COVID-19 Response: Safety for ROP Screening in the Neonatal Intensive Care Unit

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Understanding what we know about COVID-19

COVID-19 was officially named by the World Health Organization (WHO) on February 11, 2020. The abbreviation COVID-19 is noted to mean CO for 'corona', VI for 'virus', D for 'disease' and the year 2019. The new, or novel, coronavirus is a new disease that had not been seen in humans until recently. COVID-19 is believed to spread in ways similar to the common cold – such as through coughs, sneezes, or handshakes. A person who has caught the virus may not show symptoms for between 5-14 days. This is called the incubation period. The person can spread the virus during this time.[1]

Although the transmission to a person from surfaces that have been potentially contaminated is still not well documented, there are immediate concerns regarding the need to follow stringent disinfection measures on all surfaces and medical devices. The CDC has raised concern that the virus may live on non-disinfected surfaces for up to 9 days. More studies have shown that the novel coronavirus is likely spread through respiratory droplets. It is possible that by touching an infected surface or persons the virus can then be spread if one touches their own mouth, nose, and eyes.[2]

The first concerns surrounding COVID-19 were reported to WHO December 31 of 2019.[3] These initial findings are thought to be discovered by a practicing ophthalmologist showing concern for an increasing number of patients presenting with pneumonia-like symptoms.[4] Since these initial findings, the coronavirus outbreak has had a significant impact on local and global health and related economies. It also raises concern for Ophthalmology and hospital facilities regarding the future of care as it relates to screening for Retinopathy of Prematurity (ROP).

Understanding what is known about Retinopathy of Prematurity

Retinopathy of prematurity is a disease process that affects babies who are born prematurely. ROP remains a significant threat to vision health, especially in extremely premature and underweight infants. According to the National Eye Institute (NEI) between 14,000 and 16,000 infants in the United States are affected with some degree of ROP each year. Each year, 400 to 600 of those infants will become legally blind from ROP.[5]

There are five stages classified in ROP ranging from mild to severe. Most infants who develop ROP will have mild stages I or II. Those infants who may develop rapidly advancing ROP are at risk for permanent visual loss.[5]

In ROP, abnormal blood vessels can grow and spread through layers of the retina causing scarring or detaching of the retina. ROP may be caused by several complex issues. In the stages of development, the retina will begin to vascularize from the optic nerve out into the periphery. When an infant is born prematurely, before the retina has fully vascularized, normal blood vessel growth will be affected.[5]

The relation between ROP and COVID-19 is still being researched. Studies are currently underway to determine how COVID-19 may affect fetal distress and respiratory distress in preterm infants. Increases in stressors and premature birth may lead to increases in risks for infants developing ROP.[6]

Current workflows in ROP screening management

According to the American Academy of Pediatrics, the current workflow for screening for retinopathy of prematurity is supported with bedside binocular indirect ophthalmoscopy performed by an off-site physician. These exams require physicians who specialize in retinal ophthalmology to enter the NICU to perform exams with scleral depression and a high magnification lens, and then confirm ocular findings with a hand drawn image. Currently the AAP has acknowledged the need for support of telemedicine programs, and has suggested workflow options to create a successful imaging and telemedicine program.[7]

As we see the COVID-19 pandemic develop, it is likely hospital facilities will implement procedural changes related to how off-site contract physicians access the premises and patient care areas. Telemedicine for the evaluation of retinopathy of prematurity allows for the off-site ophthalmologist to appropriately and safely diagnose and follow ROP screening, avoiding repeated exposure in the NICU environment. Studies have been performed to support discussions surrounding the accuracy of telemedicine and reading images for the diagnosis and monitoring of ROP. These studies have found a sensitivity of

100% and specificity of 97% when detecting the diagnosis of pre-threshold or worse ROP. Some studies have even found that ultra-wide field imaging can capture photo documentation of mild ROP in cases ophthalmoscopy may have missed.[8]

The role of ultra-wide field imaging to improve patient care especially in times of pandemic and disease control

Ultra-wide field imaging (RetCam® 3, RetCam Shuttle, or RetCam Portable; Natus Medical Incorporated, Pleasanton, CA) facilities in creating a permanent, still or video, digital image of the retina, cornea and/or external structures of the eye. The original images cannot be altered. A digital image is not subject to the predictable inaccuracies associated with the current practice of viewing a structure and subsequently making hand written notes and/or paper sketches or drawings, in an attempt to record what was seen.[9]

Digital images are readily available for direct comparisons over time. As the images are captured at various intervals, they can be displayed side-by-side on a screen, allowing the physician to track the progress of disease and determine the need for any intervention. These permanent images can become a part of the patient's medical record.[9]

Telemedicine and ultra-wide field imaging can help hospitals and NICU's facilitate well-coordinated ROP programs and limit not only outside exposure to infants and parents but also NICU staff, physicians, and patients throughout the hospital. These solutions provide continuity of care and offer a high level of expertise to each child evaluated.

Along with protection provided to hospital staff and patients, these telemedicine solutions protect off-site physicians from having to enter a hospital facility. While ophthalmologists may have heavy clinic flows in their practices, the addition of remote viewing allows them to review images quickly and in the comfort of their office. Ultra-wide field imaging allows for closer scrutiny of diagnosis and treatment along with the ability to request second opinions when needed.

Understanding the importance of device reprocessing to minimize possible exposure

It is important to understand the importance of disinfection and reprocessing of reusable medical devices. With the onset of COVID-19, and the potential for future exposure to these viruses, the need for medical devices with thorough reprocessing instructions will be an immediate requirement for hospital facilities all over the world.

According to the Food and Drug Administration (FDA), when reusable medical devices are put into service on patients, the devices can become soiled and contaminated with microorganisms. To minimize the risk of spreading infection by a contaminated device, any reusable medical device must undergo what is known as reprocessing. The FDA defines reprocessing as "a detailed, multistep process to clean and then disinfect or sterilize" medical devices.[10]

As related to the COVID-19 response, the risks involved with exposure are directly related to the transmission of the virus through respiratory droplets that can be spread from person or surface to another. This is a direct concern in the instance of Retinopathy of Prematurity exams that involve touching areas around the eyes and also the nose and mouth of small infants who may potentially have compromised immune systems.

Both the FDA and many medical device manufacturers can agree that adequate reprocessing of reusable medical devices is vital to protecting patient safety. Taking steps to review and advance current reprocessing protocols will help protect patients in the immediate need and in the future.[10]

The role of reprocessing in screening for Retinopathy of Prematurity

When considering the need for reprocessing as it relates to screening for Retinopathy of Prematurity it is important to understand the medical instruments and medical devices that are used.

Lid Speculums: a lid speculum is a medical instrument used that is used to retract the eye lids. In the case of ROP screening, a speculum is used to hold the lids open during the examination of the retina. Speculums are typically made of stainless steel and should be autoclaved. Once lid speculums are properly sterilized, they should be packaged for single patient use. Disposable lid speculum packages should be checked for any damage and only used for a single patient. Care should be taken to review all medical safety data information regarding proper sterilization as directed by the manufacturer and hospital guidelines.

Scleral Depressors: a scleral depressor is a medical instrument used between the globe and the orbit that displaces the retina inward. For ROP screening, a scleral depressor is used to create an elevation by pushing the retina inward during examination allowing physicians to see into the far periphery. Scleral depressors are typically made of stainless steel and should be autoclaved. Once scleral depressors are properly sterilized they should be packaged for single patient use. Disposable scleral depressor packages should be checked for any damage and only used for a single patient. Care should be taken to review all medical safety data information regarding proper sterilization as directed by the manufacturer and hospital guidelines.

Ultra-Wide Field Retinal Imaging Devices: a retinal imaging device is a medical device for photo documentation of the retina and other ocular structures. For ROP screening, a retinal imaging device is used to examine the retina and allows the ophthalmologist to review the documented photos remotely. In the case of the RetCam devices (RetCam 3, RetCam Shuttle, or RetCam Portable; Natus Medical Incorporated, Pleasanton, CA) the detachable lens tip is made of stainless steel and should be disinfected following the up-to-date guidelines. Disinfection of the lens piece should be completed between each patient. The detachable lenses on the RetCam device allow a rotation in lenses for reprocessing. Care should be taken to review all medical safety data information regarding proper disinfection as directed by the device manufacturer and hospital guidelines.

The future of Retinopathy of Prematurity care

With the onset of COVID-19 the world has begun to assess the impacts on the healthcare industry. Changes will be implemented worldwide to provide the best possible care while protecting the health of staff and patients. New policies will go into place not only to address the adherence of best internal practices from an infection control standpoint, but also to minimize exposure from outside contact.

As we look over the current processes for screening for Retinopathy of Prematurity, the future may hold a greater, if not complete, telemedicine led program. With the addition of a RetCam ultra-wide field retinal imaging device, hospitals have the ability to create permanent, still, or video digital images of the retina, cornea and external structures of the eye. The original images cannot be altered. A digital image is not subject to the predictable inaccuracies associated with the current practice of viewing a structure and subsequently making handwritten notes and/or hand drawn sketches/drawings in an attempt to record what was observed.

Digital images are readily available for direct comparisons over time. As the images are captured at various intervals, they can be displayed side-by-side on a screen, allowing the physician to track the progress of disease and determine the need for any intervention. These permanent images can become a part of the patient's medical record.

The placement of an ultra-wide field imaging device can eliminate the transmission of disease or bacteria from an exposed off-site ophthalmologist to the NICU patients and staff. This option also decreases the exposure risks for those ophthalmologists who may be entering hospital facilities frequently. RetCam systems allow for disinfection of detachable lenses in an effort to minimize exposure risks and slowdowns in workflow. One lens can be set aside for controlled reprocessing, while the previously disinfected lens is put to use.

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