Methods to Evaluate Hand Hygiene Products
Prof. Timothy Landers and Dr. David Macina
A Webber Training Teleclass

Methods to Evaluate Hand Hygiene Products

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Objectives:

- Understand how the following concepts relate to hand hygiene product testing: in vivo testing, in vitro testing, log reduction, efficacy, effectiveness, and product claims.
- Apply these terms to currently approved test methods and emerging trends in the testing of hand hygiene products.
- Evaluate different test methods and their usefulness in product selection.

Hands Are the Most Common Means of Microbial Spread

- Acquisition of MRSA on hands after touching the bedrail of a colonized patient
- Acquisition of MRSA on hands after examination of a colonized patient

“Hand Hygiene is the single most important procedure for preventing the transfer of microorganisms and therefore preventing the incidence of diseases”

Multimodal Strategies for Hand Hygiene

ABHR are Recommended in Global Hand Hygiene Guidelines

“ABHR are Recommended in Global Hand Hygiene Guidelines

Regulation of Antimicrobial Hand Hygiene Products

Considered OTC drugs, biocidal products, or natural health products depending on the country and/or claims.

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Regulation of Antimicrobial Hand Hygiene Products

Regulations specify the following:
- Safe and effective active ingredients
- Usage concentrations
- Dosage forms
- Labeling
- Efficacy testing

Intended Use Examples

- Personal domestic use
- Personal commercial use
- Professional food premises
- Professional healthcare use

Labels

- “Handwash to help reduce bacteria that potentially can cause disease”
- “Hand sanitizer to help reduce bacteria on the skin”
- “Decrease transient bacteria on the skin”

Product Claims

- Must be “non-misleading statements”
  - Hypoallergenic
  - Kills the most germs
  - Leaves hands feeling soft
  - Gentle on hands
  - Fragrance-free

Efficacy Testing Requirements (Overview)

- in vitro (in a test tube)
- +
- in vivo (using human test subjects)

Methodologies for evaluating the efficacy of alcohol-based hand rubs

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In vitro Microbicidal Activity “Time-Kill”

- Measures rapid microbicidal (killing) action of products
- Can test almost any microorganism by this method

In vitro results do not predict antimicrobial performance on hands.

Log Reduction Tutorial

<table>
<thead>
<tr>
<th>Log Reduction</th>
<th>Percent Reduction of Bacteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>90%</td>
</tr>
<tr>
<td>2</td>
<td>99%</td>
</tr>
<tr>
<td>3</td>
<td>99.9%</td>
</tr>
<tr>
<td>4</td>
<td>99.99%</td>
</tr>
<tr>
<td>5</td>
<td>99.999%</td>
</tr>
</tbody>
</table>

Example: Start with 1 million bacteria
- 1 log reduction: 900,000 are killed and 100,000 remain
- 2 log reduction: 990,000 are killed and 10,000 remain
- 3 log reduction: 999,000 are killed and 1,000 remain

Examples of in vitro Microbicidal Methods

- Bactericidal:
  - ASTM E2783, EN 1040, EN 13727,
- Yeasticidal/Fungicidal
  - EN 1275, EN 13624
- Mycobactericidal
  - EN 14348
- Viricidal
  - ASTM E1052, EN14476
- Sporicidal
  - EN 14347

Healthcare Personnel Handwash: ASTM E1174

- Predicts the reduction of transient microorganisms by washing sanitizing hands.
- Measures reduction of a marker organism.
- Test products evaluated after single or multiple product uses.
- Originally designed to evaluate handwash products and later adapted to evaluate AHR.

US FDA Endpoints:
- Bacterial Reduction (log)...
  - 1st Application: 2 log
  - 10th Application: 3 log

ASTM E1174 Overview

- Contaminate hands with 10³ cfu Serratia marcescens
- Sample hands to obtain “baseline” level
- Contaminate hands again and apply test product
- Sample hands to obtain “post exposure” level
- Perform a total of 9 additional contamination and product application cycles
- Sample hands after final (10³) product application

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EN1500: Hygienic Handrub
- Challenge organism: E. coli
- Single product use
- Defined volume & contact time
- Cross-over design:
  - Subjects evaluate both the test product and an internal reference
  - Test product must show non-inferiority to internal reference

Challenges When Using ASTM E1174 to Measure ABHR Efficacy

Expert Opinions on Hand Hygiene Test Methods
- "New Methods For The Future":
  - To be plausible, results of in vivo models should show that they are realistic under practical conditions such as the duration of application...

CDC Guideline for Hand Hygiene in Health-Care Settings (2002)
- "Hand Hygiene Research Agenda":
  - Develop new protocols for evaluating the in vivo efficacy of agents, considering in particular short application times and volumes that reflect actual use in HC Facilities

WHO Guidelines on Hand Hygiene in Health Care (2009)

"Low Volume" Contamination
- Concentrate culture 10-fold by centrifugation and re-suspension in 1.10 volume of fresh broth


"Low Volume" Contamination Test Results

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Achieving Clinical Benefit With Alcohol-Based Handrubs

Efficacy vs. Effectiveness

- **Efficacy** – A measure of the reduction of pathogenic transient microorganisms on the hands.
  - Relates to controlled laboratory or clinical trials

- **Effectiveness** – A measure of the interruption the spread of pathogens and the acquisition of healthcare associated infections.
  - Relates to use in clinical practice

Achieving Clinical Benefit (Effectiveness) with ABHRs: Whole Systems Model

Factors Influencing ABHR Antimicrobial Efficacy:

- Application Technique
- Alcohol Type
- Application Volume
- Alcohol Concentration
- Product Format
- Product Formulation

In *vivo* ABHR Efficacy: Formulation has a Greater Influence than Alcohol Concentration

- Method = HCPHW
  - 2 ml application volume
- Test products = Commercial healthcare ABHRs
- No relationship between efficacy and ethanol concentration

IN FORMULATED ABHR PRODUCTS ALCOHOL CONCENTRATION IS NOT THE CRITICAL DETERMINANT OF EFFICACY: FORMULATION MATTERS

Influence of ABHR Application Volume on Efficacy

- Does Volume Matter
- How Much is Enough?

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Sources of (Conflicting?) Information

Methods to Evaluate Hand Hygiene Products

Guidance / Expert Opinions on ABHR Application Volume

Typical ABHR Dispenser Outputs and ABHR Dry Times

...But how long do healthcare workers spend disinfecting their hands?

End-User Preference

Healthcare Workers’ Perceptions of ABHR Application Volume

Influence of Application Volume on in vivo ABHR Efficacy

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Relationship Between ABHR Application Volume and Product Rub-in Time:
- Linear relationship between volume of product applied and Rub-in time.
  - Greatly influenced by test subject.
  - Influenced by alcohol type and concentration.
  - Not influenced by product form.

What is the optimal ABHR use volume?
- Current in vivo test methods are not designed to answer this question.
- Data linking product efficacy to effectiveness in clinical settings is lacking.
- Current “typical” ABHR use volumes may be insufficient.
  - A recent study suggests that HC workers are not willing to use enough product to achieve adequate efficacy.¹

Factors Influencing Hand Hygiene Compliance

ABHR Product Attributes Which Can Influence Compliance

Skin tolerability
- Alcohol concentration and type
- Emollients and moisturizers
- Excipient ingredients

Feel and aesthetics
- Product form
- Emollients and moisturizers
- Excipient ingredients
- Application Volume

Tips for evaluating effectiveness
- Know approved labelled indications
- What is the desired use?
- Which test method was used?
- Were outside/third party labs used?

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Evaluating efficacy

- Local product testing essential
- Regulatory or local requirements
- Consider all components of a program

WHO Protocol for Evaluation of ABHR

- 40 participants
- 3-5 days of use
- Compare test product to current product (Method 1) or two test products (Method 2)
- Demographics
- Skin conditions
- Current self-reported practices
- Measure use of each product

http://who.int/gpsc/5may/tools/system_change/en/

Summary

- In vitro and in vivo test methods are used to evaluate the efficacy of alcohol-based hand rubs.
- Global experts have called for the development of new methods that accurately simulate clinical use conditions and performance.
- Future studies are needed to establish evidence-based efficacy requirements and in-use volume recommendations.
- Clinical effectiveness is influenced by both product efficacy and healthcare worker compliance (which can be influenced by product attributes).
- Product selection should include evaluation of efficacy claims and local product testing.

WHO Protocol for Evaluation of the Test Product for Hand Hygiene

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

<table>
<thead>
<tr>
<th>Colour</th>
<th>Unpleasant</th>
<th>Pleasant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>Unpleasant</td>
<td>Pleasant</td>
</tr>
<tr>
<td>Texture</td>
<td>Very dry</td>
<td>Not sticky at all</td>
</tr>
<tr>
<td>Irritation on dry skin</td>
<td>Very irritating</td>
<td>Not irritating</td>
</tr>
<tr>
<td>Drying effect</td>
<td>Very much</td>
<td>Not at all</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Very difficult</td>
<td>Very easy</td>
</tr>
<tr>
<td>Speed of drying</td>
<td>Very slow</td>
<td>Very fast</td>
</tr>
<tr>
<td>Application</td>
<td>Very unpleasant</td>
<td>Very pleasant</td>
</tr>
<tr>
<td>Overall evaluation</td>
<td>Dissatisfied</td>
<td>Very satisfied</td>
</tr>
</tbody>
</table>

May 20 (Free – Broadcast live from 2014 IAPC-Canada Conference)
TOO BUSY TO WASH — Followed by ICP EDUCATION PANEL
Martin Kieran, Southport and Ormskirk Hospital Trust, UK
Teleclass broadcast sponsored by GSK (www.gsk.com)

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INFECTION CONTROL IN LONG TERM CARE
The Machnowski, Queen Elizabeth II Health Centre, Halifax, Nova Scotia
Jim Gauldrup, Providence Care, Kingston, Ontario

June 5 COME HELL OR HIGH WATER – INFECTION CONTROL DURING AND AFTER FLOODS
Dayneth Meyers & Barbara Long, Alberta Health Services, Calgary, Alberta

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