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Research Article

Problems on Going during the Application of Guidelines for COVID-19 Prevention in Dentistry

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Abstract

Regulatory boards and many dental associations, some experts on infection control published and updated regulatory burdens and recommendation on infection prevention during COVID-19 pandemic in dental settings. Our aim is to focus on some problems and difficulties in applying the recommendations concerning the supply of proper items (PPE, surface disinfectant) or concerning their specific uses and skin injuries. We searched electronic English articles published in Google Scholar databases (January-May 2020) using various combinations of the key indexing terms. 61 articles were selected for comprehensive reading according to the inclusion criteria. On the basis of our experience in a university department and private offices, we believe that regulatory burdens based on better knowledge on bioburden, task-specific, evidence-based guidelines and resources, education and training are required to improve compliance with infection control recommendations, avoid inappropriate adoption under EU and National laws and to prevent skin injuries.

Keywords: *Infection Control; Covid-19; Sars-Cov; Dentistry, Disinfectant, Ppe*

Abbreviations

ADA: American Dental Association; AGP: Areosol Generating Procedures; CDC: Centers for Disease Control and Prevention; CCSs: Clinical Contact Surfaces; DHCP: Dental Healthcare Personnel; DUWL: Dental Unit Water Line; EMRSA: Epidemic MRSA; EU: European Union; FDA: Food and Drug Administration; FFP: Filtering Facepiece; HVE: High Volume Evacuator; IFU: Instruction for Use; MSDS: Material Safety Data Sheet; NTM: Non Tuberculous *Mycobacteria*; PPE: Personal Protective Equipment; RTU: Ready-to-Use

Introduction

It is unknown the worldwide evolving nature of the COVID-19 post-pandemic era [1]. In addition, many unknowns regard the virulence/pathogenicity, SARS-CoV-2 mutations and selective advantages in transmission or resistance to interventions, the modes of transmission (via droplet, contact, airborne, feco-oral and fomite), the reservoir and the source of infection of SARS-CoV-2, the mild or asymptomatic cases, and the potential hazard of bioareosol in the dental setting. Because of the devastating consequences in the absence of effective treatments (vaccine, drugs etc.) and the evidence of asymptomatic and pre-symptomatic individuals, it is imperative to maintain a very high degree of attention by all dental health care personnel (DHCP) whilst strict adoption of infection control in the dental clinic

environment [2-7]. This is needed always for all of us and all dental patients and those who are particularly susceptible to infections (older population, men, smokers, orthodontic patients) [4].

Every day during dental work, DHCP faces up to air-borne, blood-borne and water-borne infections. Unfortunately, it is well known the limited awareness on infection prevention guidelines, and the lapses and errors during infection prevention, which sustain the evidence infection reservoirs, in dental staff, patients, dental items or in the environment, including dangerous epidemic MRSA-15 (EMRSA-15) or EMRSA-16 lineage [8,9]. The most frequent failing was poor hand hygiene and inappropriate glove use, which are standard precautions known to have high cost/benefit advantages [8,9]. Concurrently, evidence shows some cases and two epidemics of iatrogenic infections [10-12], the last ones not indicated in recent reviews [13]. Recently, some breaches on infection prevention (improper sterilized tools, forget certificates, improper DHCP formation and training) and on patient data privacy has been shown by mass media in USA.

Then, during COVID-19 pandemic, the need to prevent cross- infection caused by SARS-CoV-2 and co-infections (oral and upper respiratory commensal bacteria, rhinovirus/enterovirus, respiratory syncytial virus, non–SARS-CoV-2 Coronaviridae, mycoplasma) is added to the previous situation [14,15]. The virus spreads easily between people. Environmental contamination, by patients with SARS-CoV-2 through respiratory droplets and aerosol generating procedures (AGP) in dental office, supports the need for strict adherence to environmental, respiratory and hand hygiene [16]. Recently, asymptomatic COVID-19 patients have also been reported to contaminate their surroundings [7]. Moreover, hospital COVID-19 spread could increase by the lack of proper triage and guidelines for dental health care facilities or lapses and errors during infection prevention, including inappropriate nail hygiene and personal protective equipment (PPE) use among dental hygienists [8,17-19].

During COVID-19 pandemic, gold standard recommendation and those from many other dental associations faced infection prevention mainly for emergency dental cares [20-22]. Firstly, Californian Dental Association (CDA) published a return-to-practice roadmap and recommendations for dentists in post-COVID-19 pandemic, followed by other association and regulatory boards [23-25].

A review of eleven international sources on the recommendations for the re-opening of dental services [26]. Many experts published other comments with more suggestions and operative details [13,17,27-30], but references regarding CDC guidelines are sometimes not updated or occupational laws taken into account [30]. All sources emphasize the need to focus on activities that minimize risk (to staff/patients/public), but still support high quality clinical care. Nevertheless, the document [26] underlines a highly variable level of detail given across international sources, and in the majority of sources, lack of a link (reference) to sustain a strong (or any) evidence.

Now more than ever, the main aim is to minimize healthcare and occupational transmission of SARS-CO-V-2, adopting standard procedures, a rational use of PPE to avoid shortage of PPE for DHCP and, definitely to limit the cost for supplying them and overcharged cost for patients [29]. Taking into account the state of the art, our goal is to share some difficulties in relation to our different knowledge, as department heads in charge on the responsibility infection prevention (AB, ABG, FS), and as dental nurse tutor and decisions as infection control coordinator (LB). All the authors work in dental facilities located in Lombardy, the worst Italian area for COVID-19 outbreak. Barenghi previously blamed the Italian bureaucratic system for it slow response about guidelines and the danger caused by unauthorized and illegal dental practices (estimated about 14000 in Italy, with 2/3 of them located in Lombardy) without any controls [31]. Nowadays, the choices for working safely are not easy. Many products and items, proposed to sanitize or reduce dental aerosols, currently lack research demonstrating they are effective or could be insufficient in the case of poor ventilation o are counterfeit [32-34]. Some problems and difficulties in applying the recommendations have been discussed concerning the choice and supply of proper items (PPE, surface disinfectant) or concerning their specific uses and skin injuries.

Materials and Methods

Information sources and search strategy

The electronic literature search was conducted via the PubMed and Google Scholar databases (from January 2020 up to and including May 2020) using various combinations of the following key indexing terms: (a) COVID-19; (b) SARS-CoV2, (c) cross-infection control; (d) infection prevention; (e) guideline; (f) disinfection; (g) reconditioning; (h) semicritical items; (i) critical items; (j) surface disinfectant; (k) barrier. Subsequently, bibliographic material from the papers has been used in order to find updated recommendation or older appropriate sources in relation to specific topics and operative problems. A total of 61 papers and links were found suitable for inclusion in this paper. Only a few papers do not have a DOI or PubMed classification, but the available Internet link and date accessed have been added.

Results and Discussion

We discuss some problem concerning the supply of proper items (PPE, surface disinfectant), barriers or concerning their specific uses and consequences for skin.

PPE supply and use

Because of vaccine or specific drugs will be not soon available, PPE plays a major part in infection control. In the USA, the PPE availability in dental practice continues to improve [35]. DHCP and dental nurses are worried by unstable PPE supply and too often, PPEs have unclear or counterfeit declaration from offshore manufactures [34-37]. In general, DHCP doesn't feel safe, prepared or supported by adequate information about SARSCo-V-2. For example, no fit testing for filtering facepiece (FFP) respirator is needed by the Italian main recommendation [38]. This document contains other unclear and/or confused indications, has been prepared without following NICE instructions (https://www.nice.org.uk/), under interest conflicts. Up to now, it is not yet present in the Italian Guideline System (https://snlg.iss.it/?s=covid) and then, the true legal value of this document is unclear [38]. In addition, FFP respirators with different size are difficult to found and to fit them with ear loops [35]; ear skin reaction are frequent after the sessional use. Dental associations, boards and NHS recommends the use of a particulate respirator (NIOSH-certified N95, European Union (EU) standard FFP2, or equivalent), when performing undergoing procedures that might pose higher risk (e.g. those generating potentially infectious aerosols or involving anatomic regions where viral loads might be higher (tongue, glands etc.) [16-24,39]. Nevertheless, a critical review on surgical mask versus FFP reported that the advantages of FFP are often over evaluated [40]. The CDC has issued guidance to help healthcare professionals identify a NIOSH-approved respirator and avoid buying counterfeit masks [24,34,35]. Since the beginning of April 2020, NIOSH NPPTL has evaluated over 194 FFPs, but approximately 58% failed the LIMITED TEST and achieved filtration efficiency below 95% [35]. The suggested price for KN95 is $2 - $3 per unit in USA), while FFP2 is selling for 4,2 € by one of the main Italian distributors for dental supplies (https://www.dentaltrey.it/it/ricerca/q/?key=ffp2 on 30/06/2020).

According to CDA roadmap, even the near term milestones (access to appropriate and plentiful PPE to protect against potentially infectious aerosol transmission; viable options for eliminating, reducing or containing aerosol production during care; access to training on COVID-19-specific protocols and procedures) are difficult to achieve [23,35,41].

The decontamination and reuse of FFP respirators has been proposed in different ways (UV germicidal irradiation, vaporous hydrogen peroxide, moist heat), but difficult to run without effects on FFP respirator performance and/or to certify in private dental settings [42]. Because facemasks and cloth face coverings can become saturated with respiratory secretions, DHCP should take steps: a) change and cover facemasks and coverings, b) lauder cloth face coverings daily and when soiled, c) hand hygiene immediately before and after any contact with the facemask or cloth face covering, and d) provide DHCP with training about when, how, and where cloth face coverings can be used [25]. In addition to face shields, many institutions have adopted an old recommendation of wearing also a second mask to protect the N95 respirator from gross contamination, by covering the outer surface and allow for reuse. This option should further carefully evaluated taking into account the work position of DHCP and the increased breath difficulties. In addition, because the surface viability of

the SARS-Co-V2 on FFP respirators is assumed to be 72 hours, a proposed option is to rotate N95 respirator use and to allow time decontamination of FFP respirators [43]. In dental settings, we have to keep in mind the high frequency of AGP, often contaminated procedures with blood and the presence of longer microbial resistance of others pathogens (HBV; HCV, *S. aureus* and MRSA, *Candida, Mycobacterium tuberculosis, Clostridium difficile* spores, *Pseudomonas*) [44,45].

Surface disinfection and disinfectant supply

We agree with the ADA advises that it is still important to wait for disinfecting the treatment rooms after the AGPs, even through the CDC removed the recommendation calling for a 15-min waiting period [46]. Further studies are needed to reduce this period in the case of air flow rate, volume of patients, length of AGP, use of HEPA air filtration devices and rubber dams and HVE. Taking into consideration the potential hazard of bioareosol in the dental setting, no countries or authorities consider airborne spread of COVID-19 in their regulations or have recommendation for the removal of the virus-laden droplets from indoor air by ventilation [10,44,47,48].

In simulated, conditions and post aerosolization, Van Doremalen found that viable SARS-CO-V2 could be detected up to 2 - 3 days on plastic and stainless steel [47]. Nevertheless, it is not known the link among SARS-Co-V2 viability, virulence and infectivity. But, the majority of clinical contact surfaces (CCS) in dental offices are made of these materials (from dental chairs to halogen lamps, aesthetic filling material syringes, radiographs, phosphor plates, impression material mixers, face shields and metal dental instruments etc.) and then, the surface reconditioning is very important.

The surface disinfectant supply is always more difficult to avoid gray-market products (i.e. without approval in accordance with European Community product directives and/or, defective or expired). Examples have been reported in ref 8 (see section 4.2.1) and in the security notices from Italian Ministry of Health (http://www.salute.gov.it/portale /news; Accessed 2020, May, 30).

The contamination has been reported and caused by bacteria (more frequent with *Serratia marcescens, Pseudomonas, Burkholderia Cepacia*) and toxic methanol or acetone [8,45,49]. In the absence of a specific UE list for surface disinfectants certified against SARS-CoV-2, refer to List N on the EPA website for EPA-registered surface disinfectants against SARS-CoV-2 [24,25,50] and to the nonspecific indication of ECDC website [51]. There is no specific indication for dentistry in ECDC website [51]. Nevertheless, the label claim of a surface disinfectant certified only to SARS-CoV-2 is not sufficient for CCS in dentistry. It is well known that the area spreading up to one meter from the dental unit is contaminated with blood, microorganism or other more resistant infectious agents (MRSA, *Pseudomonas* etc). Then, after each patient, the CCS must be cleaned and disinfected with a certified medium level (against TBC) disinfectant [10]. The procedure is therefore carried out in two phases, best using disinfectant with low contact times (< 5 minutes) and compatible with clinical contact surfaces (mainly are at all angles and made of plastic materials). In general, there are some pitfalls in the application (operational constraints in dental settings - e.g. contact time of a surface disinfectant, insufficient dispersal, a lot of irregularly shaped surfaces and microbial niches- compared to high patient turn-over, unmotivated and/or untrained personnel; use of disinfectants with inadequate certifications). The use of spray disinfectants compared to impregnated and ready-to-use (RTU) wipes is affected by the operating constraints (e.g. vaporisation of high volatile substances, not standardized surface dispersion, improper spray nozzle technology, evaporation etc). Barenghi reported in detail the operational, occupational, ecological advantages of single-use wipes soaked with disinfectant compared to liquid disinfectant [45]. Concerning ergonomics and occupational safety, one of the main advantages of RTU impregnated wipes is minor aerosol generation by spraying. In fact, spray dispensed by pressure from a spray bottle should be avoided because it could produce aerosols and increase inhalation and dermal exposure to components and/or contaminated aerosol or surface contamination. Nevertheless, more detailed IFU on cleaning and disinfection action, are needed for RTU wipes and for upholstery maintenance and disinfection of dental chair. All PPE and puncture and chemically resistant utility gloves (by nitrile rubber) should be used for all cleaning and disinfecting procedures.

Disposable barriers

These are especially useful for protecting CCS areas that are difficult to recondition, such as certain parts of dental units or "old generation" instruments and designs. Whether the synthetic protective covers are able to effectively perform as antimicrobial barriers depends on their component's hydrophobic characteristics (polyethylene) [52]. Because the quality differences between medical and food barrier, we prefer to use disposable medical grade barriers or disposable self-adhesive protectors and then strict disinfection of all surfaces [45]. Because the electrostatic charge and the microscopic holes caused by stretching of cling film, microorganism adheres to barrier and could be transferred to the below surfaces. Then, since aerosol diffusion, disposable barriers cannot be left for hours on dental CCS (e.g. not left on dental chair during the night).

Reconditioning of dental items in UE

Sterilization protocols do not vary for respiratory pathogens [10,24,25]. Nevertheless, we underline that poor or bad instrument reconditioning practices for critical dental items are linked to cross infection [10,11]. Moreover, we previously review the failures concerning dental instrument reconditioning, which includes those happening during decontamination, cleaning, wrapping, sterilization and storage [8]. In our opinion, there are three important points to check: a) avoid the drying of biological fluids (because of saliva and blood could contain SARS-Co-V2) on instruments and long delay in reprocessing (better within 6 hr) [53]; b) the choice of disinfectant with cleaner activity; c) loss of sterility due to exposure to air or environmental contamination. We have to remember the lessons from the cases and epidemics of iatrogenic infections caused in dental surgeries by hepatitis viruses and *Enterococcus fecalis* and in pediatric department DUWLs by non tuberculous *Mycobacteria* (NTM) [10-12].

It is well known that there aren't any European guidelines for dentistry, but we have a good European Union regulatory framework for medical devices and to safeguard the health of dental workers. In general European rules have improved the quality of many items and medical devices (MD) that we currently use, from gloves, masks, disinfectants and steam autoclaves, and so on. The EU Regulation 745/2017 combined and revised two old directives (the Medical Devices Directive 93/42/EEC and Active Implantable Medical Devices Directive 90/385/EEC). This regulation has the force of a law in all states members and will eliminate country-by-country differences in the quality of a MD. It will increase scrutiny mechanism on MD for conformity assessments according to European standards. During COVID-19 epidemic we must be sure to use CE marked MD. We must be protected from the possibility of buying dental items of uncertain quality with the fake CE mark [54].

European legislation on chemicals (their classification, labeling and packaging of substances and mixtures) is important for all disinfectants. We disagree with Bizzocca concerning the possibility to use 2% glutaraldehyde in UE, the suggested procedure for dental handpieces and the indicated quality of the dental output water delivered to patients [13]. During MD reconditioning, we need to select glutaraldehyde-free disinfectants according to European law governing occupational safety, while the use of glutaraldehyde is allowed in the USA. In Italy, the use of only detergent and water for cleaning the instrument before sterilization, should be carefully evaluated in line with EN ISO 17665, IFU and Italian Laws (in particular, D.M. 8/9/1980). According to CDC guideline, the "Dental handpieces and associated attachments, including low-speed motors and reusable prophylaxis angles, should always be heat sterilized between patients and not (only) high level or surface disinfected" [10]. In our opinion, the best recommendation for dental handpieces reconditioning (including external and internal cleaning, lubrification and sterilization) is the HTM 01-05 by the UK Department of Health.

Generally speaking, there are other differences between CDC and European recommendations. We paid more attention to prions and then, steam autoclaves have been developed according to EN13060. As for quality control, we prefer the frequent use of Load Check indicator to check the efficacy of the ultrasonic washers and washer-disinfectors, and of vacuum tests, steam penetration tests and steam chemical integrators (ISO 11140- 1:2014 Type 5) rather than the frequent use of biological indicators for steam autoclave daily controls [details in ref. 8].

We disagree with Bizzocca concerning the possibility to use water compliant with Environmental Protection Agency (EPA) standards for drinking water (i.e. ≤ 500 CFU/mL of heterotrophic water bacteria) [13]. In most European countries, there are no specific standards for the quality of the dental output water delivered to patients or used for cleaning, but the standard proposed by some guidelines is 100 - 200 CFU/ml for dentistry. According to Directive 98/83/EC, the accepted level of patient water contamination is smaller than the standard established by CDC, EPA or ADA, because should meet the regulatory standards for drinking water. The heterotrophic cell count at 22°C must be lower than 100 CFU/ml, that at 37°C less than 20 CFU/ml as also stated in the Italian Guideline for *Legionella* Prevention on 2015 (http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2362).

Reconditioning of face shield

The use of solid face shield or a face shield to protect mucous membranes of the eyes, nose, and mouth is mandatory during procedures likely to generate splashing or spattering [24,25,45]. In UE, face shield have to follow EN166-class III; we prefer face shield in heat-formed acetate with anti-fog treatment and silicone band in an allergic material. The possibility to ensure perfect ventilation and to do not tarnish relies on anti-fog coating or adjustable ventilation. In addition, the fit over glasses and magnifiers is important. How to clean and disinfect face shields is of paramount importance, but often specific protocols are not indicated clearly by producers or requested by regulatory boards [25,26]. We recommend preventing the face shield contamination during AGP by using single-use transparent barrier on the critical parts. The scratch-resistance and the optical clarity resistance are important since the repeated donning on and off and the need of adaptation to glasses and magnifiers. Compatibility test should be performed in an inconspicuous place on the shield, such as the edge and out of your line of sight by applying a small amount of the product, waiting about 1h and checking for scratching or permanently cloudy surface.

During reconditioning, use utility gloves and avoid surface scratches by submerging the face shield in warm water and cleaners to dislodge particulate matter. Don't use household cleaners, abrasive creams or products formulated to clean glass surfaces because they could contain ammonia or detergents, that cause a cloudy surface. It is preferable to use ready-to-use impregnated wipes, having both cleaning and disinfectant activity strictly following IFU; then, it is important to check the plastic surface clarity and the absence of visible bioburden or particulate matter [8,45,50]. Products with short action time containing disinfectants and high amount of detergents cause faded stains on metal trays and transparent screens.

Skin injuries caused by the use of PPE

Frequent (observed in 42,8% of staff treating COVID-19-infected patients) and serious skin injuries have been reported related to the use of PPE, including masks, goggles, face shields, and protective gowns. Longer wearing time, the greater will be the risk of skin injuries. Three main types of PPE-related skin injuries have been identified: device-related pressure injuries; moist associated skin damage; skin tear [55-58]. Several factors increased the risk for skin injury: heavy sweating, greater daily wearing time, being male, and using grade 3 versus grade 2 PPE [55-57]. In the case of FFP sessional use, it is important that:

- DHCP are educated and trained to prevent the contamination of clothing, skin, and the environment during the process of PPE removing.
- DHCP should evaluate carefully the use of prophylactic dressings
- Because of breath difficulties and sweating, FFP should be replaced at least every 2 - 6h following IFU, and disposed if it becomes moist, damaged, visibly soiled [57,58].

Long term use of N95 mask in an ICU did not result in any clinically relevant physiologic burden of HCP, although many subjective symptoms (perceived shortness of air, headache, and lightheadedness, difficulty communicating and increased CO_2 level) were reported

[59]. It is hard to avoid touching (average 25 times /12 hrs) the face or touching/adjusting N95 respirator with (contaminated or gloved) hands. This is dangerous because hand touches could transfer virus to mucous membrane to face or contaminate the mask. It is not known the consequence of the use of hand sanitizer products that has been tested by FDA, labeled to contain ethanol (also known as ethyl alcohol), but that have tested positive for methanol contamination. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the lung, skin or ingested and can be life-threatening [60].

Conclusion

Waiting vaccine and drugs, and probably the second wave of SARSCoV-2, the prevention of cross infection is the main way for dentistry.

Taking into consideration COVID-19, NTM and *Enterococcus* outbreaks, we need to rapidly improve the efficacy and efficiency in infection prevention by means of:

- Better awareness on infection prevention guidelines, and the lapses and errors for all dentists working from the area with the highest COVID-19 prevalence [61].
- An European guideline for dentistry.
- The implementation of the EU Regulation 745.
- Vigilance of EU Institutions about items with fake CE mark. We must be protected from the possibility of buying dental items of uncertain quality with the fake CE mark.
- Use of surgical facemasks or FFP designed to rapidly inactivate dentistry-associated pathogens and customized for DHCP.
- More automation and no-touch procedures for cleaning and disinfection.
- More knowledge about skin injuries by PPE.

Conflict of Interest

Livia Barenghi had a service agreement with KerrKaVo and was a consultant for Dental Trey il Blog (http://blog.dentaltrey.it/), neither of which gave any input or financial support to the writing of this article. The authors (Alberto Barenghi, Francesco Spadari, Aldo Bruno Giannì) declare that there are no conficts of interest regarding the publication of this paper.

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