



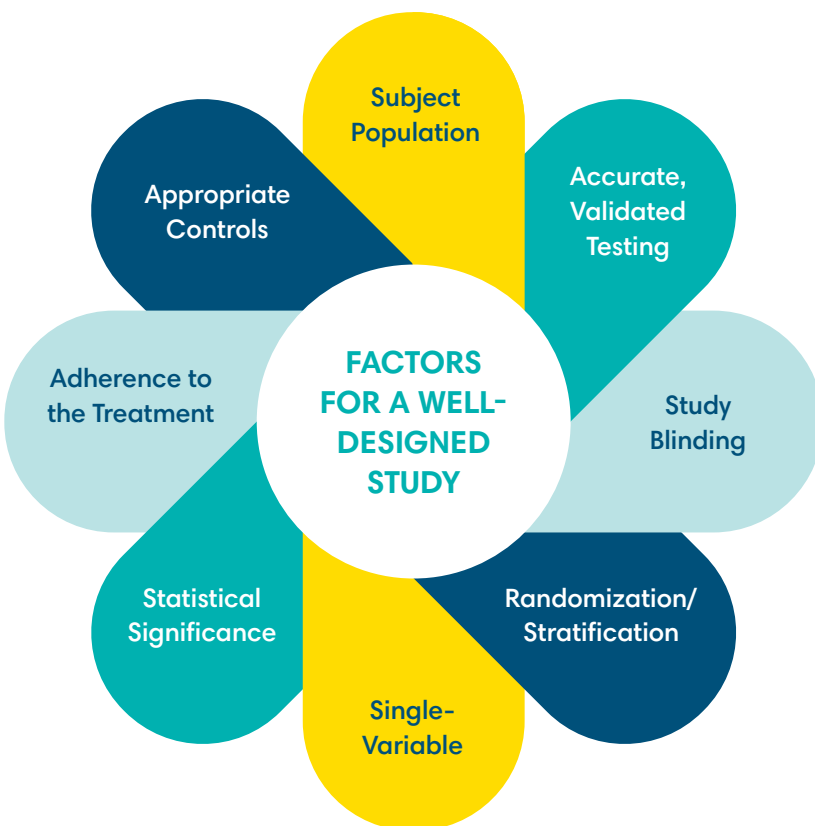
# USING EVIDENCE-BASED PRACTICES TO SELECT OPTIMIZED PRODUCTS AND PROTOCOLS

## Not All Research Studies Are The Same

### What is Evidence-Based Practice?

Evidence-based practice is the process by which healthcare professionals review and assess the most current, high-quality research to improve clinical practice and patient outcomes. A key source of scientific data comes from clinical trials and how those studies are designed, conducted and analyzed, and are critical to interpreting the data to guide patient care.

Ensuring that research findings are reliable and credible starts with a well-designed study.



- **Subject Population** — Ensure subjects are relevant to what is being measured
- **Accurate, Validated Testing** — Subjective or objective assessments should be clinically relevant, validated and sensitive to the effects of the intervention
- **Study Blinding** — Masking the treatments ensures patients, investigators and assessors are unaware of treatments to avoid bias for or against the intervention
- **Randomization/Stratification** — Randomization ensures subjects have an equal chance of being on one of the treatments, and stratification balances the group of subjects based on possible variables
- **Single-Variable** — Eliminating activities or interventions that could affect the study outcome assures the treatment or therapy being investigated was actually responsible for the response
- **Statistical Significance** — Analyses help ensure product differences did not occur by chance and are reproducible (e.g.,  $p < 0.05$ )
- **Adherence to the Treatment** — Poor compliance of study instructions can undermine any conclusions of the treatment effect
- **Appropriate Controls** — A negative control (placebo) or positive control (proven therapy) establishes the sensitivity and magnitude of any observed treatment effect



- We pledge to protect every baby's skin from day one.
- We are committed to working with clinicians, scientists and healthcare professionals to further advocate for skin health science.
- We vow to deliver innovation led by evidence-based practices while driving towards equitable healthcare for the special needs of neonates.

Because every baby deserves a healthy, happy start from womb to world.

# Evaluating WaterWipes® Studies

WaterWipes® product claims are not the result of credible and reliable clinical studies.

**CLAIM:** WaterWipes® reduces incidence and shortens duration of diaper dermatitis in premature babies.

**STUDY TYPE:** Quality Improvement (QI)



- Not single-variable — Hospital-implemented AWHONN skin care recommendations including prophylactic topical creams use. No evidence of a wipe effect.
- Lack of assessor blinding can introduce bias
- No control group to isolate impact (if any) of wipe

**CLAIM:** Babies cleansed with WaterWipes® have a lower incidence and shorter duration of diaper rash.

**STUDY TYPE:** Self-Reported Survey

- High non-compliance to assigned wipe (41%), high topical cream use (67%), imbalance in antibiotic use
- Used unvalidated cartoon of diapered area
- Wipes user was not blinded

## Comparing Published Studies

				
STUDY DESIGN ELEMENTS		Gustin et. al., 2021 <sup>1</sup>	Rogers et. al., 2021 <sup>2</sup>	Price et. al., 2021 <sup>3</sup>
DESIGN		Clinical Research Study	Quality Improvement — NICU	At-Home Survey
BRANDS USED		Pampers Regimen, Huggies Regimen, WaterWipes/Honest	Anti-Rash Skin Care Protocol + WaterWipes	WaterWipes, two other wipes
DESIGN & POPULATION	Subject Population Relevant?	✓	✓	✓
	Double-blinded?	✓	✗	✗
	Randomized Product(s)?	✓	✗	✓
METHOD & CONTROLS	Used validated scales to assess skin?	✓	✗	✗
	Was a trained grader used?	✓	✗	✗ (self-reported)
	Controlled for confounding factors? (e.g., topical cream, antibiotics)	✓	✗ (creams used prophylactically)	✗ (67% used skin treatments)
	Controlled use of product? (e.g., number of wipes used)	✓	✗	✗
	High compliance	✓	N/A	✗ (41% noncompliance)
ANALYSIS & CONCLUSION	Results	“There was a 50% reduction in the number of more severe erythema events (scores ≥2) at any diaper region while infants followed Regimen A vs. Regimen B (Figure 3B, P < 0.05).”	“[An] additional study is needed to validate whether the diaper wipes with grapefruit seed extract have proven a benefit and justify the cost burden.”	“However, it is not possible to determine whether it was the exclusion or inclusion of a specific ingredient that causes this difference [incidence of rash].”

<sup>1</sup>Gustin J, Bohman L, Ogle J, et al. Improving newborn skin health: Effects of diaper care regimens on skin pH and erythema. *Pediatr Dermatol.* 2021;00:1–7. <sup>2</sup>Rogers, S., et al. A Quality Improvement Approach to Perineal Skin Care: Using Standardized Guidelines and Novel Diaper Wipes to Reduce Diaper Dermatitis in NICU Infants. *Adv Neonatal Care.* 2021;21(3):189–197. <sup>3</sup>Price, AD, et al. The BaSICS (Baby Skin Integrity Comparison Survey) study: A prospective experimental study using maternal observations to report the effect of baby wipes on the incidence of irritant diaper dermatitis in infants, from birth to eight weeks of age. *Pediatrics & Neonatology.* 2021;62(2):138–145.



### Partner With Pampers

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