



SKIN TOLERANCE TO ALCOHOL-BASED PREPARATIONS: BASIS FOR IMPROVEMENT OF HAND HYGIENE PRACTICES

TOLERÂNCIA DA PELE ÀS PREPARAÇÕES ALCOÓLICAS: SUBSÍDIOS PARA MELHORIA DAS PRÁTICAS DE HIGIENE DAS MÃOS

TOLERANCIA DE LA PIEL A LAS PREPARACIONES ALCOHÓLICAS: SUBSIDIOS PARA MEJORAR LAS PRÁCTICAS DE HIGIENE DE LAS MANOS

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ABSTRACT

Objective: to evaluate the tolerance of the skin of nursing professionals to two alcohol-based preparations with the implementation of the protocol "Multimodal Strategy for improving HH". **Method:** cross-over, randomized and double-blind study with 42 nursing professionals from a public hospital of medium complexity. **Results:** the use of *handrub* did not have positive tolerance for the characteristic appearance, but aspects related to integrity and humidity stood out. In the case of alcohol gel, there was positive tolerance for appearance and sensation. Higher tolerance was observed after using alcohol gel. For *handrub*, appearance was the only characteristic that did not show positive tolerance in the self-assessment. In the objective evaluations, there was a decrease of cases of dry and/or red skin and very dry skin with whitish appearance after the use of both alcohol-based preparations. **Conclusion:** singularities of professionals must be considered, with promotion of participatory decision-making in order to ensure the creation of a true atmosphere of institutional safety. **Descriptors:** Hands Hygiene; Alcohols; Cutaneous Manifestations; Skin; Nursing.

RESUMO

Objetivo: avaliar a tolerância da pele de profissionais de enfermagem em relação às duas preparações alcoólicas com a aplicação do protocolo da "Estratégia Multimodal para melhoria da HM". **Método:** estudo cross-over, randomizado e duplo-cego com 42 profissionais de enfermagem de um hospital público de média complexidade. **Resultados:** não houve tolerância positiva para o *handrub* para a característica aparência, porém destacaram-se aspectos relacionados à integridade e à umidade. Para o álcool em gel, houve tolerância positiva para aparência e sensação. Evidenciou-se maior tolerância, após a utilização do álcool em gel. Na autoavaliação, para o *handrub*, somente a característica aparência não apresentou tolerância positiva. Para as avaliações objetivas, houve diminuição dos casos pele seca e/ou vermelha, e muito seca com aparência esbranquiçada após a utilização de ambas as preparações alcoólicas. **Conclusão:** devem-se considerar as singularidades dos profissionais com a promoção de processo decisório participativo para garantir a criação de um verdadeiro clima de segurança institucional. **Descritores:** Higiene das Mãos; Álcoois; Manifestações Cutâneas; Pele; Enfermagem.

RESUMEN

Objetivo: evaluar la tolerancia de la piel de profesionales de enfermería en relación a las dos preparaciones alcohólicas con la aplicación del protocolo de la "Estrategia Multimodal para mejoría de HM". **Método:** estudio cross-over, aleatorio y duplo-cego con 42 profesionales de enfermería de un hospital público de media complejidad. **Resultados:** no hubo tolerancia positiva para el *handrub* para la característica apariencia, sin embargo se destacaron aspectos relacionados a la integridad y a la humedad. Para el alcohol en general, hubo tolerancia positiva para apariencia y sensación. Se evidenció mayor tolerancia, después de la utilización del alcohol en general. En la auto-evaluación, para el *handrub*, solamente la característica apariencia no presentó tolerancia positiva. Para las evaluaciones objetivas, hubo disminución de los casos de piel seca y/o roja, y muy seca con apariencia blanqueada después de la utilización de ambas preparaciones alcohólicas. **Conclusión:** se deben considerar las singularidades de los profesionales con la promoción del proceso decisivo participativo para garantizar la creación de un verdadero clima de seguridad institucional. **Descriptores:** Higiene de las Manos; Alcoholes; Manifestaciones Cutánea; Piel; Enfermería.

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INTRODUCTION

The emergence of pathogens and the resurgence of old pathogens, as well as new microbial resistance mechanisms stand out in the context of current public health, and this phenomenon is influenced by many factors that are beyond the current medicine. As a result, several changes in health care are needed, particularly with regard to prevention of Health Care Associated Infections (HAIs), which represent one of the most important adverse effects resulting from the care process.¹⁻²

The World Health Organization (WHO) estimates that hundreds of millions of patients are affected each year by HAIs, specifically, about 7% of patients admitted to health institutions in developed countries and 15% in countries with lower socioeconomic development. In the United States, 1.7 million episodes of HAIs were reported in 2002, which resulted in approximately 100,000 deaths. In addition to individual effects, the occurrence of HAIs increases the cost of the health care, with substantial increase in morbidity and mortality rates in all countries.³⁻⁴

In the health care setting, the hands of professionals are the main vehicle of transmission of microorganisms and transport of pathogens, causing HAIs. Thus, the practice of Hand Hygiene (HH) is the primary mechanism for prevention and control of this type of infection.⁵

Poor adherence to HH practice by health professionals is evidenced in several studies conducted over the past decade. Conversely, strategies to promote the improvement of this practice have been developed and implemented by everyone in different care situations, with significant improvement of this practice to ensure greater security in the care process.⁶⁻¹¹

The "Multimodal Strategy for improvement of HH" promoted by WHO as part of the World Alliance for Patient Safety is one of the most extensive and significant strategies in promoting changes in practices related to the control of HAIs and encompasses a number of components aiming to put into practice the WHO recommendations on HH.^{5,10,12}

One of the recommendations relates to the creation of an atmosphere of institutional safety, which concerns the implementation of changes towards a differentiated environment in the institution, to promote activities that may lead to awareness of health professionals with respect to the patient safety and with active participation of all involved in the

process, to raise awareness of individual and institutional responsibility in these changes.⁵

Among the measures proposed by the WHO to improve the adherence, the availability of alcohol-based preparations has been shown to be an excellent alternative to ensure greater adherence of health professionals to HH. Results of many studies have given support to the WHO recommendations, because there has been a significant increase in the rates of adherence to HH after the implementation of the multimodal strategy in health services.^{5,9-10,12-5}

In the national context, the importance of alcohol-based preparations in promoting improvement of HH practices was acknowledged by the National Health Surveillance Agency (ANVISA) through the publication of Resolution nº 42, October 25, 2010, which "*establishes the mandatory provision of alcohol-based antiseptic preparation for antiseptic rubbing of hands in the health services of the country*".¹⁶

Faced with evidence of the benefits of the use of alcohol-based preparations to HH practice, studies with behavioral approach have identified several barriers in the use of these products, such as work overload, poor physical infrastructure of health facilities, inadequate supply of inputs, lack of training and poor quality products, and, particularly, the report of products that cause skin reactions.^{15,17-19}

The availability of alcohol-based preparations free from harmful effects to the skin of health professionals is an important measure to improve the adherence to HH. From this perspective, the acceptance and satisfaction of users, as well as good skin tolerance to products should be considered as criteria for selection of alcohol-based preparations, for their acquisition and provision by health institutions. This will help in the effective creation of an atmosphere of institutional safety for the prevention and control of HAIs, what, in turn, reflects on the quality of care.²⁰⁻²¹

Taking into consideration the recommendations related to the use of alcohol-based preparations and highlighting the strategy to improve HH, our investigative focus is linked to the need to understand the aspects related to the tolerance of the use of this product by health professionals as an strategy for promoting acceptance and improved adherence to HH practices in an atmosphere of institutional safety.

This study aims to evaluate the tolerance of the skin of nursing professionals in relation to two different alcohol-based preparations

with the implementation of the protocol "Multimodal Strategy for improvement of HH", recommended by the WHO.

METHOD

This study was extracted from the dissertation "Multimodal strategy to promote hand hygiene: attributes for acceptance and tolerance of alcohol-based preparations". It was a *cross-over*, randomized and double-blind study carried out with nursing professionals who work in a public hospital of medium complexity. We used the protocol "Evaluation and comparison of tolerance and acceptance of different alcohol-based preparations" proposed by the WHO as one of the tools for the implementation of the "Multimodal Strategy for improving HH".

In this study, we compared two different alcohol-based preparations: one formulated as gel, which is the product available for everyday use by nursing professionals working in the institution studied; and other formulated as liquid (*handrub*), produced according to the instructions of the manual "*Guide to Local Production: WHO-recommended Handrub Formulations*".²²

Samples of the product in gel were provided by the Warehouse sector of the health institution to ensure the use of the product with the same physical and chemical characteristics of the one that is made available to nursing professionals. The liquid form (*handrub*) was produced in the laboratory of the Center for Research on Prevention and Control of Infections in Health Care Services (NEPECISS) of the School of Nursing of Ribeirão Preto, University of São Paulo.

In order to ensure double-blind methodology, the researcher was unaware of the content of identical containers (white plastic bottles with lids of the type *flip-top*) which were provided to participants of the study only with the name **Solution A** and **Solution B**. Participants were also unaware of the formulation and the origin of products.

The labels of the bottles also had the identification number of each participant (from 1 to 60) followed by the number of the bottle (1 to 3), since three bottles with 100 grams (g) of the product, that is, 300 g of each alcohol preparation for the period of use previously established, were supplied for each participant. Bottles of alcohol-based preparations were packed in plastic bags, stored in dry and ventilated places for the preservation of their characteristics and organized according to the period of use.

After the recruitment of participants, two random groups were created, Group A (participants 01- 30) and Group B (participants 31 - 60), noting that the WHO suggests to implement the use of the protocol of evaluation of acceptance and tolerance to alcohol-based preparations with a minimum of 40 participants. For this study, we chose to consider an index of safety of 50% in the process of recruitment of interested participants, totaling a group of 60 participants to the start the study.

After the period of use of each alcohol-based preparation, an interval (period of *wash-out*) of at least two days before changing the product was established. The study participants were informed about the period of *wash-out*, during which they should only use water and soap in the HH process and suspend the use of lotions or creams in the hands. An additional work on call for the use of the tested product was carried out for participants who had days-off.

The second phase occurred after a period of *wash-out* when the researcher then returned to the institution for delivery of bottles. In the second period of use of alcohol-based preparations, all pre-established criteria were respected, including the evaluation of the acceptability of the product.

Data collection was based on an instrument developed by the WHO as part of the package of tools for the implementation of multimodal strategy, which was translated and validated by ANVISA for use in Brazilian health institutions.

After a structural review, in order to adapt the instrument for data collection to the place of research, this consisted of three distinct parts: Part 1 - Questionnaire for personal and professional characteristics and factors that can influence the tolerance of the skin; Part 2 - Questionnaire for subjective assessment of the criteria of acceptance of alcohol-based preparations and self-assessment of skin tolerance, which is filled by the participants at the end of each period of use of the two alcohol-based preparations compared in this study; and Part 3 - Objective assessment scale applied by the researcher for evaluation and comparison of the general conditions of the skin of the study participants before and after the use of each alcohol-based preparation.

Scores for self-assessment and objective assessment of general skin conditions and criteria for the interpretation of these were also established by the WHO. For the self-assessment phase, score from 1 to 7 were used for the criteria listed by the WHO with

nominal ratings only to the minimum (1 = abnormal) and maximum (7 = normal) scores and no further nominal rating for the intermediate values. According to WHO recommendations, there should be 75%, or above this fraction, of respondents with a score higher than 4 in order to consider a positive tolerance for each of the evaluated characteristics (appearance, integrity, moisture, sensation and overall integrity).

To the *objective evaluation* of skin conditions, the WHO recommends the use of different parameters that characterize skin conditions as well as the application of an overall score scale related to the characteristics of the hand skin of professionals. Such scale is validated by ANVISA for use in national health services. In the present study, we chose to emphasize the data obtained through the overall score scale, which has scores ranging from 0 to 5 (*0 = No observable scale or irritation; Scale 1 = Occasional scale, not necessarily evenly distributed; 2 = Dry and/or red skin; 3 = Very dry, whitish, rough and/or reddish skin, without cracks; 4 = Cracked skin surface without bleeding/secretion; 5 = Extensive cracks in the skin surface with bleeding/secretion*).

The results were entered into a database in the program *Microsoft Office Excel*, by double entry for validation, and loaded in the program *Statistical Package for Social Science* (SPSS) version 19.0. The study has been approved by the Ethics Committee in Research with Human Beings of the Health Center School of the Medical College of Ribeirão Preto, of the University of São Paulo, under protocol nº 368/CEP-CSE-FMRP-USP in May 2010.

RESULTS

The study began with the participation of 60 professionals. Eighteen participants (30%) were lost during the process of data collection. The research was completed with 42 nursing professionals. Losses happened due to dismissals or sick leave, unforeseen after recruitment for research; interruption of the use of the alcohol-based preparation for longer than four days or loss of bottles; and not suspension of the use of lotions and hand creams due to fear of appearance of injuries.

Among participants, there was a prevalence of 36 (85.7%) female professionals as well as 14 (33.4%) individuals aged between 36 and 45 years. With regard to the professional category, there was a prevalence of 32 (76.2%) nursing assistants and technicians.

Participants were also evaluated for the characteristics and habits, that may influence the tolerance of the skin in relation to alcohol-based preparations, as recommended by the protocol proposed by the WHO. It was found that 16 (38.1%) participants had clear skin and 13 (31.0%) had light brown skin tone. For this ethnic feature, the definition referred by the own individual was respected.

The practice of other activities such as handling chemicals or tools, gardening practice, among others, that could cause damage to the skin, in addition to damages caused by excessive HH or use of inadequate products and/or products of poor quality, was also investigated. This was reported by only five (11.9%) of the study participants.

The use of protective creams or lotions to the skin of hands had their frequency reported by 11 (26.2%) participants as rarely performed; It was also significant use associated with climatic conditions for nine (21.4%) participants, who mentioned the use depending on the season of the year.

As for pre-existing medical conditions, 30 (71.4%) participants denied any kind of irritant dermatitis. In addition, 37 (88.1%) denied history of atopic dermatitis. In addition to that, there was no reference to intolerance to alcohol by any of the study participants, what represented one inclusion criteria.

♦ Self-assessment of skin conditions of the hands of nurses

The Table 1 presents data on the self-assessment of skin tolerance. Notably, for the preparation of the alcohol-based *handrub*, only the characteristic "appearance" did not have positive tolerance, since only 29 (69.0%) participants opted for values higher than 4 in the score, not reaching the parameter set by the WHO.

Table 1. Self-assessment of nursing professionals on the skin tolerance after use of alcohol-based preparations (*handrub* and alcohol gel). Londrina/PR, 2012.

Characteristic	Handrub		Alcohol gel	
	Positive tolerance	Negative tolerance	Positive tolerance	Negative tolerance
	N (%)	N (%)	N (%)	N (%)
Appearance	29 (69.0)	13 (31.0)	35 (83.3)	7 (16.7)
Integrity	36 (85.7)	6 (14.3)	35 (83.3)	7 (16.7)
Humidity	33 (78.5)	9 (21.4)	32 (76.2)	10 (23.8)
Sensation	36 (85.7)	6 (14.3)	39 (92.9)	3 (7.1)
Overall integrity	34 (80.9)	8 (19.1)	36 (85.7)	6 (14.3)

For the other characteristics evaluated, there was positive tolerance according to the WHO classification. However, there were differences in the characteristics between the two alcohol-based preparations, as for *handrub*, the characteristics integrity and humidity stood out, with respectively 85.7% and 78.5% positive tolerance; and for alcohol gel, the characteristics appearance, with 35 (83.3%) positive tolerance, and sensation, with 39 (92.9%) positive tolerance, stood out.

The appearance refers to the presence of redness and/or blemishes, as well as visual perception of roughness. Integrity was evaluated based on the presence of abrasions or cracks and moisture with respect to skin dryness. Sensation is related to the presence of itching, burning and/or discomfort.

When asked about a self-assessment of the overall integrity of the skin of the hands, the participants also used a scale with scores from 1 to 7, being assigned as nominal classification: *very changed* and *perfect* for the minimum and maximum values, respectively. For both alcohol-based

preparations, positive tolerance was observed. However, higher tolerance was seen after the use of alcohol gel.

• **Objective assessment of the skin conditions of the hands of nurses**

With regard to objective assessments, the WHO recommends that evaluation of data focus on the moment after the use of the products, because the objective of the application of the scale is to evaluate the effect of the product on the skin of professionals. Thus, there were pre-intervention and post-intervention assessments, for the periods of use of the two alcohol-based preparations.

Table 2 summarizes the scores of the objective assessment of the skin of nursing professionals, according to the skin tolerance scale recommended by WHO and validated by ANVISA.

Table 2. Objective assessment of the assessment of the researcher about the skin tolerance of nursing professionals after the use of preparations.

Visual Score of Skin Scale	Handrub		Alcohol gel	
	Pre-intervention n (%)	Post-intervention n (%)	Pre-intervention n (%)	Post-intervention n (%)
0 - No observable scale or irritation of any kind	12 (28.6)	17 (40.5)	14 (33.3)	13 (31.0)
1 - Occasional scale, not necessarily evenly distributed	13 (31.0)	16 (38.1)	11 (26.2)	17 (40.5)
2 - Dry and/or red skin	12 (28.6)	6 (14.3)	12 (28.6)	8 (19.0)
3 - Very dry skin with whitish appearance, rough to the touch and/or reddish, but without cracks	4 (9.5)	1 (2.4)	3 (7.1)	2 (4.8)
4 - Cracked skin surface without bleeding and/or secretion	1 (2.4)	2 (4.8)	3 (7.1)	2 (4.8)
5 - Extensive cracks in the skin surface with bleeding and/or secretion	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)

It is noteworthy that after using the *handrub*, there was increase in the number of individuals without any change in the skin of the hands for 17 (40.5%). However, after the period of use of alcohol gel, a decrease of individuals classified into the same group was observed.

For both alcohol-based preparations, there was a decrease of cases classified as 2 (dry and/or red skin), particularly following the use of *handrub*. Individuals with skin conditions classified in the group 3 (very dry skin with whitish appearance) decreased significantly after using the *handrub* (1-2.4%),

with a slight increase in cases in this classification after the use of alcohol gel.

As for the group 4 (cracked skin surface), there was an increase in only one individual after the use of the *handrub* and reduction in one individual after the use of alcohol gel. No cases classified as 5 (extensive cracks) after the use of both alcohol-based preparations were observed.

DISCUSSION

The practice of antiseptic rubbing of hands is not the only factor that causes irritation to the skin of health professionals, but a number of aspects inherent to the use of alcohol-based preparations and detergents. Frequent HH removes the layer of lipids present on the surface of the skin and promotes the action of alcohol on the lipid structure of the stratum corneum, with consequent loss of intracellular lipids, which form a semi-permeable barrier responsible for water conservation and natural moisturizing factors.²³ Added to this, poor skin hydration by health professionals and the prolonged use of gloves, which are used as self-protective mechanisms, increase skin dryness leading to the emergence of injuries.^{8,23-4}

Changes in skin conditions and adverse reactions to products used in HH are common events among nursing professionals. Notably, these effects vary considerably according to climatic and environmental conditions, as well as according to specific features for each skin type.⁵

The use of lotions and creams containing wetting agents in this sense is recommended because they increase the hydration of the skin and provide a protective barrier to the irritating action of products used in HH, preventing and treating irritant effects associated with excessive HH.²⁵

For the alcohol-based preparations evaluated in this study, *handrub* did not show positive tolerance for the characteristic "appearance" in the self-assessment of nursing professionals, suggesting a perception on their part of the negative effect related to the presence of redness, blemishes and roughness of the skin. This product also obtained a lower percentage of positive tolerance on the criterion of "overall integrity". However, the data collected by the researcher during the objective assessment showed a significant improvement with regard to skin dryness, considering the decrease in the number of individuals who had "dry and/or red skin" as well as "very dry skin with whitish appearance" after the period of use of *handrub*.

These data contradict evidence found in the literature, in which alcohol-based preparations in gel formulation performed significantly better than the liquid formulation, in relation to maintaining the epidermal water content, as well as regarding satisfaction on the part of health professionals, promoting higher rates of adherence to HH.¹³

The use of products, mainly alcohol-based preparations containing emollients may reduce the effects of dryness. However, in face of the variety of products available in the market, it is necessary to evaluate the formulation of each sample tested for the presence of wetting agents and concentration of the alcohols.²³

It is also important to highlight the contrast between the self-assessment of nursing professionals and the objective evaluation by the researcher, based on the criteria and classification recommended by the WHO. As regards the criteria established for evaluating skin tolerance, the professionals highlighted the characteristics moisture and integrity for the *handrub*; and appearance and sensation for the gel formulation.

As discussed above, the objective assessment showed significant improvement for drying of the skin after using the *handrub*. However, in the self-assessment, professionals gave more positive tolerance for the aspect overall integrity after use of the gel formulation. This result may be related to the fact that the alcoholic gel preparation is already be used by nursing professionals of this health institution, ensuring greater safety for them in their use.

The formula of the *handrub*, proposed by the WHO has different physical characteristics, and its composition contains addition of hydrogen peroxide, which gives the product a distinctive odor. This has already been reported in the literature as a negative factor for promoting tolerance and acceptance of health professionals.^{22,26}

Despite the consistent scientific evidence regarding the effectiveness of alcohol-based preparations and their advantages to promote HH, some studies also show resistance from health professionals regarding the use of these products, reporting belief in the greater efficiency of HH practice with detergents and antiseptic agents, as well as the perception that the alcohol-based preparations may be potentially harmful to the skin.^{17,19,27}

Evidence relating to skin tolerance further reinforce the role of alcohol-based preparations, regardless of physical form, such as better tolerated and less harmful than

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products intended for HH such as plain soap or soaps with antimicrobial agents in their formulation.^{26,28}

Based on these, it can be said that the evaluation of skin tolerance is a key point for a good acceptability of products for HH, especially with regard to alcohol-based preparations. The appreciation of the opinion of the health team is also fundamental for promotion of improved HH practices.

Dissatisfaction of professionals prevent them from devoting their efforts, knowledge and skills in order to improve the care and adherence to HH practice. Thus, it is necessary to ensure a relationship of exchange between the agents of the work process to achieve better results in healthcare.²⁹

The implementation of multimodal strategies have shown to have positive effects on the behavior of individuals, promoting a more active attitude towards skin care and prevention of damage inherent in HH practice, an essential practice in the health care context. The associations with motivational strategies make the changes more effective when compared to the availability of physical resources alone.^{20,24,30}

Surveillance of HH practice and the factors that influence give managers and health professionals the opportunity to carry out a reflection on behavior change and patient safety, ensuring the effective creation of an atmosphere of institutional safety.¹¹

Thus, the active participation of health professionals in the process of evaluation of products to be made available for HH is an important strategy for promoting improvement of HH practices. The appreciation of the component of the individual aspects and those related to staff preferences generate feelings of satisfaction and enhance involvement with the purpose of promoting safer and more qualified care.

CONCLUSION

Among the 42 participants, there was a predominance of female individuals (36 - 85.7%) and of the age group between 36 and 45 years (14 - 33.4%), and of nursing assistants and technicians (32 - 76.2%). With regard to pre-existing medical conditions, most of participants (30 to 71.4%) denied any kind of irritant dermatitis.

After the period of use of the two alcohol-based preparations, it was observed that only the *handrub* did not have positive tolerance for the characteristic appearance, proposed by the WHO. Considering the other characteristics evaluated for the *handrub*

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integrity (36 - 85.7%) and humidity (33 - 78.5%) stood out; and for the alcohol gel, appearance (35 - 83.3%) and sensation (39 - 92.9%) stood out with positive tolerance. Both alcohol-based preparations obtained positive tolerance for the overall integrity in the self-assessment. However, there was evidence of increased tolerance after using the alcohol gel, and this was in disagreement with the results obtained by applying the scale of visual evaluation of the skin.

As for the objective evaluation by the researcher, there was a decrease of cases classified as 2 (dry and/or red skin) and 3 (very dry skin with whitish appearance) after the period of use of both alcohol-based preparations, but more significantly after using *handrub*. The results of this study agree with the evidences of the recent literature data, which demonstrate better performance of alcohol-based preparations in gel formulation to ensure the conservation of moisture, thus preventing dryness and the appearance of changes in skin integrity.

The present results reinforce the need to ensure that the health team may participate in the evaluation of products to be made available for the practice of HH in health institutions. For this, it is important to consider the singularities of professionals, through the application of protocols that are validated and recognized by national and international agencies. The promotion of a participatory decision-making process may ensure success in the creation of an atmosphere of true institutional safety.

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