Quality Resource Guide

Infection Control and OSHA Update Part One

Author Acknowledgements

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Educational Objectives

Following this unit of instruction, the practitioner should be able to:

1. Understand the rationale for effective infection control precautions.
2. Distinguish between OSHA Bloodborne Pathogens regulations and recommended isolation (*i.e.*, transmission-based), universal and standard precautions.
3. Comprehend recommended transmission-based precautions associated with controlling aerosols and airborne pathogens.
4. Discuss the most current healthcare professional vaccination recommendations for hepatitis B and SARS-CoV-2 infection (COVID-19).
5. Describe biofilm accumulation and infection control challenges in dental devices that use water.
6. Utilize strategies that can minimize dental water contamination and reduce potential risks.

MetLife designates this activity for **2.0 continuing education credits** for the review of this Quality Resource Guide and successful completion of the post test.

Originally published July 2009. Updated and revised October 2012, October 2015 and October 2018, December 2021 and December 2024. Expiration date: December 2027.

The content of this Guide is subject to change as new scientific information becomes available.

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Introduction - Infectious Diseases and the Health Care Worker

The history of infection control in healthcare settings has been marked by steady progress highlighted by extraordinary individual achievements. The implementation of an extensive array of appropriate practices, procedures, and devices initially required recognition of infectious disease risks as well as determined cooperation by numerous professional groups. This approach led to the development and refinement of principles, procedures, and products to meet the increasingly complex demands of patient care. This created a safer environment for both patients and healthcare workers (**HCWs**). The routine application of effective infection control strategies continues to require both a major commitment by medical and dental care providers, along with a willingness to respond to emerging biomedical information.

As a result of an investigation describing the discovery of an *Australia antigen*[1] and subsequent reports of infections in medical[2,3] and dental settings,[4-6] infection control practices were developed in the 1970s[7,8] to limit the potential transmission of bloodborne pathogens in clinical settings. The primary target of those precautions was hepatitis B virus (HBV). This viral pathogen remains the most infectious bloodborne microbial risk for HCWs. Even though HBV was documented as the major occupational microbial challenge for dentistry, widespread implementation of infection control principles and procedures did not become integrated into many dental practices until after the emergence and recognition of the acquired immunodeficiency syndrome (AIDS) pandemic in the early 1980s. The protocols recommended for minimizing HBV infection were subsequently applied to both human immunodeficiency virus (HIV), the etiologic agent of AIDS, and more recently, hepatitis C virus (HCV). While initial infection control recommendations were published by the American Dental Association (ADA) in 19788, it was the impact of HBV and HIV infections in the 1980s that forever changed the way dentistry is practiced. The recognition that many persons infected with HIV, HBV, and other microbial pathogens showed neither symptoms for extended periods nor gave positive histories of prior infection led the Centers for Disease Control and Prevention (CDC) to recommend the practice of treating all patients as though they are infected with HBV or HIV. This approach to patient care was termed “universal precautions.” The terminology was later expanded and modified to “standard precautions”.

Table 1 - OSHA Regulations vs. CDC Recommendations

OSHA	CDC
• Regulatory agency • Set and enforce standards • Investigates and inspects • Blood-borne Pathogen Standards • Employee protection	• Non-regulatory agency • Science- and Evidence-based Guidelines/ Recommendations • Morbidity and Mortality Weekly Report Recommendations and Reports • Often enforced by state

Although the rationale for infection control remains the same, the information contained in infection control practices and protocols is not static and must be modified in response to challenges presented by new microbial diseases. In 2020, the world was forever changed and required to face a new normal with the deadly emergence of SARS-CoV-2 virus and the COVID-19 pandemic. Delivery of health care in all medical and dental facilities was significantly impacted. The following two-part discussion will provide an update on recently instituted infection prevention precautions for dentistry, as well as consideration of long standing, representative components of a practical dental infection control program.

Guidelines and Regulations

It is important to recognize that the Occupational Safety and Health Administration (OSHA) and the Center for Disease Control and Prevention (CDC) are two completely different governmental agencies with different mandates (**Table 1**). The CDC develops guidelines designed to protect both patients and HCWs, while OSHA regulations apply only to the latter. Guidelines published by the CDC and other advisory agencies do not carry the weight of law possessed by a regulatory agency such as OSHA. OSHA has the authority to require and enforce compliance with recommended infection control practices and procedures. OSHA relies upon appropriate authorities, including the CDC, to provide background information when they formulate their standards. It is important that dental providers be aware of updates or changes to recommended infection control practices to provide the safest environment possible for their patients and employees, as well as to remain in compliance with OSHA regulations.

Governmental regulations from federal agencies such as OSHA, state, and local health departments require HCWs to be trained in appropriate infection control practices and other safety precautions. They also require the application of these measures during patient care to reduce potential risks of disease transmission to the patient and HCWs. The development of a specific set of OSHA regulations to protect HCWs from occupational risks associated with bloodborne disease transmission began in the 1980’s when unions representing HCWs petitioned OSHA to require employers to have a workplace free from recognized harm. More specifically, unions wanted employers to protect employees from occupational HBV infection. After a series of public hearings, OSHA published the Bloodborne Pathogens Standard.[9] These regulations were based on CDC universal precautions recommendations and were enacted in early 1992.[10] The OSHA standard imposed obligations on employers to provide safe and healthful work environments for all HCWs. Requirements included work practice controls, engineering controls, personal protective equipment, and administrative controls. In the dental setting, these controls can be described as:

1. work practice controls relating to how a task is performed and advising the use of safer work practices designed to minimize the risk of disease transmission.

2. engineering controls that are technology-based (refer to items or instruments that isolate a hazard, such as a sharps disposal container).

3. personal protective equipment (PPE) including the use of gloves, masks, protective eyewear, and protective clothing to prevent contamination of the HCWs during the delivery of dental care.

4. administrative controls (the policies, procedures, and practices within a dental office that reduce risks associated with bloodborne disease transmission).

Revisions to the Bloodborne Pathogens Standard were mandated in 2001.[11] These revisions clarified the need for employers to consider safer needle devices as they become available and to involve employees directly responsible for patient care (*e.g.,* dentists, hygienists, and dental assistants) in identifying and choosing such devices. Engineering controls are available, which can be used as the primary method to reduce exposure to bloodborne pathogens. These include sharps containers, self-sheathing needles, safety scalpels with retractable blades or covers, as well as safer medical devices, such as sharps with engineered injury protection and needless systems. Dental anesthetic syringes and needles that incorporate safety features have been developed for dental procedures, and their implementation and routine use in dental facilities is increasing. In 2015 OSHA also published revisions to previous regulations related to occupational exposures to tuberculosis in healthcare facilities. This instruction provided information concerning OSHA's general enforcement policy and procedures for conducting inspections and issuing citations related to occupational tuberculosis (TB) hazards.[12]

The rapid spread and impact of the COVID-19 pandemic on all workplaces required OSHA to respond in March 2020 with a series of recommendations in a booklet entitled Guidance on Preparing Workplaces for COVID-19.[13] In addition to providing guidance to protect workers and the public against COVID-19 disease, the dental profession was categorized by OSHA as an overall "Very High Risk" category for COVID-19. This assessment was due to the potential for exposure to known or suspected sources of SARS-COV-2 during specific aerosol-generating procedures (AGPs). In dentistry, AGPs include procedures using high and low speed handpieces, ultrasonic scalers, air/water syringes and air polishing. OSHA further designated risk levels broken down by task. Later OSHA infection control directives and recommendations were published as new science-based evidence became known about this airborne disease. That evidence led to updates and reinforcement of OSHA's "hierarchy of controls" for limiting the spread of COVID-19 (**Table 2**).[14,15] Many of these steps were also incorporated into later CDC recommendations for COVID-19 infection control in dental settings.[16,17]

While much of previous guidelines remained unchanged, there were later substantive modifications aimed at addressing droplet and airborne transmission of SARS-CoV-2 in clinical settings as the epidemiology of COVID-19 infections has evolved.[16,17]

Standard Precautions

Infection control recommendations published since the 1980's have routinely focused on the use of universal precautions (UP). As mentioned earlier, these precautions were designed to prevent the transmission of HBV, HIV, HCV, and other bloodborne pathogens during treatment procedures. While the adoption and routine use of UP proved to be very successful in minimizing the potential for transmission of bloodborne pathogens, these practices did not eliminate the need to address disease-specific isolation precautions for non-bloodborne infections in outpatient settings.

A body substance isolation system (BSI) was proposed in the early 1990s that focused on the reduction of transmission of infectious materials from any moist body substances. The BSI was designed to address isolation procedures of all moist, potentially infectious body substances regardless of their presumed infectious status. The BSI system protocol advocated additional protection for HCWs, including immunization against selected infectious diseases transmitted by airborne or droplet modalities (measles, mumps, rubella, varicella) and the use of appropriate barriers (protective clothing).

Table 2 - Guidance on Mitigating & Preventing the Spread of COVID-19 in Workplace

Identification of combinations of control measures to limit the spread of COVID-19 in the workplace, in line with principles of hierarchy of controls published by OSHA in 2020:

a. eliminating the hazard by separating and sending home infected or potentially infected people from the workplace;
b. implementing physical distancing in all communal work areas (includes remote work and telework);
c. installing barriers where physical distancing cannot be maintained;
d. suppressing the spread of the hazard using face coverings;
e. improving ventilation;
f. using applicable personal protective equipment (PPE) to protect workers from exposure;
g. providing the supplies necessary for good hygiene practices; and
h. performing routine cleaning and disinfection.[18]

The CDC developed and published new guidelines for isolation precautions in hospitals in 1996[19,20] to prevent any potential infectious problems that might arise due to the confusion between BSI and UP. These guidelines incorporated the major features of UP and BSI. Since that time, the use of Standard Precautions has replaced the use of both of its individual components. Standard Precautions apply to contact with blood, body fluids, secretions, and excretions (except sweat). Standard precautions should be used in the care of all patients. Included is a second tier of precautions called Transmission-Based Precautions designed for the care of specified patients. There are three types of Transmission-Based Precautions: Contact, Droplet, and Airborne Precautions (**Table 3**). These additional precautions are needed in medical and dental settings to interrupt transmission of highly transmissible or epidemiologically important pathogens (*e.g.,* tuberculosis, influenza, COVID-19, measles, and chicken pox).

Comprehensive dental infection control guidelines were published by the CDC in 2003.[21] In addition to updating the conceptual terminology from "universal" to "standard" precautions, this document contained updated knowledge pertaining to occupational infectious disease and epidemiology, available dental devices, and science-based infection control guidelines. The rationale for the published recommendations was more detailed than in previous documents and included the components of the standard precautions noted above. A CDC update was published in 2016 based on the application of Standard Precautions during patient care. This document served as a supplement to the 2003 recommendation by providing checklists pertaining to specific infection control areas and updated references. These features were included to assist dental professionals in evaluating compliance with the CDC's science-and clinical-based recommendations.[22] As mentioned above, the CDC has also continued to update guidance and publish infection control recommendations to protect healthcare workers and patients against COVID-19 and other airborne infectious diseases.[23]

Table 3 - Transmission-based Precautions for Healthcare Facilities

Contact Precautions - for patients with known or suspected infections, diseases, or micro-organisms that are spread by touching the patient or items in the room (MRSA, VRE, diarrheal illnesses, open wounds, RSV).

Droplet Precautions - to prevent diseases that are spread in large respiratory droplets caused by coughing, sneezing, and talking (pneumonia, influenza, whooping cough, bacterial meningitis).

Airborne Precautions - to prevent transmission of infectious microorganisms that remain suspended in air and travel great distances due to their small size (<5 μ) and spreading through air from one person to another (tuberculosis, measles, chickenpox, COVID-19)

Patient Screening and Evaluations

The basic premise of Standard Precautions relates to the fact that a medical history does not identify all infectious patients, and thus, should not be used to identify the "infectious disease risk" of the patient. The patient may not know their infectious status or be willing to disclose pertinent infection information in their medical history. Also, many infectious patients do not manifest classical symptoms. Therefore, Standard Precautions as defined by the CDC must be used in providing dental care for all patients.

Aseptic Procedures

Asepsis is a fundamental principle that runs through all aspects of infection control practices. Aseptic technique refers to the use of procedures that break the cycle of infection and, ideally, eliminate cross-contamination. At the heart of this principle is the requirement for cleaning. The fundamental infection control principle for all health care professionals is to "clean it first." Appropriate cleaning both reduces the number of contaminating microorganisms and assists in keeping work areas clean. HCWs are constantly reminded to: 1) wash their hands routinely before and after patient care; 2) clean instruments before employing sterilization procedures; 3) clean surfaces before applying disinfectants; 4) clean dentures before spraying them with or immersing them in chemical agents; and 5) clean and maintain dental waterlines according to public health standards.

Hand Hygiene

Hand hygiene (formerly termed "hand washing") (**Table 4**) is the single most important infection control procedure dental professionals perform to reduce the potential for the development of nosocomial (healthcare-associated) infections. Its major purpose is the mechanical removal of transient microorganisms from the skin, thereby minimizing cross-contamination and cross-infection. A non-antimicrobial liquid soap can be used for non-surgical procedures in these instances. Its primary goal is to clean the hands. In addition, hand hygiene antiseptics containing antimicrobial agents are frequently used to augment mechanical cleaning. The most frequently used antimicrobial agents include chlorhexidine gluconate, para-chlorometaxylenol (PCMX), and iodophors. Many can provide substantivity (*i.e.*, a residual antimicrobial effect) following hand wash procedures.[24,25] The CDC expanded its recommendations in 2002 to include alcohol-based hand rubs (preparations containing 60-85% alcohol), both as an option for routine hand hygiene and also for when soap and water aren't available.[26] Accumulated evidence has demonstrated that alcohol-based hand rubs can: 1) significantly reduce the number of microorganisms on skin; 2) are fast acting; 3) cause less skin irritation due to the inclusion of emollients (*i.e.,* glycerin, aloe vera, vitamin E) in the preparations; and 4) are associated with improved hand hygiene compliance. Both types of mechanical debridement agents (*i.e.,* liquid soaps and antimicrobial antiseptics), as well as alcohol-based hand rubs provide appropriate hand hygiene choices for HCWs. However, positive and negative features of each should be considered before use (**Table 5**).[27]

Table 4 - Hand Hygiene Overview Agents and Procedures

Method	Definition/Agent(s)	Purpose	Area	Duration (minimum)
Routine Handwash	Water and non-antimicrobial detergent (*e.g.*, plain soap)*	Remove soil and transient micro-organisms	Fingertips to the wrist	15 seconds†
Routine Hand Antisepsis Antiseptic Handwash	Water and antimicrobial agent/detergent (*e.g.*, chlorhexidine, iodine and iodophors, chloroxylenol [PCMX], triclosan)	Remove or destroy transient micro-organisms and reduce resident flora	Fingertips to the wrist at a minimum	15 seconds†
Antiseptic Hand Rub	Alcohol-based hand rub§			Rub hands until the agent is dry
Surgical Hand Antisepsis	Water and antimicrobial agent/detergent (*e.g.*, chlorhexidine, iodine and iodophors, chloroxylenol [PCMX], triclosan)	Remove or destroy transient microorganisms and reduce resident flora (persistent effect)	Hands and forearms¶	2-6 minutes
	Water and non-antimicrobial detergent (*e.g.*, plain soap*) followed by an alcohol-based surgical hand-scrub product with persistent activity			Follow manufacturer instructions for alcohol-based surgical hand-scrub product with persistent activity**

From: CDC Guidelines for infection control in dental health-care settings, 2003. MMWR 2003; 52 (No. RR-17):1-66.

Pathogenic organisms have been found on or around bar soap during and after use. Use of liquid soap with hands-free dispensing controls is preferable.

† For most procedures, a vigorous, brief (at least 15 seconds) rubbing together of all surfaces of premoistened lathered hands and fingers followed by rinsing under a stream of cool or tepid water is recommended. Hands should always be dried thoroughly before donning gloves.

§ Preparations containing 60-95% alcohol. Alcohol-based hand rubs should not be used in the presence of visible soil or organic material. If using an alcohol-based hand rub, apply adequate amount to palm of one hand and rub hands together, covering all surfaces of the hands and fingers, until hands are dry. Follow manufacturer's recommendations regarding the volume of product to use. If hands feel dry after rubbing hands together for 10-15 seconds, an insufficient volume of product likely was applied.

¶ Removal of all jewelry, vigorous rubbing together of all surfaces of premoistened lathered hands and forearms.

** Before applying the alcohol solution, pre-wash hands and forearms with water and a non-antimicrobial soap and dry arms and forearms completely. After application of the alcohol-based product as recommended, allow hands and forearms to dry thoroughly and immediately don sterile gloves.

Table 5 - Pros and Cons of Handwashing vs. Alcohol-Based (Antiseptic) Hand Rubs

Technique	Pros (+)	Cons (-)
Handwashing	+ Can use plain or antimicrobial soaps + Effective antimicrobial activity with antimicrobial soaps + Effectiveness only minimally affected by organic matter + Sinks readily available and accessible in most dental settings + Familiar technique + Allergic reactions to antimicrobial active ingredients are rare + Irritation dermatitis related to handwashing may be solved by relatively simple techniques/changes	- Frequent handwashing may cause skin dryness, chapping and irritation - Compliance with recommended handwashing protocol is traditionally low - Takes more time than antiseptic hand rubs - Requires sink and water and paper towels or air dryers - Personal habits and preferred products such as hand lotions may undermine professional training - Strong fragrances and other ingredients may be poorly tolerated by sensitive people - Water alone may be a skin irritant - Time and technique are critical
Alcohol-Based (Antiseptic) Hand Rub	+ Provides more effective antiseptic action on visibly clean hands than handwashing with plain or antimicrobial soaps + Faster protocol than handwashing + Reduced skin irritation and dryness compared to handwashing + May be used in absence of sinks and water, and during boil-water notices + Allergic reactions to alcohol or additives are rare + Reduces use of paper towels, waste	- Not indicated for use when hands are visibly dirty or contaminated - Dispensing proper amount is critical - Hands must be dry before agent is applied - Frequent use may cause skin dryness or irritation if product lacks effective emollients/skin conditioners - Agent may temporarily sting compromised skin - Strong fragrances and other ingredients may be poorly tolerated by sensitive people - Alcohol products are flammable – should be stored away from flames - Residual powder may interfere with effectiveness or comfort of antiseptic rub - Handwashing stations must still be accessible for times where waterless sanitizers are inappropriate

Even with the availability of multiple water-based and waterless preparations, there are several important areas HCWs should consider when selecting and using products (**Table 6**):

Table 6 - Hand Hygiene Considerations

- Consider skin sensitivities and allergies of personnel
- The initial procedure at the beginning of the day should include a thorough hand wash.
- Use appropriate handwashing and rinsing techniques, with particular attention to thumbs and fingertips.
- Subsequent hand hygiene procedures should last approximately 15 seconds or the time recommended for the specific preparation.
- Do not wear jewelry or long nails.
- Clean thoroughly under nails.
- When washing hands, rinse with cool or tepid water and dry completely before donning gloves.
- Keep epithelial integrity intact.

Skin Irritation and Dermatitis

Healthcare professionals perform many hand hygiene procedures daily by washing with soaps, antimicrobial antiseptic preparations, or using waterless, alcohol-based hand rubs and sprays. However, if proper care is not taken, hands can become dry over time, even when using mild liquid soap, eventually causing non-specific irritation dermatitis. This damage to healthy skin is among the most frequent problems reported by HCWs. The condition occurs because the physical act of hand washing can remove surface lipids, fatty acids, and other skin components that lubricate epithelium. This can result in the development of dry, abraded skin. Since most HCWs commonly perform 30–40 hand hygiene procedures a day, soaps and antimicrobial hand wash agents can dry and damage the skin when used on a regular basis. Symptoms of irritation dermatitis usually develop gradually (over days to weeks) and are localized. The discomfort, bleeding, and pain from the irritated hand surfaces can cause affected HCWs to compromise their normal hand hygiene practices. While frequent use of hand hygiene agents has been associated with irritant dermatitis among HCWs, other factors can contribute to its onset and progression (**Figure 1**). The use of many types of soaps and antiseptics is also associated with irritation dermatitis among those HCWs who have a history of skin problems. Keratinized epithelium can become red and sore from acute inflammation. This leads to more drying, even cracking and bleeding. Many of these adverse manifestations stop at the boundary of the glove cuff with the skin. In addition to frequent washing and use of harsh chemicals, dermal reactions can result from: 1) not completely rinsing antiseptics off skin after washing; 2) irritation from cornstarch powder in gloves; 3) excessive perspiration while wearing gloves; 4) improper washing techniques; 5) using hot water for handwashing; and 6) failure to dry hands completely. (**Figure 1**).

Individuals should take steps to allow re-establishment of epithelial integrity in areas of damaged skin by ceasing to use antiseptics that remove skin oils and replacing them with a non-antiseptic, mechanical cleansing agent, such as liquid soap and water. Water-based lotions are often recommended to ease the dryness from frequent hand washing and prevent dermatitis from glove use. Unfortunately, petroleum-based lotion formulations used by many people outside of healthcare settings can weaken latex and other glove types, which can cause increased material permeability. For that reason, lotions that contain petroleum or other oil emollients should not be used. Instead, multiple water-based lotions are available, which are absorbed rapidly into tissues and can potentiate healing.[28,29]

In summary, the keys to preventing hand dermatitis are understanding how it develops and knowing the factors that can contribute to its progression. In addition, damage to the epithelium can cause changes in the presence of the skin microflora. This can lead to colonization by "transient" organisms, which typically have a greater potential for causing harmful infections. Methicillin–resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa represent two medically important examples of this type of acquired pathogen. Preventive actions HCWs can take to protect themselves include the following:

1. HCWs suffering from nonspecific dermatitis can use a mild, nonantimicrobial soap to wash hands. The basic principle is to clean hands, and this can be accomplished without using antimicrobial antiseptics, which can cause further drying.

2. Cool or tepid water should be used for routine hand washing procedures. Hot water can leave epithelial pores open and accelerate leaching of skin oils and lipids. All water-based soaps and antimicrobial antiseptics should be rinsed off completely before drying hands. This is especially applicable for those HCWs with any degree of dermatitis. Damaged epithelium tends to cause soaps to adhere more tightly, thus making it more difficult to remove the agent.

Figure 1

3. The use of waterless, alcohol-based hand rubs containing emollients on unsoiled hands can help increase compliance. Alcohol is a rapidly effective, broad-spectrum antimicrobial on skin, but its denaturing and dehydrating actions on proteins can dry tissues. Emollients in the products counteract those destructive effects by lubricating the skin.

4. Periodic use of water-based lotions can be included in a regimen to further promote skin integrity.

Vaccines

The widespread use of vaccination as a major public health strategy has historically proven to be extremely successful in providing protection against many childhood and adult infectious diseases. The benefits of vaccination were so dramatic in reducing the incidence of previously common infections, such as rubella, rubeola, mumps, polio, and diphtheria — and even eradicating smallpox — that the CDC cited vaccination as one of the 10 major public health achievements of the 20th century.[30] Thanks to widespread vaccination, an increasing percentage of the population has neither experienced nor seen many vaccine-preventable diseases (**Table 7**).

Immunization of HCWs before they are placed at potential risk remains the most efficient and effective use of vaccines in healthcare settings. An earlier perception that HCW vaccination be limited to hepatitis B protection is clearly outdated. A trend of moving away from widespread dependency and use of antimicrobial chemotherapy has also gained momentum since the early 1990s. Current immunization practices are designed to protect the HCW from nosocomial transmission of vaccine-preventable infections such as influenza, COVID-19, measles, mumps, rubella, varicella, pertussis (*i.e.*, whooping cough), and *Streptococcus pneumoniae* pneumonia.[31,32]

With specific regard to the hepatitis B vaccine, employers must provide it at no cost to any employee who may have occupational exposure to bloodborne pathogens, including dentists, dental assistants, dental hygienists, and lab technicians (full-time, part-time, temporary, and probationary employees) within 10 working days of initial assignment. New employees can continue to provide patient care during the period required to complete the vaccination series. The time sequence for receipt of the vaccine has remained the same for the three originally marketed HBV vaccines (*Heptavax-B, Engerix B*, and *Recombivax B*) is zero, one and six months for the three-injection regimen. The most recently approved vaccine, *Heplasav-B*, is administered in two doses separated by one month. Presently, the U.S. Public Health Service guidelines do not recommend booster doses. However, if a booster is recommended in the future, the employer must provide it at no cost to the employee. Documentation of hepatitis B vaccination should be placed in the employee's medical record.

In early 2020, the world was in the midst of the COVID-19 pandemic — the worst infectious disease crisis since the 1918-1919 Influenza (*i.e.*, Spanish flu) pandemic. A major positive scientific response to COVID-19 was an aggressive global effort to develop effective vaccines against the SARS-CoV-2 virus, the etiologic agent for COVID-19. As of this writing, three vaccines have been developed, tested, and approved in the United States[33] (**Figure 2**).

Vaccines typically require years of developmental research and testing before governmental approval for widespread use in the population. Even though the Pfizer-BioNtech, Moderna, and Johnson & Johnson vaccines were approved by the FDA for Emergency Use Authorization (EUA) within a year after the projects began, the companies were still required to adhere to stringent safety and efficacy safeguards at each step in the process. These and other vaccines must meet established recognized CDC and FDA guidelines in multiple developmental stages: exploratory, pre-clinical, clinical, regulatory review and approval, manufacturing, and quality control.[33-34] A graphic summary of the required vaccine approval and safety monitoring steps from the CDC is shown in **Figure 3**.[35]

As mentioned above, every vaccine licensed in the United States must go through the extensive development and testing shown in **Figure 3** before being approved by the CDC Advisory Committee of Immunization Practices and recommended for clinical use.[34] In addition, the Food and Drug closely monitors manufacturing procedures to ensure compliance with established high standards for purity, potency, and safety. The initial phases of vaccine development aim to determine if a

Table 7 - Comparison of 20th Century Annual Morbidity and Current Morbidity Vaccine-Preventable Diseases

Disease	20th Century Annual Morbidity†	2022 Reported Cases††	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	1	>99%
Measles	530,217	122	>99%
Mumps	162,344	323	>99%
Pertussis	200,752	2,388	99%
Polio (paralytic)	16,316	1	>99%
Rubella	47,745	29	>99%
Congenital Rubella Syndrome	152	0	100%
Tetanus	580	24	96%
Haemophilus influenzae	20,000	13*	>99%

† JAMA. 2007;298(18):2155-2163.

†† CDC. National Notifiable Diseases Surveillance System, Weekly Tables of Infectious Disease Data. Atlanta, GA. CDC Division of Health Informatics and Surveillance. Available at: Weekly statistics from the National Notifiable Diseases Surveillance System (NNDSS). (cdc.gov). Data submitted through Dec 31, 2022; accessed on Mar 2, 2023; diphtheria and polio case counts reported by CDC Program.

* *Haemophilus influenzae* type b (Bib) < 5 years of age. An additional 11 cases of Hib are estimated to have occurred among the 242 notifications of *Haemophilus influenzae* (<5 years of age) with unknown serotype.

preparation is effective and safe in animals, and the suggestion that it may also be safe in humans is an additional consideration. Human clinical trials are conducted after these criteria are met. Trials with human volunteers involve three distinct phases:

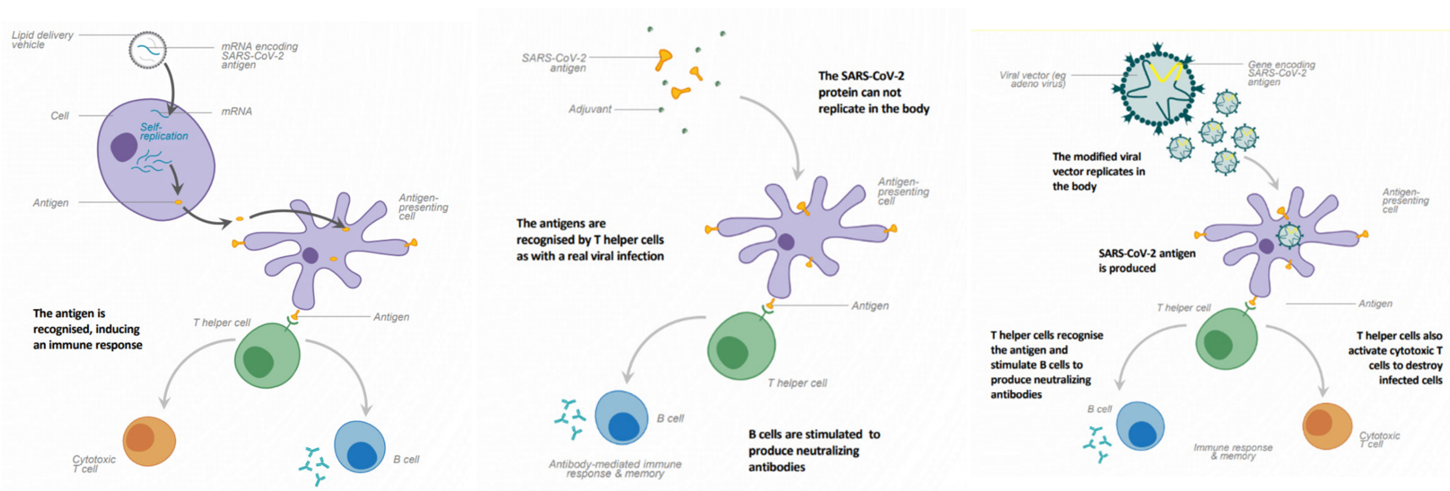
Phase 1: This initial trial involving 20 to 100 healthy people investigates vaccine effectiveness and the effects of vaccine dosage on potential adverse effects.

Phase 2: Encouraging results from Phase 1 lead to studies using a larger volunteer group (*i.e.,* several hundred people). These individuals are used to determine the most effective vaccine dosing. Also, more statistical information can be collected concerning the occurrence of common and possible rare adverse effects.

Phase 3: These clinical trials are the most extensive of the three. Thousands of volunteers are required. The individuals are divided into two groups: one is administered the vaccine, and the other receives a placebo or another vaccine. The use of a large number of test subjects allows researchers to learn more about safety and any possible adverse reactions on a much larger scale. Throughout all clinical trials, collected data are evaluated in conjunction with other information, including vaccine efficacy and safety and the vaccine's physical, chemical, and biological properties. Quality control is a prime, routine

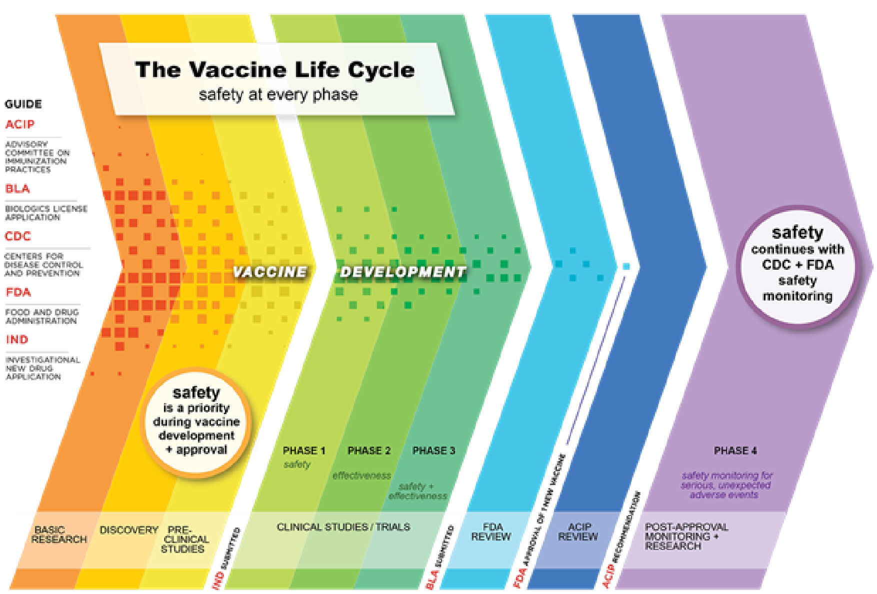
Figure 2

mRNA Pfizer-BioNTech and Moderna COVID-19 vaccines	**Protein subunit** Novavax COVID-19 vaccine	**Viral vectort** Janssen/J&J Covid-19 vaccine



Source: https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update73_covid-19-vaccines-and-immune-response.pdf?sfvrsn=7902cc35_5

Figure 3



Source: https://www.cdc.gov/vaccines/basics/how-developed-approved.html component of vaccine evaluation.[36] Finally, it must be emphasized that the FDA will only license a vaccine when the benefits of immunization far outweigh the potential risks.

Dental Water Quality

It is known that non-pathogenic and pathogenic organisms contaminate the dental unit and its waterlines. These organisms quickly form biofilms inside the lumens of the waterlines. Although the water coming into the dental unit from an external source is of potable quality (< 500 cfu/ml of bacteria and < 1 coliform), water coming out of an improperly treated unit may be contaminated up to 1 million cfu/ml.[36-38] This occurs because several factors (system design, flow rate, materials) promote bacterial growth and development of biofilms. Naturally occurring biofilms are heterogeneous in both their composition and structures. For example, aquatic/marine environments and municipal water systems can contain fungi, algae, protozoa, and even larger microscopic worms in addition to numerous types of bacteria. Since the great majority of microbes can exist in these biofilms, it is not an overstatement to say that we live in a world of biofilms. The adaptability and resilience of these microbial accumulations in natural, municipal, and industrial (*i.e.,* manufacturing and healthcare) systems also allow for the development of group survival strategies. For example, in hospital systems slower growing microbes in biofilms can exhibit transcribed genetic modifications. These properties can protect them from mechanical removal and antibacterial chemicals, such as antibiotics and disinfectants.

Thick biofilms can also develop within a week in untreated dental unit waterlines (DUWL) when a facility is supplied with potable municipal water. Multiple structural, water flow, and other factors have been shown to be responsible (**Table 8**).[39,40] Multiple types of organisms have been identified in dental unit water samples including: *Corynebacterium* species; gram-negative bacilli and cocci; *Klebsiella* species; *Pseudomonas* species, including *P. aeruginosa, P. pyogenes,* and *P. capacia; Staphylococcus epidermidis; Streptococcus mutans, S. salivarius*, and *S. mitis; Actinomyces* species; *Enterococcus* species; a-*hemolytic streptococci*; *Staphylococcus aureus; B. subtilis; Escherichia coli; Legionella pneumophilia; Mycobacterium* species; *Aspergillus niger;* and *Alkaligenes fecalis*.[41] The Environmental Protection Agency, the American Public Health Association, and the American Water Works Association establish standards for safe drinking water.[42] They have set limits of no more than 500 colony- forming units (CFUs) of heterotrophic bacteria per ml of drinking water. Thus, the CDC and the ADA recommend that the number of bacteria in water used as a coolant/irrigant for non-surgical dental procedures should be as low as reasonably achievable and, at most < 500 CFU/ml, the regulatory standard for safe drinking water.[42,43]

Prior to 2012, there was little published evidence of serious health problems for either a patient or HCW from contact with water from a dental unit. However, in 2012 an article published in The Lancet[44] described the first documented case of a dental patient contracting Legionnaires' Disease from water used during treatment. Subsequently, in 2015[45] and 2016[46], two outbreaks of *Mycobacterium abscessus* infections were reported among pediatric dental patients after treatment with dental water that was heavily colonized with bacteria. These and other tragic cases reinforce the premise that exposing patients or dental personnel to water of poor micro-biological quality is inconsistent with both universally accepted infection control principles and the high level of asepsis standards routinely exhibited in most dental offices.

Table 8 - Representative Factors Associated with DUWL That Promote Biofilm Growth

1. Small cylinder diameter and narrow lumens:
2. System design: "dead legs;" control blocks
3. High surface to water volume ratio
4. Tubing materials conducive to microbial attachment
5. Very little water flow at hydrodynamic boundary
6. Low volume of water used during patient treatment
7. Water warms to room temperature
8. Intermittent usage of DUWL

The keys for accomplishing dental unit waterline asepsis remain the same as for other infection control goals - application of basic infection control principles and compliance with product instructions. Contaminated waterlines, like contaminated hands, instruments, and environmental surfaces, should be cleaned first to remove accumulated microbial and extracellular material before treatment. Compliance with a manufacturer's step-by-step procedures for accomplishing this removal is essential. Minimizing subsequent waterline colonization may require another series of protocols, some of which may be more time-consuming than anticipated. Thus, the whole dental team needs to be aware of product costs, necessity for compliance, and the time required to reach recommended waterline microbial concentrations. Successful engineering and manufacturing approaches to improve water quality continue to provide dental professionals with choices to attain better control over the quality of source water used in patient care. These include:

1. An alternate water supply that bypasses the community and dental unit water by providing sterile and/or distilled water directly into waterline attachments from a separate reservoir, combined with chemical treatment.
2. Filtration involving in-line filters to remove bacteria immediately before dental unit water enters instrument attachment.
3. Chemical disinfection involving periodic flushing of lines with a disinfectant followed by appropriate rinsing of lines with water or a continuous release chemical disinfection system.
4. Thermal inactivation of facility water at a centralized source.
5. Reverse osmosis or ozonation using units designed for either single chair or entire practice water lines.
6. Ultraviolet irradiation of water prior to entrance into individual unit waterlines.[21]

Research developments in recent years have led to not only greater individual options for dental practitioners, but also the availability of combination system products, which contain cleaning agents and maintenance chemicals. The following list of ideal criteria can be used when selecting an effective approach for accomplishing effective dental water infection control goals (**Table 9**).[47]

Water used for irrigation, or as a coolant, during therapy that does not involve surgery (excision, incision, or reflection of tissue) and/or exposure of bone can be of potable quality (<500 cfu/ml) and need not be sterile. When therapy involves surgery or exposes bone, sterile water or saline must be used to reduce the chance of postoperative infection. In these cases, the water delivery system must be sterile to avoid contaminating the water/saline. Filtered and bacteria-free water is not necessarily sterile; therefore, filtered or distilled water is not to be used in this instance. The clinician should also remember that conventional dental units cannot reliably deliver sterile water even when equipped with independent water reservoirs because the water-bearing pathway cannot be reliably sterilized. Periodic testing of dental waterlines to assess levels of microbial colonization is recommended to ensure bacterial levels are low. Sterile water systems for surgery procedures must bypass the dental unit and employ sterile disposable or autoclavable tubing.

Table 9 - Properties of an Ideal Waterline Infection Control Agent/System

- Rapid "cidal" (*i.e.,* lethal) antimicrobial action
- Exhibit broad-spectrum antimicrobial activity against bacteria, fungi, protozoa
- Ability to discrupt/disperse accuulated biofilms
- Exhibits "substantivity" to minimize or prevent microbial accumulation on treated surfaces
- Non-toxic to equipment or patients
- Non-pyrogenic
- Non-allergic
- Non-corrosive to metals
- No damaging effects on rubber or synthetic materials
- Does not interfere with performance of any dental restorative or therapeutic agents

In addition, handpieces or ultrasonic scalers used during surgical procedures must deliver sterile water or other solutions using sterilizable or single-use, disposable tubing.[48]

Summary

Effective infection control must occur as a routine component of dental professional activity. Much has been accomplished over the years. The routine application of validated and logical techniques and procedures discussed in this QRG protects HCWs and their patients. The recognition, understanding, and compliance with appropriate recommendations by dental professionals, health professional organizations, and regulatory governmental agencies continue to influence how dental treatment is provided. The field of infection control is constantly changing, and clinicians are reminded to periodically review existing or updated guidelines and documents to stay informed of new information and technologies as they become available.

Note:

The QRG, *Infection Control and OSHA Update Part Two 6th Edition* describes additional office procedures for infection control.

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POST-TEST

Internet Users: This page is intended to assist you in fast and accurate testing when completing the “Online Exam.”
We suggest reviewing the questions and then circling your answers on this page prior to completing the online exam.

(2.0 CE Credit Contact Hour) Please circle the correct answer. 70% equals passing grade.

1. Hand hygiene refers to:
- a. Handwashing using plain liquid soap and water.
- b. Use of an antiseptic hand rub (i.e., alcohol-based).
- c. Handwashing using an antimicrobial antiseptic and water.
- d. All of the above

2. At present, which of the following statements best applies to CDC hepatitis B vaccine recommendations?
- a. the vaccination regimen consists of 1 injection
- b. a booster dose is recommended at 5-year intervals
- c. both a and b are correct
- d. neither a nor b are correct

3. Standard precautions are designed to protect health-care workers against:
- a. bloodborne pathogens
- b. potentially infectious body fluids
- c. both a and b
- d. neither a nor b

4. At present, available COVID-19 vaccines in the United States include:
- a. messenger-RNA vaccines
- b. protein subunit vaccine
- c. viral vector vaccine
- d. All of the above

5. Microbial organisms isolated from dental waterlines have included each of the following, except:
- a. *Pseudomonas* species
- b. *Streptococcus* species
- c. *Legionella pneumophila*
- d. Hepatitis B virus

6. CDC and ADA infection control recommendations for dental unit water (DUW) state that DUW used as an irrigant or coolant during non-surgical patient procedures should contain no more than ___ colony forming units of heterotrophic bacteria/ml.
- a. 10
- b. 100
- c. 500
- d. 1,000
- e. 5,000

7. The use of “universal” and now “standard” infection control precautions during the provision of dental care reinforces the concept that:
- a. all dental practices provide the same range of treatment procedures
- b. all infectious diseases are universally dangerous for dental clinicians
- c. blood and saliva from all patients are to be treated as though they are infectious for bloodborne diseases
- d. all contaminated items must be sterilized after patient treatment

8. Engineering controls outlined in the OSHA Bloodborne Pathogens Standard include the use of:
- a. latex gloves
- b. sharps disposal containers
- c. two-handed technique for re-capping needles
- d. hand washing

9. Approaches to improve the quality of source water from dental waterlines include(s):
- a. reverse osmosis
- b. chemical disinfection of waterlines
- c. separate bottled water supply
- d. All of the above

10. Factors that promote biofilm growth in the dental waterline include:
- a. high surface-to volume ratio
- b. narrow lumens
- c. little water flow onto hydrodynamic tubing boundary
- d. All of the above

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