Painting the Roses Red: What's in Your Products

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Disclosure

Debra Thayer is an employee and stockholder of 3M Co.

This presentation does not contain mention of branded products.

Objectives

Describe 3 considerations in skin care product selection

Describe 2 elements of a robust product evaluation

Explain the benefit of a holistic approach to prevention

Skin Care Products-3 perspectives

Formulator perspective

What does it need to do? How do I get it to do that? How do I make it safe and stable?

Regulator Perspective

Is it safe? Does it follow the law? Are claims supported?

Clinician Perspective

Does it help me meet my clinical objective? Cleanse? Protect from irritants? Reduce friction? Protect from adhesives?

Is it effective? Is it safe?

How much does it cost?

Formulator Perspective

What does it need to do?

Cleanse (bathe)

(i.e. remove irritants/soil)

Solutions, lotions

Protect

Repel irritants, moisture; reduce friction; sacrificial substrate for adhesives

Moisture barrier creams, ointments, pastes
Barrier films
Specialty skin protectants

Moisturize

Smooth, soften, improve skin hydration, appearance

Lotions, creams

Treat

Creams, ointments, pastes, powders,

Creams

- Emulsions of oil in water or water in oil
- Varying viscosity-thin liquid to semi-solid
- Breathable or occlusive

Moisturizing creams contain:
Emollients +/-
Humectants +/-
(Less commonly-Occlusive skin conditioning agents)

Moisture barrier creams contain barrier ingredient(s):
Zinc oxide
Petrolatum
Dimethicone
Mineral oil

Can also make moisturizing barrier cream

Ointments and pastes

Ointments

- Semi-solids
- Anhydrous
- Occlusive
- Petrolatum base is common
- Used almost exclusively for skin protection; rarely used as moisturizer due to thick viscosity and greasiness

Pastes

- Ointments + absorbent (e.g.CMC)
- Typically 15-20% zinc oxide
- Semi-solids
- Occlusive
- Used for skin protection

Why all the ingredients?

- Therapeutic activity
  - intended effect
- Stability
  - homogeneity, viscosity, appearance
- Shelf life
- Patient acceptability
  - scent, texture, appearance

Scent ≠ Fragrance

Zatz J. *Ostomy Wound Mgt.* 2001

Ingredients-Functional Categories

Absorbents

Antifungals

Antimicrobials

Antioxidants

- Ascorbic acid

Biological additives (>1000)

Buffering agents

Chelating agents

- EDTA, K Citrate, citric acid

Colors

Emulsion Stabilizers

- PEG, Steryl alcohol

Film formers

Fragrances

Humectants

pH adjusters

Preservatives

Skin conditioning agents (> 2000)

Skin protectants (21)

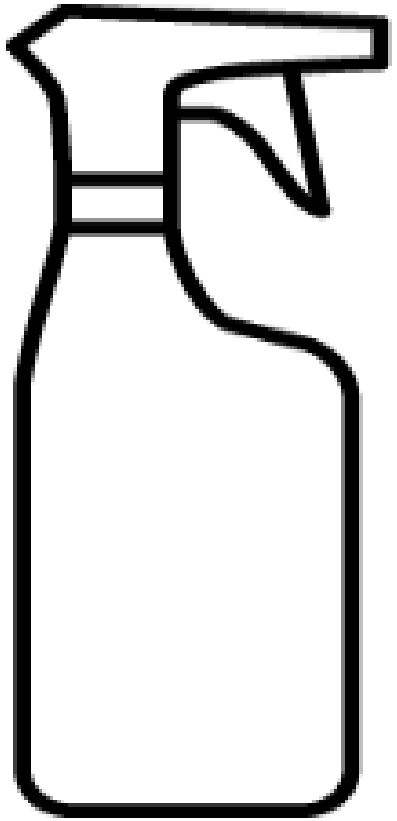
- Zinc oxide, Dimethicone, petrolatum, etc.

Solvents

Surfactants (>1500)

Viscosity increasing/decreasing agents

A cleanser for example



It’s a lot like cooking

- Specific ingredients, specific amount
- Added in defined order
- Controlled mixing method/speed
- Temperature
- “Whole vs. part”

Chemistry confusion

"Alcohol"

Functions: antifoaming agent, cosmetic astringent, solvent, viscosity decreasing agent

- Unlikely to be found in significant quantities in skin care products

VS.

"alcohol"

Structure: carbons, hydrogens, and an oxygen

- e.g. cetyl alcohol=an emollient, tocopherol= Vitamin E (skin conditioner), propylene glycol=humectant

Function confusion

What is the difference between a preservative and an antimicrobial?

Both kill microorganisms

Preservatives…"prevent spoilage or prevent growth of inadvertently added microorganism but do not contribute to claimed effects…"

- Most common-parabens
- Also used-formaldehyde donors

"Antimicrobials" have a therapeutic benefit

Multi-use products that contain water must be preserved

- Helps prevent growth of microbes, contributes to shelf life

Liquid moisture barriers

Polymers that create film coatings
Attach to skin
Can make them breathable
Allow adhesives to adhere
Anhydrous-preservatives not needed

- Barrier films

  Co- or terpolymer delivered via solvent(s)-dissolve poorly in water

- Specialty skin protectants

  Pure cyanoacrylate

  Polymer-cyanoacrylate system

What are the attributes you want in a skin care product?

?

?

?

?

?

Regulatory Perspective

Regulatory perspective

Is it safe?

Labeling, claims and promotion follow the law?

Classifications-impact labeling and claims

- Drugs
- Cosmetics
- Medical devices

Classifications

Drugs-”affect structure and function”

1. Prescription
   - Anti-inflammatories
   - Antimicrobials
2. Over the Counter (OTC) drugs

OTC Drugs

- FDA monographs (e.g. Skin protectant, Antifungal)
  - category of drug
  - active ingredients allowed
    - e.g. antifungal= Clotrimazole 1%, Miconazole nitrate 2% also “undecylenic acid and its salts (calcium, copper, and zinc …
    - e.g. skin protectants (21 ingredients, e.g. zinc oxide, petrolatum, dimethicone, etc)
  - percentage of active
  - may make claims only on active ingredients
  - balance=cosmetic ingredients listed alphabetically

- Instructions for use per monograph guidance
  - Varies by ingredient

Medical devices

- Medical Devices (Class 1)
  - Do not have an “active” ingredient
    - Barrier films
    - Liquid skin protectants

Cosmetics

Comprise majority of skin cleansers, moisturizers and some moisture barriers

- *Cleanse*
- *Beautify*
- *Improve attractiveness*
- *Alter appearance*

- No active ingredient
- Ingredients listed in order of amount
- Label should include instructions for use

Bedside chemistry (compounding)

- Why do people do it?
  - Desperation
  - Belief in “special recipe”
- Lots of issues
  - Stability
  - Safety (espec. with jars)
  - Scope of practice

Clinician Perspective

Skin Care Products-3 perspectives

Formulator perspective

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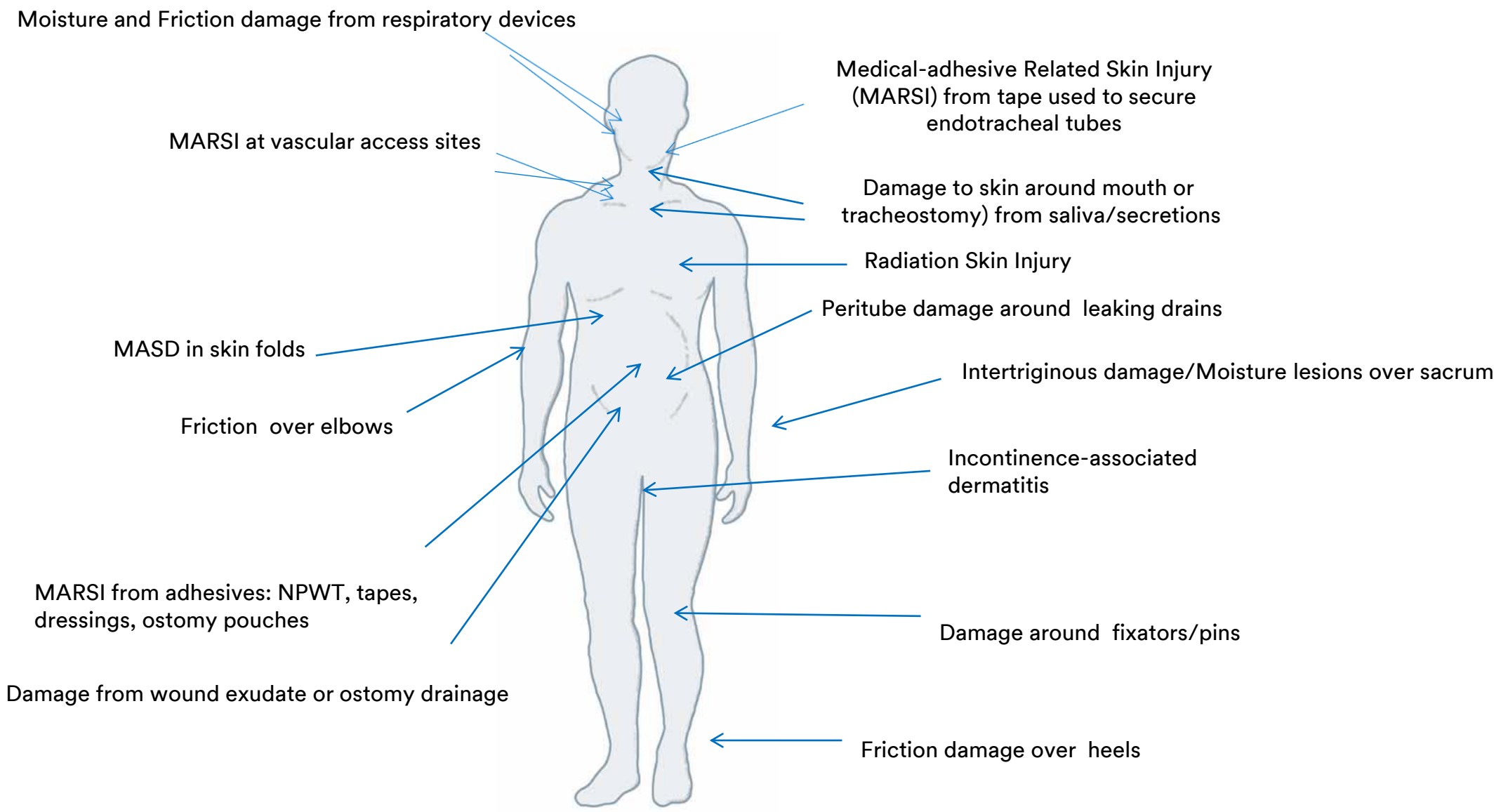
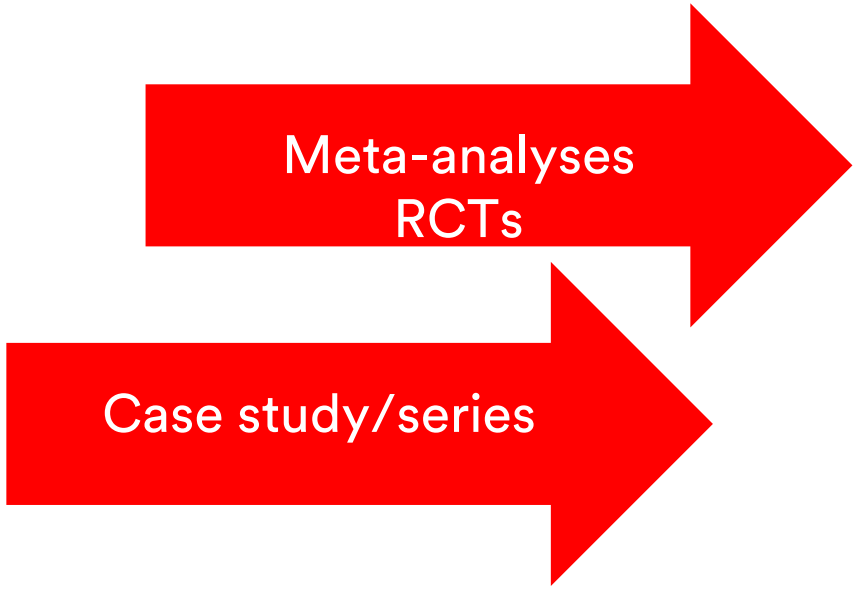
Clinical Concerns and Related Objective



Product literature and supporting tools

The bigger the claim, the more data you should expect



Research challenges!

Safety Information

1) Provided via labeling (OTC drug, cosmetics or via "product insert"

- Description
- Indications/intended use
- Ingredients
- *Contraindications/ Precautions/warnings*
- Directions for use

2) Safety testing

What about SDSs?

Formerly Material Safety Data Sheets (MSDS)

- Intended for industrial/transportation safety
- Vary by manufacturer
- *Do not consider amount of ingredient*
- Thousands of ingredients *accepted as safe* for incorporation into products
  - International cosmetic ingredient dictionary and handbook (Personal Care Products Council)

But!

"Any topically applied chemical substance has the potential to induce an irritant or hypersensitization reaction in any individual at some time."

Shelanski, Phillips and Potts. Intl J Dermatol 1996 35(2); 138.

Incontinence-associated Dermatitis

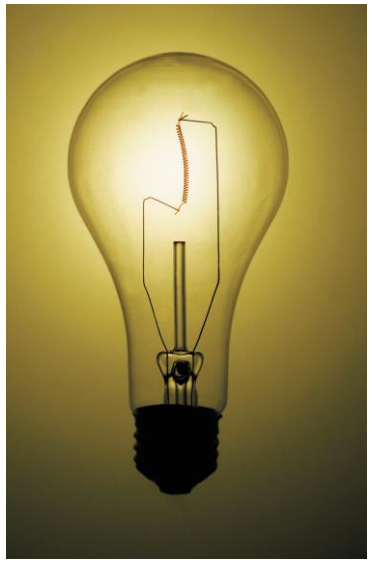
Prevention and treatment of IAD: what does the evidence tell us?

- 2016 Cochrane review
  - 2 trials comparing no-rinse cleansers with soap and water
  - 8 trials comparing various moisturizers, moisturizers/skin protectants, skin protectants
- Conclusion:
  - “Little evidence of very low to moderate quality, exists on the interventions for preventing and treating IAD in adults”.
  - Application of products “seems to be more effective” than no products
  - Performance of products depends on formulation and usage

Beeckman D et al Cochrane Database of Systematic Reviews. 2016. Issue 11. Art. No: CD011627.

Why do we need to think differently about IAD?

Current incidence data (30[1] - 42%[2]) suggests what we are doing now is not working for many patients!



1 VanDamme N et al. Intl Wound J. 2016; 801-809
2 Campbell J et al. Intl Wound J. 2014; 1-1

And! The IAD-PI (PU) relationship

Patients with IAD are at a significantly higher risk of superficial sacral pressure ulcers[1]

44%

Superficial sacral pressure ulcers developed in 44.4% of patients who had IAD versus 12.2% of patients who did not have IAD (n=610)[1]

2.99
odds ratio

The risk of developing pressure ulcers has been found to increase as the severity score for IAD increases[2]

1.99
odds ratio

The likelihood of developing a pressure ulcer increases by a ratio of **1.99 for every 1-point increase in IAD severity score** (odds ratio = 1.99, 95% CI = 1.237-2.917)[2]

[1]Demarre, J Adv Nurs 2014;Aug 19; [2]Park KH, J WOCN 2014;41(5):424-29;

Does cleansing make sense?

Goal: remove irritants, excess moisture

- Gentle, pH balanced, no-rinse liquid skin cleanser and soft cloth or
- Pre-moistened bathing/cleansing wipe
  - *Typically solutions or lotions*
    - *Contain surfactants*

Does protection make sense?

Absolutely! Need to repel irritants, moisture and *ideally friction too!*

- Traditional products
  - Creams (petrolatum; zn oxide; Dimethicone)
    - Emulsions of oil in water or water in oil;
  - Ointments (petrolatum, zn oxide, mineral oil)
    - Semi-solids, anhydrous
  - Pastes Semi-solids

When does “cleanse-*moisturize*-protect make sense?

Moisturizers make sense when the *epidermis is intact* and can benefit from moisturization and a protection

“3 in 1”wipes-considerations

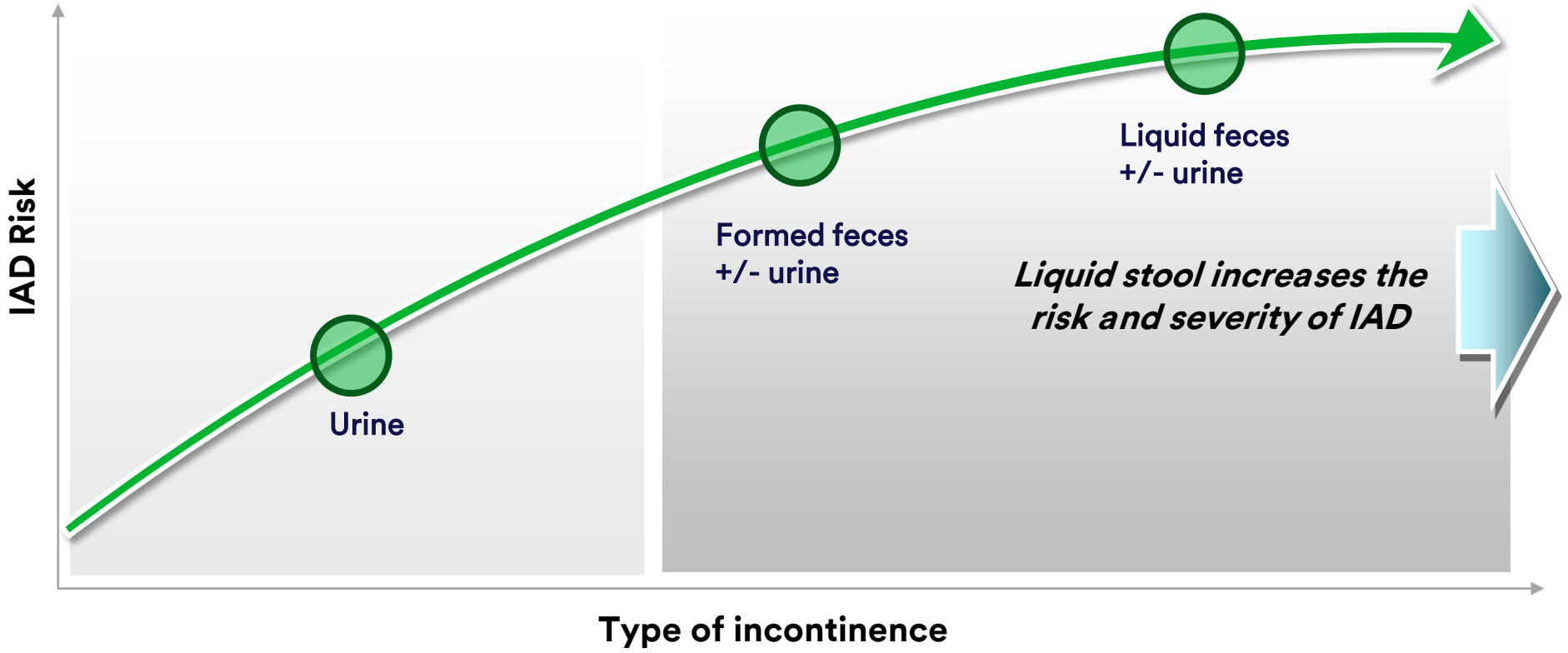
Are they effective?

- dependent on formulation and how much Dimethicone releases from wipe/left behind; ask for barrier data
- moisturizing component is ineffective/unnecessary when epidermis is overhydrated or severely damaged (absent)
- beware of antimicrobial claims
  - No evidence for benefit for using antiseptic/antimicrobial for routine incontinence care
- consider preservative effectiveness if unused product retained
- wipe confusion can be a problem

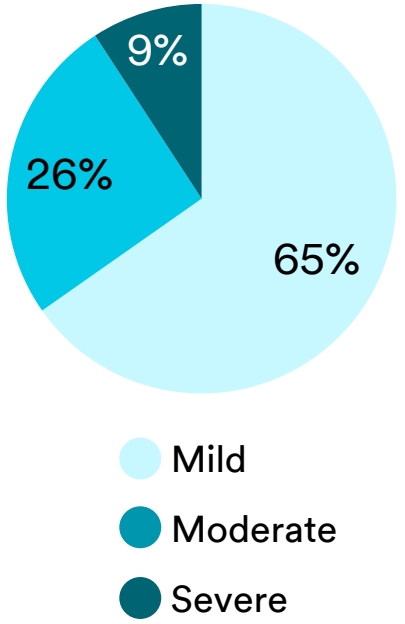
We need to recognize and manage risk!

High-risk population

All patients/residents with incontinence are at risk but those with mixed incontinence are the most vulnerable especially when stools are liquid or diarrhea is present[1]



Severe-to-moderate IAD occurs in ~35% of cases[2]



[1]Beekman et al, Wounds international 2015; [2]Gray M and Baros S. Presented at the 23rd Annual Meeting of the Wound Healing Society; SAWC Spring/WHS Joint Meeting, Denver, CO May 1-5, 2013.

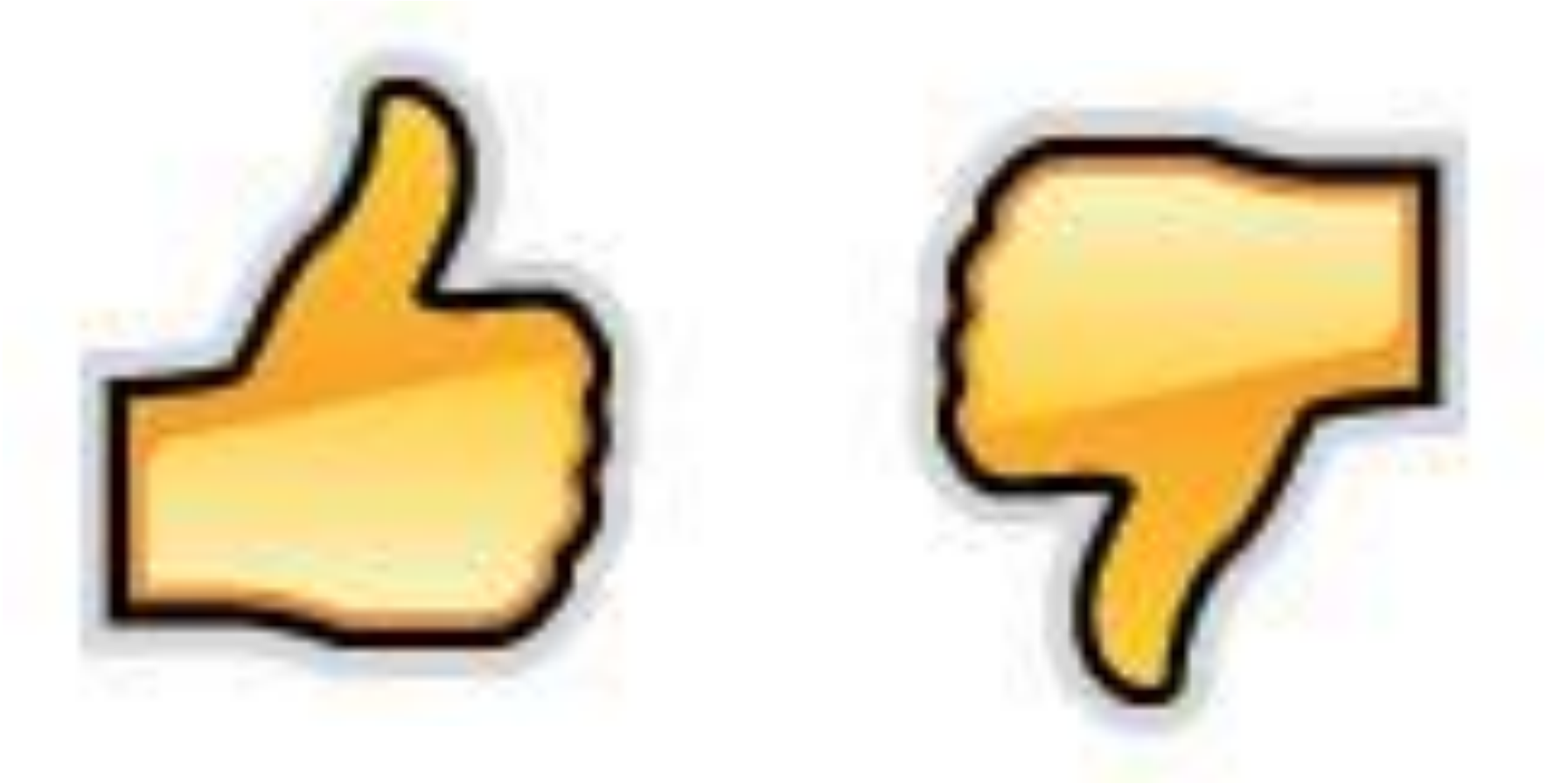
Desirable product characteristics

Consider breathability and friction

General characteristics of ideal product for prevention and management
Clinically proven to prevent and/or treat IAD
Close to skin pH
Low irritant potential/hypoallergenic
Does not sting on application
Transparent or can be easily removed for skin inspection
Removal/cleansing considers caregiver time and patient comfort
Does not increase skin damage
Does not interfere with the absorption or function of incontinence management products
Compatible with other products used (e.g. adhesive dressings)
Acceptable to patients, clinicians and caregivers
Minimizes number of products, resources and time required to complete skin care regimen
Cost-effective

Beekman D et al. Proceedings of the Global IAD Expert Panel. Incontinence-associated dermatitis: moving prevention forward. Wounds International 2015.

How do moisture barriers measure up?



A simple test you can do

1. Fill clear plastic beaker with warm water
2. Apply product(s) to hand(s)
3. Immerse hand(s) and gently move fingers
4. Water-soluble products will make water cloudy

So, what do nurses do?

Work-arounds of course

- Too occlusive?
  - Use less than optimal amount
  - Don’t use in folds
- Wont adhere to wet surfaces?
  - Powder underlying surface or “crust”
- Adheres skin to skin or underpads?
  - Coat surface with petrolatum
- Too difficult to get off?
  - “Only remove soiled layer”

Another consideration!

- Are *we* spreading pathogens during incontinence care?
  - *Multi-use* products handled by *multiple* caregivers and left at bedside
    - No guidelines for:
      - large volume F.I. episode clean up
      - management (cleaning?) of incontinence skin care supplies

Nurse do not change gloves as often as they should

Other options for skin protection

- Liquid moisture barriers
  - Barrier films
    - Copolymers or terpolymer
    - Do not attach to wet surface
  - Specialty skin protectants
    - Offer wet adhesion

Looking for thin, flexible, breathable coatings that are not water soluble
(beware of product info: “easily removed with soap and water”)
Should be non-irritating, non-cytotoxic
Can minimize friction
Compatible with silicone dressings

Some final thoughts

What Does It Take to Create a Successful Skin Damage Prevention Program?

Senior management is engaged and committed to the program

- Invests in FTEs and equipment
  - Supports allocated time for program leader and staff
  - Recognizes importance of and requires specialized education/certification
- Requires:
  - specific targets and outcome metrics
  - relevant root cause analysis (RCA) for specified HA skin injuries
  - ongoing communication of facility-wide goals, metrics and outcomes
- Policy and culture provides for effective communication of skin injury risk and preventive interventions between caregivers, disciplines, departments, and care settings-no blame!

Successful Skin Damage Prevention Program cont.

Clinical champion shows strong qualifications and demonstrates leadership of program

- Education/clinical background demonstrate expertise in prevention and management of skin and wound conditions

Program has a designated, engaged, interdisciplinary team

- Includes representation from relevant disciplines, departments, and care settings

Front line staff is empowered and accountable for decision making

- Unit based skin teams
- Resourced for and participate in relevant meetings/RCA
- Evaluated on achievement of skin safety goals

Successful Skin Damage Prevention Program cont.

Specific, understandable, accessible written prevention protocols

Program delivers creative and effective *staff and patient* education

Product formulary is comprehensive, staff accessible, and user-friendly with a process for ongoing review

Creating a formulary: evaluating and selecting skin care products

Develop a relationship with your business buyer/HVAP

- "What's on the shelves ? Do you know?

Formulary of skin care products should be tied to protocols or care pathway

- If you have multiple products in a single category, ask why?

Proof of claims-what is the data?

- IFU/labeling, safety data

Conduct structured evaluations

- Defined objectives, number of patients/staff-Keep it manageable
- Start-stop dates
- Data collection tool

New thinking

A comprehensive and innovative approach to skin safety is essential to deal with increasing patient age, acuity, and complexity; increasing fiscal challenges; and the fundamental expectation that care is safe.

*Campbell J, Coyer F, and Osborne SR. The Skin Safety Model: Reconceptualizing Skin Vulnerability in Older Patients. *J of Nurs Scholarship*. 2016; 48 (1): 14-22.

The Skin Safety Model: Reconceptualizing Skin Vulnerability in Older Patients[1]

Multiple types of HA skin injury share root causal/contributing factors

- ***Potential Contributing Factors***: patient factors, situational stressors, system factors, process **plus**
- ***Exacerbating Elements***: Skin irritants, friction, pressure, shear

Should approach prevention holistically vs. “silo’d” care and thinking

Could and should drive product selection

Products should be versatile and able to “multitask”

Campbell J The Skin Safety Model: Reconceptualizing Skin Vulnerability in Older Patients[1] Journal of Nursing Scholarship Volume 48, Issue 1, pages 14-22, 18 NOV 2015 DOI: 10.1111/jnu.12176
http://onlinelibrary.wiley.com/doi/10.1111/jnu.12176/full#jnu12176-fig-0001

Thank you!

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