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Guidelines

Guidelines for clothing in the operating theatre, 2021☆,☆☆

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ABSTRACT

Objective: To provide guidelines for the choice of items of clothing (except sterile surgical gown) for staff working in the operating theatre.
Design: A committee of nine experts from SFAR and the SF2H learned societies was convened. A formal conflict-of-interest policy was developed at the beginning of the process and enforced throughout. Likewise, it did not benefit from any funding from a company marketing a health product (drug or medical device). The authors were required to follow the rules of the GRADE® method (Grading of Recommendations Assessment, Development and Evaluation) to assess the quality of the evidence on which the recommendations were based.
Methods: We aimed to formulate recommendations according to the GRADE® methodology for four different fields: operating theatre suits, operating theatre hats, masks, and shoes/over-shoes. Each question was formulated according to the PICO format (Patient, Intervention, Comparison, Outcome). The literature review and recommendations were formulated according to the GRADE® methodology.

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★★ Recommendations for Professional Practice issued by the French Society of Anaesthesia and Intensive Care Medicine (Société française d'anesthésie et de réanimation, SFAR) and the French Society of Hospital Hygiene (Société française d'hygiène hospitalière, SF2H).

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Results: The experts' synthesis work and their application of the GRADE® method resulted in 13 recommendations. As the GRADE® method could not be integrally applied to all questions, some recommendations were formulated as expert opinions.
Conclusion: Based on strong agreement between experts, we produced 13 recommendations to guide the choice of operating theatre attire.

Expert group

Serge Aho (SF2H, medical health officer), Pierre Albaladejo (SFAR, intensive care anaesthetist), Hélène Beloeil (SFAR, intensive care anaesthetist), Evelyne Boudot (SF2H, managing hygienist), Philippe Carenco (SF2H, medical health officer), Florence Lallemant (SFAR, intensive care anaesthetist), Marie Gabrielle Leroy (SF2H, chief hygienist), Jane Muret (SFAR, intensive care anaesthetist), Corinne Tamames (SF2H, managing hygienist).

Study groups

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Introduction

Operating theatre attire is of essential importance in preventing postoperative infections insofar as it limits the transfer of microorganisms and body fluids between caregivers and patients. It consists in:

- Operating theatre scrub suit, with a short-sleeved, V-neck shirt and loose-fitting pants.
- Head cover (surgical hat types; skull cap, bouffant cap, and surgical headgear).
- Surgical mask.
- Shoes.

The decision to privilege reusable or single-use attire, manufactured from different materials, corresponds to a selection process based on four criteria:

- Efficacy of the barrier represented by the surgical outfit.
- Environmental impact.
- Economic cost.
- User comfort.

French standard EN 13795 defines reusable or single-use operating theatre attire as "attire meant to show and having shown its effectiveness in reducing contamination of the operating wound by skin flakes containing infectious agents coming from the person with that attire via the air of the operating theatre, thereby limiting the risks of wound infection" [1].

Operating theatre attire differs from the sterile gown, which is a work garment meant for operating theatre staff and is not specifically designed to prevent the dispersion of airborne particles from healthcare professionals. The performance level of this attire is determined, among other factors, by the barrier properties of the tissues and particle release. No rules exist concerning the utilisation of reusable or single-use attire.

As cutting-edge technology and clinical practice evolve and given the emerging issues that healthcare establishments are called upon to address, the French Society of Hospital Hygiene (SF2H) and the French Society of Anaesthesia and Intensive Care Medicine (SFAR) have joined forces to elaborate a reference document on the optimisation of choices for attire in the operating theatre.

The present guidelines for professional practice pertain to attire to be worn by operating theatre staff: state-licensed anaesthesia nurses, state-licensed operating theatre nurses, nursing auxiliaries, surgeons, interventional doctors, intensive care anaesthetists, etc. These guidelines do not pertain to surgical draping, sterile surgical gowns, or to the garments worn by patients.

Objective of the recommendations

The objective of these recommendations is to develop a framework facilitating decision- making on operating theatre attire. The expert group has drawn up a minimal number of recommendations in view of highlighting the key points to remember in the four predefined fields: operating theatre scrub suit, head covering, surgical masks and footwear. The targeted public is sizable insofar as it corresponds to all the medical and paramedical professionals practicing in the operating theatre.

Methodology

General organisation

These recommendations result from the proceedings of a group of experts brought together by SFAR and the SF2H. Each expert filled out a conflict-of-interest declaration prior to participation in analysis. During an initial phase, the organising committee defined the objectives, the methodology, the field of applications, and the questions to be put forward regarding the recommendations; these elements were then modified prior to being validated by the experts.

To the greatest possible extent, the questions were formulated in accordance with the PICO format: Population – Intervention – Comparison – Outcome). The population concerned by these recommendations (the "P" in PICO) consists in staff practicing in

the operating theatre and is not mentioned regarding each recommendation.

Fields of the recommendations

The experts unanimously decided to retain the four following fields for the present recommendations:

FIELD 1 – Operating theatre scrub suit
FIELD 2 – Head covering
FIELD 3 – Surgical masks
FIELD 4 – Shoes/Overshoes

The four fields were chosen on account of their homogeneity as means of ensuring patient protection. The experts unanimously decided not to apply these recommendations to personal protective equipment (PPE) such as gloves, glasses/protection screens, overblouses, given their role as protection for caregivers and their non-specificity to the operating theatre; all in all; PPE does not correspond to the role of "operating theatre attire", which is to protect the patient.

From January 2020 to January 2021, extensive bibliographic research was carried out from the PubMed™ and www.clinicaltrials.gov data bases by two experts for each field of application in accordance with the PRISMA method for systematic reviews.

Were included in the analysis: meta-analyses, randomised controlled trials, non-randomised prospective trials, retrospective cohorts, cases series and case reports; conducted with patients and caregivers in the operating theatre, dealing with surgical attire; published in English or French.

Analysis of the existing literature was then carried out in accordance with the GRADE® (**G**rade of **R**ecommendation **A**ssessment, **D**evelopment and **E**valuation) methodology. The endpoints were defined as follows. Primary endpoint: prevention of surgical site infection (7 points); secondary endpoints: environmental impact (6 points), contamination of the operating theatre environment (5 points), and properties of use (comfort, resistance, etc.) (4 points).

Given the very small number of studies having the power to effectively address the primary endpoint accorded the highest degree of importance (*i.e.*, the prevention of surgical site infections), prior to the drafting of the recommendations it was decided to adopt the "Recommendations for Professional Practice" (RPP) format, rather than the "Formalised Expert Recommendations" (FER) format. That said, the GRADE® methodology was applied for analysis of the literature and elaboration of the overview tables summarising the data of the literature. A level of evidence was consequently determined for each of the cited bibliographic references according to type of study. The level of evidence was reappraised by considering the methodological quality of the study, the coherence of the results between the different studies, the direct or indirect nature of the evidence, and analysis of the costs and the significance of the benefits. The recommendations were then written out, using the terminology of the SFAR RPPs: "The experts suggest that it be done" or "The experts suggest that it not be done". The proposed recommendations were presented and discussed one by one. The goal was not to come to a single and convergent conclusion regarding the different propositions, but to establish not only points of agreement, but also points of disagreement or indecision.

Each recommendation was evaluated by each one of the experts and given an individual rating on a scale ranging from 1 (complete agreement) to 9 (complete disagreement). The cumulative ratings were validated by the experts according to the GRADE® grid methodology. To validate a recommendation, at least 70% of the experts had to express a concordant opinion, while fewer of 20% of them expressed an opposed opinion. When one or more recommendations were not validated, they were reformulated and resubmitted for rating, the objective being to arrive at a consensus.

Results

The fields of recommendation

During the first physical meeting dedicated to RPP organisation, the experts consensually agreed to consider nine questions, which were divided into four fields. The following questions were chosen for collection and analysis of the literature:

FIELD 1 – Operating theatre scrub suit

Question 1: Does the reusable operating theatre scrub suit offer advantages as compared to the single-use scrub suit?

Question 2: Is limitation of the attire to the perimeter of the operating theatre more effective in preventing infectious risk for the patient undergoing treatment in the operating theatre?

Question 3: Does regular change of operating theatre attire help to prevent infectious risk for the patient undergoing treatment in the operating theatre?

FIELD 2 – Head covering

Question 1: Does reusable head covering offer advantages as compared to single-use head covering?

Question 2: Does an article covering head, hair and ears (bouffant, and surgical headgear) afford more effective prevention of infectious risk for the patient undergoing treatment in the operating theatre than an article not covering the ears ("skullcap")?

FIELD 3 – Surgical masks

Question 1: Does mask wearing by non-surgical staff afford more effective prevention of infectious risk for the patient undergoing treatment in the operating theatre?

Question 2: Does regular mask changing afford more effective prevention of infectious risk for the patient undergoing treatment in the operating theatre?

FIELD 4 – Shoes/Overshoes

Question 1: Does reservation of a pair of shoes for use within the perimeter of the operating theatre afford more effective prevention of infectious risk for the patient undergoing treatment in the operating theatre?

Question 2: Does the wearing of overshoes afford more effective prevention of infectious risk for the patient undergoing treatment in the operating theatre?

Synthesis of the results

Following a synthesis of the work of the experts and application of the GRADE® method, 13 recommendations were formalised. They were then submitted to the expert group for rating in accordance with the GRADE® Grid method. After one round of rating, strong agreement was reached on 100% of the recommendations.

These RPPs supersede the preceding recommendations of the SFAR and/or the SF2H regarding a given field of application. The SFAR urges all intensive care anaesthetists to comply with the RPPs to ensure high-quality patient care. When applying these

recommendations, however, a practitioner is called upon to exercise his own judgment, taking into full account his field of exercise and the specificities of his establishment, the objective being to decide on the means of intervention best adapted to the state of the patient of whom he is in charge.

FIELD 1: operating THEATRE scrub suit

Question 1: Does a reusable operating theatre scrub suit offer advantages as compared to a single-use scrub suit?

Experts: Philippe Carenco (Hyères), Florence Lallemant (Lille), Corinne Tamames (Paris)

R1.1.1 – The experts suggest that operating theatre staff wear dedicated single-use OT reusable attire in the operating theatre, the objective being to minimise the risk of patient infection.
EXPERT OPINION (STRONG AGREEMENT)
R1.1.2 – The experts suggest that the operating theatre staff wear reusable rather than single-use attire, the objective being to reduce environmental impact.
EXPERT OPINION (STRONG AGREEMENT)

Rationale

The objective of wearing operating theatre scrub suits is to reduce contamination of the air by caregiver flakes or skins. It is but one of several measures recommended for that purpose; the others include air content control, patient skin asepsis and limitation of the number of persons admitted to the operating theatre. The relationship between operating theatre air contamination and surgical site infection is necessarily complex and far from straightforward. That said, healthcare establishments are called upon to take all incumbent measures in view of reducing the number of particles carriers of microorganisms emitted into the air [1]. The textiles of the clothes used in operating theatre are undeniably implicated in the process of airborne contamination. In an observational prospective study financed by the industry of single-use outfits, Kasina et al. compared the air quality found with three combinations of reusable or single-use clothing systems, accompanied or not by a device-assisted airflow system [2]. They found that as compared to the two types of reusable wear, single-use polypropylene suits consistently reduced the median quantity of bacterial CFUs/m^3. That much said, to our knowledge no study has focused on the impact of type of operating theatre attire on surgical site infection rates. The existing studies comparing reusable to single-use systems have been essentially concerned with sterile gowns and surgical drapes. With regard to these articles, the majority of available studies and reviews have concluded that there is no difference between single-use non-woven surgical textiles and reusable cotton attire [3–5]. This result was confirmed by the most recent review conducted as a framework for the WHO guidelines for prevention of surgical site infection [6]. By extrapolating from the results observed with surgical gowns, which are close to the patient during a surgical procedure, the effectiveness as a protective barrier of single-use or reusable outfits is likely to be equivalent, provided that the recommendations are observed (especially in changing areas). With this in mind, the French Society of Digestive Surgery and the French Association of Hepato-Bilio-Pancreatic Surgery and Transplantation have stipulated in their clinical practice recommendations for operating theatre hygiene [7] that the operating theatre teams may wear either single-use or washable outfits, provided that the latter be changed after each procedure when stained or else, at the very least, at the end of each day.

As regards environmental impact, there have been no studies exclusively dedicated to operating theatre scrub suits. With this in mind, we have analysed the data in the literature on the life cycles of outfits with similar functions (surgical gowns and attire for patients in protective isolation). It bears mentioning that a product's life cycle retraces all the phases of its evolution from preliminary design through market withdrawal. More specifically, the notion of "life cycle" considers all the activities that come into play over the course of the manufacture, utilisation, transport, and elimination of the product; at each step, its environmental impact is assessed and appraised. In a review published in 2012 [8], five studies and reports [9–13] compared the life cycle of a reusable gown (50 to 75 utilisations) to an equivalent number of single-use garments. They concluded that the environmental impact of disposable wear was pronouncedly greater than that of reusable attire: +200 to 300% in carbon footprint secondary to energy consumption, +250 to 330% in water needs and +750% in production of solid wastes. Moreover, single-use textile is associated with emissions of volatile organic compounds (VOC) as many as five times higher [9,11,12]. The VOC emissions arise from the dyeing and finishing operations necessary only once for a reusable article, whereas they are repeated 50 to 75 times for a single-use textile. Lastly, use by staff members in contact with isolated patients of reusable rather than single-use gowns has been associated with reduced production of greenhouse gases [14]. For these reasons and by analogy with the data in the literature pertaining to the use of gowns with similar functions, a lesser environmental impact of reusable operating theatre scrub suits is probable.

R1.2 – The experts suggest field testing of the products selected according to the preceding criteria (efficacy, environmental cost) on the operating staff that will use them, the objective being to appraise their practical characteristics.
EXPERT OPINION (STRONG AGREEMENT)

Rationale

To our knowledge, no study has compared the comfort aspects of single-use and reusable operating theatre attire. As formulated in R1.1.2., the recommendation of reusable operating theatre attire due to its reduced environmental impact is not called into question.

With regard to operating theatre attire, perception of comfort is a subjective notion, which can be influenced by the following criteria [15]:

- Drapability, which means the property of a material to conform to a shape or to a given object.
- Resistance to water vapor, defined as the difference in water vapor pressure between the two sides of a material, divided by the heat of evaporation by surface unit in the direction of the gradient.
- Thermal resistance, property of a material that can be measured by a thermal manikin so as to determine the major parameters applicable to the thermal comfort afforded by clothing.
- Tactile comfort, also known as "mildness", which largely depends on fiber flexibility and finishing technologies.
- Properties such as extensibility and adjustability of size and weight.
- Properties causing discomfort, such as rustling and irritation of the skin; since they are problematically measurable, product trials and feedback on practical experience would seem necessary.

Other user-related factors may influence the perception of comfort: state of health, physical condition, workload, mental

stress, and environmental conditions such as temperature, relative humidity and renewal of operating theatre ventilation.

To conclude, to appraise, in real-life conditions, the properties of the different textiles proposed by suppliers, we would suggest organisation of a field test with future users before selecting a type of attire.

R1.3.1 – The experts suggest that when wishing for protection from the cold, the operating theatre staff should cover his or her attire with either a single-use or a reusable long-sleeved jacket, the objective being to minimise the risk of patient infection.

EXPERT OPINION (STRONG AGREEMENT)

R1.3.2 – The experts suggest that the operating theatre staff wishing for protection from the cold not use a sterile surgical gown.

EXPERT OPINION (STRONG AGREEMENT)

Rationale

In 2016 [16], the American Association of Perioperative Registered Nurses (AORN) recommended that all operating theatre staff not required to conduct surgical hand washing cover all exposed skin on their arms with a reusable or a single-use long-sleeved jacket. In today's literature, questions concerning long sleeves for the caregiver preparing the patient's skin have been put forward. Markel et al. found no reduction in the total number of bacteria in the operating theatre environment when staff members wore long-sleeved garments [17]. Nor did Elmously et al. report any diminution of surgical site infections associated with long sleeves; that said, for the American healthcare system the additional yearly cost of these garments came to an estimated 540 million dollars [18]. As a result, the wearing of long-sleeved attire or a long-sleeved jacket as covering for short-sleeved attire does not seem worthwhile in terms of reduced contamination of the operating theatre environment or lower risk of patient infection. In conclusion, the one interest of long-sleeved attire or a long-sleeved jacket covering short-sleeved attire consists in their providing comfort for staff members wishing to protect themselves from the cold in the event of low temperatures in the operating theatre.

By analogy with the data in the literature previously detailed in the argumentation of R1.2, a lessened environmental impact of reusable jackets is highly probable. However, few structures are presently equipped in their laundry circuits with reusable jackets. Moreover, the jackets are complementary to usual operating theatre attire, and the volumes used are correspondingly lower. Even though reusable jackets would ideally be placed at the disposal of all relevant staff, single-use jackets are conceivable, provided that their utilisation be closely monitored; if their quantity is high, it would probably make sense for the establishment to consider the acquisition of suitable equipment and laundering of reusable jackets.

Lastly, the experts suggest that a sterile surgical gown over the scrub suit (worn inside out, like a bathrobe or a dressing gown) not be used as a means of isolation from the cold. The practice generates avoidable additional costs, makes unneeded use of sterile accessories, and can contaminate usual operating theatre attire insofar as a long gown may be dragged along the floor when staff members sit.

Question 2: Is limitation of the attire to the perimeter of the operating theatre more effective in preventing infectious risk for the patient undergoing treatment in the operating theatre?

Experts: Evelyne Boudot (Montpellier), Pierre Albaladejo (Grenoble)

R1.4.1 – The experts suggest that staff not leave the operating theatre with their operating theatre attire, the objective being to limit contamination and thereby to prevent infectious risk for the patient.

EXPERT OPINION (STRONG AGREEMENT)

R1.4.2 – The experts suggest that if staff must exceptionally and for imperative reasons leave the operating theatre with their operating theatre attire, they must change their clothes on their return to the operating theatre to limit infectious risk for the patient.

EXPERT OPINION (STRONG AGREEMENT)

R1.4.3 – The experts suggest that in the event of a brief departure (a few minutes) from the operating theatre, an alternative strategy can consist in covering the operating theatre attire with a closed gown if they stay outside.

EXPERT OPINION (STRONG AGREEMENT)

Rationale

The issue of operating theatre attire worn outside the operating theatre is encountered in numerous establishments and is often considered in the process of accreditation as a dysfunctional aspect. Few studies have demonstrated that the wearing of operating theatre clothes outside the operating theatre and returning to the latter without changing increases the rate of surgical site infection. In a randomised prospective study, Hee et al. [19] assessed the bacterial contamination of surgical outfits worn outside the operating theatre by a small population of 16 intensive care anaesthetists. The authors found no significantly increased bacterial contamination outside the perimeter of the operating theatre in the vicinity of an office or surgery ward. That said, another randomised study, conducted by Copp et al. [20], showed that a closed gown exterior worn outside the operating theatre reduced the bacterial contamination of the surgical scrub suits worn underneath. In the United Kingdom, the Association for Perioperative Practice guidelines stipulate that when leaving the operating theatre, usual attire must be covered by a clean gown integrally secured by fasteners or closing buttons [21]. Lastly, in 2013, the Royal Colleges of Surgeons of Edinburgh and Ireland issued a recommendation that surgeons not leave the operating theatre with their usual attire except when necessary, in which case they must cover the attire or change their clothes upon their return to the operating area [22].

Question 3: Does regular change of operating theatre attire help to prevent infectious risk for the patient undergoing treatment in the operating theatre?

Experts: Evelyne Boudot (Montpellier), Pierre Albaladejo (Grenoble)

R1.5 – The experts suggest that in the event of staining, or at least at the end of each day of work, the staff change their surgical scrubs, the objective being to limit contamination and to prevent infectious risk for the patient.

EXPERT OPINION (STRONG AGREEMENT)

Rationale

No study up until now has directly considered the frequency with which operating theatre staff should change their operating theatre scrub suits. That said, the different published works on clothing in contact with the skin present a similar result; even in the absence of staining, the garments are far more dirtied by wear than by extrinsic contamination; it is the wearer's skin that contaminates the clothes with the flakes and bacteria at its surface. In the study by de Copp et al. [20] on contamination of operating theatre attire, mean bacterial count amongst all the included physicians increased significantly during a typical workday. These

findings suggested a need for regular change of clothes, and pointed out that departure from the operating areas represented a suitable occasion to don clean garments. Issued in 2019 by the French Society of Digestive Surgery (SFCD) and the French Association of Hepato-Bilio-Pancreatic Surgery and Liver Transplantation (ACHBT) [7], this recommendation also suggested that operating theatre staff wear either washable or one-use attire, to be changed following each procedure and, at the very least, at the end of each day of work.

FIELD 2: HEAD COVERING

Question 1: Does reusable head covering offer advantages as compared to single-use head covering?

Experts: *Serge Aho (Dijon), Hélène Beloeil (Rennes).*

R2.1.1 – The experts suggest that operating theatre staff wear single-use or reusable head covering whenever present in the operating theatre, the objective being to minimise the risk of patient infection.
EXPERT OPINION (STRONG AGREEMENT)
R2.1.2 – The experts suggest that operating theatre staff wear reusable and regularly cleaned head covering rather than single-use head covering, whenever present in the operating theatre, the objective being to reduce environmental impact.
EXPERT OPINION (STRONG AGREEMENT)

Rationale

In 2008, a guide published by the southwest French coordination center for the fight against hospital-acquired infection (CCLIN) recommended the wearing of an unwoven, single-use surgical head covering [23]. In 2015, the SF2H recommended complete and preferably single-use covering of hair and beard, the objective being to avoid air contamination due to flaking (desquamation) [1]. These recommendations were extrapolated from the study by Kasina et al. [2] in which they compared single-use to reusable attire. The reader will remember that financed by industry, this study recommended single use due to air contamination rather than surgical site infection. So it is that as of now, the literature offers no formal guidance on the choice of reusable or single-use headwear as the better way to prevent infectious risk for the patient.

As regards environmental impact, to our knowledge there exists no study specifically comparing reusable to single-use headwear. On the other hand, as described in the argumentation of R1.2, several studies have demonstrated that the environmental impact of disposable "clean air suits" is much greater than that of similar but reusable attire. And so, by analogy with the different data in the literature concerning the other aspects of attire in the operating theatre, reusable headpieces are quite likely to have less environmental impact. Just like reusable surgical scrub suits, reusable headwear should be changed daily and more often, when necessary (stains...), and taken to laundry facilities every day, preferentially via an internal laundering structure, the objective being to ensure successful execution of their prime mission, which is to function as a safety barrier. It nonetheless bears mentioning that during the washing process, tissue tends to deteriorate, generating permeability and particulate emissions. It is consequently important to regularly renew reusable headwear.

Question 2: Is headwear covering head, hair and ears (bouffant, and surgical headgear) more effective in preventing infectious risk for the patient undergoing treatment in the operating theatre then headwear not covering the ears ("skullcap")?

Experts: *Serge Aho (Dijon), Hélène Beloeil (Rennes).*

R2.2 – The experts suggest that operating theatre staff use headwear (bouffant cap, skullcap, headgear...), the objective being to minimise the risk of patient infection.
EXPERT OPINION (STRONG AGREEMENT)

Rationale

In the 2017 Association of periOperative Registered Nurses (AORN) recommendations [16], it was stipulated that operating theatres staff wear a headgear covering head, hair and ears. The argumentation favouring this recommendation is based mainly on two old studies, one of which is a retrospective study dating back to 1965 and describing hair as a reservoir for staphylococci, but without postulating a cause-and-effect link with surgical site infections (SSI) [24], while the second is a 1973 single-centre study including 11 patients and reporting an SSI epidemic that seemed to have originated in the hair of a single surgeon [25]. In opposition to the above-mentioned measures, the American College of Surgeons (ACS) left the choice of a headpiece covering or not covering the ears to surgeons' discretion [26]. This controversy between American nurses and surgeons triggered the organisation of a series of studies on the different types of headwear and their respective impacts on infectious risk. An initial before/after study on 16,000 neurosurgical procedures revealed no significant difference in SSI incidence between traditional surgical skull caps and "bouffant" caps (hair nets) [27]. A second, in vitro study investigated degrees of contamination when different forms of headwear were used. This study showed that particulate contamination of the air was significantly greater with a disposable bouffant hat than with a disposable skull cap [17]. Following which, two retrospective studies analysed the data collected by learned surgery societies. Several comparisons were made between different types of headwear and their respective impacts on the rates of surgical site infection, and no significant association was observed [28,29]. In 2016, an American hospital implemented the AORN guidelines [16] in its operating theatres; before/after comparison showed no difference in SSI incidence [18]. Lastly, analysis of the data from a prospective randomised study likewise showed no difference between bouffant cap and skull cap regarding SSI incidence [30], and inclusion of surgery duration did not modify the results. Subsequent to these studies, the ACS, the ASA, the AORN, the Association for Professionals in Infection Control and Epidemiology (Apic), the Association of Surgical Technologists (AST), the Council on Surgical and Perioperative Safety (CSPS) and *Joint action* published a statement according to which "the requirement for ear coverage is not supported by sufficient evidence" and "other issues regarding areas of surgical attire require further evaluation" [31,32].

FIELD 3 – MASKS

Question 1: Does mask wearing by non-surgical staff afford more effective prevention of infective risk for the patient undergoing treatment in the operating theatre?

Experts: *Marie Gabrielle Leroy (Montpellier), Jane Muret (Paris).*

R3.1 – The experts suggest that non-surgical staff in the operating theatre wear a type II or IIR medical mask (standard CSN EN 14683:2019) in the operating theatre, the objective being to reduce the risk of microorganisms issued from the oropharynx or the nose.
EXPERT OPINION (STRONG AGREEMENT)

Rationale

The type II or IIR medical mask is part and parcel of the attire of surgical teams and of other persons intervening in the operating

theatre. When put forward by non-surgical staff, the question regarding its role in the prevention of surgical site infections has yet to be satisfactorily answered. To this day, there have been few published studies on the interest in the operating theatre of mask wearing by non-surgical staff to prevent surgical site infections. A 2016 meta-analysis by Vincent et al. [33] dealt with the wearing of disposable masks in clean surgical procedures as a means of preventing surgical wound infection. The authors analysed 2106 patients from three relatively old studies, which showed that wearing a face mask during surgical procedures neither increased nor decreased postoperative surgical wound infections. They concluded that there exists no clear evidence that the wearing of masks in "real-life" conditions affects the occurrence of surgical site infections, the main reasons being that the mask may be poorly positioned and/or show leakage due to its not being sufficiently tightened around the face.

Among the studies included in this meta-analysis, only the one by Webster et al. [34] published in 2010 dealt with the interest of having non-medical staff wear a medical mask on the operating theatre. In this prospective study, non-surgical staff was randomised in two groups (with and without mask). The results, which pertained to 811 operated patients, found no significant difference in SSI occurrence between the masked group (11.5%) and the non-masked group (9%) (p = 0.15). In this study, the type of mask worn was not specified, and compliance with rules for wearing was not studied; moreover, the surgical procedures taken into consideration could be either clean or contaminated; a subgroup study of the "clean" surgery patients yielded the same results.

To conclude, given the limited data in the literature published to date, it is not possible to establish a formal association between mask wearing by non-surgical staff and SSI prevention. That much said, mask wearing corresponds to the obligation for all persons intervening in the operating theatre to protect themselves from exposure to blood and any other organic product of human origin. Moreover, it has been conclusively established that the mask constitutes an effective barrier to the aerosolisation and transmission of bacterial as well as viral microorganisms [33]. Those are the reasons why a type II or IIR medical mask is recommended by different learned societies such as the French Society for Hospital Hygiene (SF2H) [35] and the Association of periOperative Registered Nurses (AORN) for the non-surgical operating theatre staff [16].

Question 2: Does regular mask changing afford more effective prevention of infective risk for the patient undergoing treatment in the operating theatre?

Experts: Marie Gabrielle Leroy (Montpellier), Jane Muret (Paris).

R3.2 – The experts suggest that the operating theatre staff change surgical masks when the one being worn becomes humid or presents traces of the projections of biological fluids, the objective being to reduce the risk of microorganism transmission.

EXPERT OPINION (STRONG AGREEMENT)

Rationale

If the effectiveness of correct mask wearing on the reduction of surgical site infections has not been demonstrated, the effect of regular mask changing on the reduction of infectious risk will remain an open question. However, Zhiqing et al. [36] measured the bacterial inoculum of the masks worn by surgeons during orthopaedic surgeries, and they did so at different time intervals : a first measurement when the mask was being put on (T0); a second between 0 and 2 hours, a third between 2 and 4 hours, and a fourth between 4 and 6 hours. The results of this study showed that mask contamination significantly increased over the course of time for the same surgeon, with pronounced inter-individual variation. More precisely, starting with the 2 to 4 hour interval (p = 0.005), the number of CFU/mm^2 of mask surface increased significantly from baseline (T0), and rose to an even greater extent during the 4 to 6 hour interval ($p < 0.001$); to conclude, the authors suggested a mask change following 2 hours of intervention. Based as it is on quantification of the inoculum on the mask, the clinical relevance of their recommendation as concerns the incidence of surgical site infection remains debatable. If this recommendation were to be followed, there would have to exist a direct relationship between the presence of bacteria on the masks and the occurrence of surgical site infection; up until now, this has not been demonstrated. It also bears mentioning that in the absence of any notion of mask wearing duration, it behoves the practitioner to change a stained or humid mask [35].

FIELD 4 – SHOES/OVERSHOES

Question 1: Does reservation of a pair of shoes for use within the perimeter of the operating theatre afford more effective prevention of infectious risk for the patient undergoing a procedure in the operating theatre?

Question 2: Does the wearing of overshoes afford more effective prevention of infectious risk for the patient undergoing a procedure in the operating theatre?

Experts: Evelyne Boudot (Montpellier), Pierre Albaladejo (Grenoble)

R4.1 – The experts suggest that in order to reduce contamination of the operating theatre environment, staff wear shoes reserved exclusively for use within the perimeter of the operating theatre, in compliance with standard EN ISO 20347:2012. These specifically reserved shoes must be changed at least once a day, and more often in the presence of visible stains, and they need to be regularly machine washed.

EXPERT OPINION (STRONG AGREEMENT)

R4.2 – The experts suggest that operating theatre staff not accompany the dedicated shoes with overshoes, which not only are ineffective in reducing environmental contamination, but also entail a risk of contamination of the hands.

EXPERT OPINION (STRONG AGREEMENT)

Rationale

The wearing by operating theatre professionals of dedicated clean shoes represents a "traditional" measure to prevent surgical site infection. The theoretical objective of this type of measure is to reduce contamination of operation theatre floors, which is potentially associated with contamination of the operating theatre [37]. In fact, these measures are part and parcel of most of the national and international reference documents on operating theatre attire [16,38]. To our knowledge, there exists no study showing a direct connection between these measures and reduced infectious risk in the operating theatre. On the other hand, most of the published studies highlight a relation between floor contamination and shoes [39]. These studies compare three strategies: town footwear, dedicated shoes (associated with a washing protocol), and single-use overshoes. In a double-blind randomised study, Amirfeyz et al. showed that the bacterial inoculum in outdoor shoes were significantly more present than in shoes dedicated for use in the operating theatre [40]. In an older study by Copp et al., town shoes were shown to entail bacterial contamination significantly higher than in shoes dedicated for use in the operating theatre; the authors also showed that wearing overshoes in the operating theatre did not reduce bacterial

contamination of the floors [41]. In detail, these studies highlighted more contamination of operating theatre floors in the morning with town shoes than with dedicated shoes, increased contamination of floors or shoes over the course of the day, and less contamination of the floors with dedicated shoes. To conclude, these results are closely connected with daytime floor-washing protocols.

There is no consideration in the literature of how to maintain the shoes reserved for use in the operating theatre, even though it would appear that dedicated but poorly maintained shoes could finally become germ carriers as much as would a pair of town shoes, and perhaps to an even greater extent due to exposure to organic contaminants. From a pragmatic standpoint, daily shoe changing would imply daily machine washing, and would favor rubber shoes or polymer materials (polyurethane, polyvinyl chloride...).

Moreover, dedicated shoes are considered as personal protective equipment for hospital staff, and they fall under the jurisdiction of standard EN ISO 20347:2012, which considers them as "occupational footwear that is not exposed to any mechanical risks". The experts consequently suggest that the shoes reserved for the operating theatre be in compliance with this norm; in detail, they must be weatherproof, closed in front, and without perforation at the back of the foot, the objective being to protect the front of the foot from sharp-pointed, sharp-edged or jagged objects.

The experts also suggest that establishments maintain a "collective" stock of shoes dedicated to the operating theatre, thereby facilitating distribution to staff, organisation of the daily laundering circuit, and satisfactory control of the hermetic quality as well as the wear and tear of the shoes, which could be adequately replaced once their protective functions are no longer ensured. Lastly, the experts suggest that the collective stock include dedicated shoes reserved for occasional visitors to the operating theatre.

Lastly, the study by Humphreys et al. underlined the low level of interest in the supplementary use of overshoes as a means of reducing contamination of the operating theatre floor [42]. Moreover, there exists a risk of contamination of the hands that would be associated with overshoes [43], of which the risk of deterioration by the end of a given day is estimated at 10%. To conclude, overshoes should be considered as exceptional, and when used, they need to be placed above the dedicated operating theatre shoes, the objective being to afford supplementary protection in case of high risk of projection of blood and/or large quantities of organic fluids. The staff will be called upon to disinfect their hands after having put on and removed the overshoes.

Conflicts of interest

The authors have no conflicts of interest to declare.

References

[1] Société Française d'Hygiène hospitalière. Qualité de l'air au bloc opératoire et autres secteurs interventionnels 2015. https://www.sf2h.net/publications/qualite-de-lair-bloc-operatoire-autres-secteurs-interventionnels.

[2] Kasina P, Tammelin A, Blomfeldt A-M, Ljungqvist B, Reinmüller B, Ottosson C. Comparison of three distinct clean air suits to decrease the bacterial load in the operating theatre: an observational study. Patient Saf Surg 2016;10:1. http://dx.doi.org/10.1186/s13037-015-0091-4.

[3] Garibaldi RA, Maglio S, Lerer T, Becker D, Lyons R. Comparison of nonwoven and woven gown and drape fabric to prevent intraoperative wound contamination and postoperative infection. Am J Surg 1986;152:505–9. http://dx.doi.org/10.1016/0002-9610(86)90216-3.

[4] Moylan JA, Fitzpatrick KT, Davenport KE. Reducing wound infections. Improved gown and drape barrier performance. Arch Surg Chic Ill 1960 1987;122:152–7. http://dx.doi.org/10.1001/archsurg.1987.01400140034003.

[5] Rutala WA, Weber DJ. A review of single-use and reusable gowns and drapes in health care. Infect Control Hosp Epidemiol 2001;22:248–57. http://dx.doi.org/10.1086/501895.

[6] WHO. Global guidelines on the prevention of surgical site infection - Summary of a systematic review on drapes and gowns;https://www.ncbi.nlm.nih.gov/books/NBK536404/2018.

[7] Moszkowicz D, Hobeika C, Collard M, Bruzzi M, Beghdadi N, Catry J. Operating theatre hygiene: clinical practice guidelines SFCD-ACHBT. J Visc Surg 2021;158(June (3)):285–6. http://dx.doi.org/10.1016/j.jviscsurg.2021.01.010. Epub 2021 Feb 11. PMID: 33583727.

[8] Overcash M. A comparison of reusable and disposable perioperative textiles: sustainability state-of-the-art 2012. Anesth Analg 2012;114:1055–66. http://dx.doi.org/10.1213/ANE.0b013e31824d9cc3.

[9] McDowell J. An environmental, economic, and health comparison of single-use and reusable drapes and gowns. Asepsis; 1993.

[10] European Textile Services Association. Simplified life cycle assessment of surgical gowns; 2000.

[11] RMIT University. Life cycle assessment comparing laundred surgical gowns with polypropylene based disposable gowns; 2008.

[12] Van de Berghe A, Riegel A, Zimmer C. Comparative life cycle assessment of disposable and reusable surgical gowns; 2010.

[13] UniTech. Life cycle inventory compariosns of radiological protective garments. Sprinfield, MA: UniTech Cordp; 2010, n.d..

[14] Vozzola E, Overcash M, Griffing E. Environmental considerations in the selection of isolation gowns: A life cycle assessment of reusable and disposable alternatives. Am J Infect Control 2018;46:881–6. http://dx.doi.org/10.1016/j.ajic.2018.02.002.

[15] AFNOR. Norme NF EN 13795-2, Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 2 : tenues de bloc 2019. https://www.boutique.afnor.org/fr-fr/norme/nf-en-137952/vetements-et-champs-chirurgicaux-exigences-et-methodes-dessai-partie-2-tenu/fa177176/1819.

[16] Association of periOperative Registered Nurses. AORN Guideline for Surgical Attire 2017. https://www.aorn.org/about-aorn/aorn-newsroom/health-policy-news/2017-health-policy-news/aorn-guideline-for-surgical-attire.

[17] Markel TA, Gormley T, Greeley D, Ostojic J, Wise A, Rajala J, et al. Hats off: a study of different operating theatre headgear assessed by environmental quality indicators. J Am Coll Surg 2017;225:573–81. http://dx.doi.org/10.1016/j.jamcollsurg.2017.08.014.

[18] Elmously A, Gray KD, Michelassi F, Afaneh C, Kluger MD, Salemi A, et al. Operating theatre attire policy and healthcare cost: favoring evidence over action for prevention of surgical site infections. J Am Coll Surg 2019;228:98–106. http://dx.doi.org/10.1016/j.jamcollsurg.2018.06.010.

[19] Hee HI, Lee S, Chia SN, Lu QS, Liew APQ, Ng A. Bacterial contamination of surgical scrub suits worn outside the operating theatre: a randomised crossover study. Anaesthesia 2014;69:816–25. http://dx.doi.org/10.1111/anae.12633.

[20] Copp G, Mailhot CB, Zalar M, Slezak L, Copp AJ. Covergowns and the control of operating theatre contamination. Nurs Res 1986;35:263–8. PMID: 3529043.

[21] Rohrlach G. Does NATN have any advice or research available about home laundering of scrub attire? Br J Perioper Nurs J Natl Assoc Theatre Nurses 2001;11:101. PMID: 11892101.

[22] McHugh SM, Corrigan MA, Hill ADK, Humphreys H. Surgical attire, practices and their perception in the prevention of surgical site infection. Surg J R Coll Surg Edinb Irel 2014;12:47–52. http://dx.doi.org/10.1016/j.surge.2013.10.006.

[23] CCLIN Sud-Est. Les tenues professionnelles dans les établissements de santé 2008. http://www.cpias.fr/nosobase/recommandations/cclin_arlin/cclinSudEst/2008_personnel_CCLIN.pdf.

[24] Summers MM, Lynch PF, Black T. Hair as a reservoir of staphylococci. J Clin Pathol 1965;18:13–5. http://dx.doi.org/10.1136/jcp.18.1.13.

[25] Dineen P, Drusin L. Epidemics of postoperative wound infections associated with hair carriers. Lancet Lond Engl 1973;2:1157–9. http://dx.doi.org/10.1016/s0140-6736(73)92933-4.

[26] American College of Surgeons. Statement on operating theatre attire. Bull Am Coll Surg 2016;105, https://www.facs.org/about-acs/statements/87-surgical-attire.

[27] Shallwani H, Shakir HJ, Aldridge AM, Donovan MT, Levy EI, Gibbons KJ. Mandatory change from surgical skull caps to bouffant caps among operating theatre personnel does not reduce surgical site infections in class i surgical cases: a single-center experience with more than 15 000 patients. Neurosurgery 2018;82:548–54. http://dx.doi.org/10.1093/neuros/nyx211.

[28] Haskins IN, Prabhu AS, Krpata DM, Perez AJ, Tastaldi L, Tu C, et al. Is there an association between surgeon hat type and 30-day wound events following ventral hernia repair? Hernia J Hernias Abdom Wall Surg 2017;21:495–503. http://dx.doi.org/10.1007/s10029-017-1626-7.

[29] Farach SM, Kelly KN, Farkas RL, Ruan DT, Matroniano A, Linehan DC, et al. Have recent modifications of operating theatre attire policies decreased surgical site infections? An American College of Surgeons NSQIP Review of 6,517 Patients. J Am Coll Surg 2018;226:804–13. http://dx.doi.org/10.1016/j.jamcollsurg.2018.01.005.

[30] Kothari SN, Anderson MJ, Borgert AJ, Kallies KJ, Kowalski TJ. Bouffant vs skull cap and impact on surgical site infection: does operating theatre headwear really matter? J Am Coll Surg 2018;227:198–202. http://dx.doi.org/10.1016/j.jamcollsurg.2018.04.029.

[31] American College of Surgeons. A Statement from the Meeting of ACS, AORN, ASA, APIC, AST, and TJC Concerning Recommendations for Operating theatre Attire 2018. https://www.facs.org/about-acs/consensus-statements/or-attire.

[32] American College of Surgeons. Proceedings and recommendations from the OR attire summit: A collaborative model for guideline development 2019;104. https://bulletin.facs.org/2019/05/proceedings-and-recommendations-from-the-or-attire-summit-a-collaborative-model-for-guideline-development/.
[33] Vincent M, Edwards P. Disposable surgical face masks for preventing surgical wound infection in clean surgery. Cochrane Database Syst Rev 2016;4. http://dx.doi.org/10.1002/14651858.CD002929.pub3. CD002929.
[34] Webster J, Croger S, Lister C, Doidge M, Terry MJ, Jones I. Use of face masks by non-scrubbed operating theatre staff: a randomized controlled trial. ANZ J Surg 2010;80:169–73. http://dx.doi.org/10.1111/j.1445-2197.2009.05200.x.
[35] Société Française d'Hygiène Hospitalière. Actualisation des Précautions standard 2017. https://www.sf2h.net/publications/actualisation-precautions-standard-2017.
[36] Zhiqing L, Yongyun C, Wenxiang C, Mengning Y, Yuanqing M, Zhenan Z, et al. Surgical masks as source of bacterial contamination during operative procedures. J Orthop Transl 2018;14:57–62. http://dx.doi.org/10.1016/j.jot.2018.06.002.
[37] Hambraeus A, Bengtsson S, Laurell G. Bacterial contamination in a modern operating suite. 3. Importance of floor contamination as a source of airborne bacteria. J Hyg (Lond) 1978;80:169–74. http://dx.doi.org/10.1017/s0022172400053511.
[38] Société Française d'Hygiène Hospitalière. Surveiller et prévenir les infections associées aux soins 2010. https://www.sf2h.net/publications/surveiller-prevenir-infections-associees-aux-soins.
[39] Clesham K, Ryan PR, Murphy CG. Assessment of theatre shoe contamination in an orthopaedic theatre. J Hosp Infect 2018;99:299–302. http://dx.doi.org/10.1016/j.jhin.2018.03.009.
[40] Amirfeyz R, Tasker A, Ali S, Bowker K, Blom A. Theatre shoes - a link in the common pathway of postoperative wound infection? Ann R Coll Surg Engl 2007;89:605–8. http://dx.doi.org/10.1308/003588407X205440.
[41] Copp G, Slezak L, Dudley N, Mailhot CB. Footwear practices and operating theatre contamination. Nurs Res 1987;36:366–9. PMID: 3671124.
[42] Humphreys H, Marshall RJ, Ricketts VE, Russell AJ, Reeves DS. Theatre over-shoes do not reduce operating theatre floor bacterial counts. J Hosp Infect 1991;17:117–23. http://dx.doi.org/10.1016/0195-6701(91)90175-8.
[43] Carter R. The journal of infection control nursing. Ritual and risk. Nurs Times 1990;86:63–4. PMID: 2320459.