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The challenge in the use of alcoholic preparations for hand hygiene in healthcare services

Desafio ao uso das preparações alcoólicas para higienização das mãos nos serviços de saúde

Desafíos en la utilización de preparaciones alcohólicas para higiene de las manos en servicios de salud

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Abstract

Objective: The article proposes a theoretical reflection on aspects related to the use of these products in the context of health services from the national and international perspective recommendations, the antimicrobial efficacy and associated factors. **Method:** Theoretical reflection on aspects related to the use of alcoholic preparations in the context of health services from the perspective of national and international recommendations. **Results:** The proof of the effectiveness of antimicrobial alcoholic preparations by rigorous methods that simulate practical conditions of use are fundamental to the use of these products, which still coexist other variables involved in the efficacy of the procedure, such as its duration, the volume of product being applied and acceptability. **Conclusion:** Gaps in official regulations are identified, the regard that may compromise one of the most important components of infection control and patient safety.

Keywords: Handwashing; Anti-infective agents local; Health services; Cross infection.

Resumo

Objetivo: Propor uma reflexão teórica sobre os aspectos relacionados ao uso das preparações alcoólicas para higienização das mãos, no contexto dos serviços de saúde, na perspectiva das recomendações internacionais e nacionais, da eficácia antimicrobiana e fatores associados. **Método:** Reflexão teórica acerca do uso das preparações alcoólicas para a higienização das mãos nos serviços de saúde, fundamentada nas normativas internacionais e nacionais vigentes. **Resultados:** A comprovação da eficácia antimicrobiana das preparações alcoólicas por métodos rigorosos que simulam condições práticas de uso é fundamental para a utilização destes produtos nos serviços de saúde. Coexistem ainda outras variáveis envolvidas na eficácia do procedimento de higienização das mãos, tais como a sua duração, o volume do produto a ser aplicado e a aceitabilidade. **Conclusão:** Identificam-se lacunas nas normativas oficiais, referentes aos aspectos supracitados que podem comprometer um dos componentes mais importantes do controle de infecções e a segurança do paciente.

Palavras-chave: Lavagem de mãos; Antiinfecciosos locais; Serviços de saúde; Infecção hospitalar.

Resumen

Objetivo: El artículo propone una reflexión teórica sobre los aspectos relacionados con el uso de preparaciones alcohólicas en el contexto de los servicios de salud, la eficacia antimicrobiana y factores asociados. **Métodos:** Reflexión teórica sobre los aspectos relacionados con el uso de estos productos en el contexto de los servicios de salud, basado en las normas internacionales e nacionales. **Resultados:** La prueba de la eficacia de las preparaciones alcohólicas por métodos rigurosos que simulan las condiciones reales de empleo es la clave para usar estos productos. Coexisten otras variables importantes, tales como duración, el volumen de producto que se aplica y la aceptabilidad. **Conclusión:** Se notan lagunas en las normas oficiales que pueden poner en peligro uno de los componentes más importantes de control de la infección y la seguridad del paciente.

Palabras-clave: Lavado de manos; Agentes antiinfecciosos locales; Servicios de salud; Infección hospitalaria.

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INTRODUCTION

The infections related to healthcare can be considered a global public health problem, because they cause suffering to the patient and their family, increases rates of morbidity, mortality, length of hospital stay and raise the costs of treatment[1].

In light of the magnitude of this problem, the washing of hands is considered the individual procedure, simpler and more effective in the prevention and control of these infections, since they can be transmitted by contaminated hands of health professionals during their care practice[1,2].

Despite evidence showing the importance of hand hygiene in the prevention and control of health care-associated infections, adherence to this practice remains unacceptably low. They are factors that contribute to this, skin irritation due to frequent hand washing, work overload, excessive use of gloves, misplaced sinks and inadequate knowledge of health professionals about the signs for sanitizing them[2].

In recent years, various preparations in alcoholic gel were launched in the market to stimulate adherence to hand hygiene. The advantages of these products include the greater effectiveness in reducing the bacterial count on hands, cause less dryness than common soap and the solutions many antiseptic chemicals detergents, present greater ease of use, require less time of action and may be available at the patient's bedside by facilitating access and stimulating the use of the product[3].

In Europe and in the United States of America, the marketing of these products is subject to proof of antimicrobial effectiveness *in vivo*, by tests that simulate practical conditions of use[4,5]. In Brazil, for the record, among other requirements, the product must demonstrate antibacterial efficacy *in vitro*, because there is no official method recommended by the Ministry of Health, to evaluate *in vivo*, these products.

In this context, this study proposes to reflect on the aspects related to the use of alcoholic preparations for hand hygiene, especially in the perspective of international recommendations and national, on the antimicrobial efficacy and other important factors for the use of these products in health services.

International Recommendations on the use of alcoholic preparations in hand hygiene

The new recommendations for hand hygiene ratified by the World Health Organization (WHO)[2], propose the use of alcoholic preparations as standard procedure for the antisepsis of the hands by health professionals, in replacing the traditional washing of hands with soap and water, when these are not visible or contaminated with organic material.

For this reason, in Europe, the method employed is the European Standard 1500 (EN-1500), which compares the antimicrobial effectiveness *in vivo* of the product to be tested against that of a reference alcohol (2-propanol at 60%, v/v), in the removal of a standard sample of *Escherichia coli* of artificially contaminated hands. The product is only released to the market provided that it has an equal or higher activity of reference alcohol[4].

In the United States, these products are tested by the method of antimicrobial effectiveness assessment *in vivo* which consists of ten applications of the product to be tested after the artificial contamination of hands with a sample of *Serratia marcescens* (bacterial microorganism test). The product is considered approved when reduces 2 $\log_{10}$ of the micro-organism test in each hand within five minutes after the first application or 3 $\log_{10}$ after five minutes of the tenth application[5].

National Recommendations on the use of alcoholic preparations in hand hygiene

Due to the recent introduction of alcoholic preparations in gel in Brazilian hospitals, the National Health Surveillance Agency (ANVISA) in 2010 published a Resolution of the Board (RDC) no. 42 to promote the use of alcoholic preparations in hand hygiene[6]. This resolution requires the use of these products in health services, regardless of the level of complexity of the service, provided that there is proof of the effectiveness of antimicrobial tests *in vitro* or *in vivo*.

In Brazil, however, the antimicrobial efficacy test *in vivo* of these products is difficult because there is not an official method standardized for the assessment of these products. For registration with the Ministry of Health, the products are tested by the test of suspension, which consists in an *in vitro* test and quantitative to assess the bactericidal activity of disinfectants and antiseptics[7].

Antimicrobial Efficacy of alcoholic preparations: alcohol gel *versus* liquid alcohol

In general, alcoholic preparations are available in the presentation liquid or gel and antimicrobial effectiveness *in vivo* of these products have been proven in several countries[8]. However, the antimicrobial effectiveness may differ between the formulations, because usually the alcoholic gel formulations are less than the liquids[9-11].

In this perspective, a European study evaluated the antimicrobial efficacy than ten gel alcohols manufactured in Europe, using the methodology of EN-1500, the results showed that none of the gels alcohols reached the criteria for antimicrobial effectiveness required by the standard[12].

In Brazil, a similar study has tested twelve alcohol gels manufactured and marketed in accordance with the EN-1500, the results showed that the majority 8/12 (67%) of the alcohol gels showed limited antimicrobial efficacy in 30 seconds and, in contrast, the ethyl alcohol solution 70% (p/p) had its antimicrobial efficacy proven[13].

This is because, in order to increase the viscosity, the gels often contain ingredients such as the glacial polyacryate (thickener) and polyamine (disabling) that limit in some extent the quantity of alcohol that can be incorporated into the product[9]. The thickener can still hinder the release of alcohol, thus reducing the effectiveness of the product[11]. To compensate for this lower antimicrobial activity, the alcohols ethanol-based gels should contain at least 80% (v/v) alcohol in their formulation[11,12].

Faced with the limited effectiveness of alcohol gel in relation to liquid, caution is advised in the use of alcohol gel for the antisepsis of hands in healthcare services. Due to the antimicrobial efficacy of these products possibly being insufficient in preventing the transmission of microorganisms by the hands of health professionals during their care practice[11]. Thus, the introduction of alcohol gel in clinics and hospitals should only be recommended if present activity at least equal to the ethyl alcohol 70% (p/p) in solution, which has proven antimicrobial effectiveness and long tradition of use in hand hygiene in health services[2].

Additional Factors involved in the effectiveness of hand hygiene with alcoholic preparations

The key factor to be considered for the use of these products in the health services is its antimicrobial efficacy. However, other factors may interfere indirectly in hand hygiene, such as the correct performance of the technique, the indications for carrying it out and the acceptability of products.

For hand hygiene, the Ministry of Health recommends the use of alcohol gel preferably 70% or in solution of 70% of 1-3% glycerine, the amount recommended by the manufacturer and application time of 20 to 30 seconds, following a standard sequence of steps[1].

When considering that many products sold in the country do not bring the label information of the amount applicable, it is clear that the Ministry of Health in regulatory nature should require manufacturers this adjustment. In fact, international studies emphasize the application of three ml of product to cover the entire surface of the hands and improve the effectiveness of the antiseptic friction, they even highlight that the effectiveness of antimicrobial alcoholic preparations is strongly correlated to the volume used and the time of execution of the procedure[3].

It is noteworthy that, considering the time and the frequency in the practice of hand washing is essential, even more considering the quality of the execution of the procedure, because the failures in relation to technique can be observed in 50% of the procedures performed, which reduces by 35% its effectiveness[3]. For this reason, it is recommended to monitor this practice in healthcare services[14].

In the guarantee of correct performance, the WHO recommends that educational campaigns directed at health professionals emphasize the elements related to the hand washing technique and the indications for sanitizing them, i.e. the five moments that should sanitize the hands, which includes: before the contact with the patient, before the implementation of clean and aseptic procedures, after contact with body fluids, after contact with the patient and after contact with the environment. This concept provides a unified view of the indications to sanitize their hands, facilitating education, minimizing the inter-individual variation and increasing adherence to this practice[2].

A third factor to be considered is the acceptability and tolerance to the product, which are influenced by their composition and addition of emollients, in consequence, it is necessary to choose the product that possesses antimicrobial effectiveness and proper composition[10]. In this respect, the alcoholic preparations are more tolerated by health professionals than other products for the hygiene of hands, because it maintains the protective layer of fat skin and usually contains emollients that prevent their dryness[15].

CONCLUSION

They are undeniable advantages of alcoholic preparations in relation to other products for hand hygiene. However, given the complexity that involves the incorporation of these products in the context of healthcare services, some institutional challenges need to be overcome. Being that there is the superiority of liquid alcohol gel, in relation to other indirect variables involved in the efficacy of the procedure, such as its duration, the volume of product to be applied, directions for sanitizing and acceptability. Further adding to the mandatory use of alcoholic preparations in health services and the existence of gaps in official regulations in this regard.

Considering the problem of infections related to healthcare and the recognition of the effects of hand hygiene in reducing rates of these infections, advances on two central points: the challenges imposed on the prevention and control of infections within governmental and in the context of each healthcare service.

It recognizes the effort undertaken by the Ministry of Health to promote hand hygiene in accordance with international recommendations. However, the RDC no. 42 proposes the use of alcoholic preparations upon proof of the effectiveness of antimicrobial tests *in vitro* or *in vivo*. As there is no a recommended official method evaluation for *in vivo* of these products in Brazil, like the European and U.S. standards using rigorous methods under practical conditions of use, it is suggested to the Ministry of Health the need for revision of the antimicrobial efficacy test used to record the alcoholic preparations marketed in Brazil. Another important aspect is the need to require manufacturers to indication of the volume and time of application of the product labels, to give more credibility to alcohol gels marketed in Brazil.

Launching concern about the following scenario: insufficient number of health professionals, inadequate physical infrastructure, and insufficient knowledge of the professionals on the topic and lack of monitoring of the practice by those responsible for infection control, which hinders adherence to hand hygiene. It is not enough meeting the RDC no. 42 resorting to the use of alcoholic preparations. It is imperative to ensure a safe institutional environment. Thus, it is suggested that the healthcare services permanently adopt the multimodal strategies recommended by the WHO that include education, monitoring of practices and performance feedback from health professionals, fixing of reminders and posters in strategic locations on the technique and the indications to sanitize their hands.

It is believed that the articulation of an institutional policy with solid foundations and a consistent strategy for adherence to hand hygiene are commitments to be undertaken to successfully overcome all the challenges imposed on this practice with a view to ensuring the quality of healthcare and the overall safety of the patient.

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