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Glycerol content within the WHO ethanol-based handrub formulation: balancing tolerability with antimicrobial efficacy

Train the Trainers in Hand Hygiene

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Introduction

• Alcohol-based handrub (ABHR) is universally available in high-income countries

• However, the availability of these products in healthcare facilities from low- and middle-income countries is inconsistent.

• In several countries in Africa, Asia, and Latin America such products are unavailable or inaccessible due to their high cost

World Health Organization (WHO). WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft). World Alliance for Patient Safety. Global Patient Safety Challenge 2005–2006: "Clean care is safer care" Geneva: World Health Organization, 2006.

Introduction

- The World Health Organization (WHO) has developed two formulations that can be locally prepared by healthcare facilities. One formulation contains ethanol 80% (v/v), glycerol 1.45% (v/v) and hydrogen peroxide 0.125% (v/v), and the other isopropanol 75% (v/v), glycerol 1.45% (v/v) and hydrogen peroxide 0.125% (v/v)
- In both preparations, the addition of glycerol as an emollient aims to protect the hand skin against dryness and dermatitis potentially resulting from repeated use

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Introduction

 Importantly, however, the 1.45% glycerol content within both WHO ABHR formulations has been shown to reduce the antimicrobial efficacy of the alcohols in laboratory-based microbiological investigation.

 Furthermore, the minimal concentration of glycerol required to protect hands remains unknown and that minimum may vary according to the climate in which professionals are practicing.

Suchomel M, Rotter M, Weinlich M, Kundi M. Glycerol significantly decreases the three hour efficacy of alcohol-based surgical hand rubs. J Hosp Infect. 2013;83:284–287

Objetive

To evaluate the skin tolerability of healthcare workers' (HCW) to the WHO ethanol-based handrub formulation (EBHR) using different concentrations of glycerol in a tropical climate healthcare setting.

This was a blinded and randomized crossover experimental study performed in an Intensive Care Unit (ICU) of a tertiary-care hospital in Ribeirão Preto, Brazil

Study population consisted of all 45 HCW dedicated to the ICU

We tested WHO ABHR original formulation against three variations of the glycerol concentration (0, 0.5, and 0.75%)

After using the solutions for seven days, HCWs' hands were assessed

 Assessment of skin tolerance (by external rater): this instrument is composed of four items: redness, ranging from 0 (not red) to 4 (very vivid red with edema); scaliness, ranging from 0 (not squamous) to 3 (very pronounced separation of the edges of the skin scale); fissures ranging from 0 (no cracks) to 3 (extensive cracks with bleeding or secretion, and visual score of skin); visual rating of skin from 0 (no irritation of any kind) to 5 (extensive cracking of the surface with bleeding and/or secretion)

• Self-assessment of skin condition (by participant): this instrument is composed by five items: appearance; integrity; humidity, sensation (all ranging from 1 [abnormal] to 7 [normal]), and general integrity (ranging from 1 [very compromised] to 7 [perfect])

• A dichotomous variable was created for rater evaluation: good tolerability (if all items above zero) or not good tolerability (at least one item with a score of 1 to 4)

• A dichotomous variable was created for the self-evaluation of the skin condition: good condition (all items above receiving scores 6 or 7), and not good condition (at least one item receiving score 1 to 5)

• The two dichotomous variables were analyzed separately as response variables using generalized estimating equations (GEE), with logit link, and unstructured covariance matrix. Glycerol concentration was included in the model as the explanatory variable



Fig. 1

Phases of the study implementation

All the 45 potentially eligible participants were randomized and included in the study.

However, five among them took a vacation period during the study implementation and could not complete 7 working days using one of the study formulations.

Table 1

Selected baseline clinical and demographical characteristics of the healthcare workers participating in the study

Age, years, mean (standard deviation [SD])	39 (1.45)			
Sex, female, n (%)	28 (70.0)			
Profession, n (%)				
Medical doctor	4 (10.0)			
Registered nurse	5 (12.5)			
Auxiliary nurse	28 (70.0)			
Physiotherapist	3 (7.5)			
Working time, n (%)				
Full-time	18 (45.0)			
Part-time (50-90%)	22 (55.0)			
Work shift				
Day shift	26 (65.0)			
Night shift	14 (35.0)			
Skin type				
Caucasian	31 (77.5)			
Non-Caucasian	9 (22.5)			
frritative dermatitis, n (%)	7 (17.5)			
Atopic dermatitis, n (%)	1 (2.5)			
Rhinitis and/or allergic conjunctivitis, n (%)	18 (45.0)			

Skin assessment by external rater and study participants across different glycerol concentrations in WHO ethanol-based handrub formulation

Without glycerol N ^a (%)	Glycerol 0.5% N ^a (%)	Glycerol 0.75% N ^a (%)	Glycerol 1.45% N ^a (%)
38 (95.0)	40 (100.0)	40 (100.0)	40 (100.0)
28 (70.0)	40 (100.0)	38 (95.0)	39 (97.5)
33 (82.5)	37 (92.5)	38 (95.0)	38 (95.0)
15 (37.5)	30 (75.0)	25 (62.5)	27 (67.5)
15 (37.5)	32 (80.0)	26 (65.0)	30 (75.0)
34 (85.0)	37 (92.5)	38 (95.0)	37 (92.5)
17 (42.5)	30 (75.0)	29 (72.5)	30 (75.0)
35 (87.5)	38 (95.0)	39 (97.5)	38 (95.0)
23 (57.5)	32 (80.0)	32 (80.0)	32 (80.0)
	Without glycerol N ^a (%) 38 (95.0) 28 (70.0) 33 (82.5) 15 (37.5) 15 (37.5) 34 (85.0) 17 (42.5) 35 (87.5) 23 (57.5)	Without glycerolGlycerol 0.5% Na (%)38 (95.0)40 (100.0)28 (70.0)40 (100.0)33 (82.5)37 (92.5)15 (37.5)30 (75.0)15 (37.5)32 (80.0)34 (85.0)37 (92.5)17 (42.5)30 (75.0)35 (87.5)38 (95.0)23 (57.5)32 (80.0)	Without glycerolGlycerol 0.5%Glycerol 0.75%Na (%)Na (%)38 (95.0)40 (100.0)28 (70.0)40 (100.0)33 (82.5)37 (92.5)33 (82.5)30 (75.0)15 (37.5)32 (80.0)15 (37.5)32 (80.0)34 (85.0)37 (92.5)35 (87.5)38 (95.0)35 (87.5)38 (95.0)32 (80.0)39 (97.5)23 (57.5)32 (80.0)32 (80.0)39 (97.5)



<u>Fig. 2</u>

External rater evaluation of redness, scaliness, fissures, and visual rating of the skin by glycerol concentration; distribution of scoring results for 40 participants

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Appearance









Sensation





Model of generalized logistic estimation equations for evaluation considered good for the variables of the skin observation scale performed by the external rater and the study participant for the different alcohol-based formulations

Glycerol Concentration	Proportion with a good outcome	Model Coefficients	Odds Ratio (95% CI) ^a
External rater evaluation ^b	1		
Glycerol 0%	0.4	-0.92	0.20-0.79
Glycerol 0.5%	2.4	0.88	1.12–5.15
Glycerol 0.75%	0.9	-0.10	0.46–1.77
Glycerol 1.45%	1	_	-
Self-assessment ^c			
Glycerol 0%	0.23	-1.47	0.11-0.49
Glycerol 0.5%	1.12	0.11	0.53-2.36
Glycerol 0.75%	0.73	-0.32	0.35-1.51
Glycerol 1.45%	1	-	-

^a95% CI = 95% confidence interval

^bExternal rater evaluation: defined as "good" when all four ratings from rater evaluation were 0 (no redness, no scaling, no fissures, and no irritation)

^cSelf-assessment: defined as "good" when all five ratings from self-evaluation were 6 or 7 (normal or perfect)

Discussion

- Considering that most of the low- and middle-income countries are located in tropical and subtropical areas of Africa, Asia and Latin America, where locally-produced WHO ABHR formulations are needed the most, we decided to conduct the current study in a tropical climate healthcare setting.
- Our results clearly indicate that the addition of glycerol to the WHO formulation is important for the maintenance of the HCW skin integrity

Discussion

- We conducted the study in real-life conditions during a sufficient period of time for cumulative skin adverse effects to happen (7 working days for each tested ABHR formulation)
- According to Larson and colleagues, 3 working days is the minimum period necessary to effectively compare the skin tolerance of different agents for hand hygiene

Conclusion

In a tropical climate setting, the WHO-modified EBHR formulation containing 0.5% glycerol led to better ratings of skin tolerance than the original formulation, and, therefore, may offer the best balance between skin tolerance and antimicrobial efficacy.

Questions ???