

Protocol for Evaluation of Tolerability and Acceptability of Alcohol-based Handrub in Use or Planned to be Introduced: Method 1

Summary

Introduction

User's acceptance and good skin tolerability are considered among the most important criteria for the selection of an alcohol-based handrub, according to the WHO Guidelines on Hand Hygiene in Health Care (2009). A product that is pleasant to use with no harmful effect to the hands is a major asset for the promotion of optimal hand hygiene practices.

Within the Implementation Toolkit of the WHO multimodal hand hygiene improvement strategy, two methods for the evaluation of the tolerability and acceptability of one single product (Method 1) and the comparison of more than one product (Method 2) are proposed. These were validated by previous studies and allow both objective evaluation by an observer and subjective evaluation by health-care workers. Method 2 is slightly more complex to apply but it can be particularly useful when the choice among different products must be made. The possibility of considering the user's opinion and experience on a certain product through the use of these methods brings an important added value to the process of alcohol-based handrub selection.

Study Method

- Approximately 40 volunteer participants using at least 30 ml of product per day.
- Evaluation includes the following two components:
 1. Objective evaluation: the observer uses validated scales¹ to evaluate health-care worker's skin state
 2. Subjective evaluation: health-care workers answer to a questionnaire designed to assess all risk factors for skin damage (and not only those related to product use) together with product acceptability and dermal tolerance^{2,3}.
- This protocol may be applied at different stages, at least: before using the test product; after 3–5 consecutive working days; and after 1 month.

Information and Instructions

- The study concerns one hand hygiene product. The type of product can be either blinded (by distributing bottles without any label) or known by the observer and the health-care workers.
- The health-care workers must meet the observer on the first day and collect the bottles containing the test product; they must meet again after the first 3–5 consecutive days of use and after 1 month of use.
- For the test period (1 month), only the test product must be used for hand antiseptics.
- An evaluation of skin integrity by the observer is required before, after the first 3–5 consecutive days and after 1 month of product use.
- The participant must complete a questionnaire after the first 3–5 consecutive days and after 1 month of product use.
- The amount of test product distributed for the first 3–5 days is recorded and compared with the first 3–5 days amount left over.
- Opened bottles, either empty or partially full, must be returned for weighing to the observer at the end of the first 3–5 consecutive days of product use.

¹ Larson EL, Aiello AE, Bastyr J, et al. Assessment of two hand hygiene regimens for intensive care unit personnel. *Critical Care Medicine* 2001; 29: 944-951.

² Pittet D, Allegranzi B, Sax H, Chraïti M-N, Griffiths W, Richet H. Double-blind, randomized, crossover trial of 3 hand rub formulations: fast-track evaluation of tolerability and acceptability. *Infection Control and Hospital Epidemiology* 2007;28:1344-51.

³ World Health Organization. WHO Guidelines on Hand Hygiene in Health Care. Geneva: World Health Organization, 2009.

- The participant is requested not to use hand lotion or cream during the first 3–5 consecutive days of product use.
- The participant must inform the observer if he/she stops the test prematurely.

Detailed Instructions

The aim of the study is to ascertain skin tolerability and acceptability of a product in use or is planned to be introduced, without comparison with other products. The product test lasts 1 month (of product use per participant). The criteria for skin tolerability and product acceptability are determined prior to the test.

Proposed criteria, according to the assigned ranking

Criteria for product acceptability:

- Questionnaire – Part 2 "Product evaluation" – Items Colour & Fragrance: $\geq 50\%$ above 4
- Questionnaire – Part 2 "Product evaluation" – Other items: $\geq 75\%$ above 4

Criteria for skin tolerability:

- Questionnaire – Part 2 "Self evaluation of state of skin on hands" – all items: $\geq 75\%$ above 4
- Questionnaire – Part 3 "Evaluation of the state of skin on hands by the observer": $\geq 75\%$ below 2

The test consists of the following stages:

1. Information, identification of participants, and individual test planning
2. Use of the product and evaluation
3. Data entry and analysis
4. Presentation of the results

1. Information, identification, planning

The observer's tasks are to:

- Obtain the support of the service supervisors for the testing of the product among their staff;
- Organize information sessions for potential recruits among health-care workers (aim, procedure, conditions, constraints, etc.);
- Identify by name approximately 40 volunteer health-care workers and assign an identification number (participant n°) using the Control Form;

It is essential to know participants' identity in order for the observer to organize and carry out the study; their identity is concealed when the data are analysed.

The number assigned to participants is copied onto the questionnaires together with the evaluation and planning forms and the bottles distributed on the first day of the test.

- Obtain a temporary workplace in the health-care service/unit for the duration of the study to interview participants and store products;
- Schedule appointments with each participant on the basis of their working hours to give the schedule in writing to each participant (Planning for Evaluation of Tolerability and Acceptability of an Alcohol-based Handrub – Method 1) and copy the schedule on the Control Form;

Appointments take place in the health-care service/unit in which the participants work and in accordance with their working hours:

- On day 1, before starting work, the observer should 1) distribute the bottles of the product being tested, 2) distribute Part 2 of the questionnaire, and 3) evaluate the state of the participants' hands (Objective skin evaluation – Part 3);
- After the first 3–5 days of consecutive use of the product and after they have finished work, participants should 1) Return the bottles distributed and 2) return Part 2 of the questionnaire. The observer should evaluate the state of participants' hands (Objective skin evaluation – Part 3);
- After using the product for 1 month and after participants have finished work, the observer should 1) distribute and collect the completed Parts 1 and 2 of the questionnaires, and 2) evaluate the state of the participants' hands (Objective skin evaluation – Part 3).

Note: if any participant has to withdraw from the study for no more than 5 days for an unforeseen reason other than a severe deterioration of the hand skin, the duration of the test is extended for the same number of days. If they are absent for more than 5 days, a completely new test period is organized.

- Count the number of bottles distributed for the first 3–5 days of the test, record the number distributed on the control form and part 2 of the questionnaire, and mark the bottles with the participant number;

The number of bottles distributed depends on the size of the bottles and the number of days of the test. As an example, for a daily consumption of 30 to 50 ml, two 100 ml bottles are more than enough for 3 working days, and three 100 ml bottles for 5 days.

- Ensure supplies of the alcohol-based handrub and its availability to participants for the duration of the study;
- Record each stage of the study for each participant on the control form;
- Measure the amount of product used by each participant during the first 3–5 days of the test by weighing the bottles distributed and returned; note this information on Part 2 of the questionnaire and the control form;

Two operations are required to calculate the amount of product used (on the basis of the weight of a given volume of product): $1 \text{ ml} = x \text{ g}$ (reference weight)

1. Convert the remaining weight (g) into remaining volume (ml): $\text{remaining weight} / \text{reference weight} (x \text{ g}) = \text{ml remaining}$
2. Subtract the amount remaining from the amount distributed = amount used

- Evaluate the state of participant hand skin before, during and after the test, using the scores proposed (Objective skin evaluation – Part 3) and schedule future appointments.

2. Use and evaluation of the product

Each participant undertakes to:

- Only use the alcohol-based handrub being tested (except in situations where the indication to wash with soap and water applies) for hand hygiene for 1 month;
- Use no hand-care cream or lotion for the first 3–5 days of the test;
- Complete the questionnaire – Part 2 (2 x 5 minutes) after the first 3–5 consecutive days and after 1 month's use of the product;
- Complete the questionnaire – Part 1 (1 x 5 minutes) after 1 month;
- Meet with the observer before the test, after the first 3–5 days and after 1 month's test of the product, for an evaluation of the state of the skin on hands (Objective skin evaluation – Part 3), distribution and return of the bottles and questionnaires (3 minutes per appointment);

Participants evaluate the product using the questionnaire – Part 2; skin state evaluation is made up of a subjective evaluation by participants using Part 2 of the questionnaire and an objective evaluation by the observer using validated scales and scores (objective skin evaluation – Part 3). The data are analysed on the basis of risk factors of skin damage, regardless of the composition of the product (questionnaire – Part 1)

- Return all the bottles of product distributed for the first 3–5 days of the test, regardless of the volume of product used (empty, full, partly used);

3. Data entry and analysis

- Before entering any data for analysis, the observer should complete and classify the different documents and check their content and consistency;

Each participant must be assigned:

- 1 numbered line (participation n°) on the control form;
 - 1 questionnaire – Part 1
 - 2 questionnaires – Part 2
 - 1 skin evaluation form, to be completed by the observer (Objective skin evaluation – Part 3)
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- Once the documents have been classified and checked, the observer must remove any names and keep only the participant identification number;
 - Data are entered directly into the Data Entry Analysis Tool available from WHO or sent to the local data manager;
 - Data are analysed and when the results are known, the pharmacist unblinds the confidentiality of the type of product tested.

Results

If the tests fail to give a clear-cut result, i.e. if there is no clear outcome in terms of tolerability and acceptability, the test may be repeated and/or extended and the number of participants increased in order to confirm or invalidate the results for product tolerability and acceptability.

4. Presentation of the results

When the results of the data analysis are available, the pharmacist, the observer and any other key professional involved in the testing agree on how to present these to the facility administration and management and participants, and on how to disseminate them if they are likely to have a direct impact on staff.



Questionnaire – Part 1

(To complete **once** per participant, after 1 month)

Participant no:

Date of questionnaire's return: (day / month / year)

Evaluation of factors influencing skin tolerance

Age

Sex: F M

Professional group:

- Nurse Midwife Student Auxiliary Medical doctor Medical student
- Therapist Technician Other

Skin:

- Very fair with freckles Fair ± freckles Light brown Brown
- Dark brown Black

Climate:

- Polar Continental / Temperate Subtropical / Mediterranean Tropical / Equatorial
- Desert

Present season:

- Dry Humid Cold Hot Intermediate

Do you have non work-related activity(ies) likely to cause damage to your skin? Yes No

Do you normally use a protective hand lotion/cream (outside the test period)?

- As often as possible Several times/day Once/day
- Sometimes, depending on the season Rarely Never

Do you develop irritative dermatitis?

- Never Sometimes (depending on season/activity) Always

Do you develop atopic dermatitis?

- Yes No

Do you develop rhinitis / allergic conjunctivitis?

- Yes No

Are you asthmatic?

Yes No

Do you have a known intolerance to alcohol?

Yes No

Evaluation of frequency of hand hygiene practices

Do you work full-time?

Yes No

If part-time, please indicate which of the following best fits your work

< 50% 50% 60% 70% 80% 90%

For how long have you been using an alcohol-based hand hygiene product at work?

It's the first time Since < 1 year Since > 1 year and < 5 years Since > 5 years

Do you think you can improve your own hand hygiene compliance?

Yes No Perhaps

It may be difficult for you to use an alcohol-based hand hygiene product because of:

Forgetfulness Always Never

Lack of time Always Never

Damaged skin Always Never



Questionnaire – Part 2

(To be completed **after the first 3–5 consecutive days** of product use and **after 1 month** of product use)

Participant n°:

Product:

Date of questionnaire's return
(day / month / year):

Participant name:

Number of distributed bottles

Amount of Product
used (ml):

Evaluation of frequency of hand hygiene practices

During how many consecutive working days have you used the test product?

- 3 days 4 days 5 days 6 days 7 days > 7 days

How often do you have direct contact with patients during your working day (during the test period)?

- < 1 contact Between 1 and 5 Between 6 and 10 Between 11 and 15 > 15 contacts

In what percentage of times where hand hygiene is recommended, do you really clean your hands?

- 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Has the present study changed your hand hygiene practice?

- Yes No

During your last 5 opportunities for hand hygiene, how many times did you use handrubbing to clean your hands?

- 0 1 2 3 4 5

On average, how often do you practise hand hygiene during a working hour (during the test period)?

- < 1 Between 1 and 5 Between 6 and 10 Between 11 and 15 > 15

Evaluation of the test product

What is your opinion of the test product for hand hygiene?

Colour	Unpleasant	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pleasant
Smell	Unpleasant	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pleasant
Texture	Very sticky	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not sticky at all
Irritation (stinging)	Very irritating	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not irritating
Drying effect	Very much	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not at all
Ease of use	Very difficult	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very easy
Speed of drying	Very slow	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very fast
Application	Very unpleasant	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very pleasant
Overall evaluation	Dissatisfied	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very satisfied

Are there differences between the test product and the product used in your hospital?

Major No

Which product do you prefer?

Usual product Test product No preference

Do you think that the test product could improve your hand hygiene compliance?

Yes, absolutely Not at all

Evaluation of skin condition

Self-assessment of the skin on your hands (after use of the test product):

Appearance <i>(supple, red, blotchy, rash)</i>	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal
Intactness <i>(abrasions, fissures)</i>	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal
Moisture content <i>(dryness)</i>	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal
Sensation <i>(itching, burning, soreness)</i>	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal

How would you assess the overall integrity of the skin on your hands?

Very altered Perfect

Thank you for your participation!

Skin Objective Evaluation – Part 3

(to be completed three times: **before** the product use; **after the first 3–5 consecutive days** of product use; and **after 1 month** of product use)

Participant no:

Date of the 1st evaluation (day / month / year)

Date of the 2nd evaluation (day / month / year)

Date of the 3rd evaluation (day / month / year)

Scales to evaluate skin condition by the observer (objective evaluation)

	Before					After 3–5 days					After 1 month				
Redness	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
<i>0=no redness, 1=slight redness or blotchiness, 2=moderate redness, uniformly distributed, 3=bright red, widespread, 4=very bright red with oedema present</i>															
Scaliness	0	1	2	3		0	1	2	3		0	1	2	3	
<i>0=non scaliness, 1=very slight and occasional, 2=moderate, 3=very pronounced separation of scale edges from skin</i>															
Fissures	0	1	2	3		0	1	2	3		0	1	2	3	
<i>0=no fissure 1=very fine, 2=large, either single or multiple, 3=extensive cracks with bleeding or seeping</i>															
Visual Scoring of Skin Scale															
No observable scale or irritation of any kind	0					0					0				
Occasional scale that is not necessarily uniformly distributed	1					1					1				
Dry skin and/or redness	2					2					2				
Very dry skin with whitish appearance, rough to touch and/or redness, but without fissures	3					3					3				
Cracked skin surface but without bleeding/seeping	4					4					4				
Extensive cracking of skin surface with bleeding/seeping	5					5					5				

Planning for Evaluation of Tolerability and Acceptability of an Alcohol-based Handrub – Method 1

Name:

Participant no:

Test Period: (day / month / year) From / / to / /

Please note the timetable of your appointments

WHEN		WHY
1st Date and time	/ / (day / month / year) Time: <input type="text"/>	To collect bottles containing the test product (amount defined according to number of working days and volume of bottles) To collect the questionnaire – Part 2 For skin assessment by the observer
2nd Date and time (after the first 3–5 consecutive days)	/ / (day / month / year) Time: <input type="text"/>	To return all bottles To return the questionnaire – Part 2 For skin assessment by the observer
3rd Date and time (after 1 month)	/ / (day / month / year) Time: <input type="text"/>	To collect and return the questionnaire – Part 1 To collect and return the questionnaire – Part 2 For skin assessment by the observer

The observer can be contacted during working hours throughout the test period for questions and/or problems on the following number:

Telephone Number:

Control Form for Test of Tolerability and Acceptability of an Alcohol-based Handrub Method 1

Participant N°	Name	Appointment	Distributed bottles/ Returned bottles	Remaining weight/ Amount used	Questionnaire check	Skin assessment
1		1 st day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 distributed 1 st day <input type="checkbox"/>	Before 1 st day <input type="checkbox"/>
		3 rd to 5 th day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 returned 3 rd –5 th day <input type="checkbox"/>	After 3–5 days <input type="checkbox"/>
		Last day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part1/2 distributed last day <input type="checkbox"/> Part1/2 returned last day <input type="checkbox"/>	After 1 month <input type="checkbox"/>
2		1 st day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 distributed 1 st day <input type="checkbox"/>	Before 1 st day <input type="checkbox"/>
		3 rd to 5 th day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 returned 3 rd –5 th day <input type="checkbox"/>	After 3–5 days <input type="checkbox"/>
		Last day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part1/2 distributed last day <input type="checkbox"/> Part1/2 returned last day <input type="checkbox"/>	After 1 month <input type="checkbox"/>
3		1 st day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 distributed 1 st day <input type="checkbox"/>	Before 1 st day <input type="checkbox"/>
		3 rd to 5 th day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 returned 3 rd –5 th day <input type="checkbox"/>	After 3–5 days <input type="checkbox"/>
		Last day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part1/2 distributed last day <input type="checkbox"/> Part1/2 returned last day <input type="checkbox"/>	After 1 month <input type="checkbox"/>

Participant N°	Name	Appointment	Distributed bottles/ Returned bottles	Remaining weight/ Amount used	Questionnaire check	Skin assessment
4		1 st day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 distributed 1 st day <input type="checkbox"/>	Before 1 st day <input type="checkbox"/>
		3 rd to 5 th day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 returned 3 rd –5 th day <input type="checkbox"/>	After 3–5 days <input type="checkbox"/>
		Last day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part1/2 distributed last day <input type="checkbox"/> Part1/2 returned last day <input type="checkbox"/>	After 1 month <input type="checkbox"/>
5		1 st day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 distributed 1 st day <input type="checkbox"/>	Before 1 st day <input type="checkbox"/>
		3 rd to 5 th day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 returned 3 rd –5 th day <input type="checkbox"/>	After 3–5 days <input type="checkbox"/>
		Last day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part1/2 distributed last day <input type="checkbox"/> Part1/2 returned last day <input type="checkbox"/>	After 1 month <input type="checkbox"/>
6		1 st day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 distributed 1 st day <input type="checkbox"/>	Before 1 st day <input type="checkbox"/>
		3 rd to 5 th day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 2 returned 3 rd –5 th day <input type="checkbox"/>	After 3–5 days <input type="checkbox"/>
		Last day / / Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part1/2 distributed last day <input type="checkbox"/> Part1/2 returned last day <input type="checkbox"/>	After 1 month <input type="checkbox"/>

Lines may be added according to the number of participants