Learning Objectives

- Review the evidence supporting Alcohol-Based Hand Rub (ABHR) use in healthcare settings.
- Compare and contrast test methods used to evaluate ABHR.
- Review the key variables which influence the efficacy of ABHRs.
- Review the key variables which influence hand hygiene compliance.

Hand Hygiene Overview: The Importance of Alcohol-Based Hand Rubs

WHO Guidelines on Hand Hygiene in Health Care

- Alcohol-based hand rubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.
- ABHRs are recommended for the following factors:
  1. Fast-acting and broad-spectrum activity with minimal risk of generating antimicrobial resistance.
  2. Can be used in resource-limited or remote areas.
  3. Process faster and more convenient to help promote improved hand hygiene compliance.
  4. Economic benefit.
  5. Better acceptability and tolerability.
- Apply a sufficient amount of ABHR and cover all surfaces of the hands. Rub hands until dry.

PIDAC: Best Practices for Hand Hygiene

Use of Alcohol as a Skin Antiseptic

Before and/or After:
- Contact with patient or environment
- Performing invasive/aesthetic procedure
- Care involving contact with blood, body fluids, secretions and excretions
- Putting on and removing gloves
- Preparing, handling, serving food or medications
- Moving to another activity
- Leaving a contaminated body site to a clean body site
- Rub hands until product is dry. This will take a minimum of 15 seconds if sufficient product is used.
How does alcohol kill bacteria?

- Damages cell membranes → loss of cell integrity
- Inactivates proteins ("denatures")
- Acts and evaporates very rapidly

Skin Antiseptic Activity of Short-Chain Alcohols

- Alcohol-in-water mixtures tested → 1 minute contact time
- Antiviral Efficacy: Ethanol tends to have greatest activity against non-enveloped viruses

Residents and Transient Flora

- Resident microflora: Normal inhabitants of the skin:
  - Colonize deeper layers of the skin
  - Difficult to remove
  - Target for pre-surgical hand scrubs/rubs
- Transient microflora: Visitors to the skin, picked up from environment:
  - On superficial layers of skin
  - Easier to remove
  - Target for alcohol-based hand rubs

Methods to Evaluate the Efficacy of Alcohol-Based Hand Rubs

- ASTM E1174: Healthcare Personnel Handwash
  - Predicts the reduction of organisms by washing or sanitizing hands after handling contaminated objects
  - Measures reduction of transient organisms after single or multiple product uses

- EN1500: Hygienic Hand Rub Overview
  - Challenge organism: E. coli
  - Single product cross-over design:
    - Each volunteer uses test product and an internal reference product
  - Product application for defined volume & contact time:
    - Typical: 3 ml for 30 sec
  - Must show non-inferiority to internal reference:
    - 2 x 3 ml of 60% isopropyl alcohol
    - 60 second total rub time

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Expert Opinions on Hand Hygiene Test Methods

- "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)

- "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)

Unresolved Issues and Next Steps

- Beyond current methods:
- Predicting clinical efficacy
- Global unified method?
- In vivo antiviral methods

Current efficacy gaps/ Future needs:
- What is the relationship between log reduction and clinical benefit?
- Improved antiviral activity (norovirus solutions)
- C. difficile hand hygiene solutions

Achieving Clinical Benefit with ABHRs: Whole Systems Model

Factors Influencing ABHR Antimicrobial Efficacy:

- Alcohol Type
- Alcohol Concentration
- Formulation
- Product Form
- Application Volume
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Concentration Dependence of the Activity of Short-Chain Alcohols

- Test substances:
  - Alcohol-in-water mixtures
- Test Method = EN1500
  - 1 minute contact time

Influence of ABHR Formulation

- ABHR formulations often contain:
  - Alcohol
  - Buffering Systems
  - Surfactants
  - Water
  - Secondary Actives
  - Secondary Actives
  - Thickeners
- Ingredients create specific attributes:
  - Skin tolerance, skin moisturization, aesthetic properties (e.g., skin feel, fragrance)
  - Enable specific delivery formats (rinse, gel, foam)
- Specific ingredients may improve or inhibit antimicrobial efficacy of ABHR formulations

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

- Method = ASTM E1174
- 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 Product Form on in vivo ABHR Efficacy: Meta-Analysis

- Methods:
  - 11 independent ATM E1174 experiments (2 labs)
  - 2 ml application volume of 70% ethanol gel and foam ABHR formulations
- Meta-analysis: No significant differences based on ABHR form

Recommendations Regarding ABHR Application Volume

- "Apply a palmtop of alcohol-based hand rub and cover all surfaces of the hands, and rub hands until dry. Entire process should take 20-30 seconds."
- Apply sufficient product such that it will remain in contact with the hands for a minimum of 15 seconds before the product becomes dry (usually six to two pumps). Ideal volume of product to apply to the hands is not known and may vary for different formulations. However, if hands are dry after rubbing hands together for 15-15 seconds, an insufficient volume of product likely was applied.

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Audience Poll:

- Is ABHR efficacy dependent upon how much I apply to my hands?

Healthcare Workers’ Perceptions of ABHR Application Volume

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Influence of Application Volume on in vivo ABHR Efficacy

- Test method: E2755
- Test product: 62% ethanol ABHR gel

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In vivo ABHR Efficacy at More Realistic Volumes

- ASTM E1174: Application 10 log reductions for various marketed ABHRs
- Only 2 products met efficacy requirements at 2 ml application volume
- Alcohol concentration does not drive efficacy

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Factors Influencing Hand Hygiene Compliance

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Factors Influencing Hand Hygiene Compliance

- Multimodal Hand Hygiene Program
- ABHR Product Attributes
- ABHR Dispensing and Delivery

Reasons Reported by Healthcare Workers for Lack of Adherence with Hand Hygiene Recommendations

- Skin irritation
- Inaccessible supplies
- Interference with worker/patient relation
- Patient needs perceived as priority
- Wearing gloves
- Forgetfulness
- Ignorance of guidelines
- Insufficient time
- High workload and understaffing
- Lack of scientific information demonstrating impact of improved hand hygiene on hospital infection rates

Multimodal Strategies for Successful Promotion of Hand Hygiene

<table>
<thead>
<tr>
<th>Multimodal strategy</th>
<th>Minimum criteria for implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. System change: alcohol-based handrub</td>
<td>Bottles of alcohol-based handrub positioned at the point of care in each ward, or given to staff</td>
</tr>
<tr>
<td>B. System change: access to safe continuous water supply and towels</td>
<td>One sink to at least every 10 beds, soap and fresh towels available at every sink</td>
</tr>
<tr>
<td>1B. System change: access to safe continuous water supply and towels</td>
<td>One sink to at least every 10 beds, soap and fresh towels available at every sink</td>
</tr>
<tr>
<td>2. Training and education</td>
<td>All staff involved in the test phase receive training during Step 3. A programme to update training over the short-, medium- and long-term is established</td>
</tr>
<tr>
<td>3. Observation and feedback</td>
<td>Two periods of observational monitoring are undertaken during Steps 2 and 4</td>
</tr>
<tr>
<td>4. Reminders in the workplace</td>
<td>&quot;How to&quot; and &quot;5 Moments&quot; posters are displayed in all wards (e.g., patients' rooms; staff areas; out-patient/ambulatory departments)</td>
</tr>
<tr>
<td>5. Institutional safety climate</td>
<td>The chief executive, chief medical officer/medical superintendent and chief nurses all make a visible commitment to support hand hygiene improvement during Step 3 in all announcements and/or formal letters to staff</td>
</tr>
</tbody>
</table>

WHO Hand Hygiene Guidelines on Hand Hygiene in Health Care, 2009

Impact of a Multimodal Hand Hygiene Program

- ABHR use associated with increasing compliance and reduction of transmission of healthcare-associated infections (HAIs)

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</thead>
<tbody>
<tr>
<td>Hand disinfection</td>
<td>100</td>
<td>90</td>
<td>80</td>
<td>70</td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>Attack rates of MRSA (new cases per 100 admissions)</td>
<td>0.5</td>
<td>0.4</td>
<td>0.3</td>
<td>0.2</td>
<td>0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>HAIs infections (cases per 100 admissions)</td>
<td>10</td>
<td>9</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

Increased Alcohol Use
Fewer Infections

ABHR Product Attributes Which Can Influence Compliance

- Skin tolerability
- Alcohol concentration and type
- Presence (or absence) of emollients and moisturizers
- Excipient ingredients

Impact of ABHR Acceptance on Hand Hygiene Frequency

- Prospective evaluation of a new ABHR formulation conducted in a SICU and on a general medical ward
- Hand hygiene frequency monitored using electronic counters

Source: 5th Decennial Conference on HAIs, March 2010  Abstr # 270
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Product Acceptance & Clinical Effectiveness

- The "best" ABHR are those that achieve at least a threshold of antimicrobial efficacy while optimizing product acceptance elements to ensure maximum product usage.
- Product efficacy can be outweighed if products are not accepted by healthcare workers.
- The most efficacious product is not necessarily the most effective (Semmelweis).
- The importance of product acceptability is noted in both the CDC and WHO Hand Hygiene Guidelines.

Impact of Product Dispensing on Compliance

- Dispenser Placement...
  - Point of Care vs. hallway dispensers.
- Reliability...
  - Are the dispensers functional?
  - Batteries?
- Dispensed Volumes...
  - Influence product dry time
  - Influence product feel
- Manual or Touch Free...
  - Touch-free dispensers may promote compliance

Product Acceptance & Clinical Effectiveness

- Frequency of use of manually operated and touch-free ABHR dispensers compared over 4 month period.

<table>
<thead>
<tr>
<th>Dispenser Type</th>
<th>Manual</th>
<th>Touch-Free</th>
</tr>
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</table>
| No. of uses per day | 25 ± 12.6 | 41 ± 18.6
| Per day, mean SD* | 35* | 34 |

Touch-free dispensers were used significantly more often than manual dispensers.

How Accurate is Visual Monitoring of Hand Hygiene Compliance?

- How many healthcare workers can be visualized at one time: FEW
- What percent of all healthcare workers can be visualized at one time: FEW
- How reproducible is visual observation of hand hygiene compliance: Poor
- Visual monitoring: Resource and personnel intensive.

Electronic Monitoring of Hand Hygiene (HH) Compliance May Be Much More Accurate

- Study design: Before/after study in 17-bed intensive care unit from June 2008-June 2010. Initially visual observation. Then, video recording of HH (remote video auditing and real-time feedback) on entry and exit of rooms (16 weeks). Video recordings HH compliance analyzed in India and results fed back (91 weeks).
- Results: Visual observation reported 55-65% compliance. Video monitoring identified <10% compliance (3933/6054). With immediate feedback, HH compliance increased to 87% (262826/298386).

Video or electronic evaluation of hand hygiene compliance should be the “gold standard”.

Advantages of Electronic or Video Monitoring of Hand Hygiene (HH) Compliance

- More comprehensive. Can monitor all areas of the hospital 24/7 (all healthcare workers and all areas).
- Reduced individual variation.
- Reproducible
- More accurate
- Less resource intensive
- Can provide real-time feedback
- Can even review video with healthcare workers who are disbelievers.

Video or electronic monitoring/evaluation of HH compliance should be the “gold standard”.

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Achieving Clinical Benefit with ABHR: Whole Systems Model

- ABHR Formulation
  - Efficacy
  - Skin Compatibility (Tolerance)
  - Feel/Aesthetics (Acceptance)

- Dispensing
  - Placement
  - Stability
  - Output

- Compliance Program
  - Education
  - Monitoring
  - Feedback

Clinical Benefit
- Reduced Pathogen Transmission
- Reduced Infections

Open Questions and Future Research

- Relative influence of the variables on clinical effectiveness is unknown
  - Do differences in product efficacy translate to measurable differences in clinical effectiveness?
  - How much of an increase in compliance is needed to significantly improve effectiveness?
  - What is the optimal ABHR use volume and are current ABHR use volumes too low?

Conclusions

- ABHRs should be considered from a whole system approach to maximize clinical effectiveness
- Formulation matters
  - Efficacy should be judged on in vivo Health Canada performance criteria and not on only alcohol content or dry time
- Dispenser output matters
  - When evaluating in vivo data, the test volume relative to dispenser output is critical
- Product acceptance and tolerability is critical to driving compliance
  - End user trials of both formulations and dispensers should be conducted to aid in purchasing decisions

Thank you!

Coming Soon

09 October (FREE, WHO Teleclass - Europe)
IMPLEMENTING INFECTION CONTROL THROUGH A PATIENT SAFETY PARTNERSHIP APPROACH IN AFRICA
Julie Storr, World Health Organization, Geneva

17 October (FREE, Teleclass)
THE ROAD TO CIC CERTIFICATION: GETTING STARTED AND WORKING TOWARD SUCCESS
Dr. Kathleen N. Suh, The Ottawa Hospital, and Prof. Ruth M. Carrico, University of Louisville

24 October
INFECTION CONTROL CONCERNING MRSA IN A LOW-ENDEMIC AREA
Prof. Bjørg Marit Andersen, Oslo University, Norway

30 October (South Pacific Teleclass)
THE ROAD TO CIC CERTIFICATION: GETTING STARTED AND WORKING TOWARD SUCCESS
Liz McDonald, Melbourne School of Health Research, Australia

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