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The analysis of tolerance and acceptability of alcohol substance for hand disinfection – practical verification of the WHO protocol with equipment rating

Abstract

Introduction. Hand hygiene is a basic procedure in the prevention of nosocomial infections, but it is not obeyed or improperly performed by the staff. One of the main reasons for non-compliance with procedure is the lack or incomplete acceptability of the alcohol-based substance for hand disinfection and bad tolerance of routinely used disinfectant by the hospital staff.
The purpose. 1. Assessment of tolerance and acceptability of an alcohol-based hand disinfectant (VE 214) by medical personnel and non-medical personnel (providing cosmetic services), including assessment of the skin condition, using specialized equipment. **2.** Determine if the tested alcohol-based hand disinfectant (VE 214) meets the WHO criteria for acceptability and tolerance. **3.** Determining the applicability of the World Health Organization (WHO) protocol to assess the formal acceptability and tolerability of the newly introduced hand disinfectant for usage at the place of use. **4.** Determine the practical feasibility of the WHO protocol *„Method 1 for the evaluation of tolerance and acceptability of an alcohol-based hand disinfectant that is currently in use or is to be introduced "*.
The innovative aspect of the study. To make such research for the first time in Poland. To Evaluate the tolerance and acceptability of the substance for hand disinfection with the use of WHO protocol along with the supplementary equipment rating of skin state. The data obtained may be used by the Infection Teams at health care facilities in order to optimize the choice of purchased hand disinfectants.
Material and methods. For the interventional study, without randomization, 126 participants were included: 65 employees representing medical professions (doctors, nurses); 61 employees performing the cosmetic services. Acceptance criteria: age > 18 years, written, informed consent to participate in the study. Exclusion criteria: age < 18 years, lack of informed consent for participation in the study, occurrence of skin diseases, known allergy to the components of the tested hand disinfection substance. The research methodology is based on the WHO protocol. *„Method 1 for the evaluation of tolerance and acceptability of an alcohol-based hand disinfectant that is currently in use or is to be introduced "*. The study participant received the test product (alcohol based hand disinfectant substance, VE 214) in a personal dispenser (bottle, 100 ml). Three visits of the researcher, are planned for each participant: I visit on day 0, II visit - between 3-5 days of using the product; III visit - after 30 days of applying the product. The evaluation which was done, during the visits, the main endpoint (while visits I-III) by assessing the condition of the skin (made by the researcher, using a scale taken from the WHO protocol, where the higher results mean worse skin condition, including: redness, scalyness, cracks, and overall visual skin evaluation; performing of equipment investigation with the use of: Derma Visualizer camcoder, tewameter, sebumeter and corneometer; secondary end points (during visits II and III), by assessing the tolerance and acceptance of the alcohol based hand disinfection, used by the study participants, using the seven-point Likert scale, including the assessment of such parameters as for the tolerance of the substance: skin appearance, skin intact, the level of skin moisture, the feeling after using a hand disinfectant, general skin evaluation; for the acceptability of the substance: odor, color, consistency, drying time, skin irritation, dry skin effect, ease of use, general evaluation of the substance.

In order to assess the condition of the skin before, during and after the application of a new alcoholbased hand disinfection substance, measurements were made using specialized equipment: tewameter, sebumeter, a corneometer, a Derma Visualizer camcoder (to assess discolorations). The substance evaluation was done, based on WHO criteria, which are covering the acceptable quality level of alcoholbased hand disinfection substances; objective results for skin condition < 2 points for ≥ 75% of ratings, assessment of the condition of the skin by the participant > 4 points for ≥ 75% of ratings; user's level of acceptability of color and smell > 4 points for ≥ 50% of ratings, user's level of acceptance > 4 points for ≥ 75% of assessments for other elements in this range. To assess the feasibility of the protocol, the time of execution of individual elements of the study was measured (in minutes), which the investigator and the examined person devoted. Statistical analysis. In order to verify the dependences of ordinal variables, a chi-square test was used for dependent samples or the Wilcoxon signed rank test was applied. In order to assess the dynamics of changes depending on the profession, sex, working time, the Mann Whitney U test was used. In order to compare the significance of differences in the three tests using specialized equipment, analysis of Anova variance with repeated measurements was performed. Significant contrasts were calculated for Scheffe's post-hoc detailed statistics. The calculations were carried out at the statistical significance level alpha = 0.05, using the SPSS Statistic 24 program (version from 2018).

Results. 1. The tested alcohol-based hand disinfectant, in the opinion of the recipients, was accepted by them and well tolerated. The applied substance, in the opinion of the recipients, did not worsen the condition of the skin, and even in some aspects skin condition was improved, while using it, the skin was less frequent reddening, occurrence of scales and cracks on the skin was lower($p < 0.05$). After conducting tests using specialized equipment, it was found that the applied substance did not significantly affect the condition of the skin in terms of its greasing, hydration and discoloration, however transepidermal water loss decreased while using it. (Scheffe post hoc test, $F(1; 125) = 33.268$; $p < 0.001$). While using the new substance, it's tolerance was improved in the respondents' assessment, The recipients provided higher rates for features like; appearance of the skin, skin intact, the level of humidity and the sensation of pruritus, redness and pain ($p < 0.05$). During the period of usage of the tested substance, based on respondents' assessment, its overall acceptability deteriorated (but WHO criteria were still met). It was also found, that during the III visit compared to the II visit, the number of reported skin irritations, significantly decreased, but difficulties with using the tested substance were reported more frequently and the feeling of pleasure while applying the tested sample decreased ($p < 0.05$). It was observed that the profession and the working time were influencing the acceptability andtolerance of the alcohol-based hand disinfection substance. Along with age and work experience, the overall tolerance of tested sample increased, while using the substance, although the skin condition did not change significantly and the acceptance related to the ease of application of the hand disinfection preparation did not increase. **2.** The tested substance met the WHO requirements in terms of impact on skin condition, acceptability and tolerance. **3.** Regarding the practical feasibility of the WHO protocol, it was determined that the time needed to perform the tests without instrumental assesment was 9,375 working days for the researcher (assuming an 8 hour working day) or 10 working days (assuming a 7,5 hour working day); for the respondent it was 1 hour of work. The time needed to perform the test with the instrumental assesment was for the researcher 25,125 working days (assuming an 8-hour working day) or 26,8 working days (assuming a 7,5 hour working day); for the respondent it was 2 hours of work.

Conclusions. 1. The tested alcohol-based hand disinfectant is well tolerated and accepted by people who have used it, it meets the criteria of the World Health Organization in this respect, and therefore it may be recommended for usage. **2.** The condition of the skin, while using the tested alcohol-based hand disinfection was improved, in the subjective assessment made by the users, which allows to dispel the myth with unfavorable influence of disinfectants on the condition of the skin. **3.** Profession is a factor that may influence the assessment of the tolerance and acceptability of alcohol-based hands disinfectant,

which may result from differences in the knowledge of the principles of hand hygiene procedures and indicates the need to intensify educational activities in this area. **4.** WHO protocol, *„Method 1 for the evaluation of tolerance and acceptability of an alcohol-based hand disinfectant that is currently in use* or is to be introduced it is useful, but its use is time-consuming, which may limit its frequent use in practice.