COVID-19: ensuring safety in endoscopy

Devices such as flexible endoscopes can be used for treatment and management of COVID-19 patients. Although endoscopies remain safe and provide clinicians with a significant diagnostic and therapeutic utility, they may present a potential risk of infection. To prevent such infections, products and processes have been made available to protect patient safety. **Professor Didier Lepelletier, Paul Caesar** and **Dr. Daniel Vinteler** provide an insight.

Professor Lepelletier, Centre Hospitalier Universitaire de Nantes, points out that healthcare professionals are at increased risk of infection by COVID-19 from inhalation of airborne droplets, conjunctival contact, and faeces contamination. The virus has been found to live in patient stool and angiotensin-converting enzyme II (ACE2), the receptor used by the virus to enter human cells, is widely expressed in the intestinal tract. Healthcare workers may transmit the infection to their patients as hospital-based epidemics have been reported. The virus seems to be transmitted mainly via small respiratory droplets through sneezing, coughing or when people interact with each other for some time in close proximity.[1] The droplets can then be inhaled, or they can land on surfaces that others may come into contact with. Individuals can then become infected when they touch their nose, mouth or eyes.

The virus can survive on different surfaces such as copper and cardboard for several hours, and plastic and stainless steel for up to a few days.[2] However, the amount of viable virus declines over time and may not always be present in sufficient number to cause infection.[3,4]

Transmission by surfaces can occur between healthcare workers and patients during endoscopy activity if the environment is contaminated and undisinfected. Enveloped viruses such as COVID-19 can easily be inactivated by commonly used disinfectants. The coronavirus can remain infectious on inanimate surfaces for up to 9 days. Surface disinfection with 0.1% sodium hypochlorite or 62 to 71% ethanol significantly reduces coronavirus infectivity on surfaces. Due to these concerns, when endoscopes have been used, they should be considered at risk of contamination.[5]

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Endoscopy departments must implement additional hygiene procedures

Consequences of contaminated endoscopes

The use of endoscopes for diagnosis and/or intubation of patients suggests the importance of endoscopes' function to patient health. Yet in a study by Bang JY, *et al*, "22% of the 'ready for patient use' duodenoscopes were found contaminated."[6] Concerns for patient health stem from carbapenem-resistant Enterobacteriaceae (CRE) and other infections, which may also be linked to improper cleaning and/or disinfection of endoscopes. In 2018, the Erasmus University indicated: "Increasing numbers of outbreaks caused by contaminated duodenoscopes used for Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures have been reported, some with fatal outcomes."[7] This research indicates that it can be difficult to properly reprocess endoscopes. However, what has yet to be demonstrated are the solutions available to ensure patient safety using reusable endoscopes. Due to the important function of these devices, an emphasis on improved products and processes is crucial to reducing the risk of infection. Establishing greater measures and solutions to prevent contamination of endoscopes may help prevent fatal outcomes.

While the concern of contaminated endoscopes has been apparent for years, additional challenges related to the COVID-19 virus, present an even greater risk of life-threatening infections. All endoscopes ▶

used on COVID-19 patients, or suspected COVID-19 patients, should be considered high risk. The main endoscopic challenge is minimising the risk of contamination from procedure to procedure. Endoscopy departments must now implement additional hygiene procedures while treating patients affected by COVID-19, for diseases not related to the SARS-COV2 outbreak. To ensure patient safety, proper processes must be in place to minimise the risk of cross contamination.

The importance of drying in reprocessing

Research shows that to create and maintain an endoscope's disinfected status, complete drying is an absolute necessity.[8] Dr. Kovaleva, MD, PhD, clinical microbiologist and clinical pathologist, department of laboratory medicine, AZ Rivierenland, points out that during an endoscopy, the environment provides optimal conditions for contamination and subsequent growth of biofilms. Biofilms are communities of microorganisms within extracellular polymeric material attached to different surfaces, including human tissues, medical devices, water supply systems, or endoscope channels. Development of a biofilm in endoscopes is probably associated with residual moisture in endoscope channels. This likely originates from water sources (endoscope washers disinfectors and insufficient dried endoscope channels) containing waterborne microorganisms.

Microorganisms in biofilms are very resistant to antimicrobial agents, allowing pathogens to survive under conditions of drying and chemical exposure. The ability for pathogens to survive these treatments,

makes the importance of drying all the more critical. Drying the endoscope is important to the prevention of pathogen transmission and nosocomial infection. Flexible endoscopes should be dried after completion of the cleaning and disinfection process. If the endoscope is not to be reused immediately and is to be stored, the endoscope channels and outer surfaces should be dried thoroughly, in order to avoid exponential microbial growth of possible remaining bacteria.

It is crucial to remember that drying and storage, in endoscopy reprocessing, are just as important for preventing against infection as cleaning and high-level disinfection. Accurate drying greatly reduces bacterial contamination of stored endoscopes. When we discuss storage, an automated cabinet is advantageous for rapid drying of endoscope channels and in reducing the risk of microbial growth during storage.

Solutions to preventing contaminated endoscopes

Appropriate endoscope reprocessing is an essential part of patient safety and quality assurance in endoscopy. Dr. Vinteler, CEO and founder of PlasmaBiotics, reiterates that appropriate drying and storage are just as important during endoscope reprocessing, as pre-cleaning, manual cleaning and disinfection. Failure of drying can result in growth of biofilms inside endoscope channels during storage, an important factor in the pathogenesis of endoscopy-related infections. Currently, some drying solutions include using storage cabinets in which the drying time can vary between 30-90 minutes, or even more depending on the manufacturer's instruction-for-use (MIFU) and the endoscope type. The problem with a longer drying time means a possible delay in endoscope availability. For this reason, certain countries, such the UK or the Netherlands, still allow endoscopes to be used without drying after reprocessing, if they are intended to be used within three or four hours (respectively) after reprocessing. However, this can be a risk for proliferation if microorganisms and recontamination remain on the endoscope.[9]

As insufficient drying can be a source of microbial contamination and the transmission of infectious material, the PlasmaTyphoon is designed to reduce the risk of infection by optimising the drying of the scopes using plasma. The drying process is managed by a patented curve of pressure and temperature. The unit uses a laminar flow to eliminate the water from the endoscope channels followed by a turbulent heated flow to dry the walls.

The solution is designed to a dry endoscope in one to five[11] minutes (the drying time depends on the endoscope type), and storage up to 31 days[12] in a fully controlled environment.[13] A perfectly dried scope after reprocessing avoids exponential growth of pathogens that can lead to

endoscopy-related infections.

Dr. Vinteler explains that after the completion of the drying process, a single-use PlasmaBag is utilised. Plasma, containing ozone molecules, is insufflated into the bag ensuring the dry and disinfected state of the endoscope is maintained due to the biocidal effect of the ozone. It allows safe endoscope transportation while reducing the need for repeated reprocessing. This stores the endoscopes in a closed environment – dry, free of dust and pathogens – in a disinfected state, for 31 days.[14,15] This solution allows for time and space to be saved, improved mobility of the scopes while they are stored in the bag, as well as an improved level of hygiene.

High risk endoscopies: how effective drying and storage systems assist ICUs

Professor Lepelletier warns that, as the transmission of the coronavirus presents an additional risk to patient safety, endoscopic units must enforce greater measures to prevent infections. Drying of endoscopes can be achieved in different ways, but most are time consuming. A new technique that dries endoscopes in an ultra-fast way is crucial to having the endoscope return more quickly to the emergency room or ICU. As clinicians need more scopes to support increased demand, caused by COVID-19 infections, they require greater assurance that the products they have readily available remain safe. By using the PlasmaTyphoon, drying and storage system hospitals can ensure a closed environment for the scope during transportation and easy transportation between hospital rooms and buildings is important to keeping up with high demand. [16]

In addition, the ozone has the ability to reduce the potential remaining bacteria inside the working channel by 99.9%, which gives confidence that the instrument is perfectly disinfected.[16]

New solutions:

Paul Caesar, reprocessing and infection control leader at Pentax Medical, points out that improving outcomes requires several approaches to avoid contamination of endoscopes. Concerns for patient health remain crucial as a result of increasing incidences of carbapenem-resistant Enterobacteriaceae and other infections, which may also be linked to improper cleaning and/or disinfection of a duodenoscope's elevator mechanism. Technical solutions can contribute to the development of a safer device. Reducing parts of the endoscope, thus making it easier for staff to clean, improves the safety of the endoscope for the next patient. The need to reduce the risk of infection transmission has led to the development of a single-patient use, sterile, disposable elevator cap (Dec). With this solution, there is also greater reprocessing efficiency, a 35% reduction in distal end reprocessing due to better access for cleaning and disinfection, as well as offering the benefit of disposability of the elevator.

He adds that complying to all defined steps in reprocessing guidelines is essential. Periodic technical checks of the endoscope should be provided to have confidence in the quality of the endoscope. Additionally, regular checks on reprocessing outcomes should be performed, such as quick tests, for example protein residue check, or ATP, completed with periodic microbial sampling.

In conclusion, at a time in which COVID-19 presents an additional infectious risk, we must seek to innovate new ways to better protect patients and medical professionals from life-threating infections. Although endoscopies remain safe and provide guided intubation for treatment and airway management of COVID-19 patients, they can be a potential risk of infection. At a time in which we are experiencing a global health pandemic, it is crucial to support hospitals and ICUs facing challenges resulting in risk of infection and fatal outcomes. When products and solutions are in place to prevent infection, 22% of the 'ready for patient use' duodenoscopes found contaminated is too great a statistic. In addition ▶

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to barrier measures (i.e. hand, hygiene, wearing of mask, environment cleaning, etc.), we must focus on crucial reprocessing steps such as drying and storage, and use solutions that reduce the risk of infection. CSJ

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Daniel Vinteler

Daniel Vinteler received his Ph.D. degree in Mechanical Engineering from Université Pierre et Marie Curie at Paris where he performed research in aerodynamics. After working for more than 20 years in a high tech environment (aerospace industry and computational fluid dynamics) Daniel created PlasmaBiotics company located close to Paris. Daniel has served as the president and CEO of the company since its inception, in March 2011, leading the development and validation of PlasmaBiotics products. In July 2018, Hoya-Pentax Medical acquired PlasmaBiotics.

Didier Lepelletier

Didier Lepelletier is a lecturer-researcher at the University of Nantes. Didier is the head of the department of bacteriology-virology and hospital hygiene, he teaches at the Faculty of Medicine about hospital hygiene and the epidemiology of transmissible infectious diseases. Didier is also the vice president of the Specialized Commission on Health Systems and Patient Safety at the Ministry of Health.

Paul Caesar

Paul J Caesar has more than 25 years' experience in hygiene and infection control, especially in medical devices and reprocessing flexible endoscopes. He has published articles on endoscope reprocessing, hand hygiene and other items on infection control, and presented on those issues at many international conferences.
He also has developed teaching programmes on hygiene and infection control, reprocessing endoscopes and cleaning, disinfection and sterilisation of medical devices.
From 2015 – 2019 he was chair of a Dutch Expert Group for reprocessing flexible endoscopes. In 2020, he started working as reprocessing and infection control leader EMEA at Pentax Medical Europe.