxidation System)

- Uses 3% H₂O₂ peroxide. Red tip on bottle indicates not to be placed in eye
- Some systems use a one step or two step system
- Peroxide systems must use a neutralizer to break peroxide down to water

- Most peroxide systems require a minimum of 6 hours and some may require 10 minutes depending on manufacturer

Advantages of Peroxide Systems

- Minimal risk of hypersensitivity
- Can be used with any type of lens
- Effective means of cleaning

Disadvantages

- Complexity of procedure
- Irritation from solution if not neutralized
- Possible fading of tinted lenses

Care Instructions

- Written
- Pictorial
- Video

Lens Deposits – Organic Deposits

- Protein – most common deposit on soft lenses, Derived from mucoproteins, albumin, globulins, glycoproteins, mucin and lysozyme
- Pigment deposits – deposits that are yellow to brown in color. High incidence of pigmentation is found among smokers produced by nicotine
- Microorganisms – such as fungi and yeasts grow on or into the soft lenses. Can be black, grey, brown or white. Lenses stored in non-preserved saline for an extended time are prone to these deposits
- Lipid deposits – derived from meibomian gland secretions. Lipids are best removed by surfactant cleaners
- Miscellaneous deposits – Brown to dark discoloredation have been found with topical use of Epinephrine or the use of vasoconstrictors

Lens Deposits – Inorganic Deposits – often penetrate soft lens surfaces and can cause greater ocular discomfort. Composed mainly of calcium phosphates from the tear film

- **Lens Calculi** – made up of lipid and inorganic compounds, “**jelly bumps**,” usually found with extended wear lenses. Cannot be removed and lenses should be replaced
- Mercury deposits – visible gray to black discolorations common in heat disinfected lenses. Probable cause is the multiple reuses of preserved saline.
- Rust Colored spots are superficial orange to rust colored spots. They have been linked to iron containing particles in contact with the lens that oxidize to form these rust spots.
- Mucin Balls – connected to early silicone hydrogel lenses, also referred to pre-corneal deposit or lipid plug. Usually associated with high modulus silicone lenses because of the surface properties and lens rigidity. They tend to form in the superior half of the cornea under the upper lid and are the result of poor tear exchange failing to remove cell debris with the tear exchange. Patients are usually asymptomatic.

Silicone Hydrogel Lenses:

- a) Advantages – better durability, less protein deposition and increased end-of-day comfort. At present, 82% of practitioners are selecting Silicone Hydrogel materials for new spherical contact lens patients
- b) Potential Drawbacks – increased lipid deposits and stiffness of the material
- c) Group I Low Water, < 50%, non-ionic
- d) Group III Low Water, < 50%, ionic
- e) Group V - is in the process of being evaluated and subdivided
- f) Unlike HEMA based soft polymers, silicone hydrogels are hydrophobic
- g) Nite & Day, Purevision, Acuvue Oasys, Acuvue Advance *except* Biofinity and Avaira have to be surface treated or contain an internal wetting agent for successful wear

Giant Papillary Conjunctivitis (GPC):

- a) **Symptoms**- Awareness, Itching, Excessive Lens Movement, Papillae Formation under lids
- b) **Etiology**- Mechanical irritation, Hypersensitivity to solutions
- c) **Management**- Meticulous Cleaning, Reduce Wearing Time, Peroxide
- d) **Treatment**- Ocular Medication

Contact Lens Induced Superior Limbal Keratoconjunctivitis (SLK):

- a) Thimerosal Sensitivity
- b) Clinical Signs- Vessel Engorgement, Itching

Infiltrates:

- c) Accumulation of white blood cells
- d) Associated with Thimerosal sensitivity
- e) Redness, photophobia
- f) Switch to non-preserved solutions

Acanthamoeba:

- Rare painful and potentially blinding infection to the cornea
- Found in all environments: soil, fresh water, swimming pools, hot tubs, tap water and even bottled water
- Use of tap water during lens care (to rinse lenses or the storage case)
- Wearing contact lenses without goggles
- Use of Ineffective or expired lens care solutions

Adaptive Symptoms

Slight Awareness
Slight redness
Fuzzy Vision
Difficulty in handling lenses
Photophobia
One eye sees better than the other

Subjective Symptoms

Blurred Vision

Improper Refractive Power
Switched Lenses
Dirty Lenses
Environmental Change
Residual Astigmatism

Fluctuating Vision

Tight or Loose Lens

Lens Awareness

Dirty Lenses
Damaged lens or lenses
Loose lens or lenses
Bad or defective edge

Burning, Gritty Feeling

Poor Environment
Conjunctivitis
Tight Fit
Allergy to Solutions
Chemical remaining on lenses after disinfection

Objective Symptoms

Ocular Redness

Conjunctivitis
Mechanical Irritation
Allergy
Dirty Lens
Incompatible Lens Solutions
Poor Blinking

Bubbles under Lens

Steep Fit

Excessive Lens Movement

Inverted Lens
Loose Fit

Minimal Movement

Marginal Tight Fit

Lens Rides to Side

Against the Rule Astigmatism
Lens to Small

Lens Discoloration

Protein Buildup
Use of Decongestant in eye with contact
Lenses

Edge Standoff

Lens too Flat (Very common with silicone hydrogel lenses)

Why Follow-Up?

- To encourage compliance with care and handling techniques
- To discuss the areas of instruction that may have been confusing to the patient

Follow-Up – SOAP – Subjective, Objective Assessment Plan

- a. Review their Lens Care System
- b. Ask them to demonstrate how they are cleaning their lenses
- c. Is your patient using a lens lubricant?
Lubricant – a solution to make more slippery or smooth and maximize comfort while a contact lens is in the eye.
Artificial Tears - solution to supplement the loss of tear formation.
- d. Lens verification prior to insertion (TACO Test)
- e. Wearing History

Soft Lens Vision Problems and Assessment

Fuzzy or Blurry Vision

Uncorrected cylinder power – Residual Astigmatism
Spherical Equivalent or thick soft lens
 $-3.00 - 1.00 \times 180 \frac{1}{2}$ the cylinder power added to the sphere
New CL Rx = -3.50
Fit Toric Soft Lens
 $-3.00 - .75 \times 180$ or $-2.75 - 1.00 \times 180$
Most patients will tolerate up to .75 diopters of uncorrected astigmatism

Debris on Lens

- Review cleaning procedures or replace lens

Lens Switched

- Verify power and Switch
- Usually through Over-Refraction
Ex. O.D. -3.00
O.S. -2.50

Patient comes in complaining of reduced visual acuity
Assume -3.00 is in left eye and -2.50 is in right eye
O/R would reveal +.50 in O.S. and -.50 in O.D.

Inverted Lens

- Review Insertion Verification

Uncomfortable Vision

- Verify change in accommodation or convergence at near point
- For patients that are pre-presbyopic (36 – 40) for Myopic prescriptions reduce CL Rx from -.50 to -.75 diopters
- For Hyperopes increase CL Rx from +.50 to = +.75
- College students or post-graduate students should be under-corrected for near vision comfort.
- Recommend the use of eyeglasses for long periods of reading instead of using their contact lenses

Objective Symptoms

- Ocular Redness
- Conjunctivitis
- Mechanical Irritation
- Allergy
- Dirty Lens – Poor cleaning
- Incompatible Lens Solutions
- Poor Blinking – Use of Lubricant?
- Ask about Work Environment

Extended Wear

1979 – Extended Wear introduced in the United States for Aphakic Wear
for 30 days of continuous wear

1981 – Introduced 30 day extended wear lenses for myopia

Success With Extended Wear

- General Health
- Tear Function
- Motivation
- Hygienic habits
- Visual Requirements
- Good Follow-Up

Extended Wear Candidates

- Aphakic Patients
- Children with monocular aphakia
- Therapeutic cases
- Vocations where good vision is required immediately upon waking
- Patients with physical handicaps
- Will probably need assistance from a caregiver or family member

Contraindications

- Patients with one functioning eye
- Existing corneal vascularization
- Unable to remove or insert lenses
- Diabetics
- Dry Eye
- Eye Diseases or Old Eye Injuries
- Chronic Allergies

Fitting Criteria

- Fit Silicone Hydrogel lenses when possible
- Lenses should be flatter than "K", "Three point Touch"
- Minimal movement should be 0.5 mm – 1.00 mm, ideally 1 – 2 mm
- Proper Centering
- Stable Vision before and after the blink

Diagnostic Fitting

- Spectacle Rx in minus cylinder form
- Spherical Equivalent = $\frac{1}{2}$ the cylinder added to the sphere
- Vertex Calculation - ± 4.00 D
- Base Curve Selection – Fit the flattest base curve that provides adequate movement, good centration and stable vision

Instruction and Care

- Discuss hygiene
- Demonstrate insertion, removal and recentering
- Discuss cleaning and disinfection
- Discuss adaptive symptoms
- Discuss consequences of non-compliance
- Discuss make-up application
- Give written instructions
- Recommend lubricating drops in the morning and at night

Follow-Up

- First Follow-Up - Patient should be seen 24 hours after sleeping with their lenses, preferably in the morning

- Second Follow-Up – one week later
- Any symptoms, Slit Lamp Evaluation, Visual Acuity, Review Aftercare instructions
- Stress the importance of Follow-Up
- One month, three months, six months, 1 year

Complications

- Infections
- Edema during the adaptive period (Vertical Striae) Should disappear with 1-2 weeks
- Tight lens syndrome (Use of eye lubricant before bed)
- Giant Papillary Conjunctivitis (GPC)
- Vascularization from Over-wear
- Corneal Infiltrates – linked to protein deposits on lenses
- Reduced oxygen supply over a long period of time can reduce metabolic activity at the endothelium, Polymegathism or Polymorphism

Disposable Contact Lenses

- Disposables follow same fitting rules as Daily soft contact lenses
- Generally fit from an inventory
- Follow-Up can follow the same protocols depending if the lenses are going to be fit as a daily wear or extended wear lens
- The same method of cleaning and disinfecting are just as important as with daily wear lenses
- Only main difference is **Replacement Time Frame**

Daily Disposable Contact Lenses

- Worn daily and then discarded
- Less maintenance, but should be rinsed with a MPS solution prior to insertion
- Advantages are: Convenience and Hygiene
- Reduce the risk of eye infections
- Yearly cost will be higher
- Patients tend to Over-wear

Follow-Up and Aftercare

- Follow the same protocols as daily wear contact lenses
- For both Disposables and Daily disposables, most practices “Bundle” a year's supply

- Once the year is up, if they try to reorder, patient must return for a follow-up visit. Remember Prescription Release

RGP Insertion & Removal:

- Solutions should not be interchanged with Soft Lens Solutions unless FDA approved
- RGP Lens Fitting is different than Soft Lens Fitting because all RGP lenses are custom fitted to the patient
- Always wash and rinse your hands thoroughly before handling your lenses. Clearer soaps are better since they contain less lanolin which can smear the contact lens surface. Avoid liquid soaps which often contain moisturizers that coat lenses. Dry your hands with a lint-free cloth to reduce the chance of trapped dust under the lens.
- Insert lenses before applying make-up and when using hairspray, close your eyes.
- Examine the lens before insertion for damage, scratches, nicks or chips, and only wear the lenses for the recommended time.
- Avoid levering or scraping lenses off flat surface with your fingernails or sharp pointed objects.

Insertion

- Remove the lens from the storage case by gently putting your finger into the lens, it should stick to your finger and lift out. Wiping it out will scratch the lens.
- Hold the upper lid firmly from above with the middle finger of the other hand. Make sure the finger is placed just where the eyelid meets the eyelashes.
- Now that the eye is wide open, place the lens on the cornea.
- Release the lower lid and then the upper lid and blink
- Recentering**- Occasionally, a lens may be displaced onto the conjunctiva, (white of the eye) when inserting, or with sudden eye movements or excessive tear flow.
- Move the lens with the eyelids until it is adjacent to the cornea.
- It is often easiest to re-center the lens from directly below the cornea by pushing it upwards with the bottom lid.
- Removal:** A suction holder is the most recommended method for lens removal. Make sure that it is applied directly to the lens and not onto the eye. When the 'sucker' has suctioned onto the lens gently twist the lens off your eye. To remove the lens from the sucker hold the contact lens and slide off the 'sucker' sideways. Pulling the lens directly off the sucker may result in lens warpage.
- Blink Removal

Cleaning and Disinfecting:

- Place the lens on the palm of your hand.
- Apply 1 or 2 drops of your specified cleaning solution on the lens.
- Rub gently with a back and forth motion for about 10 seconds. Make sure both sides of the lens are cleaned
- Rinse off THOROUGHLY with conditioning solution. You may need to rinse and rub more than once to ensure the entire cleaner is removed.
- Rinse hands with water to remove any cleaner. Insufficient rinsing will mean that the contact lens may sting on insertion the next time.
- Place lenses in storage case ready for sterilization and rewetting.

Follow-Up with GP Contact Lenses and Troubleshooting

Rigid and GP Physical or Fitting Issues

Correction of a Low Riding Lens (Minus Lens)

- Intrapalpebral Fit (Lens may be too flat)
- Steepen base curve

- Upper Lid Attachment (Lens may be too steep)
- Flatten base curve or increase lens diameter or combination of both

Correction of a High Riding Lens (Minus Lens)

- Intrapalpebral Fit (Lens may be too flat) Note: This is if edge of lens is slightly under upper lid
- Steepen base curve or increase lens diameter

- Upper Lid Attachment (Lens may be too flat)
- Steepen base curve or increase lens diameter or combination of both
- Thin out edge design (CN Bevel or Hyperflange design)

Lens Centering or Displacement

- Probable Cause: Lens too small or too flat
- Correction – larger diameter or steeper base curve

Excessive Movement

- Probable Cause: Too loose or too flat or diameter too small

- Correction: Steepen base curve or increase lens diameter or a combination of both

No Movement

- Probable Cause: Lens too tight or Diameter too large
- Correction: Flatten base curve or decrease lens diameter or combination of both

Bubbles under Contact Lens

- Probable Cause: Lens too tight or too steep
- Correction: Flatten base curve or Smaller Diameter

Difficulty in looking Up

- Probable Cause: Poor edge design
- Correction: Re-edge or round out edges

Mild Discomfort

Probable Cause: Poor Edge, sharp junctions, Surface scratches

Correction: Re-shape or round out edges

Blend peripheral curves

Polish lenses and round out edges

Rigid and GP Vision Issues

Lens Flexure:

- New GP lenses are thinner
- If vision fluctuates, either:
 - Flatten base curve first or increase CT by .02 - .04 mm
 - Change in base curve made need Contact Lens Power change, SAM or FAP
- Depending on corneal toricity sometimes new GP lens materials will bend on the eye after blinking

Flare

- Probable Cause: Insufficient Pupil Coverage
- Make POZ larger
- Lens Decentering
- Correction: Steeper base curve or larger diameter

Poor Visual Acuity (Initially)

Probable Cause: Wrong Power, Lenses switched

- Correction: Over-refract or verify if lenses were switched

Poor Vision, One Eye

- Probable Cause: Lenses in Wrong Eyes
- Correction: Switch Contact Lenses
Verify Right from Left Lens
Dot Right Lens

Fogging

- Probable Cause: Dirty Lens, Beading up on lens surface especially on silicone acrylate lenses initially
- Correction: Clean Lenses and re-instruct on cleaning

Reading Blur

- Probable Cause: Over Minus in Contact Lens
- Correction: Verify with Red-Green (Duochrome Test)
- Probable Cause: Accommodation Issue
- Age, Reading glasses, Reduce Rx

Photophobia

- Probable Cause: Edema, Tight Fit (Lower DK contact lenses)
- Correction: Loosen Fit
- Correction: Switch to higher DK Lens Material

Regulations:

- **Malpractice**- Unethical conduct or negligence by a professional usually in the health care field, Can be intentional or not intentional
- **Tort**- Injury or misconduct that causes harm to a person or a person's property
- **Principles of Informed Consent**- You must provide the patient with enough information so that he or she can make a reasonable decision (Risks of procedure, including loss of vision, Complications)
- **Duty of Disclosure**- To frankly answer questions about the risk. To disclose alternative procedures available and their risks.

- **Consent-** may be written, oral or implied. Regardless of the form of consent, the practitioner must be able to prove that the duty of disclosure was met before the consent was obtained

FCLCA – Fairness to Contact Lens Consumers Act:

- The **FCLCA** took effect in August 2004 and is enforced by the FTC
- After the finished fitting, the Rx must be provided even if the patient does not ask for it
- Contact lens verification must be made within 8 hours
- A Valid Contact Lens Prescription includes
 - *Patient's Name*
 - *Issue Date of Prescription*
 - *Expiration Date*
 - *Prescriber's Name, Address, Phone Number, and Fax Number*
- **Lens Parameters** must include:
 - *Base Curve*
 - *Power*
 - *Diameter*
 - *Manufacturer (enough information to duplicate lens)*
 - *In Private Label cases, the name of the manufacturer, trade name or equivalent is given*

Contact Lens Rule - October 2020

- a. Releasing prescription as in the original FCLCA and documentation form that patient signs acknowledging patients received prescription
- b. Must be kept on file for three years

Contact Lens Rule Update, April, 2021

- a. A copy of the prescription must be given with an expiration date and in addition, an acknowledgement form that the patient received the prescription and must be signed by the patient and dated. The acknowledgement must be kept on file for three years
- b. Adherence to the new regulations can be to seek patient consent to send contact lens prescriptions through a patient portal or via email

Acceptable ways to document:

Patients sign a separate form
 Patients can sign sales receipt
 Patients can sign their prescription
 Patients can esign and receive a copy electronically
 If patient is unwillingly to sign, this should be documented on the patient record card regard refusal to sign.

FDA – Food and Drug Administration:

- Created in 1907
- To promote and protect the public health by helping safe and effective products reach the market in a timely way.
- Regulates: Food, Drugs, Medical Devices, Animal Feed and Drugs, Radiation Emitting Products and monitors products not regulated

FTC – Federal Trade Commission

- Independent agency of US Government and created in 1914
- Investigates price fixing, and unfair methods in competition
- In the ophthalmic industry the greatest impact was in 1978 regarding “Prescription Release Rule”

OSHA – Occupational Safety and Health Administration:

- a. Mission to save lives, prevent injuries and protect the health of workers
- b. OSHA has established emergency procedures
- c. MSDS – Material Safety Data Sheets- located in every business and lists various steps and procedures to be followed if an accident occurs Also referred to **SDS**

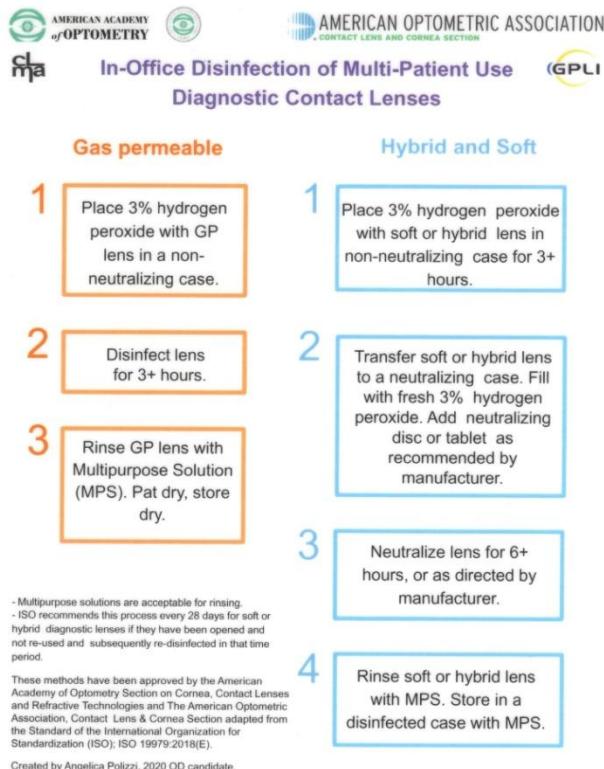
HIPAA – Health Insurance Portability and Accountability Act (1996)

The goal of the law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information and help the healthcare industry control administrative costs.

HIV and Contact Lenses:

- Hand Washing – Hand Washing represents one of the most effective means of avoiding the risk of transmitting or acquiring infections
- The use of gloves or finger cots by clinicians when cuts, scratches or dermatologic lesions are present on the hands or fingers
- Instruments that come in direct contact with the patient such as occluders, head rests, chin rests etc. should be wiped clean with alcohol and allow to dry

- Contact lenses and carrying cases used in trial fittings and follow-up fittings should be disinfected.
- Hydrogen Peroxide disinfection is the recommended



ANSI – The National Institute:

American Standards

- Formed in 1918
- Private, non-profit based membership to establish voluntary quality standards for American made products

Contact Lens Tolerances

American National Standard Institute; ANSI Z80.20-

The following chart provides information on the tolerances established for general manufacturing. It is advised to know what a contact lens measures before modification. Some procedures may cause a change in lens parameters and understanding tolerances will prove beneficial.

	Power	Tolerance		Parameter	Tolerance
Sphere Power	0.0 to 5.00D	+/- 0.12D	Base Curve	Toric base curve	+/- 0.05mm
	5.12 to 10.00D	+/- 0.18D		dd r 0 to 0.20mm	+/- 0.05mm
	10.12 to 15.00D	+/- 0.25D		dd r 0.21 to 0.40mm	+/- 0.06mm
	15.12 to 20.00D	+/- 0.50D		dd r 0.41 to 0.60mm	+/- 0.07mm
Cylinder Power	0.0 to 2.00D	+/- 0.25D	Lens Parameters	dd r more than 0.60mm	+/- 0.09mm
	2.12 to 4.00D	+/- 0.37D		Diameter	+/- 0.05mm
	Over 4.00D	+/- 0.50D		Optic Zone	+/- 0.10mm
Cylinder Axis	any	+/- 5 degrees		Center Thickness	+/- 0.02mm
Bifocal Refractive			Bifocal Refractive	Add power	+/- 0.25D
				Seg height	+/- 0.10mm

*dd = difference between radii of principal meridians

Base Curve (\pm mm) for Spherical Rigid Lenses - \pm 0.05 mm

HCFA-1500 - Heath Care Financing Association

- is the basic form prescribed by HCFA for the Medicare program for claims from physicians and suppliers

CPT Codes - American Medical Association

- Current Procedural Terminology (CPT) is a medical code set that enables healthcare providers to describe and report medical, surgical and diagnostic procedures and services they perform to government and private payers.
- CPT 92340 - spectacle services including prosthesis for Aphakia
- CPT 92354 - fitting of spectacles for single vision lenses

HCPCS - Healthcare Common Procedure Coding System

- is a collection of standardized codes that represent medical procedures, supplies, products and services.
- V2020-V2025 - Spectacle frames
- V2100-V2199 - Single Vision lenses
- V2200-V2299 - Bifocal

ICD-10-CM - International Classification of Diseases, 10th revision

- are a classification of diagnosis and procedure codes used in healthcare.
- H52.13 - Myopia Bilateral
- H52.11 - Myopia, right eye
- H52.12 - Myopia, left eye
- H27.03 - Aphakia in both eyes

Good Luck on the NCLE
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