the mask. Masks should not contact the mouth while being worn as the moisture generated will decrease the mask filtration efficiency. A mask should be selected that conforms well to the shape of the face. A faceshield does not substitute for a surgical mask.

Protective eyewear must have solid side-shields and be decontaminated by immersion in a cleaning agent between patients. A faceshield may substitute for protective eye wear. If protective eyewear or a faceshield is used to protect against damage from solid projectiles, the protective eyewear should meet American National Standards Institute (ANSI) Occupational and Educational Eye and Face Protection Standard (Z87.1-1989) and be clearly marked as such.

Protective clothing must have a high neck and protect the arms if splash and spatter are reasonably anticipated. Cotton or cotton/polyester or disposable clinic jackets or lab coats are usually satisfactory attire for routine dental procedures. The type and characteristics of protective clothing depend on the type of exposure anticipated. Gowns or jackets worn as protective attire should be changed at least daily, or more often if visibly soiled. Protective gowns or covers must be removed before leaving the work area. Protective attire may not be taken home and washed by employees. It may be laundered in the office if equipment is available and universal precautions are followed for handling and laundering contaminated attire. Contaminated linens transported away from the office for laundering should be in appropriate bags to prevent leaking, with a biohazard label or appropriately color-coded, unless the laundry facility employees practice universal precautions in the handling of all laundry. Disposable gowns may be used but must be discarded daily, or more often if visibly soiled.

Utility gloves that are puncture-resistant, a mask, protective clothing and protective eyewear must be worn when handling and cleaning contaminated instruments, when performing operatory cleanup, and for surface cleaning and disinfecting. Utility gloves must be discarded if their barrier properties become compromised. Utility gloves, protective eye wear or face shields, and masks must be worn when mixing and/or using chemical sterilants or disinfectants. Used utility gloves must be considered contaminated and handled appropriately until properly disinfected or sterilized.

NOTE: Along with the increased use of latex gloves for infection control purposes has been an increased incidence of latex allergies and other sensitivities. Certain individuals are considered to be at an increased risk of latex sensitivity. These individuals include persons who have had multiple surgeries (especially involving the placement of rubber tubes or drains), spina bifida patients, health care workers, and individuals with other documented allergies. Medical histories should include questions which may alert the DHCW that a patient is latex-sensitive. If a person is found to be sensitive to latex, precautions such as non-latex gloves, non-latex rubber dams, and avoidance of any other latex-containing products should be implemented in the treatment of those patients. Latex-sensitive patients should also be scheduled at the beginning of the day to minimize exposure to latex residue and powder.

DHCWs who experience symptoms consistent with sensitivity including skin rash, itching, or wheezing should seek the advice of a qualified medical professional for diagnosis of the symptoms. Because a variety of materials may be responsible for the sensitivity, including resin materials which may permeate the gloves, self-diagnosis is ill-advised and could increase the risk of a serious allergic response.

7. Instrument Sterilization

Puncture-resistant utility gloves, a mask, protective eyewear, and a protective gown or apron must be worn throughout instrument processing.

Single use disposable items must be disposed after each use. All reusable items that come in contact with the patient's blood, saliva or mucous membranes must be sterilized in an autoclave,

unsaturated chemical vapor sterilizer, dry heat sterilizer (must be FDA-cleared for use as a medical device), or ethylene oxide gas sterilizer before reuse. Ethylene oxide is inappropriate for use with lubricated items such as handpieces, due to failure of the gas to penetrate lubricants.

Sterilization by immersion in a chemical sterilant which has been FDA-cleared for use as a sterilizing agent is only appropriate for those items which may be damaged by the sterilization methods referred to in the paragraph above. Use the concentration, contact time, and temperature stated on the product label to achieve chemical sterilization. The solution should be routinely checked during use with a glutaraldehyde indicator to assure a minimum effective glutaraldehyde concentration. Note that glutaraldehyde cannot be biologically monitored to verify sterilization, nor can items be packaged prior to chemical sterilization.

The procedure for processing reusable instruments begins at chairside. It is important to keep instruments moist to facilitate cleaning. Therefore, if instruments are not immediately processed, they should be placed in a "holding" solution (soapy water or a commercially available surfactant solution) to prevent the drying of blood and debris. All items must be properly cleaned in an ultrasonic cleaning unit or instrument washer. Only cleaners intended for use in an ultrasonic cleaner or instrument washer should be used. Chemical germicides are inappropriate for use with these devices. Hand scrubbing of sharp instruments should be avoided. However, if hand scrubbing or cleaning is required, use a clean long-handled brush and keep instruments submerged while scrubbing to reduce spatter. Brushes should be disposable or autoclavable. Care must be taken to avoid injuries with hand (brush) scrubbing. Instruments must be dry if ethylene oxide gas, dry heat, or unsaturated chemical vapor sterilizers are used. Instruments must be packaged (using proper pouches, bags or wrapped cassettes or packs) before steam, chemical vapor, dry heat or gas sterilization and remain packaged for storage to protect the items from environmental contamination after sterilization. Mark packages with date and sterilizer number for tracking purposes. Note: Do not write with ink directly on paper (wrap or pouches). Autoclave tape, bar code stickers, or writing on plastic side of pouches is acceptable.

8. Handpiece Sterilization

All high-speed handpieces, nose cones, contra-angles, low-speed motors, motor-to-angle adapters and prophylaxis angles (unless disposable prophylaxis angles are used) must be heat sterilized between patients. The cleaning, sterilization and maintenance procedures described by the handpiece manufacturer must be meticulously followed to ensure proper sterilization and maximum longevity from the handpiece.

After patient treatment, flush the water/air lines for 20-30 seconds with the high speed handpieces still attached. Remove the handpieces and thoroughly clean the external/internal surfaces as directed. Package before sterilization, and process through the sterilizer according to the sterilizer and handpiece manufacturers' instructions. If lubrication is indicated by the handpiece manufacturer either before or after sterilization, follow the procedures as outlined by the manufacturer. It is recommended that a separate container of lubricant be reserved for this purpose as a cross-contamination avoidance strategy.

9. Sterilization Monitoring

The use and functioning of heat sterilizers should be biologically monitored at least weekly, or more often if the practice demands it, with appropriate spore tests. Place the spore strips or vials inside a pouch, bag, pack or cassette, and include this package as part of the normal load through a normal sterilizer cycle. Always use a control spore strip or vial (not heat processed but otherwise treated identically to the test strips or vials) with each spore test performed. Additionally, chemical indicators should be used on the inside of each package during every sterilizer load. Accurate records of sterilization monitoring must be maintained. A chemical indicator from inside each pack may be initialed and dated for each day of patient care and kept in a file. The weekly spore test for each heat sterilization unit may be kept in the same file. Biologically monitor whenever there is a change in packaging, following equipment repair; retest after failure and when training new employees.

10. Environmental Surface and Equipment Asepsis

Current CDC Guidelines recommend that all waterlines for syringes and/or handpieces should be turned on and flushed for several minutes with handpieces disconnected at the beginning of the day and 20-30 seconds between patients. However, research has shown this protocol alone to be temporary and inadequate in controlling water contamination.

Sterile cooling and irrigating solutions must be used as an irrigant during surgical procedures. This water must be delivered from a source separate from the dental unit. Dental unit water which contains fewer than 200 CFU/ml of heterotrophic mesophilic bacteria is acceptable for use as a coolant or irrigant for all non-surgical dental procedures. Dental water delivery systems which are fitted with anti-retraction valves must be checked weekly. Alternatively, systems which provide constant positive pressure may be used. Heat sterilized or disposable air/water syringe tips and vacuum tips must be used. All vacuum lines must be flushed after every patient procedure to prevent drying of blood and debris in the lines.

To develop an effective asepsis protocol, operatory surfaces including walls, floors, cabinetry and equipment should be classified and managed under three categories: touch surfaces, transfer surfaces and splash/spatter surfaces.

(a) Touch Surfaces:
Surfaces that are usually touched and contaminated during dental procedures. Examples include dental light handles, dental unit handle and controls, headrest adjustment mechanisms, or dental chair switches.

Touch surfaces should be kept at a minimum. If a surface must or might be touched, it should be cleaned and disinfected, or covered with a barrier that is impervious to liquid. Barriers must be single-use and replaced between patients. Offices should develop a standard procedure for installing and removing barriers that will prevent cross contamination. All office staff responsible for operatory turnover between patients should be trained in this standard procedure. Contaminated barriers must be properly discarded. If a covered touch surface is compromised and becomes visibly contaminated, it should be cleaned and disinfected with an low or intermediate-level disinfectant before applying the barriers for the next patient. Touch surfaces that have been covered with barriers should be cleaned and disinfected at the end of each clinical day. Before the first patient of the next clinical day, new barriers should be installed.

(b) Transfer Surfaces:
Surfaces that are not touched, but which are usually contacted by contaminated instruments. Examples include instrument trays and dental unit handpiece holders. Asepsis for transfer surfaces is the same as for touch surfaces.

(c) Splash, Spatter and Aerosol Surfaces:
All surfaces in the operatory other than touch or transfer surfaces. Splash and spatter surfaces need not be disinfected, but should be cleaned (at least daily, or more often if possible).

11. Laboratory Asepsis

Open communication must exist between the dental office and the dental laboratory concerning infection control protocols and delineation of responsibilities between the office and lab.

Materials, impressions and intra-oral appliances must be cleaned and disinfected before being handled, adjusted, or sent to a dental lab. Personal protective equipment including gown, gloves, mask and protective eyewear should be worn.

Before selecting a disinfecting agent, consult the manufacturers of specific materials as to the stability of their material relative to disinfection agents and procedures. Then, disinfect for the specified length of time with the appropriate chemical (1:10 sodium hypochlorite solution or an EPA-registered,[8] tuberculocidal disinfectant that also kills hydrophilic and lipophilic (enveloped and nonenveloped)[9] viruses). Finally, rinse thoroughly. Do not transfer to laboratory in container containing disinfectant.

If items are properly disinfected before being taken into or sent out to the laboratory, then lab equipment and surfaces should not become contaminated. However, a laboratory that provides services to numerous clients may become subject to contamination from other sources. All items returned from a commercial laboratory should be considered clean for handling but should be disinfected before placing in a patients' mouth. If laboratory equipment, surfaces and attachments become contaminated with blood or saliva, they must be thoroughly cleaned and then sterilized or disinfected before use on another case.

12. Waste Disposal

a. General

All waste must be disposed according to applicable federal, state and local regulations and recommendations. Generally, blood and /or saliva-tinged items are not regulated waste. Hard and soft tissue and soaked items, that is, blood or saliva can be squeezed out, or blood may flake from the item, are considered regulated medical waste. Always consult the state or local government agency regarding specific exemptions and disposal/treatment requirements.

b. Infectious Disease Hazard (Biohazard) Communication

Containers of regulated medical waste (as defined above) are to be labeled and/or identified in compliance with local regulations. These containers include contaminated sharps containers, contaminated reusable sharps containers (i.e., pans used for holding contaminated instruments), bags of contaminated laundry, specimen containers, and storage containers.

c. Handling and disposing sharps

Place needles and other disposable sharps, such as scalpel blades, orthodontic wires and broken glass into a puncture resistant, leak-proof container that is closable and color-coded or labeled with the biohazard symbol. The container must be located as close as possible to the point of use for immediate disposal. Do not cut, bend, break or remove needles by hand before disposal, and do not remove needles from disposable syringes.

To recap a needle on a non-disposable anesthetic syringe, lay the needle cover on a firm surface and guide the needle into the cover using only one hand; OR use one-handed resheathing with a resheathing device. Alternatively, self-sheathing needles may also be used. If the device is one that is hand-held, it must provide full hand protection for the hand holding the device. When the sharps container is 3/4 full, securely close and treat or dispose according to state and local laws.

d. Non-sharp disposable items

Non-sharp disposable items that are considered regulated waste by state or local laws must be disposed of and/or transported according to specific state and/or local regulations. At a minimum, these items must always be placed in labeled, leak-proof bags or containers. Disposable items that may contain the body fluids of patients, but are not subject to medical waste regulations, such as gloves and patient bibs, should be placed in a lined trash receptacle. Red bags should not be used for non-regulated waste. Check the specific requirements of the local regulatory agency (usually state or county health departments).

13. Tuberculosis

With the reemergence of *Mycobacterium* tuberculosis (TB) infection and active tuberculosis as demonstrated risk factors for health care workers (HCW), consult the following reference "Guidelines for Preventing the Transmission of TB in Health Care Facilities, 1994," CDC. (appendix A)

14. Training

All DHCWs involved in the direct provision of patient care should receive regular training in infection control and safety issues. Training should include coverage of OSHA's pertinent regulations such as the Bloodborne Pathogens and Hazard Communication standards.

15. Other

a. A dental dam and high volume evacuation may be used during dental procedures, when indicated, to minimize the amount of potentially contaminated splash and spatter, and to minimize direct contact with patients' oral mucosa.

b. Ventilation devices such as a one-way CPR airway (e.g., a pocket mask with a one-way valve) or oxygen with bagging capability must be available for those qualified to provide such care.

c. Eating, Drinking, Smoking

Do not eat, drink, smoke, apply cosmetics or lip balm, handle contact lenses or store food or drink in areas of possible exposure to (or storage of) blood, saliva, tissue or other potentially infectious materials. This would include the dental operatory, dental laboratory, sterilization area and darkroom/x-ray processing area.

d. Decontamination of Equipment for Servicing or Maintenance

Contaminated equipment or instruments that are to be repaired on site or shipped for service are first to be cleaned and sterilized or disinfected. If a portion of the equipment cannot be cleaned and sterilized or disinfected, that portion should be identified with a biohazard label and an explanation to those who may handle the contaminated item. Utility gloves, masks and protective eyewear must be worn when routine maintenance is performed on equipment such as replacing filters on suction pumps, etc. Infection control practices/procedures should be communicated to the repair personnel.

e. Radiographic Asepsis

Wear gloves while exposing films in the patient's mouth. Place exposed films in a paper cup. When all films are exposed, remove and discard gloves. Reglove and transport to the darkroom, carefully open the packs and drop the films on a clean surface. Discard the contaminated wrappers, remove and discard the gloves, and process the films.

(1) Daylight loader:

When using an x-ray processor with a daylight loader, extra precautions are required to avoid contamination of the sleeves, and external and internal components of the processor. Place films in a paper cup as they are exposed. When all the films have been taken, remove gloves and place the paper cup containing exposed film packets into the daylight loader. Wearing clean gloves, insert hands through the sleeves of daylight loader. Open all film packets, allowing films to drop onto a clean surface. Do not touch films with gloved hands. Once all the film packets have been opened, discard empty film wrappers, remove gloves and process films with bare hands. For disposal, empty film packets and used gloves may be placed in the paper cup that was originally used to transport films into the daylight loader. If the insides of the insertion sleeves have ever been contaminated, double gloving may be used for protection when removing hands from the daylight loader. One pair of gloves should be removed after opening film packets, leaving a clean pair of gloves for handling films and touching the sleeves of the daylight loader.

(2) Barrier Pack Films

X-ray films packaged in fluid impervious barriers are available. A slight modification of the recommended x-ray and darkroom protocol is indicated. After exposing the film, pull on the edges of the barrier pack, allowing the film to drop into a clean paper cup without contaminating the inner film packet. When all films have been exposed and collected in the cup, remove procedure gloves and take films to the darkroom or daylight loader for processing.

Chemical Agents for Surface Disinfection Reference Chart

CHEMICAL CLASSIFICATION	PRODUCTS										
	Advantages	Disadvantages	Example of Active Ingredient and Listed on Product Label	Name	EPA Reg #	Dilution	TB Time	TB Temperature*	Hydrophilic Virus Kill**	Total Time for Surface Disinfection	FOR MORE INFORMATION CONTACT
Alcohols	Do not use for environmental surface disinfection. Rapid evaporation rate. Diminished activity with bioburden.										
Chlorines	Rapid acting; Broad spectrum; Economical (Bleach)	Discard diluted solutions daily; Diminished activity by organic matter; Corrosive	sodium hypochlorite; chlorine dioxide	Clorox Dispatch (0.55%)	5813-1 56392-7	1:100 None	10 min 2 min	20° C 20-25° C	Yes Yes	10 min 2 min	Clorox Caltech
Iodophors	Broad spectrum; Few reactions; Residual biocidal activity	Unstable at high temperatures; Dilution & contact time critical; Discard daily; Discoloration of some surfaces; Inactivated by hard water	butoxpolypropoxy-polyethoxyethanol iodine complex	IodoFive Biocide Iodophor Disinfect.	4939-16 " " " "	1:213 " " " "	10 min " " " "	20° C " " " "	Yes " " " "	10 min " " " "	Cottrell, Ltd Biotrol Smart Practice
Synthetic Phenolics	Broad spectrum; Residual biocidal activity	Discard daily for most diluted solutions; Degrades certain plastic over time; Difficult to rinse; Film accumulation	WATER-BASED Dual Phenolics phenylphenol and benzylchlorophenol or tertiary amylphenol Tri-Phenolics phenylphenol benzylchlorophenol tertiary amylphenol ALCOHOL-BASED tertiary amylphenol and/or phenylphenol plus ethyl alcohol or isopropyl alcohol	Omni II ProPhene Vital Defense-D ProSpray Birex Dual Phenol Germicidal Cleaner BiArrest-2 Tri-Cide Dencide Asepti-phene 128 PUMP CoeSpray Asepti-phene RTU AEROSOL Lysol IC Disinfect. Asepti-Steryl Discide Disinf Spray Citrace Medicide/ADC Disinfect. Deodor.	46851-1 " " " " 46851-5 1043-92 67813-3 67813-1 11725-7 63281-4 303-223 334-417 " " 777-53 706-69 " " 56392-2 334-214	1:32 " " " " none 1:256 1:256 1:256 1:256 1:256 1:128 none " " none none " " none none	10 min " " " " 10 min 10 min 10 min 10 min 10 min 10 min 10 min 10 min 10 min 10 min 10 min " " 10 min 10 min	20° C " " " " 20° C 20° C 20° C 20° C 20° C 20° C 20° C 20° C " " 20° C 25° C " " 20-25° C 25° C	Yes " " " " Yes No*** No*** No Yes Yes Yes Yes " " Yes Yes " " Yes No	10 min " " " " 10 min 10 min 10 min 10 min 10 min 10 min 10 min 10 min " " 10 min 10 min " " 10 min 10 min	Cottrell Cottrell Block Cottrell Biotrol Smart Practice Infection Control Technology HealthSonics Dentsply Huntington GC America Huntington Sultan Huntington Palmero Caltech ADC
Dual or Synergized Quaternaries (do not use older generations of quats as surface disinfectants)	Broad spectrum; Contains detergent for cleaning; Few reactions	Easily inactivated by anionic detergents and organic matter; Deleterious to some materials	diisobutylphenoxy-ethoxyethyl dimethyl benzyl ammonium chloride; isopropanol	Cavicide DisCide TB Precise QTB GC Spray-Cide SaniTex Plus Asepticare *II	46781-6 1839-83 " " 1130-15 " " 1130-13	None None " " None " " None	10 min 10 min " " 6 min " " 10 min	20° C 20° C " " 20° C " " 20° C	Yes Yes " " Yes " " Yes	10 min 10 min " " 10 min " " 10 min	Kerr Palmero Caltech GC America CrossTex Huntington
Sodium Bromide and Chlorine	Broad spectrum; Reduced storage (tablets)	May not be used for immersion (hard surfaces only); Chlorine smell	sodium bromide; sodium dichloro-isocyanurate dihydrate	Microstat 2	70369-1	2 tablets per quart	5min	20° C	Yes	5 min	Septodont

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* Temperature: 20°C=68°F; 25°C=77°F

**Studies by Klein and DeForest suggest that hydrophilic are more resistant than lipophilic viruses and therefore represent a better gauge of a disinfectant's virucidal efficacy. Hydrophilic viruses include various strains of *Polio, Coxsackie, Rhinovirus* and *Rotavirus.*

***Demonstrates activity toward *Adeno* virus (resistance level between hydrophilic and lipophilic.)

IMPORTANT INFORMATION

All products to be used as disinfectants on precleaned surfaces must be EPA-registered. Listing does not imply endorsement, recommendation or warranty. Other products available. Purchasers are legally required to consult the package insert for changes in formulation and recommended product uses. Check compatibility of material before use on dental/medical equipment.

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ORGANIZATION FOR SAFETY & ASEPSIS PROCEDURES (OSAP)

Chemicals for Immersion Sterilization of Heat-Sensitive Instruments

October, 1998

Chemical Classification		Product	510(K) #	TB Directions Test* Intermediate-level Disinfection			Sterilization		For More Information
				Temp	*Time*		*Temp*	*Time*	
GLUTARALDEHYDE	**Alkaline:**								
	3.4%	Cidex Plus	K923744	25°C	20 min	Quant	25°C	10 hrs	Advanced Sterilization Products
		Procide Plus	K932922	20°C	45 min	Quant	20°C	10 hrs	Metrex
		Banicide Plus	K931592	25°C	90 min	Quant	25°C	10 hrs	Pascal
		Cida-Steryl Plus	"	"	"	"	"	"	Huntington/Ecolab
		CoeCide XL Plus	"	"	"	"	"	"	GC America
		Security 3.4%	"	"	"	"	"	"	Kerr
	2.5%	Cida-Steryl 28	K931052	25°C	90 min	Quant	25°C	10 hrs	Huntington/Ecolab
		CoeCide XL	"	"	"	"	"	"	GC America
	2.4%	ProCide	K932922	20°C	45 min	Quant	20°C	10 hrs	Metrex
	Acidic:								
	2.5%	Banicide	K914749	22°C	45 min	Quant	22°C	10 hrs	Pascal
		Sterall	"	"	"	"	"	"	Colgate
HYDROGEN PEROXIDE		Sporox	K970230	20°C	30 min	Quant	20°C	6 hrs	Sultan Chemists
PARACETIC ACID		Cidex PA	K960513	20°C	25 min	AOAC	20°C	8 hrs	Advanced Sterilization Products

NOTE: Sterilization by immersion in a chemical is only appropriate for those items which may be damaged through steam, dry heat or chemical vapor sterilization. Glutaraldehydes, hydrogen peroxide, and paracetic acid may NOT be used as surface disinfectants. All products for immersion must be FDA-cleared.

20°C = 68°F; 22°C = 72°F; 25°C = 77°F

*Tests for TB label claim: Quant = Quantitative; AOAC = Association of Official Analytical Chemists

All products are to be used full strength, undiluted on precleaned instruments. Other products are available. Listing does not imply endorsement, recommendation or warranty. Purchasers are legally required to consult the package insert for changes in formulation and recommended product uses.
This chart is a publication of the Organization for Safety & Asepsis Procedures (OSAP). OSAP assumes no liability for actions taken based on the information herein.

Updated tables are available from OSAP by calling 410-571-0003; FAX: 410-571-0028.

OSAP Position Paper

January, 1997

DENTAL UNIT WATERLINES

This position paper was developed by the Dental Unit Waterline Working Group of OSAP.

The Dental Unit Waterline Working Group has the following members:

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BACKGROUND

Microbial biofilms are ubiquitous in nature and can be found virtually anywhere there is moisture and a suitable solid substrate for attachment (1). Biofilms, consisting primarily of naturally occurring, slime producing bacteria and fungi, form on the walls of small-bore plastic tubing in dental units which deliver coolant water for dental handpieces, sonic and ultrasonic scalers, and air-water syringes used in patient care (2,3,4,5,6,). Levels of contamination in dental unit treatment water frequently exceed 100,000 colony forming units per milliliter (CFU/mL)(2,3,4,5). Although bacteria of possible human origin have been reported, most of the organisms recovered from dental unit waterlines are heterotrophic mesophilic bacteria which naturally occur in smaller numbers in drinking water (1).

While there is no current epidemiological evidence of a public health problem, the presence in dental waterlines of potential human pathogens including *Pseudomonas* (2,3,4), *Legionella* (3,7), and non-tuberculous *Mycobacterium* (8) species suggests reason for concern. Serological evidence of chronic exposure to *Legionella* bacteria in dental health care workers (9,10), and a suspected fatal legionellosis (10) have been reported. A published case report associated two post operative *Pseudomonas* infections in immunocompromised patients with exposure to contaminated dental coolant water. (11)

The 1993 Recommendations for Infection Control in Dentistry from the Centers for Disease Control and Prevention (CDC) state that sterile irrigating solutions should be used for all surgical procedures which involve the cutting of bone.(12) In 1995, the American Dental Association (ADA) published a statement on dental unit waterlines that challenges dental equipment manufacturers to produce systems that can reduce the level of bacteria in water used for non-surgical dental treatment to 200 CFU/mL or fewer by the year 2000. (13)

There is an urgent need for reliable and economical engineering methods to control or prevent the formation of microbial biofilms in dental unit waterlines with minimal user intervention. Such methods must be able to produce water that does not exceed the recommended ADA goal of 200 CFU/mL. The water produced must also be compatible with dental restorative materials and free of potentially toxic or carcinogenic chemicals. Manufacturers should identify and develop economical methods for the clinical monitoring of water quality to assess compliance with recommended treatment protocols.

EXCLUSIONS

OSAP concurs with current recommendations from the Centers for Disease Control and Prevention and the American Dental Association on the use of coolant and irrigation solutions in dentistry and the control of microbial contamination in dental unit waterlines. The following statements are intended to expand and clarify these guidelines. These statements are not intended to serve as a clinical manual for the control of waterline contamination. They should however, provide a framework for collaborative efforts between industry, academic institutions and clinicians to improve the quality of water used in clinical dental practice to assure the health and safety of dental patients and health care workers.

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DENTAL UNIT WATERLINES

Position Paper

OSAP

STATEMENTS ON THE USE OF COOLANT AND IRRIGATING SOLUTIONS IN DENTISTRY:

Statement: Sterile coolant and irrigating solutions which meet the standards for sterility described in the United States Pharmacopoeia (USP) should be used for all dental procedures which involve the intentional penetration, incision, excision, abrasion or ablation of intact, non-sulcular oral mucosa, and which results in exposure of normally uncontaminated bone or soft tissue.
Rationale: OSAP concurs with the 1993 recommendation of the CDC that only sterile irrigating solutions should be used for surgical procedures which involve the cutting of bone. The OSAP statement further clarifies this position by including other invasive surgical procedures which expose normally uncontaminated tissues and result in penetration of the vascular system. The use of solutions which meet the standards of the USP for sterile water assures that they are free not only of viable microorganisms, but of bacterial endotoxins, pyrogens, and other potentially harmful chemicals.

Statement: Dental unit water which contains fewer than 200 CFU/mL of heterotrophic mesophilic bacteria as recommended by the American Dental Association's Statement on Dental Unit Waterlines is acceptable for use as a coolant or irrigant for all non-surgical dental procedures. This includes most procedures which enter the dental sulcus and for initial access into the dental pulp.
Rationale: OSAP accepts the recommendations of the American Dental Association expert panel on dental unit waterlines which suggest a maximum limit for bacterial contamination in water used for non-surgical dental treatment at 200 CFU/mL.

Although procedures which enter the gingival sulcus are often invasive, sulcular tissues are already colonized with microorganisms. Since initial access into the pulp chamber is often performed in conjunction with restorative dental procedures, the use of dental unit water which meets or exceeds the recommended ADA goal of 200 or fewer CFU/mL is acceptable for use as a coolant/irrigant for pulp extirpation. Sterile solutions should be used for subsequent canal preparation and for all endodontic surgery.

Statement: Devices which are intended for surgical irrigation must provide a sterile, non-pyrogenic pathway for coolant or irrigants which will enter the surgical site. All components of this pathway must be single-use disposable or heat sterilizable. Acceptable sterilization methods should include table-top steam autoclaves or alcohol/formaldehyde chemical vapor sterilizers. All reusable devices should be tested by the manufacturer to verify the efficacy of recommended sterilization procedures.
Rationale: A sterile, non-pyrogenic pathway for surgical coolant or irrigants assures that these solutions meet current standards of care for surgical procedures. Reusable components must be demonstrated to be heat sterilizable in table-top steam autoclaves or chemical vapor sterilizers since these are the devices most commonly found in private dental offices. Very few dental offices are equipped with pre-vacuum autoclaves or ethylene oxide sterilizers.

STATEMENTS ON METHODS FOR CONTROL OF MICROBIAL CONTAMINATION IN DENTAL UNIT WATERLINES

Statement: OSAP cautions that flushing waterlines without chemical treatment, filtration, or other scientifically validated intervention to control microbial contamination should be used only as an interim measure until more effective methods can be applied. The practice of briefly flushing waterlines between patients to remove patient material potentially retracted during treatment may be efficacious and should be continued.
Rationale: The efficacy of mechanical flushing alone to control microbial contamination in dental unit water is not well supported by the scientific literature and should be used only as an interim procedure until other scientifically validated interventions can be implemented. Although flushing can temporarily reduce the number of organisms suspended in dental waterlines, this procedure has no predictable effect on adherent biofilms. Bacterial aggregates breaking free from the biofilm could recontaminate dental unit water during the course of clinical treatment.

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OSAP Position Paper

DENTAL UNIT WATERLINES

Statement: OSAP strongly discourages the use of water heating systems in dental units which may increase the numbers and/or the potential pathogenicity of waterline microorganisms.
Rationale: Dental unit water heaters are designed to maintain dental treatment water at or near human body temperature. This will tend to stimulate bacterial proliferation and may select organisms which are pre-adapted to growth at body temperature. Water in separate reservoir systems that are maintained at room temperature can provide adequate patient comfort while discouraging the growth of potential human pathogens.

Statement: Manufacturers of devices, solutions, and protocols marketed for the control of microbial contamination in dental unit water systems are responsible for testing to ascertain the safety and efficacy of products and obtaining appropriate regulatory clearances.
Rationale: Untested devices and protocols may be ineffective, or potentially harmful to patients, dental health care workers and dental equipment. Dental equipment manufacturers are legally and ethically obligated to assure the safety and efficacy of devices which claim to improve the quality of water used in dental treatment.

Statement: Commercial devices, including retrofittable devices, which are marketed for the control of microbial contamination in dental unit water systems should be cleared to market by the US Food and Drug Administration (FDA).
Rationale: The FDA classifies dental water treatment and delivery systems as medical devices which are subject to pre-market clearance requirements under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FD&C). Dental health care workers should be aware that dental units are subject to FDA pre-market clearance requirements, and any retrofittable devices for use with dental unit waterlines also require 510(k) clearance.

Statement: Chemical germicides and cleaners used for the control of microbial contamination of dental treatment water should be biocompatible; and,if not completely removed, leave only safe levels of residues. Cleaners and germicides intended for use in dental unit water systems must meet all applicable federal regulatory requirements.
Rationale: Chemical germicides and cleaning agents which have a claim for use with a specific medical device are considered by the FDA to be accessories to medical devices and therefore, are considered medical devices as well. They are subject to labeling requirements under either FDA or Environmental Protection Agency (EPA) rules depending on the claims. Occupational Safety and Health Administration (OSHA) rules on labeling and storage of hazardous chemicals are also applicable.

Statement: Devices and solutions commercially marketed for the control of microbial contamination in dental unit water systems should be compatible with the materials used in the construction of the dental units on which they are to be installed. Manufacturers of these products should be responsible for performing appropriate compatibility testing with commonly used dental unit waterline materials. Manufacturers must inform users if devices or solutions are known to be incompatible with specific types or models of dental delivery systems and should disclose completely in labeling all material compatibility information.
Rationale: Chemical germicides and cleaners may have unintended effects on materials used in the construction of dental water delivery systems and may damage components or produce potentially hazardous disinfectant by-products. This concern is most acute in the marketing of devices or chemicals which may be retrofitted on a wide variety of dental units.

Statement: Dental unit water systems must be designed to limit the potential for retraction of patient material to the maximum extent possible. Manufacturers should provide instructions for periodic testing, maintenance or replacement of components intended for this purpose as applicable.
Rationale: Retraction of patient material by dental water systems offers the potential for patient-to-patient transmission either directly, or by permitting colonization of waterline biofilms by organisms from the human reservoir. There is evidence that the performance of anti-retraction devices--whether active or passive--may degrade over time. Manufacturers should be aware of the limitations of the devices installed on their dental units and provide users with appropriate

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guidance to maintain optimal performance. Retrofittable anti-retraction devices are subject to FDA pre-market clearance requirements.

Statement: All devices and solutions marketed for the purpose of improving, maintaining, or monitoring the quality of dental treatment water must have clearly written precautions and user instructions for installation, use and maintenance.
Rationale: Treatment methods which have been evaluated for the control of microbial contamination of dental treatment water are often very technique sensitive. Simple, well-written instructions can greatly enhance the probability of clinical success and reduce the potential for damage to equipment or injury to staff or patients.

Statement: Manufacturers of dental unit water treatment devices should identify and recommend reliable and economical methods to monitor the effectiveness of water treatment protocols and devices in the clinical setting. Clinical monitoring should be designed to evaluate compliance with recommended protocols and should not be intended to re-validate the efficacy of recommended protocols. Testing for specific organisms in treatment water is unnecessary as a routine procedure.
Rationale: The current ADA guidelines for dental treatment water recommend a maximum level of microbial contamination which is 200 or fewer CFU/mL of heterotrophic mesophilic bacteria. Monitoring procedures should be designed to provide a positive reinforcement feedback loop for the dental staff and to identify technique errors or non-compliance. By implementing scientifically validated protocols to attain colony counts in treatment water which are as low as reasonably achievable (200 CFU/mL or fewer), the need to routinely identify specific organisms in the clinical setting is not cost effective.

CONCLUSIONS

The presence of large numbers of potentially pathogenic microorganisms in water used for dental treatment justifies the implementation of scientifically validated treatment protocols for control of microbial contamination in dental unit waterlines.

Mechanical flushing of waterlines has not been shown to consistently reduce the number of bacteria present in water used in dental treatment (4,5,6). Other methods proposed for control of waterline biofilms include filtration, and chemical treatment with or without the use of separate water reservoirs. Several different products and protocols using chemical treatment, separate water reservoir systems, and microfiltration are now commercially available.

Separate water reservoir systems, when used with a periodic chemical treatment protocol, have demonstrated safety and efficacy in both clinical and laboratory settings.(2,14,15,16) Since the materials and design of dental water systems vary greatly, no universal treatment protocol can be recommended. Interactions between chemical germicides and cleaners and waterline materials can damage systems and can theoretically produce a wide range of disinfectant by-products (DBPs) with unknown biological effects. Without conscientious performance of recommended treatment regimens, damage to equipment and clinical failure to control biofilms have been reported. Safety issues associated with the potential failure of pressurized system components must also be addressed.

Microfiltration technology, widely used in other areas of medicine and industry, offers a promising alternative. Although microfilters appear to greatly reduce the numbers of bacteria in output water (17,18), they have no effect on biofilms or their potential to obstruct and corrode water delivery systems (18). As with separate reservoir systems, user maintenance is an important factor in achieving clinical success.

When used in a conscientiously applied manner, both properly maintained separate water reservoir systems and microfiltration technology can produce treatment water with 200 or fewer CFU/mL of heterotrophic mesophilic bacteria. A combination of these approaches may offer the best available assurance of high quality dental treatment water quality. Sterile water delivery systems are also available which use either heat sterilizable or sterile disposable components.

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Since virtually every one of over 150,000 dental offices in the United States (and thousands more worldwide) is affected by this problem, there is a compelling need for cost effective solutions. Increased public awareness of this issue provides additional impetus for development of appropriate technology.

In order to best ensure the health and safety of dental patients and staff, manufacturers of dental equipment, chemical germicides and cleaners must base their product development and marketing on a strong foundation of peer-reviewed science. OSAP encourages collaborative efforts between industry, academia and clinicians to develop effective approaches to ensure the safety of all coolants and irrigants used in the clinical setting.

REFERENCES

1. Costerton, J. W., Lewandowski, Z., Caldwell, D.E. Korber, D.R., and Lapin Scott, H.M. Microbial Biofilms. Ann Rev of Micrbiol 49:711-45, 1995.
2. Kelstrup, J., Funder-Nielsen, T.D., and Theilade, J., Microbial aggregate contamination of water lines in dental equipment and its control. Acta Path Microbiol Scand B, 85:177-183, 1977.2. Shearer, B.G. Biofilm in the dental office. J Am Dent Assoc 127: 181-9, 1996
3. Williams, J.F., Johnston, A.M., Johnson, B., Huntington, M.K., and Mackenzie, C.D., Microbial contamination of dental unit waterlines: Prevalence, intensity, and microbiological characteristics. J Am Dent Assoc 124:59-65, 1993.
4. Santiago, J.I., Huntington, M.K., et al. Microbial contamination of dental unit waterlines: Short- and long-term effects of flushing. Gen Dent 42(6):528-44, 1994.
5. Williams, H.N., et al. Contribution of biofilm bacteria to the contamination of the dental unit water supply. J Am Dent Assoc 126:1255-60., 1995
6. Mayo, J.A., Oertling, K.M., and Andrieu, S.C. Bacterial biofilm: A source of contamination in dental air-water syringes. Clin Prev Dent 12:13-20, 1990.22.
7. Atlas, R.M., Williams, J.F., et al. Legionella contamination of dental-unit waters. Appl Environ Microbiol 61:1208-13, 1995
8. Rosen, S., and Ramos, E., et al. Pathogenic microflora in the water lines leading to the dental handpiece. Transmissions 9(2):2 (Abstract), 1994
9. Fotos, P.G., Westfall, H.H., Snyder I.S., Miller R.W., and Mutchler B. M., Prevalence of Legionella-specific IgG and IgM antibody in a dental clinic population. J of Hosp Infec, 64:1382-1385, 1985.
10. Reinthaler, F.F., Mascher, F. and Stunzer, D., Serological examination for antibodies against Legionella species in dental personnel. J Dent Res 67:942-3, 1988
11. Martin, M.V., The significance of the bacterial contamination of the dental water system, Br Dent J 163:15204, 1987.
12. Centers for Control and Prevention: Recommended infection control practices for dentistry, 1993. MMWR 42 No. RR-8:7, 1993
13. Shearer, B.G. Biofilm in the dental office. J Am Dent Assoc 127:181-9, 1996
14. Williams, H.N., Kelley, J., *et al.* Assessing microbial contamination in clean water dental units and compliance with disinfection protocol. J Am Dent Assoc 125:1205-11, 1994.
15. Sherman, L.R., Mills, S.E., and Plamondon, T.P. Identification of mineralization in clean and biofilm contaminated dental unit waterlines. J Pa Acad Sci 69(1):31-4, 1995.
16. Plamondon, T.P., Mills, S.E., Sherman, L.R., Nemeth, J., and Puttaiah, R. Effect of bleach on mature biofilm in dental unit waterlines. J Dent Res (IADR Abstract) 75:414, 1996.
17. Puttaiah, R., Mills, S.E., Sherman, L.R., Plamondon, T.P., Thrash, J., Cottone, J.A. A Multi-Group Longitudinal Study of Dental Unit Waterline Contamination. J Dent Res (IADR Abstract #3176) 75:414, 1996
18. Piche, J.E., Mills, S.E., Plamondon, T.P. Decontamination of Coolant Water from Ultrasonic Scalers Using a Proprietary 0.22 Micron Filter. Abstract #9614, OSAP Annual Symposium, Las Colinas, TX. 13 June, 1996

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OSAP Position Paper

INSTRUMENT PROCESSING

January, 1997

This position paper was developed by the Instrument Processing Working Group of OSAP.

The **Instrument Processing Working Group** has the following members:

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INTRODUCTION

The goal of this position paper is to describe procedures for the processing of contaminated dental instruments from the point of retrieving the instruments from chairside to the presentation of sterile instruments at the point of reuse. This information should assist dental health care workers in making decisions about instrument processing procedures. A major consideration during development of this document was safety for those who process instruments. Other considerations included time efficiency of handling instruments, minimizing instrument damage, and staff training. This document is consistent with the recommended practices from the Association for the Advancement of Medical Instrumentation (AAMI) for managing instruments prior to processing through portable steam or dry heat sterilizers (see references). The enclosed Table presents general information on the physical conditions, advantages, precautions, and monitoring of sterilization processes.

EXCLUSIONS

This position paper does not address procedures for gross debridement of instruments at chairside or details of sterilization monitoring.

PROCEDURES FOR INSTRUMENT PROCESSING

Wear appropriate personal protective equipment (PPE) when processing contaminated instruments including utility gloves and, if there is a potential for splash and spatter, a mask, protective eyewear and a protective gown or apron.

Step 1 - Transport: Transport contaminated instruments to the processing area in manner that minimizes the risk of exposure to persons and the environment.

- Use a rigid, leak-proof container.
- Use appropriate personal protective equipment.

Step 2 - Cleaning: Clean instruments with a hands-free, mechanical process such as an ultrasonic cleaner or instrument washer.

- If instruments cannot be cleaned immediately, pre-soaking or maintaining them in a moist environment may improve the cleaning process.

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- Insure that instruments are rinsed thoroughly.
- Visually inspect the instruments for residual debris and damage, and reclean or replace as appropriate.
- Dry instruments before packaging.
- Follow manufacturers' recommendations to lubricate and/or use rust inhibitors that are appropriate for the sterilization process as needed.

Step 3 - Packaging: In a cleaned, low-contamination environment, wrap/package instruments in materials that are appropriate for the sterilization process to be used.

- Loose instruments should be packaged so that they lay in a single layer, not wrapped up so tightly as to exclude exposure to the sterilizing agent.
- Avoid excess packaging material by using appropriately sized (not over-sized) packaging materials.
- Chemical indicators are placed next to the instruments inside the packages. If an indicator is not visible on the outside of the package, place an external process indicator on the package.
  - -- Use of multiparameter indicators (integrators) may provide a higher standard of sterility assurance.
- To maintain integrity of the package, follow only manufacturers' recommendations for sealing the package; and do not use staples, pins, or paper clips to seal packages.
- The shelf life of wrapped instruments processed through a sterilizer is event-related. Thus, the shelf life of a package ends when the integrity of the package becomes compromised, e.g., torn, punctured or moistened.
- Packages are dated on the date processed using methods that do not compromise the integrity of the wrapping material
  - -- Label information can be pencil-written on tape and then the tape is placed on the package.
  - -- Label information may be written on the outside of the sealed area of packages.
    - --- Do not mark on non-woven wrapping materials.
    - --- Do not use ink on paper packaging materials.

Step 4 - Sterilization: Sterilization is to be accomplished using a device that has been cleared by the U.S. Food & Drug Administration (FDA) as a sterilizer.

- Load the sterilizer according to manufacturers' instructions.
  - -- Do not overload the sterilizer.
  - -- Place packages on their edge, in single layers, or on racks to increase circulation of the sterilizing agent around the instruments.
- Use manufacturers' recommended cycle times for wrapped instruments.
- Operate the sterilizer according to manufacturers' instructions.
- Allow packages to dry before removing them from the sterilizer.
- Allow packages to cool before handling.

Step 5 - Storage: Store instruments in a clean, dry environment in a manner that maintains the integrity of the package. Rotate packages so that those with the oldest sterilization dates will be used first.

- Enclosed cabinets will increase the assurance that sterility of the package is maintained.

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Heat Sterilization Methods

Method	Temperature/Pressure	Exposure Time[a]	Advantages	Precautions
Steam autoclave[b]	121°C (250°F) 115 kPa 134°C (273°F) 216 kPa	15-30 minutes 3.5-12 minutes	Good penetration Non-toxic Time efficient	Nonstainless steel items corrode May damage rubber & plastics Do not use closed containers Unwrapped items quickly contaminated after cycle
Dry heat[c] (oven-type)	160°C (320°F)	60-120 minutes	No corrosion Non-toxic Items are dry after cycle Can use closed container[d]	Long cycle time May damage rubber & plastics Door can be opened during cycle Unwrapped items quickly contaminated after cycle
Dry heat[c] (rapid heat transfer)	191°C (375°)	12 minutes (wrapped) 6 minutes (unwrapped)	No corrosion Non-toxic Time efficient Items are dry after cycle	May damage rubber & plastics Door can be opened during cycle Unwrapped items quickly contaminated after cycle
Unsaturated chemical vapor[b]	134°C (273°F) 216 kPa	20 minutes	No corrosion Time efficient Items dry quickly	May damage rubber & plastics Do not use closed containers Must use special solution Uses hazardous chemical Unwrapped items quickly contaminated after cycle

[a] These exposure times relate only to the sterilization portion of the total cycle and do not include any warm-up, come-down or drying times. The exposure time may vary depending upon the load and should be verified during actual use by biological monitoring (spore-testing) and the use of chemical indicators.

[b] Monitor with spores of *Bacillus stearothermophilus.*

[c] Monitor with spores of *Bacillus subtilis.*

[d] Confirm by using biological indicator on inside of container.

Adapted from: Miller, CH: Update on heat sterilization and sterilization monitoring. Compend Contin Educ Dent 1993; 14:304-316

CH Miller 1996 - Ster-net.sam

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Processing impressions and trays

Impressions should be rinsed under running tap water then immersed# in a tuberculocidal hospital disinfectant prepared according to the label instructions for surface or immersion disinfection. After the manufacturer-recommended contact time has elapsed (usually ten to 30 minutes), the disinfected impression should be thoroughly rinsed under tap water to remove any residual antimicrobial chemicals and gently (to minimize spatter) shaken dry.
Incompatibilities between fabrication materials and surface disinfectants are known to exist. Physical and chemical properties can vary within a given category of material or solution. An in-office "test run" therefore is highly recommended when using new combinations of impression materials and disinfectants.

Material:	Acceptable processing methods:
Alginate	1:213 iodophors; 1:10 sodium hypochlorite solution
Polysulfide	glutaraldehydes; 1:213 iodophors; 1:10 sodium hypochlorite solution; complex phenolics*
Silicone	glutaraldehydes; 1:213 iodophors; 1:10 sodium hypochlorite solution; complex phenolics*
Polyether#	1:213 iodophors;# 1:10 sodium hypochlorite solution# ; complex phenolics#*
ZOE impression paste	glutaraldehydes; 1:213 iodophors
Reversible hydrocolloid	1:213 iodophors; 1:10 sodium hypochlorite solution
Compound	1:213 iodophors; 1:10 sodium hypochlorite solution
Impression trays:	
Aluminum	heat sterilize via autoclave, chemical vapor, or dry heat; ethylene oxide sterilization
Chrome-plated	heat sterilize via autoclave, chemical vapor, or dry heat; ethylene oxide sterilization
Custom acrylic resin	discard after intraoral use on a patient; disinfect with tuberculocidal hospital disinfectant for reuse during the same patient's next visit
Plastic	discard

Polyethers can be sensitive to immersion. Immersion for up to ten minutes or disinfection by spraying is the method of choice.
* Complex phenols cannot be reused and cost significantly more than bleach or iodophors. For these reasons, some experts contend that their practical use is limited to spraying.

Adapted from: Merchant, VA. Infection control in the dental laboratory environment. In Cottone JA, Terezhalmy GT, Molinari GT. Practical Infection Control in Dentistry, second edition. Philadelphia:Williams & Wilkins, 1996:239-248; Dean MC, Wooten RK. Special infection control considerations: restorative dentistry, periodontics, pediatric dentistry, prosthodontics, endodontics, orthodontics, and oral and maxillofacial surgery. In Cottone JA, Terezhalmy GT, Molinari GT. Practical Infection Control in Dentistry, second edition. Philadelphia:Williams & Wilkins, 1996:272-273; and Miller CH, Palenik CJ. Laboratory and radiographic asepsis. Infection Control and Management of Hazardous Materials for the Dental Team, second edition. St. Louis:Mosby (1998):213-215.

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16 臨床検査部門におけるエイズ対策に関する研究

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研究要旨：

HIV感染症の医療体制の充実のためには、HIVのスクリーニング検査（抗体検査・抗原検査・遺伝子検査）とフォローアップ検査(HIV定量・薬剤耐性検査)が必要に応じて的確に行われることが重要である。本年度はこれら個々のHIV検査法の問題点を明らかにし、および新たな検査法の開発を試みた。また、それら検査法が迅速に臨床応用できるようにするため、病院・研究機関・民間検査センター等の連携を密にするためのシステムの検討を行った。

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研究目的

1．HIV関連検査の確立と普及

HIV感染者の治療をバックアップするため必要となるHIV検査法の検討・開発を行い、さらにその普及を計りその後の精度管理等もできるようにする。

2．医療機関と研究期間・検査機関との連携

上記（1）の目的を達成するため、医療機関と研究機関・検査機関との連携のためのシステムを構築する。

研究方法

HIVの抗体検査・抗原検査・遺伝子検査・ウイルスの定量検査・薬剤耐性検査等について、各班員が分担してその検査法の検討・開発等の研究を行い、グループ内で必要に応じ討議し検討する。検査法に問題のある場合また新たな検査法が開発された場合は、出来るだけ早い段階で実際に活用できるよう、各医療機関への普及に努める。

当面は、HIV定量と薬剤耐性の検査法に関する研究が最も重要な課題であり、本年度もこれら課題を中心に研究を行った。

研究結果

1．HIV定量キット（アンプリコアHIVモニター）の検討

サブタイプE,Aの定量値：

現在、血中HIVの定量用に認可され使用されているアンプリコアモニターHIVはサブタイプBの定量に関しては問題無いが、サブタイプEとAについては定量値が実際より低い値を示すことがわかり問題となっている。当研究グループでは、新たなプライマーを開発し、サブタイプE,Aについてもより正確な定量値が得られる定量法を確立しその普及にも努めてきた（文献1）。現在ロシュでも暫定的改良キットが開発され試験的に使用されているが、正式に認可されたキットでないため保険適用にならず研究的使用に限られている。最近、本格的な改良キットが開発され近々申請になる予定である（資料1，吉原班員研究報告参照）。異性間の感染者ではサブタイプEの感染例も増えてきており（文献2，資料4）、現在の定量キットを使用する場合サブタイプを考慮して測定値を評価することが重要である。今後できるだけ早い時期に、いずれのサブタイプでも正確に測定可能な定量キットが使用可能となることが望まれる。

定量値の再現性：

抗HIV剤による治療の開始または治療効果の判定に、血中HIVの定量が極めて重要な意味を持っている。このため測定値のばらつきの程度を知るため、測定値の再現性のコントロールサーベイを行った（吉原班員）。コントロールサーベイの結果では、ほとんどの検査・研究機関のHIV定量結果はCV値も予測値内であり、いずれの機関での測定値も十分信頼性のあることがわかった。（但し測定値が2倍または半減程度の変化については一回の検査結果を基に、そのままの値でウイルス量が増減していると考えることは出来ない。2回以上の測定で3倍以上の増減が確認できれば、その信憑性はかなり高い。）

2．抗HIV薬に対する耐性変異の解析

フェノタイプ（薬剤感受性）の解析：

ウイルス培養による薬剤感受性実験は薬剤耐性を直接的に証明する最も有効な方法である。

但し、検査法が複雑で時間と費用がかかるため、通常の臨床検査としての応用にはかなり困難がある。そのため、現在はかなり限られた研究施設で検査法そのものの研究がなされ、一部その臨床検体への応用が検討されている。当研究グループでは、加藤班員、大石班員、今井班員らのグループで薬剤感受性試験の検討を行っている。加藤班員は特にプラーク法による感受性試験法を開発し、遺伝子変異から推測された薬剤耐性と実際のプラーク法により測定した薬剤耐性とに乖離のある例を見いだした（資料３，加藤班員研究報告参照）。遺伝子変異から推測する薬剤耐性が、実際の臨床例の薬剤耐性をどこまで適切に反映しているか、今後の重要な検討課題である。

ジェノタイプ（遺伝子変異）の解析：

現在抗HIV薬として使用されている、逆転写酵素阻害薬・プロテアーゼ阻害薬のいずれに対しても、耐性変異株が出現することが知られている。またそれら変異株の遺伝子変異について多くの知見が集積されつつある。このため、患者血液中のHIVに関して、遺伝子解析を行うことにより、各抗HIV薬に対する耐性の有無をある程度予測可能となった。当研究グループの各班員も、遺伝子解析を積極的に行い、治療の際の使用薬剤の選択・変更にそれら結果は有効利用されている（文献６，資料３）。

しかし、今後多剤併用療法が普及するに従い、薬剤耐性変異の出現様式も多様化することが予測される。従ってこれら多剤併用に伴い出現する新たな耐性変異をどう検出するか、また個々の薬剤に対する種々の変異をどう評価すべきか等多くの問題が、今後の課題として残されている（文献６）。

３．HIV関連検査の確立と問題点

”エイズ医療体制の確立を目指して”の公開シンポジウムの中で、ワークショップ”HIV関連検査の確立と問題点”のタイトルでワークショップを行った。ワークショップでは、５名の班員と杉浦先生（国立感染研）にHIV検査法の問題点、病院と研究機関・検査機関との連携のありかた等について報告して頂き、熱心な討議を行い以下の抄録をまとめた。

HIV関連検査の確立と問題点

座長：　今井光信　伊藤章

話題提供者：

1. HIV定量キットの現状と問題点
　吉原なみ子　（資料１）
2. 薬剤耐性検査（フェノタイプ）の現状と問題点
　加藤真吾　（資料２）
3. 薬剤耐性検査（ジェノタイプ）の現状と問題点
　杉浦　亙　（資料３）
4. 病院検査室におけるHIV検査の現状と問題点
　伊藤　章　（資料４）
5. 地方衛生研究所におけるHIV検査の現状と問題点
　大石　功　（資料５）
6. 民間検査センターにおけるHIV検

査の現状と問題点
植田昌宏 （資料６）

本ワークショップでは、HIV関連検査の現状と問題点について、検査法と検査体制の両面から検討した。

HIVのスクリーニング検査は検出感度、特異性の両面でかなり改良されてきたが感染初期（ウインドウ期）の検査への対応と偽陽性をさらに減らす努力が今後も必要。

HIVのフォローアップ検査ではまず第一にウイルス量の正確な定量が必要。

現在認可されている定量キットでは、サブタイプEの定量値が実際の値より低値を示すためサブタイプを考慮した注意深い評価が必要。すでに、どのサブタイプをも正確に定量できるキットも開発されており、できるだけ早い時期に使用可能になることが望まれる。

HIVフォローアップ検査として薬剤耐性検査が次に重要である。
現在研究レベルでは、薬剤耐性に関与する遺伝子変異の解明がかなり進んでいる。
ただし、実際の多剤併用療法後に出現してくる薬剤耐性変異株を、的確に検出し臨床に役立てるためには、検査法の迅速化と低コスト化を含む検査システムの開発が必要。また遺伝子の耐性変異と実際の薬剤感受性には不一致例もあり、今後さらに検討が必要である。またその研究成果を迅速に、実際の検査に反映させることが重要である。

検査体制としては、最も直接に関わりのある病院検査室、各地域の検査・研究拠点としての地方衛生研究所、最も多くの検体を集中的に検査している民間検査センターがそれぞれの特性を生かしつつ、いかに連携して効率のよい、また質の高い検査体制を構築するかが今後の課題。

結論：

HIV感染者の病態把握、また抗HIV薬の治療効果等の判定に血中HIV量の正確な測定が極めて重要である。現在使用されているHIV定量キット”アンプリコアHIVモニター”はサブタイプEとAとの測定値が実際の値より低値を示すため、注意を要する。異性間の性感染例ではサブタイプEの例が増えており、特にこれら症例については、サブタイプE用のプライマーを加えてHIV定量する事が必要である。既に全てのサブタイプに対応出来る定量キット”アンプリコアHIVモニターversion1.5”が開発されており、それらキットの使用によりHIV定量におけるサブタイプ問題が早く解決される事を希望する。

薬剤耐性の検査に関しては、遺伝子変異の解析結果が集積されつつあり、逆転写酵素の変異と逆転写阻害剤に対する耐性変異、プロテアーゼの変異とプロテアーゼ阻害剤に対する耐性変異、等の関連が明らかになりつつある。しかしながら、実際に分離ウイルスを用いた培養実験による薬剤感受性試験の結果は必ずしも遺伝し解析の結果とは一致しない例もあり、遺伝子変異による薬剤耐性の判断は慎重に行う必要がある。現段階では、患者血中のウイルスの遺伝子解析の結果と臨床データ（特に血中ウイルス量の推移）とを総合的に判断して薬剤耐性変異株の動向を判断し、必要があれば、