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**Review Article** 

## Continuum of care for patients with obstructive sleep apnea after one year from the COVID-19 pandemic onset: no time for further delays practical issues for a safe and effective management

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#### ABSTRACT

Since the SARS-CoV-2 pandemic onset, many routine medical activities have been put on hold and this has deeply affected the management of patients with chronic diseases such as obstructive sleep apnea. Untreated OSA is associated with increased mortality and difficulties in social functioning. A delay in initiating treatment may therefore have harmful consequences. Between February and April 2020, the so-called first wave of the pandemic, the overall activity of sleep centers in Europe was reduced by 80%. As the international infection control authorities released guidelines for SARS-CoV-2 outbreak control, many of the national sleep societies provided strategies for a gradual re-opening of sleep facilities. Most of these strategies were not evidences-based and, in a climate of general concern, worldwide it was strongly advised to post-pone any non-urgent sleep-related procedure. Despite the initial idea that the outbreak could be transient, after one year it is still ongoing and the price we are paying, not only includes deaths caused by COVID-19, but also deaths caused by missed or late diagnosis. As further delays in diagnosing and treating patients with sleep apnea are no more acceptable, a new arrangement of sleep facilities and resources, in order to operate safely and effectively, is now mandatory. In this article, we review most recent literature and guidelines in order to provide practical advice for a new arrangement of sleep laboratories and the care of patients with obstructive sleep apnea after one year from the onset of the COVID-19 pandemic.

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#### 1. Introduction

Since December 2019 the novel coronavirus SARS-CoV-2 has emerged as the cause of a pandemic disease known as coronavirus disease 19 (COVID-19) [1]. The virus spreads rapidly, through airborne droplets, aerosols and close contact, with great risks for all healthcare workers and particularly for those involved in aerosol producing procedures. The pandemic has deeply affected health systems worldwide and the routine medical practice and two main problems have emerged since its onset. First, most of the countries' healthcare resources have been rechanneled from elective care to the care of patients with COVID-19. Second, the fear of the virus spread in healthcare environments has prompted international health authorities to advise the postponing of non-urgent medical

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or surgical interventions, thus reducing patients' access to hospitals and health facilities. Consequentially, since February 2020 many medical activities have been put on hold and this has deeply penalized patients with chronic diseases, requiring constant monitoring and care.

Obstructive sleep apnea (OSA) is among those chronic diseases associated with relevant morbidity, mortality and social problems [2]. In addition, in recent months some studies suggest that the presence of OSA as a co-morbidity in patients with COVID-19 increases the risk of hospitalization and mortality [3,4].

Management of patients with OSA in sleep centers includes diagnostic procedures such as nocturnal sleep studies and treatment with positive air pressure (PAP). As both these procedures are risky for virus spread, many sleep centers in western countries have suspended routine procedures, limiting activity to urgent cases. One study reported that in Europe, from February to April 2020, the first wave of the COVID-19 pandemic, the overall activity of sleep centers was reduced by 80% [5]. A reduction in sleep testing up to 90% was also documented in US in April 2020 [6]. During this first







stage of the emergency the World Health Organization (WHO) and the Centre for Disease Control and Prevention (CDC) have provided constantly updated recommendations for SARS-CoV-2 infection prevention and control in healthcare environments [7,8]. Between March and June 2020 many national sleep medicine societies have provided guidelines for the implementation of these infection control strategies in sleep centers. The British Thoracic Society joined with the British Sleep Society provided the first recommendation to avoid any out-patient visit in sleep centers, unless urgent [9]. An early mitigation strategy document, from the authoritative American Academy of Sleep Medicine (AASM), also strongly recommended to postpone procedures, unless urgent [10] These recommendations were confirmed worldwide [11–15]. These early suggestions were not evidenced-based at the time of their release, as little was known on the modalities of virus transmission, permanence on surfaces and on the proper disinfection procedures for environment and medical equipment. However, for many months patients with suspected OSA, that usually wait a variable time from the first triage visit to the treatment, had to suffer a further delay to get their treatment. As by the end of April the first epidemic wave was waning, efforts were made to organizing re-opening of sleep laboratories, aware of the difficulty to reconcile the strict rules needed to guaranty safety with the burden of patients now urging a treatment. The big challenge was to implement new protocols without the help of evidenced-based information. After first "ad interim" recommendations, some other updated guidelines were released in August 2020 [15,16]. While efforts were made to re-open healthcare facilities, a second wave of the epidemic started last autumn, affecting countries all over the world, with some European countries, guite spared by the first wave (eg UK), experiencing a dramatic spread and an overwhelming number of deaths. The British Thoracic Society and the British Sleep Society updated recommendations in December 2020, still discouraging from routine performance of sleep studies [17]. At the end of 2020 the European Respiratory Society published a document on sleep laboratories re-opening, summarizing the different approaches followed in Europe and USA, which reflect National recommendations according to the epidemiological phase of the COVID-19 pandemic [18].

This article aims to revise available data in order to provide practical advice for a safe and effective management of patients with sleep apnea after one year from the onset of the COVID-19 pandemic. In addition to revise literature, we provide examples of protocols for the organization of a sleep laboratory, also in light of our own experience, since Italy has been affected by the pandemic earlier than other western countries, thus arrangements for reopening have been made in an earlier phase. The concepts behind this article are the following: 1) OSA is associated with relevant mortality/mortality and sleepiness is cause of road accidents and work accidents, thus there is urgency to control the disease; 2) OSA is among risk factors for severe COVID-19 illness; 3) currently, we are not able to predict the duration of the pandemic, so that "postponing" treatments might be a dangerous approach, whereas learning to coexist with COVID-19 might be a wiser approach; 3) since the time of first recommendations from sleep societies last year, the knowledge on virus transmission has gone on and more rapid diagnostic tests are now available, so that it is necessary to update protocols.

#### 2. Current knowledge on virus spread and transmission

SARS-CoV-2 is a single stranded RNA virus belonging to the family of coronaviridae. The transmission of a virus is influenced by various factors such as virus infectivity, host behaviors, defense mechanisms and environmental factors [19]. Pathways of transmission include direct and indirect ways. Direct transmission refers to the transfer from one infected person to another, whereas indirect transmission is the transfer through contact with a contaminated intermediate object [20]. Accurately identifying the contribution of each mode of transmission to the overall transmission of respiratory viruses still remains a challenge. SARS-CoV-2 is primarily transmitted through droplets (droplet transmission), through droplet nuclei (airborne transmission) or through contaminated objects (fomite-based transmission) [21,22]. Transmission through droplets occurs during breathing, coughing, sneezing or talking and once released the virus remains viable in aerosols for up to 3 h [23]. Emission of droplets has been widely explored, in order to understand host-to host transmission and contamination of surfaces. Early remarks on SARS-CoV-2, along with the knowledge on previous SARS-CoV viruses, led the CDC to recommend a minimum 6 feet separation between subjects to avoid transmission [24]. One study has shown that exhalations not only consist of mucous-salivary droplets, following short-range semi-ballistic emission trajectories, but are also made of a turbulent gas cloud (puff) that entrains ambient air and carries within it clusters of droplets [25]. Peak exhalation speed can reach up to 10-30 m/s creating a cloud that can span to 7-8 m [25]. In experimental conditions, the survival time of SARS-CoV-2 varies from hours to days depending on environmental factors (humidity and temperature), viral titer and volume and on the type of surface [26]. The most accredited study by van Doremalen et al., showed that after application of a large inoculum, SARS-CoV-2, likewise SARS-CoV-1, can been viable on environmental surfaces for up to 3 days (2-3 days on plastic and up to 24h on cardboard), suggesting a potential transmission from passive vectors [23]. This study has provided the basis for the assumption that a period of 3 days of guarantine is sufficiently safe to avoid transmission from contaminated surfaces [27]. However, other studies have shown that in different experimental conditions, with a different temperature and humidity levels, the stability of the virus on surfaces varies greatly [28,29]. It is noteworthy that these laboratory studies do not necessary reflect the real-life scenario. Usually, the virus load used during experiments is high, thus there is growing opinion that transmission of SARS-CoV-2 by inanimate surfaces or outside person-to-person mode is smaller than what commonly believed [30].

#### 2.1. Healthcare environment contamination

Contamination of healthcare environmental surfaces and medical devices with SARS-CoV-2 has been well established by reverse polymerase chain reaction (RT-PCR). According to recent data, the contamination rate of healthcare environments can reach a 75% rate before cleaning/disinfection, while it is infrequent (0% rate) after cleaning/disinfection [31-33]. The cleaning and disinfection status is more relevant than the patient status in terms of infectivity [31–33]. Most of the studies on this topic have been performed in medical care areas, such as emergency rooms, wards and intensive units, at high risk of contamination for an heavy burden of infected patients. As expected, in COVID-19 hospitals SARS-CoV-2 RNA has been detected also outside patients' areas and in living quarters [34], thus a precise separation between COVID-19 and non-COVID-19 facilities is mandatory. For this reason, one important problem concerning the activity of sleep laboratories worldwide, is that many laboratories are encompassed within hospitals and health facilities turned into COVID-19 care centers, so that division of patients is unfeasible. Although SARS-CoV-2 RNA has been found in medical environment, whether this viral RNA represents living virus remains unknown, similarly, the infectious dose of SARS-CoV-2 is unknown [35]. Theoretically, as shown for previous SARS-CoV outbreaks, environmental contamination can lead to contamination of hands or medical devices and, in turn, to the transmission of the virus to patients or staff *via* nose, mouth or eyes [21]. Indeed, nosocomial outbreaks of SARS-CoV-2 have been well documented [36,37], but the mode of transmission is not clearly established and a close contact of healthcare workers (HCW) with infected patients seems the main mechanism [38–40]. While it is well acquired that environmental contamination occurs, the transmission to human beings is not necessarily consequential [26]. Moreover, although the presence of SARS-CoV-2 on inanimate surfaces can represent a potential route of transmission, appropriate disinfection measures significantly reduce the chance of transmission [27]. Recent reviews have extensively revised the relevance of environmental contamination by SARS-CoV-2 [19,26,27].

#### 2.2. How this knowledge applies to sleep laboratories?

In sleep laboratories, outpatients' areas, as well as in-patients rooms for night studies, and medical equipment are at risk of contamination. To avoid the risk, a patients' triage before accessing health-care facilities has been implemented worldwide, soon after the outspread of COVID-19 in February 2020, consisting in temperature measurement and search for suggestive symptoms. If such screening is performed correctly before accessing the sleep center, the risk of contamination and spread of SARS-CoV-2 will be associated mainly with: 1) virus spread from asymptomatic infected patients or infected staff members in the environment; 2) direct transmission between asymptomatic staff and patients (and vice versa); 3) risk of surface contamination of sleep recording devices; 4) risk of airborne contamination during PAP titration. Therefore, the major problem is represented by asymptomatic people, around 40% of all infected, or by those who are in the incubation period [41]. Asymptomatic transmission has been shown as a pathway of COVID-19 infection [42]. One study showed that pre-symptomatic residents contributed to the widespread transmission of SARS-CoV-2 in a nursing facility [43]. Asymptomatic or pauci-symptomatic infected individuals can also contaminate surfaces [44]. As it is well acquired that disinfection procedures can easily prevent diffusion through environment and equipment, person-to-person diffusion remains the major risk. At this time, as we will see below, rapid point-of care diagnostic tests are available, that may be used to further reduce the risk by screening patients and staff [45]. Of course, single institutions must evaluate the cost-effectiveness of this prevention strategy.

#### 3. Practical issues for the diagnosis of sleep apnea

#### 3.1. Distance contacting

When patients are addressed to the sleep centre by a specialist or a general practitioner, clinical data and anamnesis can be collected by a phone call or a specific platform for video-calls. Questionnaires can be filled during the consultation or sent to the patients by email. A simple phone call is generally used for older patients or for those who are not familiar with internet. This system will allow to acquire clinical documentation and to evaluate priorities, so that the patients can be directly scheduled for instrumental evaluation, reducing the number of accesses, the time of permanence in the centre and the contact with health staff [12,18,46].

Teleconsultation with the patients is increasingly used by healthcare professionals worldwide, particularly after the onset of the emergency. In the field of sleep medicine, telemedicine protocols have been introduced some time ago and widely studied with the purpose of enhancing sleep disorders management [47]. Although in most of the countries there is no specific legal framework for the practice of telemedicine, specific programs to provide on-line care have been rapidly implemented during the last year and recognized by the health institutions [48]. Notwithstanding, the growing use of telemedicine for the management of patients with OSA is the result of an increasing number of highly performant remote monitoring systems that have become available before the emergency started [47–49]. One problem with distance consulting is that of course clinical examination cannot be performed. However, if clinical assessment to evaluate risk factors or differential diagnosis for selected patients is needed, this can be performed in the same day of the sleep study.

#### 3.2. Access to sleep laboratories

Patients' access to the sleep centre is necessary to perform the night study (in-lab) or to provide equipment for a home-study. Access to medical structures has been regulated, during the different phases of the pandemic by national and local policies, and the indication given by local health institutions should also apply to sleep centers. The recent document by the European Respiratory Society recommends to avoid access to the laboratory during periods of high transmission in the community [18]. A phone call or e-visit can be sufficient in many cases to assess symptoms of OSA and fill questionnaires, so to avoid access to the lab or to shorten the permanence of the patient in the lab.

During the phase 1 of the epidemic performing a swab test for out-patients has been considered unrealistic as only expensive and time-consuming molecular tests were available. More recently rapid antigen tests (RATs) for COVID-19, based on lateral flow immunoassays, have become available for a rapid detection of SARS-CoV-2 in nasopharyngeal samples [50]. These tests read samples containing large amounts of virus as positive, although are less sensitive, compared to RT-PCR, for samples containing small amounts of virus [51]. Indeed, these tests have the advantage to be feasible at points-of-care, giving a response within 15 min, and to have a relatively low cost [50,51]. Very recent findings suggest that large-scale RAT-based testing can be considered for detecting potentially infective individuals to reduce the virus spread [52]. At the time we are writing the evidence available is not strong enough to determine how useful RATs are in clinical practice, however in real life, depending on countries' policies, these tests are largely used as a triage to RT-PCR before accessing healthcare facilities [53,54]. We have no specific data on the use of these test as a triage for the admission of out-patients into healthcare structures. Although the sensitivity is lower than RT-PCR, it has to be considered that the RATs are sensitive in the presence of a high viral load and will likely detect those patients who are more contagious and dangerous to admit to the healthcare structures. Of course, the time needed to perform the swab for RATs and the cost of the testing must be weighed against benefits. The recent ERS document consider RATs as an option for patients accessing sleep facilities [18].

#### 3.3. Sleep studies

After the beginning of the pandemic, in April and August 2020, the AASM, and successively most of the scientific societies, advised to perform only urgent studies and to keep track of the other patients postponing visits, rescheduling appointments after resuming of the service [12–15,55]. Unfortunately, as a second wave of the epidemic soon developed, not all services have been resumed. Provided that a sleep centre has been re-organized, currently the feasibility of sleep studies and the daily number of studies will depend on the staff available, mainly physicians and nurses, as many of these are engaged in the COVID-19 emergency. Sleep technologists are not involved in the emergency, and represent a good resource, but unfortunately these professionals are not available in all centers. Four different levels of sleep testing are generally

performed. From Level 1, consisting in a full polysomnography in the lab, to Level 4 consisting in a simple home nocturnal oximetry. Level 3 sleep study, consisting in a cardio-respiratory home monitoring, is currently the most commonly used test and is recommended worldwide for non-complicated patients. These different sleep diagnostic procedures are associated with a different level of patient-staff contact, so that there is a risk grading for SARS-CoV-2 diffusion (Table 1). Of course, full polysomnography implies a closer and longer contact of health personnel with the patient, whereas level 3 systems can be easily explained to the patient in a short period of time with reduced contact time. Therefore, level 1 studies should be reserved to selected patients [12-15], if single rooms are available in the sleep centre. No doubt that most of the studies will be performed at home with a level 3 system. As safety is concerned, a respiratory polygraph has several advantages over full polysomnography. These include a shorter installation time, limiting contact between the installer and the patient, a limited number of sensors, so that there will be a reduced person-to-person contact and easier disinfection procedures. When performing home respiratory monitoring different options are available. First, the device can be given to the patient in person at the center, as was used before the emergency, as explanation of the device will take few minutes and no close contact is needed. Alternatively, during the first wave, some sleep centers preferred to avoid any contact with the patient and dispensed the devices through mail delivery or using curbside pickup and return, providing patients with an access to instructional brochures or video to ensure a proper set-up [15]. It is noteworthy that the effect of this system (delivering polygraphs. without instructing the patient directly) on diagnostic yield remains uncertain. In addition, older patients without assistance often are not able to understand instruction non-directly provided. Of course, the delivery system is mandatory in those laboratories embedded in hospitals closed to patients from local institutions for safety reason. In our sleep laboratory, which has remained for long time inaccessible to out-patients during the phase I, sleep diagnostic tests were performed at home with the collaboration of home-care respiratory providers and raw data were sent to our centre by e-mail for analysis. Many of the home-care providers, during the COVID-19 emergency engaged personnel equipped, instructed and enabled to visit patients at home in order to bring respiratory devices (ventilators, oxygen), thus opening up the possibility to send also sleep monitoring devices. The feasibility of transmitting raw data for analysis has been shown in one study, where home polygraphy recordings of 499 patients were transmitted to a major sleep center [56]. The authors concluded that the remote diagnosis strategy presented short delays, safe data transmission, and low rate of missing data [57]. A recent remarkable review has outlined the positive outcomes of OSA management through telemedicine and evidenced that telemedicine can be effectively use for the initial evaluation and diagnosis of OSA as well as for chronic care access [39]. A schematic example for performing first diagnosis of OSA is shown in Fig. 1.

#### 3.4. Environment protection

Strategies for environmental and staff protection have been widely implemented in these last months and here only few considerations will be made.

A mandatory rule is that sleep facilities should be separate from COVID-19 care zones. This is fundamental for those sleep facilities which are encompassed within large respiratory units, often converted in COVID-19 areas. Approaches include the use of a separate buildings or of designated floors with a separate entrance and minimal crossover with COVID-19 care areas [24]. The susceptibility of SARS-CoV-2 virus to various common disinfectants for hospital use has been well shown and cleaning/disinfection of sleep facilities should be performed according to institutional protocols for infection control [57]. According to the CDC, using cleaners and water to pre-clean surfaces prior to applying an EPA-registered hospital-grade disinfectant to frequently touched surfaces are appropriate procedures for SARS-CoV-2 in healthcare settings [24]. These procedures are effective also in those areas where aerosol generating procedures are performed [24]. Most of the guidelines from sleep societies have discussed practical application of these procedures [11-15].

# 3.5. Healthcare staff protection and use of Personal Protective Equipment

All healthcare workers regardless of the level of care provided, must make infection prevention a priority and must be equipped to observe standard precautions. Physical distancing of 6 feet from the patient, whenever possible, has been recommended early by the CDC and this recommendation has not been changed over the time [33]. Although distancing must be always encouraged, wearing Personal Protective Equipment (PPE) is the primary way to prevent infection. PPE refers to wearable equipment intended to protect workers from exposure to infectious agents. Examples include gloves, gowns, face masks, respirators and face shields. The correct selection of PPE is based on the nature of patient interaction and the likely mode of transmission. Thus, the use of PPE in a sleep center should be adequate to the different level of risk associated with closeness to the patient [35,58]. The CDC strongly recommends, even when the risk of contamination is low to protect both airways and eyes [59]. The use of either a well fitted facial mask or a respirator is suggested in a situation of low-moderate risk of contamination. However, it is important to note that respirators offer the highest level of both source control and protection against inhalation of infectious particles in the air [59]. The National Institute Organization for Safety and Health (NIOSH) is an internationally recognized institution responsible for approving protective equipment. The NIOSH has approved a number of respirators with different level of particulate filtering. The N95 respirator, filtering at least 95% of airborne particles, is strongly recommended in routine care. The N95 can be safely used continuously or intermittently for

#### Table 1

Risks related to diagnostic and treatment activities.

Sleep testing (level)	Close contact (<2 m)	Prolonged contact (>15 min)	Aerosol generating procedure	Technical difficulties in sanitizing	Time needed to sanitize
Pulse oximetry (4)	+	+	_	+	+
Cardio-respiratory monitoring (3)	++	+	_	++	+
Polysomnography (2)	+++	++++	_	++	++
In-lab polysomnography (1)	+++	++++	_	+++	+++
CPAP/NIV	++++	++++	++++	+++	+++
Follow-up (eg compliance)	+	+	-	-	+

By kind concession of the Italian Respiratory Failure Rehabilitation Association (ARIR) and Italian Association of Neurophysiology Technologists (AITN). Reference n. [79].



anamnesis, questionnaire, level of priority, COVID 19-triage, study day schedule



Fig. 1. A schematic example for the management of a patient with suspected OSA. Second consultation is generally performed to discuss treatment before starting PAP titration protocol (please see text) or other treatment.

up to 8 h [59–61]. Extended use of respirators, referring to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients without removing the respirator between patient encounters, is considered the best option [59]. Higher level of protection (N99 or N100) is suggested if performing aerosol-generating procedures [35,58]. Eye protection should be always worn during patient care encounters to ensure that also the eyes are protected from exposure to respiratory secretions, though this is often omitted in the ambulatory setting [59]. A large study showed that 19% of health-care workers became infected, despite wearing three-layered surgical masks, gloves and shoe covers. No worker was infected after the introduction of face shields [62]. Eye protection can be obtained using either face shield or goggles, routinely. A single pair of gloves can be used and changed after contact with each patient. In addition to this routine protection, the use of a medical gown is recommended for operators installing the monitoring system or setting PAP [12,18]. It is important to emphasize that the best PPE available will be ineffective if not properly worn and handled. Training and supervising HCW are therefore key aspect for risk control.

In the last three months an intensive vaccination campaign against COVID-19 with the goal to achieve herd immunity has started world-wide and health care workers have been highly prioritized. First reports showing a great protective benefit of mRNA COVID-19 vaccine in healthcare workers and in the general population are already available [63,64]. This will change the prevalence and contagiousness of COVID-19 in the future. However, once again, neither the testing opportunities nor the vaccination availability can exempt staff from wearing PPE continuously in the working area.

#### 3.6. Equipment cleaning, disinfection and handling

One of the most concerning issues when the emergency started was the use of sleep monitoring systems as these could represent a fearsome means of virus transmission, due to a close contact with the patient's body. Although producers usually provide indication for equipment routine disinfection, doubts have been raised on the safety of these procedures against the emerging SARS-CoV-2. At the

beginning of the emergency the first recommendation by all societies, in the absence of scientific evidences was the use of "disposable" equipments whenever possible. However, not all sleep monitoring systems are fully provided with disposable sensors. In addition, disposable accessories such as thoracic and abdominal bands, available in few polygraphs, are expensive, so that the cost of the test can exceed national health system or private reimbursement. Noteworthy, soon after the epidemic onset most of the producers have further tested disinfection procedures against SARS-CoV-2 on their devices and provided the centers with updated recommendations. These should be strictly followed to guarantee effective sanitization and to avoid damage to the polygraphs' surfaces and to fabric fibers (bands). Particular concern has been raised on airflow detection by thermistors and disposable nasal cannulas, for the close contact with the patient's airway. The use of nasal cannula has been at first strongly discouraged for the risk of contaminating the reading chamber downstream of the cannula, a site that cannot be sanitized [10,12,46]. Some cannulas are provided with moisture repellent filters, however these filters, with a filtration size of 0.45 µm, do not protect against coronavirus  $(0.06-0.14 \mu m)$ . Therefore, in a first phase, thermistors, that can be easily sanitized were preferred for flow detection. Soon after, tests have been performed on many commonly used polygraphs by the manufacturers and most of these have found that the use of disposable cannulas is safe. Disposable cannulas with a filter suitable for SARS-CoV-2 are under evaluation but still not available in commerce [18]. As other coronaviruses the SARS-CoV-2 virus is highly sensitive to ultraviolet radiation (UV) [65]. Therefore, in addition to EPA-registered disinfectants, UV boxes provide another safe and cost-effective option for quickly disinfecting (within minutes) surfaces. As an example, in Table 2 is shown the protocol for sanitizing common home-polygraphs, used in our lab and designed merging the instructions of three different manufacturers. Some authors have reported detailed instructions on sanitization of monitoring systems and accessories [46,66]. Handling of the equipment is also important. The polygraph must be placed in a sealed plastic bag when is handled to the patient and when is returned to the operator. Instruction on washing hands before setting up the equipment

In UV Box

In LIV Box

# Pable 2 Care of commonly used home sleep-monitoring systems and safety issues. Polygraph Clean the surface with a microfiber cloth moistened with a disinfectant solution<sup>a</sup>. SaO<sub>2</sub> sensor Oro-nasal- Thermistor Pletysmograph bands Spray disinfectant solution over the surfaces and air dry<sup>a</sup>. Inductive bands Suggestions for safe diagnostic procedures • After cleaning, store equipment in a "clean" area

After cleaning, store equipment in a "clean" at
No need for a 72 h quarantine for polygraphs

Use a sealed plastic bag to handle the device to the patient and ask the patient to return the device in the same bag

Returned devices must be handled in a separate dedicated area to avoid contamination of clean equipment

- Throw away disposable materials (mainly nasal cannulas) in the infectious waste
- Changes gloves after handling used devices

UV radiation time should be set according to the UV box producer's instructions and all surfaces should be exposed to the light for efficient disinfection.

<sup>a</sup> Disinfectant solution used is an alcohol-based rapid disinfectant for non-invasive medical products.

should be given to the patient. Two separate desks (areas) for clean/ sanitized and used equipments should be organized, to avoid contamination if all operations are made in the same room. At epidemic onset for maximum safety, the AASM considered the option of a 72 h quarantine before re-using the equipment, as this guarantees no survival of viable virus [23]. This is not feasible in those labs provided with a limited number of monitoring systems and, as there is sound evidence on the sensitivity of this virus to a number of hospital disinfectants, correct sanitization without quarantine seems sensible. A rotation use of the polygraphs is an option if the number of tests is limited. Key aspects for a safe organization of a sleep laboratory are shown in Table 3.

#### 4. Treatment with positive airway pressure: can we?

# 4.1. Risk of SARS-CoV-2 transmission during aerosol-generating procedures

Maximal attention has been paid to the use of aerosol generating procedures. Published data are limited and suggest that there may be a potential increase in particle dispersion during the use of PAP. Though, the danger of a PAP therapy in the context of COVID-19 pandemic has been only partially explored. As said above, aerosols can cause transmission of infectious virus-laden particles. Aerosolgenerating procedures include the application of an external pressure or flow to the respiratory system. In addition to invasive ventilation, concern has been expressed for noninvasive procedures including continuous positive airway pressure (CPAP), noninvasive ventilation (NIV) and high flow nasal cannula [51]. Before the COVID-19 emergency, only few studies were performed measuring the expired pathogens load during application of a PAP [67,68]. These studies showed a dispersion of particles from vented NIV masks reaching a maximum distance of 0.85 m [69]. Particles are also dispersed by mask leakages, although dispersion in real life is not easily quantifiable [70]. Generally, during PAP treatment airborne particle formation will dependent on airway pressure differentials, gas flow velocities and open-close cycling of distal airways [71]. The quantity of fugitive particles escaping into the atmosphere will depend on circuits, mask leaks, viral filters and minute volumes [71,72]. In contrast with older reports, one more recent study showed that NIV does not generate significant aerosols [73]. Accordingly, Hui and co-workers recently found that air dispersion during CPAP via different interfaces is limited, provided there is good mask interface fitting [74]. In one review, nine years ago, it was concluded that some procedures, potentially capable of generating aerosols, are associated with an increased risk of SARS-CoV-2 transmission to health workers and, when ranking procedures in term of risk, NIV was second after tracheal intubation [75]. Nevertheless, Wilson and co-authors, in the most up-to-date review on this topic, conclude that currently there is no proven relationship between any aerosol-generating procedure and airborne viral content, since the evidence defining aerosol-generating procedures

#### Table 3

Main issues to address for a safe organization of a sleep laboratory during the COVID-19 emergency.

Safety of the environment
Location of the laboratory distinct from any COVID-19 area
Cleaning/disinfecting
Check the proper functioning of heating, ventilation and air-conditioning systems
Healthcare staff safety
Level of protection and PPE
Instruction on personal protection and contact with the patient
Handling of the devices
Systems to triage patients to be admitted in the lab
Check for COVID-19 symptoms
Use of rapid diagnostic tests
Re-arrangement of staff tasks, if staff members are reduced
Establishing cleaning/disinfection protocols for diagnostic devices
Organization of telemedicine services
E-mail
Video-call platforms
Software for PAP titration and monitoring
Other internet resources
Adjust protocols of PAP prescription
New accordance with the NHS, assurances or payers
Collaboration protocols with home-care respiratory providers
PPE: personal protection equipment; NHS: national health system.

comes largely from low-quality case and cohort studies, where the exact mode of transmission is unknown as aerosol production was never quantified [71]. These authors suggest that several aerosol-generating procedures may in fact result in less pathogen aero-solization than a dyspneic and coughing patient [71]. Therefore, the evidences to answer our question on PAP treatment safety are still controversial. However, although the precise risk for health workers during CPAP treatment remains undefined, it is it is comforting to know that the efficacy of airway protecting systems for SARS-CoV-2 transmission prevention has been well established [61,76].

#### 4.2. CPAP titration and follow-up

CPAP is the gold standard treatment for patient with OSA. A delay in initiating CPAP therapy, particularly in severe OSA, may have harmful effects therefore it is not justified and ethically unacceptable. In addition, studies on the impact of COVID-19 on CPAP users are lacking. Usually, titration of CPAP, to set the correct pressure before prescription, is performed in-lab during standard polysomnography or at home with automatic CPAP (auto-CPAP). This latest mode, which is now the most commonly used, also includes a short trial with CPAP performed in the lab to test patient's adaptation and the correct interface. Between February and June 2020 all sleep societies discouraged the use of CPAP in-lab for the potential risk of particle dispersion, and since then, as said above no definitive conclusion has been drawn on the risk of this procedure. Therefore, a remote titration, previously suggested, still remains a valid option, although sporadic cases can be safely adapted in the lab using proper protection. Furthermore, we believe that currently there is sufficient scientific support to recommend remote control of CPAP treatment [38-40].

Although auto-CPAP at home is the best option, however, passing machines owned by the center from one patient to another for titration should be avoided, as sanitation is difficult. So, each patient needs his own machine. One option, as we have been doing in our sleep center in the last year, is that auto-CPAP should be prescribed to the patient as soon as the diagnosis is made. Soon after the patient has come into possession of the machine, titration will be performed at home. Often the machine is not directly paid by the patient but by the public health systems or health assurances, who often require evidence of treatment effectiveness. If this is the case, new protocols for CPAP's payment must be developed taking into account the need of the patient to have his own machine in order to perform home titration and the need for a distance follow-up. Once the patient is provided with his own CPAP, explanation on the proper use can be done with teleconsultation or with a second visit to the center, where explanation will be given without setting the machine on, unless is strictly necessary. Prescribing the correct interface without a test is another important issue. The size and shape of the mask will be established according to the operator's experience or with the help of fitting templates provided by some CPAP producers. While nasal mask is the preferred option, it is likely that patient with nasal obstruction will less tolerate a nasal interface.

Once the patient has started home adaptation and treatment, a number of software for data transmission are now provided by the most important producers involved in sleep management. Remote data available include compliance, pressures, leaks and apnea index for every night of use, so that the operator will be able to follow-up daily the night treatment (at least for the first weeks) and contact the patient if problems arise. Some software provide the remote control of CPAP pressures so that, after a period of time (from few weeks to one month) the CPAP pressure can be set remotely at a fixed value. To check improvement in symptoms and somnolence the patient can be contacted telephonically. Of course, if

#### Table 4

Telemedicine options fo	the management of c	bstructive sleep apnea.
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Communicating with the patient	Collecting/Transmitting data
Phone calls Videoconference, Skype Electronic Health Records platform Alert messages E-mail Text PAP messages	E-Questionnaires On-line sleep study data Transmission from CPAP devices Smartphone Other clinical software

somnolence persists and problems are observed during the treatment, an in-lab visit is necessary. Also, complex patients (complex apnea, heart failure, obesity-hypoventilation) need an in-lab evaluation.

Suggestions provided so far are largely supported by published data on CPAP therapy remote monitoring, one of the most explored aspects of sleep telemedicine [38-40,47,48]. There are some suggestions that telemonitoring CPAP, not only avoid contact with the patient but also may improve compliance with the treatment [37-39]. In those patients under chronic follow-up the use of telemedicine can have an essential role in monitoring their chronic status and in providing explanation if problems arise [77]. Again, one of the main issues is that local health authorities should work to expand as much as possible the telemedicine coverage in the territory. The AASM has stressed the concept that one of the main steps for telehealth system to work, is that payment for telemedicine services furnished to patients should be available worldwide, in all areas of the country and in all settings, including the home. Also, tele-consults and e-visits, should be considered and paid as in-person visits [78] (Table 4).

Although the implementation of telemedicine has multiple advantages it also carries a number of problems. The main issue is that the results of telemedicine obtained in the context of research work are not necessarily similar to those obtained in real life. These results should be evaluated in each sleep unit, by the unit's sleep staff. In addition, complex patients (heart failure, complex apneas or elderly patients) are not suitable for initial management by telemedicine. It is noteworthy that the care of these complex patients has been particularly affected by the pandemic and is one of the current challenges of sleep units. Finally, adequate patient's data protection protocols are now lacking and need implementation.

#### 5. Conclusion

After one year from the SARS-CoV-2 pandemic onset, there is an urgent need for a fully resumption of sleep services for patients with OSA. Differently from other chronic diseases, managing patients with OSA during the emergency, might be challenging, as, in addition to routine visits, instrumental tests and contact with the patient are required. The concept that local practices and policies in resuming services should be different due to different local spread of the disease appears now outdated. As most of western countries, as well as other countries in the world, are equally affected by SARS-CoV-2 spread, common strategies for routine care of patients with OSA should be adopted. One advantage in sleep medicine is that telemedicine has been widely studied in the last decade and now this is an opportunity to implement it. An adequate plan for the disease management should include a change in laboratory logistic, implementation of telemedicine, with an extension of the covered areas, and new health policies, including repayments of all practices performed at distance without on site visit. Currently, the implementation of telemedicine is based on the assumption that general guidelines for sleep practice should be respected. Though, some minor changes in traditional protocols that we are now applying for a practical advantage, might be proven to be valid in the next future. A balance between health and safety needs remains of course the main objective to pursue, but this requires substantial efforts mainly consisting in the reorganization of the health system at different levels.

#### **Conflict of interest**

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: https://doi.org/10.1016/j.sleep.2021.05.026.

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#### List of abbreviations

- OSA : obstructive sleep apnea
- PAP : positive airway pressure
- WHO : world health organization
- CDC : centre for disease control and prevention
  - AASM : American academy of sleep medicine
- CPAP : continuous positive airway pressure
- NIV : non invasive ventilation