# TRENDS AND CHALLENGES **OF SURGICAL HAND PREPARATION**

Tendências e desafios do preparo cirúrgico das mãos Tendencias y desafíos em la preparación quirúrgica de las manos

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ABSTRACT: Objective: To describe trends and challenges of surgical hand preparation. Method: Narrative literature review, consulting the current international and national guidelines and searching the following databases: the Cochrane Systematic Reviews and the VHL portal (Latin American and Caribbean Center on Health Sciences Information), LILACS, IBECS, MEDLINE, Nursing Reference Center, and SciELO, using the keywords: Desinfecção das Mãos, Salas Cirúrgicas; Hand Disinfection, Operating Rooms; Desinfección de las Manos, Quirófanos, and Boolean connectors AND/OR in the period between 2006 and 2016. Results: Five guidelines of surgical hand preparation and two regulations on product evaluation for surgical hand preparation were consulted. Twenty-two articles were identified in the database search and seven were selected: four literature reviews - three of them were systematic reviews - and three studies evaluating cost and ecological sustainability. Conclusion: In the last decades, there have been major changes in the type of antiseptic product, which favored the use of alcoholic preparation (AP), without using water and brush, considering the cost-effectiveness and ecological sustainability when compared to traditional procedures such as surgical hand scrubbing with Polyvinylpyrrolidone Iodine (PVP-I) or Chlorhexedine Gluconate (CHG). To incorporate best practices based on scientific evidence, a programmatic approach must be adopted, policies, and programs must be implemented in order to manage including products and processes and monitor compliance with the procedures. Keywords: Hand disinfection. Operating rooms. Hand hygiene.

RESUMO: Objetivo: Descrever tendências e desafios no preparo cirúrgico das mãos. Método: Revisão de literatura narrativa, consulta aos manuais internacionais e nacionais atuais, além de consulta à Cochrane Database of Systematic Reviews, e ao portal BVS, à base de dados LILACS, IBECS, MEDLINE, Nursing Reference Center e SciELO, utilizando os descritores: Desinfecção das Mãos, Salas Cirúrgicas; Hand Disinfection, Operating Rooms; Desinfección de las Manos, Quirófanos e conectores booleanos AND/OR no período entre 2006 e 2016. Resultados: Foram consultados cinco manuais sobre preparo cirúrgico das mãos; duas normatizações de avaliação de produtos para preparo cirúrgico das mãos. Dos 22 artigos identificados na busca, foram selecionados sete: quatro revisões de literatura, sendo três revisões sistemáticas; e três estudos avaliando o custo e a sustentabilidade ecológica. Conclusão: Nas últimas décadas, houve grandes mudanças quanto ao tipo de produto antisséptico - favorecendo o uso de preparação alcoólica (PA), sem o uso de água e escova, representando custo-efetividade e sustentabilidade ecológica quando comparada aos procedimentos tradicionais como a degermação cirúrgica das mãos com Polivinilpirrolidona Iodo (PVP-I) ou Gluconato de Clorexedina (CHG). Para incorporar melhores práticas baseadas em evidências científicas, deve-se adotar abordagem programática, implementar políticas e programas que regem os processos e produtos utilizados, bem como o controle dessecumprimento. Palavras-chave: Desinfecção de mãos. Salas cirúrgicas. Higiene das mãos.

RESUMEN: Objetivo: Describir tendencias y desafios en la preparación quirúrgica de las manos. Método: Revisión de literatura narrativa, consulta a los manuales internacionales y nacionales actuales, además de consulta a Cochrane Database of Systematic Reviews, al portal BVS, y a la base de datos LILACS, IBECS, MEDLINE, Nursing Reference Center y SciELO, utilizando los descriptores: Desinfecção das Mãos, Salas Cirúrgicas; Hand Disinfection, Operating Rooms; Desinfección de las Manos, Quirófanos y conectores booleanos AND/OR en el período entre 2006 y 2016. Resultados: Se consultaron cinco manuales sobre la preparación quirúrgica de

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las manos y dos normatizaciones de evaluación de productos para la preparación quirúrgica de las manos. Veintidós fueron los artículos identificados en la búsqueda en la base de datos y se seleccionaron 7: cuatro revisiones de literatura — tres de ellas revisiones sistemáticas; y tres estudios evaluando el costo y la sustentabilidad ecológica. **Conclusión:** En las últimas décadas, hubo grandes cambios referente al tipo de producto antiséptico — favoreciendo el uso de preparación alcohólica (PA), sin el uso de agua y cepillo, representando costo-efectividad y sustentabilidad ecológica comparada a los procedimientos tradicionales como la degermación quirúrgica de las manos con polivinil-pirrolidona yodada (PVP-I) o Gluconato de Clorhexidina (CHG). Para incorporar mejores prácticas basadas en evidencias científicas, se debe adoptar un abordaje programático, implementar políticas y programas que rigen los procesos y productos utilizados, así como el control de ese cumplimiento. Palabras clave: Desinfección de las manos. Quirófanos. Higiene de las manos.

# INTRODUCTION

Surgical patients safety is a global concern that affects patients in developed and developing countries. Healthcare-associated infections (HAI), and mainly the surgical site infections are a public health problem, considering their magnitude and impact on morbidity and mortality<sup>1</sup>.

As part of the World Alliance for Patient Safety launched in October 2004, the World Health Organization (WHO) published, in June 2008, the WHO Guidelines for safe surgery (First Edition) to ensure a safer care to the patient. One of this guideline objective was based on the assumption that the team will consistently use methods known to minimize the risk for surgical site infection (SSI)<sup>2</sup>.

Among the preventive measures of HAI in surgical patients during the perioperative period is hand hygiene (HH). On May 5<sup>th</sup>, 2016, the WHO launched the following theme on the campaign "Clean care is safer care:" "See your hands: hand hygiene supports safe surgical care," whose poster is available on the Brazilian Health Surveillance Agency (ANVISA) website<sup>3</sup>.

Considering the surgical patient safety, this literature review had the following guiding question: what are the trends and challenges of surgical hand preparation in the international and national contexts?

# OBJECTIVE

To describe trends and challenges in the surgical hand preparation through a literature review.

#### METHOD

A narrative literature review was carried out by analyzing current international and national guidelines, as well as searching Cochrane Database of Systematic Reviews, BVS website, LILACS, IBECS, and MEDLINE databases, Nursing Reference Center, and SciELO. The following descriptors (keywords and Medical Subject Headings -MeSH) were used: in Portuguese — *Desinfecção das Mãos, Salas Cirúrgicas*; in English – Hand Disinfection, Operating Rooms; in Spanish — *Desinfección de las Manos, Quirófanos*; and Boolean connectors AND/OR between 2006 and 2016.

Papers were selected based on the reading of the abstracts. Those papers that addressed significant changes over time in surgical hand preparation with regard to the product, methods, and duration of the procedures, as well as those articles that included cost-effectiveness analysis, were selected.

# RESULTS

Five guidelines on surgical hand preparation and two regulations on the assessment of related products were analyzed. Of the 22 articles identified in the search, 7 were included: 4 literature reviews – 3 of them were systematic reviews – and 3 studies evaluating the costs and ecological sustainability.

# Recommendations on surgical hand preparation

The following manuals were consulted: Prevention of Surgical Site Infection (Centers for Disease Control and Prevention – CDC)<sup>4</sup>, Hand Hygiene in Health-Care Settings (CDC)<sup>5</sup>, Hand Hygiene in Health Care (WHO)<sup>6</sup>, Guidelines from the Association of periOperative Registered Nurses (AORN)<sup>7</sup>, and ANVISA Guidelines on HH<sup>8</sup>.

In the perioperative period, there are basically two HH components<sup>4-8</sup>:

- routine hand hygiene: to rub hands with alcohol-based products – or to wash hands with plain or antimicrobial soap and water if the hands are visibly soiled;
- 2. pre-surgical hand antisepsis: corresponds to the surgical hand preparation with an antimicrobial product containing Polyvinylpyrrolidone iodine (PVP-I) or Gluconate Chlorhexidine (CHG), or rubbing with alcohol-based preparation (AP).

The Centers for Disease Control and Prevention (CDC), in the Guideline for Prevention of Surgical Site Infection<sup>4</sup>, recommends a surgical scrub in hands and forearms up to the elbows for at least two to five minutes. Only in 2002, in the Guideline for Hand Hygiene in Health-Care Settings, the CDC<sup>5</sup> has included the recommendation on the alcohol-based hand antisepsis, with sustained activity, before donning sterile gloves to perform surgical procedure, in addition to the use of antimicrobial soap. In this regard, the CDC recommends to follow the manufacturer's instructions, prewash hands and forearms with a non-antimicrobial soap and dry completely before applying the AP. After application of the AP as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves. CDC also recommends avoiding excessive antisepsis time (10 minutes) and the use of brush, which are unnecessary as it may cause dermatitis of the hands and forearms.

In 2009<sup>6</sup>, WHO published HH manual in accordance with the recommendations of the CDC (2002), emphasizing that the surgical hand antisepsis should be performed using antiseptic agents or suitable AP, preferably with a product that ensures sustained activity, before donning sterile gloves. If hands are visibly soiled, one should wash them with plain liquid soap before surgical hand preparation, removing residues from underneath fingernails using a nail cleaner, preferably under running water. If the water quality is not assured in the operating facility, surgical hand antisepsis with AP is recommended before donning sterile gloves when performing surgical procedures.

The technique to perform surgical hand antisepsis using an antiseptic agent containing PVP-I or CHG consists of the following steps<sup>6</sup>:

- scrub hands and forearms surfaces for the length of time recommended by the manufacturer, usually two to five minutes. Long scrub times, for example, ten minutes, are not necessary and the use of brushes is not recommended.
- rinse hands and arms by passing them through the water in one direction only, from fingertips to elbow.
- dry hands and arms using a sterile towel and aseptic technique before donning gown and gloves.

In the surgical hands antisepsis using AP, the following steps are recommended<sup>6</sup>:

- perform surgical hand antisepsis by rubbing AP with sustained activity (residual) according to the manufacturer's instructions for the application times;
- apply the product only in dry hands, using sufficient product to keep hands and forearms wet with the AP throughout the surgical hand preparation procedure;

- do not sequentially combine other antiseptic agents and alcohol-based products;
- after the AP application as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves<sup>6</sup>.

According to The Association of periOperative Registered Nurses (AORN)<sup>7</sup>, the surgical hand preparation should be performed before donning sterile gloves for surgical or invasive procedures. AORN recommends the use of antimicrobial agent for the surgical hand scrub or AP for rubbing hands with sustained and cumulative documented activity that meets the requirements of the *Food and Drug Administration* (FDA). The product selection for surgical hand antisepsis should consider the effectiveness of the product, the application requirements, and user acceptance<sup>7</sup>.

ANVISA guideline "Patient Safety – Hand Hygiene"<sup>8</sup> recommends using disposable soft bristles brushes in surgical hand preparation only in the subungual area. The duration of the procedure should be three to five minutes for the first surgery and two to three minutes for subsequent surgeries. With regard to the technique, one should collect the antiseptic with the hands cupped and spread it over the hands, forearms, and elbows. If the brush is impregnated with antiseptics, one need to press the side of the sponge against the skin and spread all over or scrub the hands, between fingers and forearms, holding hands above the elbows.

## Methods to evaluate the antimicrobial efficacy of products for surgical hand preparation

Basically, there are two methods to evaluate the antimicrobial efficacy for approval of antiseptics for surgical hand preparation: EN 12791, from the European Committee for Standardization (CEN)<sup>9</sup>; and E 1115, from the American Society for Testing and Methods (ASTM)<sup>10</sup>. These tests verify the reduction of resident hand flora, and the persistence and/or cumulative effect.

The European Standard EN 12791<sup>9</sup> recommends testing 18 to 22 subjects, using the split-hands model to assess the immediate effect in one hand while the other continues wearing gloves, aiming at evaluating the sustained/residual effect in 3 hours. The crossover study design should be applied. Two experiments are carried out with an interval of one week to compare the bacterial reduction. The reference product is n-propanol 60% (per volume), applied with approximately three milliliters for three minutes to keep the hands wet. The test product must follow manufacturer's recommendations; however, it should be applied for less than five minutes. Microbial samples are collected after handwashing with soap without antimicrobial agents (baseline), immediately after antisepsis (immediate effect) and after three hours with gloved hands (residual effect), by the method of fingertips friction on plates with culture medium and neutralizers, one for each hand. The product is approved if:

- immediate and three-hours values may not be smaller than the reference product (n-propanol 60%)
- if the product has sustained activity, bacterial release from skin should be lower than the product reference in the 3rd hour.

American ASTM E1115<sup>10</sup> - in vivo - evaluates the immediate and sustained effect. The study design employed is the randomized, blinded, with parallel group (parallel arm), whose sample size is defined according to the formula  $n\geq 2S^2$  $(Za/2 + Zb)^2/D^2$ , where S<sup>2</sup> is the estimated variation, Za/2 corresponds to the test level (to 5%, test level = 1.96), Zb is the power of the test (to 80%, power = 0.842), and D is a clinically significant difference of the exclusions. The test product is used for five consecutive days: days 1 and 5 - only one antisepsis; days 2, 3, and 4 — three times a day, with a minimum interval of one hour between the procedures; total of 11 procedures at the end of the study. Microbial samples are taken before the beginning of the study (baseline); immediately after antisepsis (immediate effect); three hours and six hours after the antisepsis with gloved hands on day 1 (sustained effect) and on the days 2 and 5 (cumulative effect), using the glove juice method. For the product to be approved, following requirements must be met:

- day 1: within a minute after the procedure, reduce the number of bacteria 1-log<sub>10</sub>; after six hours, not exceed the baseline (residual effect);
- day 2: within one minute after the last application of the day (3rd use), reduce the number of bacteria 2-log<sub>10</sub>,
- day 5: within one minute after the procedure, reduce the bacterial counts 3-log<sub>10</sub> (cumulative effect).

## Effectiveness of alcoholic preparation in surgical hand preparation

Three systematic reviews assessed the AP in the surgical hand preparation: Gonçalves et al.<sup>11</sup>, Tanner et al.<sup>12</sup>, and Liu et al.<sup>13</sup>.

The systematic review of Gonçalves et al.<sup>11</sup> aimed at comparing the antimicrobial effectiveness of AP with traditional products (TP) in surgical hand antisepsis. The authors evaluated 25 studies. In most of them, AP had a microbial reduction greater or equal to TP, and SSI rates were similar in five studies. The authors concluded that there is scientific evidence supporting AP safety for surgical hand antisepsis.

The review of Tanner et al.<sup>12</sup> intended to evaluate the effects of surgical hand antisepsis in the prevention of SSI; the secondary objective was to evaluate the number of colony forming units (CFU) of bacteria in the hands of the surgical team. Fourteen studies were included in the updated review of 2006. Four studies reported the results of SSI rates and showed no difference between AP and other antimicrobial products, and ten studies reported the number of CFU, but not SSI rates. However, the authors concluded that in general the studies were performed with a small sample, and others had no data or analysis that could be interpreted or related to clinical outcomes. These factors reduced the quality of the evidence.

Liu et al.<sup>13</sup> evaluated the effect of surgical hand preparation techniques on the integrity of the skin and in the incidence of SSI. Ten studies were included in this review; eight were randomized clinical studies and two were nonrandomized clinical studies. There was no difference in the SSI rates when comparing AP with antimicrobial products containing CHG/ PVP-I (brush/brushless); however, the AP was tolerated better and caused less skin problems. The brushless technique was associated with a better skin condition compared to brushing. The authors concluded that the surgical hand preparation protocol using AP could be as effective as the protocol that uses the traditional preparation on the prevention of SSI.

A review of literature by Widmer et al.<sup>14</sup>, which addressed the state of the art in the surgical hand preparation, summarized the evidence and the main objectives of this surgical preparation, as well as the criteria for the selection of products currently in use. Among the findings, the authors do not recommend the use of brushes for surgical hand antisepsis and reinforce the use of AP owing to fast-acting, broad-spectrum antimicrobial activity, the lower incidence of side effects, and the absence of risks of hand contamination by the water. They also recommended washing hands before surgical antisepsis only if they are visibly soiled, and considered that washing hands with nonantimicrobial soap is enough, when the surgical team enters the operating room.

In the technique of hand preparation with AP, hands must remain wet with alcohol during friction throughout the entire procedure, thus requiring approximately 9 to 15 ml, depending on the hand size. The time required for AP friction depends on the formulation, generally with exposure time of three-minutes. However, this time may be reduced to one and a half minute or less for some formulations<sup>14</sup>.

In a one-year prospective study, Jehle et al.<sup>15</sup> quantified the volume of water applied in surgical hand antisepsis to estimate the water savings and investigate the cost involved in the adoption of AP in the surgical hand preparation. Considering the standard three-minutes period for the surgical hand antisepsis procedure, the water usage was estimated at 18.5 L. The water usage for 3.25 procedures per surgery totaled 60.2 L. When multiplied by 15,500 surgical procedures per year, the annual water consumption in surgical antisepsis was equivalent to 931,938 L. The authors considered that AP had more favorable relative costs compared with PVP-I or CHG, according to the AP volume applied (6 mL).

Tavolacci et al.<sup>16</sup> compared the efficacy of surgical antisepsis using AP with surgical antisepsis using other antimicrobial agents and determined the costs of both surgical hand preparation techniques. The literature review was conducted in MEDLINE to compare the efficacy of both techniques. The costs were estimated based on standard hospital costs. Literature showed that AP has a similar immediate antimicrobial efficacy of surgical scrubbing; however, the AP had a longer lasting effect. The use of AP reduced costs by 67%. Therefore, the authors concluded that the AP is a low-cost alternative to the surgical hand preparation.

A national study carried out by Graf et al.<sup>17</sup> evaluated the cost-effectiveness of antisepsis technique with the AP during one minute — *versus* scrubbing with CHG under a Brazilian hospital perspective. The total cost of the AP was 46% lower than the average cost of scrubbing with CHG. In an ecological context, a reduction of 18.5 L of water per procedure when applying AP generates financial savings and prevent waste disposal (for example, brushes), in addition to saving a natural resource such as water.

# CONCLUSION

Guidelines and studies revealed advantages and cost-effectiveness of APs in the surgical hand preparation, such as shorter procedure time, which could facilitate compliance with the procedure, better skin condition, greater antibacterial efficacy, cost-saving, water saving, and reduction of solid waste.

The challenges surrounding the surgical hand preparation are:

- the need to produce further national scientific content to understand our reality and/or culture with regard to acceptance and implementation of the AP in Brazilian health services;
- to provide scientific updates to health professionals, particularly to surgical teams;
- to evaluate adherence to recommended procedures by using structure, processes, and results indicators.

Finally, to promote a change in this practice, it is recommended to engage the sectors and teams (multisector and multidisciplinary approach) to implement best scientific evidence-based practices, and to develop a process improvement project, containing the following phases: assessment of the current situation (baseline measurement), implementation of improvement strategies, and change impact assessment.

# REFERENCES

- Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, Sexton DJ. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol. 1999;20(11):725-30.
- World Health Organization. World Alliance for Patient Safety. WHO Guidelines for Safe Surgery (First Edition). Genebra: World Health Organization; June 2008. p. 43-71.
- Agência Nacional de Vigilância Sanitária (Ministério da Saúde). 5 de maio de 2016 - Dia Mundial de Higiene das Mãos! Disponível em: http://www20.anvisa.gov.br/segurancadopaciente/index.php/ noticias/89-5-de-maio-de-2016-dia-mundial-de-higiene-das-maos
- Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR, the Hospital Infection Control Practices Advisory Committee. Guideline for the prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol 1999; 20(4):247-280 [acesso em ago. 2016]. Disponível em: http://www.cdc.gov/hicpac/pdf/ guidelines/SSI\_1999.pdf
- Boyce JM, Pittet D. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR Morb Mortal Wkly Rep; 2002; 51:1-45. Disponível em: http://www.cdc.gov/mmwr/PDF/rr/ rr5116.pdf

- World Health Organization. WHO Guidelines on Hand Hygiene in Health Care: a Summary. Genebra: World Health Organization; 2009. [acesso em ago 2016]. Disponível em: http://whqlibdoc.who.int/ hq/2009/WHO\_IER\_PSP\_2009.07\_eng.pdf
- AORN. Recommended practices for hand hygiene in the perioperative setting. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2013. p. 63-74.
- Agência Nacional de Vigilância Sanitária (Ministério da Saúde). Segurança do Paciente – Higienização das mãos. Brasília, 2009.
- Comité Européen de Normalisation. EN 12791. Chemical disinfectants and antiseptics. Surgical hand disinfection. Test method and requirements. Brussels: European Committee for Standardization, 2005.
- American Society for Testing and Methods. E1115. Department of Health and Human Services. Food and Drug Administration. Tentative final monograph for health-care antiseptic drug products; Proposed Rule. Fed Reg. 1994;59:31401-52.
- Gonçalves KJ, Graziano KU, Kawagoe JY. Revisão sistemática sobre antissepsia cirúrgica das mãos com preparação alcoólica em comparação aos produtos tradicionais. Rev Esc Enferm USP. 2012;46(6):1484-93.

- 12. Tanner J, Dumville JC, Norman G, Fortnam M. Surgical hand antisepsis to reduce surgical site infection. Cochrane Database Syst Rev. 2016;(1).
- Liu LQ, Mehigan S. The Effects of Surgical Hand Scrubbing Protocols on Skin Integrity and Surgical Site Infection Rates: A Systematic Review. AORN J. 2016;103(5):468-82.
- 14. Widmer AF, Rotter M, Voss A, Nthumba P, Allegranzi B, Boyce J, et al. Surgical hand preparation: state-of-the-art. J Hosp Infect. 2010;74(2):112-22.
- 15. Jehle K, Jarrett N, Matthews S. Clean and green: saving water in the operating theatre. Ann R Coll Surg Engl 2008; 90(1):22-4.
- 16. Tavolacci MP, Pitrou I, Merle V, Haghighat S, Thillard D, Czernichow P. Surgical hand rubbing compared with surgical hand scrubbing: comparison of efficacy and costs. J Hospital Infect. 2006;63:(1)55-9.
- 17. Graf ME, Machado A, Mensor LL, Zampieri D, Campos R, Faham L. Antissepsia cirúrgica das mãos com preparações alcoólicas: custoefetividade, adesão de profissionais e benefícios ecológicos no cenário de saúde. J Bras Econ Saúde. 2014;6(2):71-80.