An evidence-based approach to newborn skin cleansing

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Introduction

Skin cleansing is essential for good health, but is especially relevant to infants, whose skin needs special care because of its developing structure, function and composition (Stamatas et al, 2011). Establishing good practice from birth is a foundation for healthy skin throughout life, but approaches to infant skin care are often based on tradition, personal experience and cultural factors (Ness et al, 2013). Family and friends can influence approaches to infant skin care, but parents are also likely to turn to health professionals such as midwives as trusted sources of information and advice (Lavender et al, 2009).

Current UK clinical guidelines recommend bathing newborns in water alone, using a mild, non-perfumed soap where required (NICE 2006). However, water has been shown to irritate and dry the skin (Tsai and Maibach 1999), and some health professionals and women are sceptical about its effectiveness as a cleanser when it is used alone (Lavender et al, 2009). Soap cleanses the skin, but it has been shown to impair the integrity of the skin barrier and its use has been cited as one of the most important factors in rising rates of atopic dermatitis in infants (Cork et al, 2009).

The current inconsistencies between evidence and national guidelines on newborn skin care have resulted in inconsistencies in professional practice and advice to mothers (Lavender et al, 2009; Walker et al, 2005). The result has been confusion among parents, who may choose skin care products for their baby on the basis of trial and error rather than evidence (Lavender et al, 2009).

It is important for health professionals such as midwives to be aware of both the evidence base on newborn cleansing and the need to provide women with an honest and clear picture where possible, allowing them to make their own decisions about their choices (Bedwell and Lavender, 2012). This supplement examines the latest research on the skin barrier in infants, and discusses recently published evidence and clinical studies researching best practice in infant skincare. The latest data provides evidence that the specially formulated, mild and gentle, pH-neutral cleansers investigated in these studies are safe and effective when used to cleanse newborn skin (Lavender et al 2012, Lavender et al, 2013).
bathing procedures and choice of includes detailed advice on routine comprehensive, practical guideline skin barrier (AWHONN 2013). This and promoting an intact and healthy evidence-based recommendations on practice guideline, AWHONN provides the third, 2013 edition of its clinical evidence on neonatal skin care. In Health, Obstetric and Neonatal Nurses (Blume-Peytavi et al, 2009).

CONTINUING DEBATE

In addition, other experts have come to further conclusions about optimum infant skin care. In 2009, a European Round Table panel of expert dermatologists and paediatricians published evidence-based, consensus advice on routine infant cleansing during the first year of life. After a comprehensive review of the evidence, the group recommended using mild, thoroughly tested liquid cleansers rather than water alone for newborn cleansing. They advised against using water alone or soap and water, citing evidence that these approaches are associated with adverse effects on infants’ skin, including dryness, irritation and atopic dermatitis (Blume-Peytavi et al, 2009).

The US Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) has also reviewed evolving evidence on neonatal skin care. In the third, 2013 edition of its clinical practice guideline, AWHONN provides evidence-based recommendations on protecting the newborn’s delicate skin and promoting an intact and healthy skin barrier (AWHONN 2013). This comprehensive, practical guideline includes detailed advice on routine bathing procedures and choice of cleanser, recommending use of skin cleansers that have minimal impact on a baby’s skin surface pH. The guideline also includes practical advice that midwives may find helpful when parents seek advice on choosing a cleanser for their baby’s skin.

Other authors have considered the evidence and joined the debate on newborn cleansing. A review of studies published between 2000 and 2010 reported no harmful effects on skin from either water or wash products during the first year of life (Crozier and Macdonald 2010). More recently, a similar analysis found that daily bathing with specially formulated products has no negative effects on normal skin or skin showing erythema, indurations or dryness (Blume-Peytavi et al, 2012). A second group of authors subsequently concluded that the safest cleansing products for full-term newborns are mild, neutral-pH cleansers without added dyes or fragrances (Ness et al, 2013).

Given the current lack of expert consensus and evidence-based national guidance for healthcare professionals, it is not surprising that there is ‘informed uncertainty’ among midwives, who draw on tradition, experience and opinion to inform their clinical practice (Lavender et al, 2009). The result is confusion among mothers, who may not reveal that they disregard professional advice and use baby skin care products (Lavender, et al 2009). This may be especially the case for women who lack confidence in the effectiveness of water alone when faced with the practical realities of dealing with a soiled nappy (Furber et al, 2012).

WHY ARE RANDOMISED CONTROLLED TRIALS IMPORTANT?

Randomised controlled trials are regarded as the gold-standard method of evaluating the effectiveness of a treatment or other intervention. These trials have several important features:

• Random allocation of trial participants to intervention and control groups to eliminate any bias and ensure that the treatment group is as similar as possible to the control group

• Participants and investigators should remain unaware of which treatment was given (‘blinded’) until the study is completed, although all double-blind studies are not always feasible or appropriate

• All intervention groups are treated identically except for the experimental treatment

• Participants are normally analysed within the group to which they were allocated irrespective of whether they experienced the intended intervention (called intention-to-treat analysis)

• The analysis of the trial results focuses on estimating the size of any difference between intervention groups according to predefined outcomes

Based on: Akobeng 2005

CHOOSING CLEANSERS FOR NEWBORN SKIN (AWHONN 2013)

• The role of cleansers is to emulsify oil, dirt and micro-organisms on the skin surface so that they can easily be removed by water

• Ideally, cleansers should not cause skin irritation, disrupt the normal pH of the skin surface, or cause stinging or irritation of the eyes

• Select mild lipid cleansers or cleansing bars that have a neutral or mildly acidic pH (pH 5.5-7.0) or those that have been shown to have minimal impact on the baby’s skin surface pH

• Choose cleansers with preservatives that have demonstrated safety and tolerability for newborns. Preservatives are usually needed to prevent the overgrowth of micro-organisms that may occur with normal use, but they may result in skin irritation or contact dermatitis
Understanding newborn skin

The largest organ in the body, the skin consists of three main layers: the subcutis or inner-most fatty layer, the dermis and the epidermis or outer layer. The epidermis is continually regenerated as new skin cells or keratinocytes form in the stratum germinativum or basal layer (McGrath et al, 2008). As the keratinocytes move towards the surface of the skin, they become flattened and gradually die (McGrath et al, 2008). The dead cells are called corneocytes and make up the stratum corneum. This cornified or ‘horny’ layer on the surface of the skin is constantly shed and replenished, and acts as a barrier, preventing penetration by infectious agents, irritants and allergens, while regulating loss of water and nutrients from the body (Stamatas et al, 2011). The thinnest skin on a newborn is on the face and as a result this is where skin shedding (desquamation), and maintenance of the permeability barrier and the integrity of the stratum corneum (Cork et al, 2006). Skin pH is also important because of its role in promoting the skin’s microbiome, the diverse harmless or beneficial microorganisms that colonise the human skin surface (Grice and Segre, 2011). The microbiome is gradually acquired from birth, and is thought to be critical for the effectiveness of the skin’s immune response against disease-causing bacteria, and possibly for the development of a healthy skin barrier and systemic immune system (Capone et al, 2010).

Infant skin differs from adult skin in its structure, function and composition, and needs appropriate, evidence-based care to maintain the integrity of the skin barrier (Telofski et al, 2012). At the same time, although skin is more hydrated in infants than in newborns, it has greater TEWL and a lower concentration of natural moisturising factors, surface lipids and sebum compared to the skin of newborns or adults (Stamatas et al 2011; Telofski et al, 2012). This means that a skin cleansing regimen for newborns must be able to remove unwanted material from the skin without inducing dryness, irritation, itch and barrier damage (Stamatas et al, 2012).

The pH of any newborn cleansing regimen is another important consideration because of changes in the skin acidity or ‘acid mantle’ of newborns (Stamatas et al, 2011). At birth, the skin surface in full-term newborns has a neutral pH of 6.34-7.5. This falls in the first two weeks of life to become more acidic at pH 5.0, similar to the skin surface pH of 4.0-6.7 found in adults (Telofski et al, 2012). The acid mantle has multiple effects on the skin, including a role innormal skin shedding (desquamation), and

More high-quality evidence, together with greater recognition of latest clinical data in infant skin care, is essential to resolve uncertainty among midwives and confusion among parents. Evidence from well-conducted randomised controlled trials has recently become available, but any approach to newborn skin care must also depend on an understanding of the structure and physiology of newborn skin.

FAST FACTS

- There is a lack of expert consensus concerning newborn cleansing
- This lack of consensus has led to uncertainty among midwives and confusion among parents
- Randomised controlled trials provide the best evidence for the effectiveness and safety of a treatment
- Recently published randomised controlled trials may influence updated NICE guidelines on routine newborn cleansing
time, cleansing must effectively remove unwanted substances from the skin to maintain good health and hygiene in infants (Telofski et al, 2012).

**FAST FACTS (TELOFSKI ET AL, 2012)**

- Full-term babies are born with a functioning skin barrier that continues to mature during the first year of life
- Infant skin differs from adult skin in its structure, composition and functions
- In newborns, the skin barrier is thinner than in adults, is more acidic and more easily loses water
- Infant skin needs special care to ensure that the health of the skin barrier is maintained

**The importance of effective skin cleansing**

In infants, effective cleansing is essential to remove substances such as milk, food, nasal secretions and saliva that may potentially cause irritation if left on the skin (Stamatas et al, 2011). The infant’s overall health also depends on keeping the skin free of harmful bacteria in urine and faeces that cause irritation and may lead to infection if transferred to the baby’s mouth (Stamatas et al, 2011; Telofski et al 2012).

The techniques and agents used to cleanse the skin have a role in maintaining and restoring the skin barrier (Fowler et al, 2013). Cleansing may, however, have negative effects on the stratum corneum depending on the methods chosen (Fowler et al, 2013).

**JUST SOAP AND WATER?**

Soap is an effective cleanser, but it also causes skin dryness and irritation (Telofski et al, 2012). These negative effects are likely to be due to the effects of soap on skin lipids (fats) and pH, which in turn impair the integrity of the skin barrier (Telofski et al, 2012). The lipids surrounding the cells of the stratum corneum play an essential role in preventing loss of water and essential blood minerals (electrolytes) through the skin barrier (Feingold 2007). Although any method of washing removes lipids from the outer layers of the skin, loss of lipids after washing with soap is greater than after using either water or mild, synthetic detergents (‘syndets’) (Blume-Peytavi et al, 2012). The lipid content of the skin is gradually restored over time, but it is not recovered two hours after washing with soap and such changes in the lipid composition of the stratum corneum may reduce skin barrier function (Blume-Peytavi et al, 2012).

Soaps are typically alkaline, and have been shown to increase the pH of infant skin and disturb the acid mantel for up to 30 minutes (Blume-Peytavi et al, 2012). Infant skin takes longer than adult skin to restore the acid mantle (Blume-Peytavi et al, 2012) and sustained pH increases, such as those caused by soap-based cleansers, have been shown to adversely affect barrier function in normal skin (Ali and Yosipovitch, 2013). There is a correlation between high TEWL and damage to the surface structure of the stratum corneum seen after washing with alkaline soap (Ananthapadmanabhan et al, 2004). In contrast, ‘syndets’ that are specifically formulated for use in infants minimally alter skin pH and deplete skin lipids, are associated with a lower rate of TEWL and are more able to maintain the barrier function of the skin (Stamatas et al, 2011).

Although water alone is recommended for cleansing newborn skin, it is not an effective cleanser because it cannot dissolve faeces and other greasy substances (Gelmetti 2001). Since these substances are fat-soluble, they are held on the skin by surface tension and can only be removed by surfactants (‘surface-acting’ agents) that break them down into fine droplets that can then be easily rinsed away with water (Gelmetti 2001).

Water is also a skin irritant, causing itching and dryness (Tsai and Maibach 1999). It is rapidly absorbed into the skin, especially through the still-developing infant stratum corneum. This hydrates the skin, but the effect is only temporary since the added water quickly evaporates through TEWL, leaving the skin dryer than before (Ewence et al, 2011). When it penetrates the skin, water may also increase the spaces between the corneocytes of the stratum corneum, impairing the integrity of the skin barrier and allowing pathogens and allergens through the skin (Ewence et al, 2011).

It is important to remember that tap water does not just consist of H2O—i.e. two hydrogen atoms for every one oxygen atom. It also contains dissolved minerals such as calcium or magnesium that determine whether the water is hard or soft (Ewence et al, 2011). This in turn influences the pH of water—i.e. whether
it is acid, alkaline or neutral—but both hard and soft tap water is relatively more alkaline than the acid surface pH of the skin (Ewence et al, 2011, Telofski et al 2012). Rinsing with even slightly alkaline tap water can raise skin pH for several hours, reducing the function of the acid mantel and promoting breakdown of the skin barrier (Ewence et al, 2011). Since the skin is the body’s first line of defence against harmful irritants and allergens, impairment of the delicate newborn skin barrier has been identified as one of the most important because of their effects on the stratum corneum (Cork et al, 2009).

The stratum corneum is like a brick wall in which the bricks (the corneocytes) are surrounded by mortar (the lipid lamellae) and are supported by iron rods (proteins called corneodesmosomes). When an infant is genetically predisposed to AD, inherited predisposition and breakdown of the skin barrier due to adverse environmental effects (Cork et al, 2006). Several factors are associated with the development of AD, but increasing use of soap and detergents, especially with hard water, has been cited as one of the most important because of their effects on the stratum corneum (Cork et al, 2009).

The stratum corneum is like a brick wall in which the supportive iron rods have rusted, leaving it more vulnerable to the effects of the external environment. When the stratum corneum is impaired—for example, through the effects of soap on skin lipids and pH—the skin barrier can no longer prevent allergens and infection from reaching the dermis, leading to the inflammation characteristic of AD (Cork et al, 2006).

Conversely, preservation or restoration of a functional skin barrier may reduce the risk or possibly the severity of AD (Stamatas et al, 2011). As a result, appropriate care of newborn skin may have significant long-term implications for health (Bedwell and Lavender 2012) and this highlights the need for suitable skin care regimens (Lavender et al, 2013).
Until recently, there were no robust clinical studies investigating the routine cleansing of newborn skin. Small-scale studies have in the past indicated that specially formulated products are as well tolerated as water alone when used to cleanse newborns. It has, however, been challenging to draw overall conclusions because of differences in the studies’ participants, methods and outcome measures.

A trial including 180 healthy infants (aged from one day to one year) found no significant differences between a wash product and water alone in outcomes such as swelling, redness and irritation, dryness or scaling (Dizon et al, 2010). A second study randomised 64 healthy, full-term newborns (aged less than 48 hours) to four groups: twice-weekly bathing with wash gel, or cream, or wash gel and cream, or water alone. At the end of eight weeks, there was significantly less TEWL at all studied body sites in babies randomised to wash gel and cream or cream alone compared to those assigned to water alone (Garcia Bartels, et al 2010).

Skin pH was significantly lower in the wash gel group than in babies randomised to water, an effect that persisted until the eighth week of life (Garcia Bartels et al, 2010). A higher skin surface pH has been related to higher rates of bacterial proliferation and greater activity of proteolytic enzymes that are detrimental to skin barrier function (Blume-Peytavi et al, 2012). This has potentially important implications for future skin health, since studies have found that skin pH is significantly raised in patients with AD compared to that of controls with healthy skin. This higher skin pH is seen even in unaffected skin of patients with AD, and can be expected to delay recovery and facilitate breakdown of the skin barrier (Cork et al, 2009).

**LATEST EVIDENCE**

In 2009 a European Round Table consensus on newborn cleansing called for further clinical research to investigate the potential benefits of appropriate cleansers (Blume-Peytavi et al, 2009). This research is now available in two large, investigator-led, randomised controlled trials that confirm the tolerability of some specially formulated and robustly tested, mild and gentle cleansers (Lavender et al, 2012; Lavender et al, 2013).

Both trials were conducted by a multidisciplinary team at Central Manchester NHS Foundation Trust. These studies compared the safety of JOHNSON’S® Baby Top-to-Toe® Bath and JOHNSON’S® Baby Extra Sensitive Wipes on healthy newborn skin, against water alone. The two trials were funded by an educational grant from Johnson & Johnson, who agreed that the researchers would publish the results of their studies regardless of outcomes. Both trials were independently designed and led by the researchers; this included the trial design, data analysis, interpretation of results and production of the manuscript.

Given the lack of previous large, robust randomised controlled trials, the design of both studies was based on the findings of a pilot randomised controlled trial that included 100 healthy newborns (Lavender et al, 2011). The results of this study were used to determine the number of participants needed to obtain statistically significant results in the larger trials and the validity of TEWL as an outcome in newborns.

Babies and mothers participating in both trials were recruited within 48 hours of birth. To avoid biasing the results of either study, the babies were randomly assigned to their treatment. This was done through either computer-generated telephone randomisation (Lavender et al, 2012) or consecutively numbered, sealed, opaque envelopes held by the research manager at the study hospital (Lavender et al, 2013).

In both randomised trials, the study groups were similar in terms of maternal characteristics, the babies’ gender, feeding method and birth weight, and the method of birth.

The aim of both studies was to demonstrate that the products under investigation had an equivalent effect—i.e. were ‘non-inferior’—to usual care with water and cotton wool. Outcomes of the two studies were assessed by research midwives who were unaware of the babies’ allocated treatment. The mothers also completed questionnaires and diaries. It was not possible to ‘blind’ the mothers to their babies’ allocation because of obvious differences between the treatments under investigation.

**WATER VERSUS WASH PRODUCT**

(Lavender et al, 2013)

The first trial included 307 newborns randomised to either bathing with a wash product or water alone. The wash product was non-inferior to water alone on the primary study outcome of TEWL at 14 days. There were also no significant differences on secondary outcomes, including changes in stratum corneum hydration, skin surface pH, and clinically observed dryness, redness or excoriation.

**FAST FACTS (LAVENDER ET AL., 2012; LAVENDER ET AL., 2013)**

- New evidence is now available from the two largest-ever randomised controlled trials on skin cleansing in healthy newborns
- A trial including 307 babies shows that a certain mild and gentle, pH-neutral, specifically formulated and robustly tested cleanser can be used safely on newborn skin
- A trial in 280 babies shows that a certain wipe impregnated with pH-neutral lotion is appropriately designed for use on infant skin and has been clinically tested and proven safe even for newborns
- The results of these two clinical trials cannot be extrapolated to demonstrate the efficacy and safety of other infant cleansing products

The mothers’ overall satisfaction was similar in the two groups, but there were some difference in their perceptions of their assigned treatments. Mothers using the wash product were significantly more likely than those using water to report that their newborn smelled good (p<0.001). Mothers in this group who continued using the wash product were also significantly more likely to maintain the same bathing regimen after the end of the study (p=0.010 versus water alone).

**WATER VERSUS BABY WIPES**

(Lavender et al, 2012)

For the second study, researchers recruited 280 newborns, who were randomly assigned to have their nappy area cleansed with a fragrance-free baby wipe or cotton wool and water. The wipes were equivalent to water and...
cotton wool on the primary outcome of change in skin hydration from within 48 hours to four weeks after birth. There were also no significant differences on the secondary clinical outcomes of changes in TEWL, skin surface pH, erythema, and the presence of microbial skin contaminants or irritants at four weeks. The assessing midwives reported similar rates of nappy dermatitis at four weeks in the two treatment groups. However, mothers in the wipes group were significantly less likely to report nappy dermatitis than those in the water group (p = 0.025). According to the researchers, although more credence might initially be given to the midwives' assessments, it should be seen as the experts in their babies' skin in this study. This was because the mothers assessed their babies' skin every day, whereas the midwives examined the babies twice during the study at intervals of four weeks.

**EVIDENCE INTO PRACTICE**

The findings of these two largest-ever randomised trials to investigate cleansing practices in newborns provide important evidence to support midwives when asked for advice on newborn cleansing. The results should also be reassuring to parents, but their results cannot be generalised beyond the products tested. Since the publication of the latest NICE guideline in 2006, expert debate and research into effective infant cleansing has progressed. Achieving the goal of a truly evidence-based approach to newborn skin cleansing depends on greater recognition of the latest clinical data and further high-quality randomised controlled trials to support professional advice and help to promote informed choice for parents.

When caring for newborn skin, it is essential to balance the need for effective cleansing with the preservation of the skin barrier. NICE guidance is a benchmark for advising healthcare professionals on best practice, yet in the case of infant skincare the current guideline is informed by anecdotal evidence and is now outdated due to recent evidence provided by the clinical trials discussed. Randomised controlled trials are essential to provide high-level evidence to support midwives when parents seek advice about cleansing their newborn. The two recently published studies discussed in this supplement are the largest randomised controlled trials to date to be assessing practices in healthy newborns—specifically the role of a wash product and wipes specifically formulated for newborn cleansing. Since randomised controlled trials are widely accepted as the highest level of evidence, the results of these studies may influence future recommendations from guideline developers such as NICE. Such guidelines on newborn skin care should also take into account research on the adverse effects of soap on the development of the skin barrier, and draw on the results of randomised controlled trials to provide specific recommendations on the choice of specialty formulated, pH-balanced, soap-free products.

Good practice guidelines are needed to enable midwives to provide guidance and support to parents, who will ultimately choose on how best to care for their baby's skin based on their personal preferences and beliefs (Steen and Macdonald 2008). The latest AWHONN guidelines provide helpful advice for midwives to pass on to parents who choose to use baby cleaners rather than water alone to care for their baby's skin. The two randomised clinical trials investigating the role of a specially formulated wash product and wipes in the care of newborn skin provide important evidence and some reassurance for both professionals and parents, but their results cannot be generalised beyond the products tested.

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**Conclusions**

When caring for newborn skin, it is essential to balance the need for effective cleansing with the preservation of the skin barrier. NICE guidance is a benchmark for advising healthcare professionals on best practice, yet in the case of infant skincare the current guideline is informed by anecdotal evidence and is now outdated due to recent evidence provided by the clinical trials discussed. Randomised controlled trials are essential to provide high-level evidence to support midwives when parents seek advice about cleansing their newborn. The two recently published studies discussed in this supplement are the largest randomised controlled trials to date to be assessing practices in healthy newborns—specifically the role of a wash product and wipes specifically formulated for newborn cleansing. Since randomised controlled trials are widely accepted as the highest level of evidence, the results of these studies may influence future recommendations from guideline developers such as NICE. Such guidelines on newborn skin care should also take into account research on the adverse effects of soap on the development of the skin barrier, and draw on the results of randomised controlled trials to provide specific recommendations on the choice of specialty formulated, pH-balanced, soap-free products. Good practice guidelines are needed to enable midwives to provide guidance and support to parents, who will ultimately choose on how best to care for their baby's skin based on their personal preferences and beliefs (Steen and Macdonald 2008). The latest AWHONN guidelines provide helpful advice for midwives to pass on to parents who choose to use baby cleaners rather than water alone to care for their baby's skin. The two randomised clinical trials investigating the role of a specially formulated wash product and wipes in the care of newborn skin provide important evidence and some reassurance for both professionals and parents, but their results cannot be generalised beyond the products tested. Since the publication of the latest NICE guideline in 2006, expert debate and research into effective infant cleansing has progressed. Achieving the goal of a truly evidence-based approach to newborn skin cleansing depends on greater recognition of the latest clinical data and further high-quality randomised controlled trials to support professional advice and help to promote informed choice for parents.