# EXPERT OPINION Evidence-Based Consensus Recommendations for Skin Care in Healthy, Full-Term Neonates in India

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Purpose: Neonatal skin care practices guided by personal experience and preferences might be substantially different across different hospital settings. The aim of this consensus recommendation is to provide clinical practice guidance to healthcare practitioners on evidence-based neonatal skin care practices from delivery-to-discharge, in hospital settings.

Patients and Methods: A Scientific Advisory Board meeting on "Evidence-based Neonatal Skin Care Practices and Protocols" was held in December 2020 with an expert panel comprising neonatologists, pediatricians, obstetricians and gynecologists and pediatric dermatologist. Comprehensive literature search was performed up to 23 March 2021 using PubMed and Google Scholar to retrieve relevant evidence.

**Results:** Recommendations were developed on critical aspects of skin care in healthy full-term neonates including cleansing at birth, skin-to-skin care, cord care, diaper area care, initial and routine bathing, cleansers and emollients use, and criteria to choose appropriate skin care products. Recommendations include inclusion of skin assessment in routine neonatal care, first bath timing after cardio-respiratory and thermal stabilization, 6-24 hours after birth; bathing with water alone or adding a mild liquid cleanser could be considered appropriate as it does not impact the developing skin barrier; use of emollients is recommended for neonates with higher risk of development of eczema to maintain and enhance skin barrier function and integrity; and inclusion of skin care advice in neonatal discharge checklist. Importance of rigorous quality control, high-quality clinical trials for assessment of baby products, usage of products that are formulated appropriately for newborns, and full label transparency for baby products were highlighted. The panel identified gaps in literature and discussed the scope for future research.

Conclusion: These recommendations may help to standardize evidence-based skin care for healthy full-term neonates in Indian hospital settings to improve the quality of care that neonates receive in hospital and facilitate improvement in overall neonatal health outcomes.

**Keywords:** baby products, bathing, cleanser, emollient, hospital setting, neonatal skin care practices

# Introduction

The growing trend in institutional deliveries at hospitals or primary health centers, compared to home births in India has extensively improved newborn survival over the past few decades.<sup>1,2</sup> Increased facility births have considerably enhanced the opportunity to deliver essential care to every newborn. Accelerated progress for improved neonatal health

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The neonatal skin undergoes significant developmental changes during the transition from an aquatic in utero to an aerobic extrauterine environment. Accordingly, the adaptation is facilitated by several vital functions, including thermoregulation, water and electrolyte homeostasis, and protection against trauma, environmental toxins, and infections.<sup>5,6</sup> The skin barrier is considered as a multifaceted structure comprising the microbiome, chemical, physical and immune barriers.<sup>7</sup> Full-term infants are born with a competent skin barrier; however, continual normal, healthy development during the postnatal period requires specific dermatological care.<sup>5</sup> Skin care practices can influence skin integrity, acid mantle, skin microbiome diversity, immunomodulation, and prevention of infection.<sup>6,8</sup> The far-reaching effects of skin care practices extend beyond the physical barrier and encompass neurodevelopmental outcomes of the neonate.<sup>9</sup>

There exists a substantial variability in skin care practices being followed across Indian clinical settings and the majority of the practices employed have been derived from individual experience, rather than evidence-based research. Moreover, in India, several traditional and regional practices are widely followed that may compromise skin function and newborn health.<sup>10,11</sup> Thus, there is a need to develop evidence-based consensus recommendations on neonatal skin care by the experts in the field and facilitate their implementation within Indian hospital settings as well as in domestic settings after discharge.

To this end, a Scientific Advisory Board meeting was conducted with the objectives of developing consensus recommendations on evidence-based neonatal skin care practices and designing corresponding protocols; the ultimate aim was to achieve positive health outcomes. These recommendations describe a) the approach to facilitate the adoption of evidence-based skin care practices for full-term healthy neonates within hospital settings, b) provide insights to the healthcare practitioners on the selection and use of appropriate dermatological products for newborns c) areas of limited evidence, with a need and scope for future research. In addition, implementation of the recommendation across institutions might result in new information or data to further support the neonatal skin care practices.

### **Methods**

The Scientific Advisory Board meeting on "Evidence-based Neonatal Skin Care Practices and Protocols" was held on December 12, 2020 on a virtual meeting platform. The expert panel included nationally renowned neonatologists, pediatricians, obstetricians and gynecologists and a pediatric dermatologist. The discussion was focused on current neonatal skin care practices and protocols, the review of existing evidence, the appropriate selection and use of skin care products, the approach to facilitate the adoption of documented protocols within hospitals, identifying gaps in current evidence, and the scope for evidence generation. The meeting involved extensive discussions and inputs regarding specific questions that were developed a priori and communicated beforehand to all panel members; each set of questionnaires was answered by an e-mail. The results were discussed; subsequently, the experts arrived at a consensus based on the available evidence, their collective experiences, and expertise.

The literature search, comprising observational studies, randomized controlled trials, review articles, and metaanalyses in full-term healthy neonates that evaluated the skin care practices was performed using the PubMed and Google Scholar databases on 23 March 2021. The search terms employed were "baby/newborn/neonate/infant", "skin care", "dermatology", "bath/bathing/washing/cleaning", "WHO", "guidelines/recommendations", "umbilical cord care", "nappy care", "diaper rash", "cleanser/baby wash", "emollient/cream/moisturizer", "oil", "massage", "tactile stimulation", "multisensory stimulation", "skin-to-skin care", "baby products". The search was restricted to articles in the English language published in February 2021 or prior. However, newer literature, which has relevance to these study recommendations, were also included.

The abstracts and the full text of the studies were screened to find out the relevant article for each section of the manuscript that discussed the outcomes of skin care interventions and practices in full-term healthy neonates. All members participated in the preparation and review of the draft. Following the incorporation of all suggestions, the consensus recommendations were finalized (Table 1).

#### Table I Summary of Key Consensus Statements

#### I. Need for neonatal skin care recommendations for healthy full-term newborns

- Neonatal skin care should be an integral part of routine newborn care within the hospital.<sup>4</sup>
- Neonatal skin care is of utmost significance, starting from delivery to discharge from the hospital. Follow hand hygiene each time prior to handling neonates.<sup>4</sup>
- Mothers should be trained and guided on evidence-based newborn skin care practices during their hospital stay, and as part of routine discharge advice.<sup>12,13</sup>

#### 2. Neonatal skin care at birth

- Clean gloves need to be worn to handle the newborn.<sup>14</sup>
- Remove blood, meconium, or amniotic fluid from the baby's skin.<sup>14,15</sup>
- Leave the vernix intact. Do not scrub it off as it protects the skin and favors appropriate colonization.<sup>15–18</sup>
- Use cotton swabs soaked in water boiled and cooled to an appropriate temperature to gently clean the skin and then gently dry the skin.<sup>14,15</sup>
- Establish skin-to-skin contact during the first hour after birth as it supports timely breastfeeding, thermoregulation, survival, establishment of a healthy skin microbiome, and mother-baby bonding.<sup>19-25</sup>

#### 3. Bathing the newborn

- The first bath should be given once the newborn has achieved cardiorespiratory and thermal stability; the ideal time-period may range between 6 and 24 hours after birth.<sup>15</sup> For neonates born to an HIV-positive mother, the first bath should occur at the earliest.<sup>26</sup>
- Keep the bath time short, lasting not more than 5-10 minutes.<sup>16,18</sup>
- The frequency of bathing should not exceed twice or thrice a week.<sup>16</sup> Bathing should not occur immediately after feeding. Bathing should preferably be carried out 45 minutes to 1 hour following the last feed.
- The tub swaddle bath is considered the ideal modality of bathing.<sup>27,28</sup> However, the traditional method of placing the neonate between the knees is required to be explored, and may be recommended as an alternative.
- Use lukewarm water (at around 38°C) and maintain room temperature (between 26°C-28°C). Also, a mild gentle cleanser which has been demonstrated appropriate for newborns could be used.<sup>29,30</sup> The cleanser should be formulated to be pH neutral to mildly acidic and to not disturb the normal pH of the baby skin.<sup>15</sup>

#### 4. Skin care practices within the hospital

- Neonatal skin assessment should be a part of routine newborn care.<sup>18,31</sup> The skin should be assessed at the earliest following birth, on a continuous basis, or, at least once daily using valid and reliable tools; increase frequency, if needed.
- Umbilical cord care: Follow dry cord care. If cord gets soiled with urine or feces, it may be cleaned with water, or a mild cleanser.<sup>17,20</sup>
- Diaper area cleansing and care: Use a soft cloth, water, and a mild cleanser or disposable diaper wipes to gently clean the perianal area and buttocks after each diaper change.<sup>16</sup>
- Appropriately formulated emollients for baby skin are recommended at the first signs of dryness, fissures or cracking of the skin and can be employed to maintain or enhance the skin barrier function.<sup>32–34</sup> It may also be considered in high-risk infants to prevent occurrence of Atopic Dermatitis.<sup>33,35,36</sup> Additionally, emollients may be applied on the scalp in newborns with cradle cap.
- Appropriately formulated baby oils can be lightly applied to the neonate skin before bath for transitory dryness only. Oils meant for cooking or sourced from the kitchen should not be used on the baby's skin.<sup>16,37</sup>

#### 5. Recommendations at the time of discharge

- Newborn skin care guidance should be a part of routine discharge advice.
- The mother should be instructed to assess the skin on a daily basis.<sup>12,13</sup> Parents should be guided for the management of common neonatal skin conditions, and seeking timely medical advice.<sup>12,38</sup>
- Do's and Don'ts (Figure 1) should be included in the discharge summary.

#### 6. Use of skin care products

- Parents to consider products that are exclusively tested and/or certified for newborn use.
- Parents and caregivers must read and follow product instructions.

#### 7. Recommendations for industry

- Formulations prescribed for neonatal skin care should undergo rigorous quality control.
- The safety and efficacy of products should be evaluated in high-quality clinical trials.
- The formulation should contain preservatives and fragrances that have demonstrated safety and tolerability for newborns only.<sup>16</sup>
- Formulations should not include ingredients that can be harsh and irritating to the neonatal skin and eyes, such as sodium lauryl sulfate.<sup>16</sup>
- Manufacturers should support healthcare professionals and parents by making more detailed information about ingredient specification available on the websites.

Do's	Don'ts
Continue bath as instructed in the hospital. Mild cleanser may be used if the baby is heavily oiled, unclean, or soiled	Don't apply kajal, surma, etc. in the eyes.
with feces, urine, or vomitus.	Avoid the use of abrasives, mustard oil, sunflower oil,
□ Watch for the scaling, drying, or redness of the skin. If observed, use moisturizers or emollients.	olive oil to massage the baby.
Care of the umbilicus is important . Keep the umbilical cord stump clean and dry, including the surrounding skin.	Kitchen oils should not be used; mineral oils may be
Continue to practice diaper area care as guided in the hospital.	preferred.
□ Skincare or tactile stimulation is a part of multisensory stimulation.	□ Avoid the application of besan, malai, ghee, dal, etc. on
D Massage has displayed neutral to positive impact on growth and development, and may be recommended. Emollients,	the umbilical cord stump.
including oils, demonstrated appropriate for newborns and babies, may be used. (Coconut oil, sesame oil or other oil	Do not instil oil in the ears and the nose.
that had been documented appropriate for baby skin should be preferred). Carefully handle the baby after oil massage	Do not apply tobacco, cow dung, or any other substance
as oil tends to make baby's skin slippery.	to the umbilical cord.

Figure I Do's and don'ts included in the discharge summary.

# Results

# Need for Neonatal Skin Care Recommendations for Healthy Full-Term Newborns Points of Discussion

Proper care and maintenance of hygiene are essential to improve overall neonatal health and skin integrity.<sup>6</sup> Hand hygiene (by hand washing or the use of alcohol-based hand rub) should be ensured before handling the neonate.<sup>14</sup> Owing to limited data and the absence of uniform guidelines, skin care practices in healthy full-term newborns are primarily based on experience; physicians, nurses, and other medical staff seek such guidance from non-evidence-based sources.<sup>39</sup> The United States-based cohort revealed wide variations in the neonatal skin care practices followed across medical centers and specific populations; these may even be contrary to the best practices documented in the literature.<sup>40</sup> The contrary practices include baby's first bath before cardiorespiratory and thermoregulatory stability is achieved, removal of all vernix after birth, no routine use of emollient, no use of any products in diaper area during diaper change, no use of antiseptics for the umbilical cord, and not following any specific skin care protocol to avoid skin breakdown and infections.<sup>40</sup> These disparities highlight the need for data-driven guidelines on standardized and optimized neonatal skin care. All panel members agreed to neonatal skin care guidelines in hospital settings. Furthermore, the panel emphasized the key barriers to the adoption of evidence-based skin care practices. These include lack of guidelines from centralized bodies, lack of cross-specialty coordination, lack of infrastructure, paucity of trained staff, and the preferential allocation of resources to the more critical aspects of neonatal care.

# Neonatal Skin Care at Birth

### Points of Discussion

### Cleansing the Neonate Soon After Birth

The Ministry of Health and Family Welfare (MoHFW), Govt. of India recommends that gloves and a plastic/rubber apron should be worn while handling the neonate until blood, meconium or amniotic fluid has been removed from the neonate's skin.<sup>14</sup> Blood and meconium should be gently removed from the neonate's skin using cotton swabs/soft cotton soaked in boiled warm water, followed by drying to avoid infection. Vigorous scrubbing should be avoided.<sup>14,15</sup>

### Vernix Caseosa

The vernix caseosa (vernix) is a protective layer comprising proteins, lipids, and water; it acts as a natural moisturizer and skin cleanser. It protects the fetal skin from the amniotic fluid in utero. Following birth, it helps reduce the trans-epidermal water loss (TEWL) and facilitates acid mantle formation. Additionally, it delivers antioxidant, antimicrobial, and antifungal benefits to the newborn skin.<sup>5,41</sup> Considering these benefits of the vernix, the WHO, the Association of

Women's Health, Obstetric and Neonatal Nurses (AWHONN), the European Roundtable meeting on Best Practice Healthy Infant Skin Care, and the recent pediatric skin care guidelines developed by the Indian Academy of Pediatrics (IAP) strongly recommend leaving the residual vernix intact on the neonatal skin in the period following birth.<sup>15–18</sup>

### Skin-to-Skin Care

The WHO, the United Nations International Children's Emergency Fund (UNICEF), and the pediatric skin care guidelines developed by IAP strongly recommend establishing skin-to-skin contact between all mothers and neonates without complications during the first hour after birth.<sup>18–20</sup> This helps prevent hypothermia, stimulates breastfeeding, enhances mother-baby bonding and maternal satisfaction, reduces newborn stress, enables colonization of the neonatal skin with beneficial maternal bacteria, and promotes maturation and functioning of the immune system.<sup>19–25</sup>

# Bathing the Newborn

# Points of Discussion

### The First Bath - Timing

The first bath is often scheduled around the activities of the mother and newborn, the time and mode of delivery, competing for scheduling priorities (including discharges at, or, before 24 hours), and the availability of primary care nurses to guide the parents; cultural beliefs may also play a part.<sup>42–45</sup> Table 2 summarizes various studies comparing the effect of different timings of the first bath on neonatal thermoregulatory status. Studies have demonstrated no significant impact on infant axillary temperatures, when bathing healthy newborns at different time points, from 1 hour up to 9 hours after birth.<sup>45–49</sup> However, a study conducted in Uganda demonstrated bathing term newborns at 1 hour of age significantly increases the risk of hypothermia, despite the use of warm water and skin-to-skin care following the bath.<sup>50</sup> In contrast, according to a study from Japan, the neonate bath occurring as early as 2 to 5 minutes after birth was reported to be safe; a significantly higher temperature was observed 30 minutes following the bath, compared to the dry care group.<sup>51</sup> A large observational study in the Philippines found that early bathing delays thermoregulation and initiation of breastfeeding.<sup>52</sup> Another randomized controlled study demonstrated that delaying the first bath to 48 hours postpartum, has a positive effect on preserving the body temperature and the skin moisture level of the neonate.<sup>53</sup> A few other studies also suggested that delaying the first bath encourages successful breastfeeding, enhances bonding, and facilitates timely

Study	Method	Study Population	Intervention	Primary Outcomes
Kelly et al (2018) <sup>45</sup>	Quasi-experimental, mixed-model design	75 healthy newborns	3, 6, or 9 hrs after birth	No clinically significant differences in the neonatal thermoregulatory status as indicated by the axillary and skin temperatures
Behring et al (2003) <sup>46</sup>	Quasi-experimental	51 healthy newborns	I hr vs <b>4–6</b> hrs after birth	Axillary temperatures as measured at four different times (pre-bath, immediately post- bath, one hour and two hours post-bath) did not differ significantly between the two groups
Varda et al (2000) <sup>47</sup>	Randomized, comparative study	80 healthy, full-term newborns	I hr vs 2 hrs after birth	No significant differences in axillary temperatures between the two groups before the bath or at 10, 20, or 60 min post-bath
Alizadeh Taheri et al (2007) <sup>48</sup>	Randomized, comparative study	100 healthy newborns	I–2 hrs vs 4–6 hrs after birth	Rectal temperatures as measured at four different times (pre-bath, immediately post- bath, 30 min and 60 min post-bath) did not differ significantly between the two groups

Table 2 Studies Comparing the Effect of Different	Timings of the First Bath on Neonatal	Thermoregulatory Outcome
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(Continued)

Study	Method	Study Population	Intervention	Primary Outcomes
Penny-MacGillivray et al (1996) <sup>49</sup>	Randomized, comparative study	100 healthy, full-term newborns	Immediately after initial assessment vs 4 hrs after birth	No significant differences (P<0.05) in rectal temperatures between two groups during the initial assessment examination, pre-bathing, immediately after bathing, 1 hr, or 2 hrs after bathing
Bergström et al (2005) <sup>50</sup>	RCT	249 non-asphyxiated newborns after vaginal delivery	I hr vs 2 hrs after birth	Significantly increased risk of hypothermia (at 10 min and 30 min after bathing) in newborns bathed in the first hour after delivery
Nako et al (2000) <sup>51</sup>	Randomized, comparative study	187 healthy term and near-term newborn infants	Early bathing: 2–5 min after birth vs dry care	Rectal temperatures as measured at 20 min after intervention was significantly higher in the bath group than in the dry care (P=0.000022). No significant differences in respiratory rate, heart rate, blood pressure and oxygen saturation level between two groups
Sobel et al (2011) <sup>52</sup>	Observational assessment	481 mother-baby pairs	Early bathing	Delay's thermoregulation and initiation of breastfeeding
Gözen et al (2019) <sup>53</sup>	Randomized, comparative study	73 healthy, full-term newborns	24 hrs vs 48 hrs after birth	Significantly higher body temperatures (P=0.008) and skin moisture levels (P=0.044) measured at 10 min post-bath in the infants bathed after 48 hrs vs after 24 hrs of birth
Brogan et al (2017) <sup>54</sup>	Retrospective experimental study	282 newborns	2–4 hrs after birth (sponge bathing) vs delayed immersion bath	Delayed immersion baths resulted in significant decrease in hypothermia (P=0.044) and increased parent satisfaction

#### Table 2 (Continued).

Abbreviation: Hr, hour, RCT, randomized controlled trial.

skin-to-skin care.<sup>54–57</sup> Globally, variations exist in the timing of the first bath; however, maintaining the neonatal thermoregulation is of primary importance. Therefore, the first bath should be given only after the infant has achieved cardiorespiratory and thermal stability.<sup>15,16,58</sup>

The Neonatal Skin Care Evidence-Based Clinical Practice Guideline, developed by the AWHONN, recommends the first bath as occurring between 6 hours and 24 hours after birth.<sup>15</sup> For infants born to a human immunodeficiency virus (HIV)-positive mother, the first bath should occur at the earliest, following birth, to prevent the transmission of maternal infection to the newborn.<sup>26</sup> The WHO recommends delaying the bath for 24 hours after birth; if cultural reasons do not permit such a delay, wait for a minimum of 6 hours.<sup>20</sup> All panel members agreed the first bath in full-term neonates should be given once thermal and cardiorespiratory stability has been achieved (approximately 6 hours after birth), provided the temperatures of the hospital settings and the bath water are carefully monitored.

### The First Bath – Frequency and Duration

The European Roundtable Meeting on Best Practice Healthy Infant Skin Care recommends neonatal baths should be conducted at least 2–3 times a week or as frequently as local culture requires.<sup>16</sup> The duration of the bath should not last more than 5 minutes; prolonged duration increases the hydration of the skin and reduces the threshold for friction.<sup>59,60</sup> The European Roundtable Meeting on Best Practice Healthy Infant Skin Care and the IAP recommend the duration of the infant bath should not exceed 5–10 minutes.<sup>16,18</sup>

Soaking in water (with or without cleansers) removes natural moisturizing factor (NMF) from the stratum corneum, and results in brittle and dry skin.<sup>61</sup> As NMF is low at birth and contributes to the acid mantle, removal of NMF may impact skin pH and colonization of the skin surface with appropriate bacteria in newborns.

#### Mode of Bathing

Several methods of providing the first bath to newborns are practiced in hospital settings. Sponge bathing is the act of washing using a sponge or a washcloth. It is frequently administered at birth, or within a few hours subsequently.<sup>27,43</sup> In tub or immersion bathing, the entire body of the infant (except the head and neck) is placed in warm water (approximately 38°C). This is deep enough to cover the shoulders, being more comfortable for the baby.<sup>43</sup> In swaddled immersion bathing, infants are swathed in a soft blanket and gently immersed in a tub of warm water.<sup>44</sup> The water covers up to the baby's shoulders. Each limb is individually unswaddled, washed, rinsed, and reswaddled. The water immersion, combined with the swaddling, has been shown to reduce stress during bathing.

Compared to sponge bathing, newborns who experienced tub (immersion) baths demonstrated reduced temperature variability;<sup>27,28</sup> additionally, they cried less and were found to be calmer and more content (Table 3).<sup>27</sup> Newborns receiving delayed immersion baths had a significantly higher likelihood of experiencing normothermia compared to a sponge bath shortly after birth.<sup>54</sup> Differing opinions exist if the baby should be bathed until the umbilical cord falls off, and the preferred method of bath. Traditionally, sponge bathing is preferred until the cord falls off; tub bathing is favored subsequently. However, studies demonstrated no differences in the rates of umbilical cord healing between the tub and sponge-bathed neonates; additionally, no increase in umbilical cord infections was reported through either of the methods.<sup>27,39</sup> This suggests sponge bathing has become incorporated as part of routine newborn care without adequate high-quality evidence. Studies report that swaddled immersion bathing, compared to sponge or tub bathing, effectively maintains body temperature, oxygen saturation levels, and heart rate, and reduces behavioral stress symptoms, such as crying and agitation, improving maternal satisfaction (Table 3).<sup>62–67</sup> Thus, swaddling with immersion can be adopted as part of routine newborn care for term infants during the hospital stay.

All panel members agreed the swaddle immersion method is the ideal technique for bathing healthy term newborns. However, one panelist suggested certain adaptions might be necessary while incorporating the method in Indian hospital settings. These include factors, such as training the staff, time constraint, etc. Another panel member suggested conventional or regional practices like bathing the baby on outstretched legs are required to be explored; this was agreed by all members.

### Use of Water Alone vs Mild Cleanser

Randomized studies and systematic literature reviews exhibited clinically equivalent results, upon comparing mild liquid cleansers to water alone for bathing.<sup>39,68–70</sup> The exclusive use of water may not be sufficient for the removal of impurities like urine components, fecal enzymes, and fat-soluble surface impurities like fecal remnants.<sup>29,30</sup> Having said that, the panel members agreed water alone would be sufficient for newborn bathing unless concerns exist regarding the water quality. Furthermore, a mild cleanser demonstrated appropriate for use on newborns would be recommended for situations requiring bathing of the baby post-massage, or being soiled with dirt, vomitus, feces, etc.

### Skin Care Practices Within the Hospital

### Points of Discussion

### Assessment of the Skin of the Neonate

A comprehensive examination of the newborn skin from head to toe is essential; this includes parameters, such as dryness, scaling, erythema, color, texture, and physiological changes.<sup>18,31</sup> Some of the standardized tools including Neonatal Skin Condition Score (NSCS), Neonatal Skin Risk Assessment Scale (NSRAS) and Braden Q scale can be considered for neonatal skin assessment. NSCS ranges from a score of 3 (best condition) to 9 (worst condition), based on dryness, erythema, and skin breakdown (Table 4).<sup>31</sup> NSRAS is composed of six subscales (general physical condition, mental state, mobility, activity, nutrition and moisture) and scored 6 to 24 (each subscale is scored 1 point), with a higher score indicative of lower risk. Braden Q scale composed of seven subscales (mobility, activity, sensory perception,

Study	Method	Study Population	Intervention	Primary Outcomes
Bryanton et al 2004 <sup>61</sup>	RCT	102 healthy newborns	Tub vs sponge bathing	Tub-bathed infants had less temperature loss (P<0.001), were more content (P<0.001) vs sponge-bathed infants. Mothers rated their higher pleasure with tub bathing (P<0.001). No difference in cord healing or infection.
Loring et al 2012 <sup>27</sup>	RCT	100 late-preterm infants	Tub vs sponge bathing after 24 hrs of delivery	Tub-bath had less variability in body temperature and were warmer at 10 and 30 min vs sponge-bath (P=0.024).
Çaka et al 2017 <sup>28</sup>	Randomized trial	80 healthy newborns	Swaddled vs traditional tub bathing after 24 hrs of delivery	Swaddled bathed had significantly higher body temperatures just after the bath and 10 min after the bath were compared with tub-bathed (P=0.028). Heart rate was significantly lower with swaddled than the tub bath in the post-bath period (P=0.035). Less crying and agitation with swaddled bathing.
Çınar et al 2020 <sup>62</sup>	Mixed methods research design	62 healthy newborns	Swaddled bathing vs tub bathing	No statistically significant difference in newborns' body temperatures before and after bathing (P>0.05). Swaddled bathed infants had higher oxygen saturation (P=0.024), less crying duration, less face/forehead grimacing, and less unrest with higher maternal satisfaction.
Edraki et al 2014 <sup>64</sup>	Randomized trial	50 premature infants	Swaddled vs conventional (sponge) bathing	Mean temperature loss was significantly less in the swaddle-bathed newborns compared to the conventionally-bathed newborns (P<0.001). Crying time was significantly less in swaddled bathed group (P<0.001).
Gaddam et al 2017 <sup>66</sup>	Quantitative approach, True experimental comparative research design	60 preterm infants	Swaddled vs conventional (sponge) bathing	Mean temperature loss was less in the swaddle- bathed newborns compared to the conventionally-bathed newborns (P<0.001). Swaddle bathed infants cried less compared with conventionally bathed infants (P<0.001).
Sailer et al 2017 <sup>63</sup>	Retrospective study	Sponge (n=15) and swaddle (n=21) bath comparison data	Swaddled vs sponge bathing	Delayed swaddle immersion bath resulted in a decrease of time, steps and crying in comparison to the sponge bath.

Abbreviation: RCT, randomized controlled trial.

moisture, friction/shear, nutrition and tissue perfusion) with scores 1 (least favorable) to 4 (most favorable). Scores <16 implies risk of skin breakdown. NSCS assist nurses or primary caregivers in identifying risk factors for impaired skin integrity, NSRAS considers the physical and developmental requirements of neonatal patients, and Braden Q scale predicts the risk of pressure ulcers.<sup>71,72</sup> Visscher M described a skin assessment tool (grading template) that compares the severity of erythema (9-point, 0–4 scale with 0.5 grade increments), dryness (11-point, 0–5 scale with 0.5 grade increments) or rash (7-point, 0–3 scale with 0.5 grade increments) to the normal skin of same person for the rapid measurement of skin condition in NICUs.<sup>73</sup> All panel members agreed skin assessment should be included as part of the routine newborn analysis, and NSCS is a suitable tool for the same. Based on the arrived consensus, the NSCS assessment should be performed once neonatal thermal stability has been achieved; the evaluation can be carried out

Score	Dryness
1	Normal, no sign of dry skin
2	Dry skin, visible scaling
3	Very dry skin, cracking/fissures
Score	Erythema
1	No evidence or erythema
2	Visible erythema, <50% body surface
3	Visible erythema, ≥50% body surface
Score	Breakdown
1	None evident
2	Small, localized areas
3	Extensive

 Table 4 Neonatal Skin Condition Score (NSCS)

**Notes**: Perfect score = 3; Worst score = 9. AWHONN Neonatal Skin COndition Score: used and adapted with permission AWHONN. Adapted from Lund CH, Osborne J. Validity and reliability of the neonatal skin condition score. *J Obstet Gynecol Neonatal Nurs*. 2004;33(3):320–327.<sup>31</sup>

by the pediatrician, nurse, or even potentially the mother with guidance and/or training. The assessment should be undertaken once daily, or, more frequently as clinically indicated, until discharge; new parents should be advised to continue the evaluation at home. Furthermore, panel members insisted the routine checklist for neonatal skin care for the hospital nursing staff should include the NSCS assessment, cleansing, umbilical cord care, diaper area assessment, emollient usage, and identifying risk factors for skin breakdown.

### Umbilical Cord Care

The WHO recommends clean and dry cord care for neonates born in health facilities; hand hygiene is to be followed. If soiled, the cord stump should be washed with water and a mild cleanser and dried thoroughly with a soft, clean cloth. Nothing should be applied to the stump.<sup>17,20</sup> However, further research is recommended to evaluate topical antimicrobial treatment for umbilical cord care compared to natural healing.<sup>74</sup>

### Diaper Area Care

Considering the risk of diaper dermatitis, the perianal area should be kept clean and dry; diapers should be changed as often as necessary.<sup>15,16</sup> The European Roundtable Meeting on Best Practice Healthy Infant Skin Care recommends diaper wipes should contain buffers to maintain the pH at slightly acidic to neutral. Additionally, the wipes should be free of potential irritants, such as alcohol, and harsh surfactants (eg, sodium lauryl sulfate), and must contain well-tolerated preservatives and if they contain fragrance, the wipes should be demonstrated non-irritating and well tolerated for use on newborn.<sup>16</sup> Drying can be achieved through air-drying, or gentle patting with a dry towel or a soft cloth to avoid scrubbing that can result in barrier disruption.<sup>16</sup> The application of barrier creams containing an appropriate percentage of zinc oxide and petrolatum-based formulations can treat and help prevent diaper dermatitis.<sup>75</sup>

### Emollient Therapy

According to randomized studies, emollient therapy represents a safe and effective approach to reduce TEWL, increase the stratum corneum hydration and was shown in a study to improve the skin microbial richness. In turn, this helps maintain the overall skin barrier integrity.<sup>32–34</sup> The role of early use of emollients in prevention of atopic dermatitis (AD) remains inconclusive. While certain literature reported daily application of emollient from birth reduced the occurrence

of AD in high-risk patients without increasing risk of food sensitization;  $^{33,35,36}$  the evidence to support this is equivocal with certain studies providing contradictory conclusions as well.<sup>9–11</sup> This difference in the results may be attributed to the difference in the study design, study population and the timing of intervention. Hence, further robust interventional clinical trials are required to establish a strong recommendation for the same.

# Recommendations at the Time of Discharge

### Points of Discussion

### Massage Therapy and Multisensory Stimulation

Multiple studies suggest infant massage may display beneficial effects on weight gain, growth, sleep and crying patterns, physiological responses to stress (including reductions in the levels of serum norepinephrine and epinephrine, and urinary cortisol), establishing circadian rhythms through an increase in the secretion of melatonin, decrease in hyperbilirubinemia, and improving mother–baby interaction. Many of these studies have been conducted on preterm infants.<sup>76–82</sup> An Indian study conducted on 125 healthy term infants displayed improvement in growth and post-massage sleep.<sup>83</sup> A randomized controlled study completed with 191 newborns (94 preterm, 97 term) in a Mumbai-based tertiary care center reported a significant increase in weight gain velocity in term neonates receiving massage with oil compared to the control group.<sup>84</sup> In addition, massage using oil has been shown to help lower cortisol levels, reducing stress behavior in babies.<sup>18</sup>

Massage may be combined with other types of stimulation, such as soothing talk (auditory stimulation), gentle extension and flexion of the limbs (kinesthetic stimulation), etc. The multisensory (auditory, tactile, visual, and vestibular) stimulation has been shown to improve infant growth and reduce stress, as determined by salivary cortisol levels in healthy term newborns.<sup>85,86</sup>

### Discharge Summary

Discharge advice and guidance for new parents are critical in ensuring evidence-based neonatal skin care practices are adhered to at home. Considering the lack of awareness, confusion, and fear among parents regarding the best skin care practices for the newborn, the postpartum nursing staff plays a key role.<sup>12,38</sup> Following delivery, the discharge of a healthy term newborn offers an important opportunity to counsel new parents regarding routine neonatal skincare and its significance, with emphasis on evidence-based recommendations.<sup>12,38</sup> All panel members agreed that skin care advice should be part of the newborn discharge checklist. Accordingly, mothers or caregivers are required to be educated and trained on certain practices, such as massage, bath time basics, emollient use, hair and scalp care, dry cord care, diaper area care, product advice with respect to standards and characteristics, detection and management of common conditions, warning signs, and follow-up advice.<sup>12,13</sup> Additionally, specific practices possibly harming the fragile skin of the newborn should be avoided, such as the application of kajal in the eyes, inserting oil in the ears and nose, the use of abrasives for massage, applying cow dung to the umbilical cord, etc.<sup>11,20,87</sup>

# Use of Skin Care Products

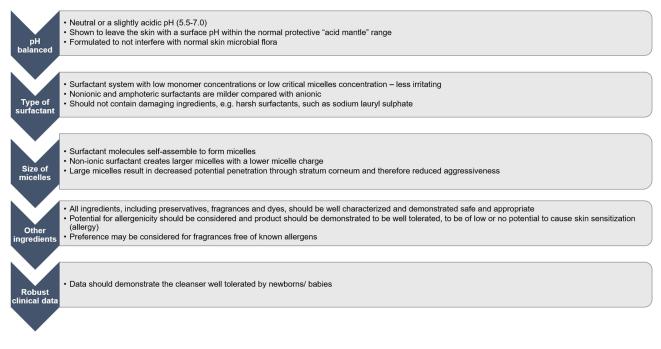
### Points of Discussion

All panel members agreed that products used for newborn care should be appropriately formulated and demonstrated to be safe and well tolerated and with special attention paid to the use of dyes, preservatives, fragrances, and new ingredients, whether natural or synthetic. All ingredients in a product should be well characterized and appropriate for newborn use and the full product should be appropriately evaluated and tested.

Further, the panel strongly insisted that products labeled as "herbal", "green", "natural" or "organic" should not be accepted blindly. The ingredients in such products may not be defined uniformly by regulatory bodies. The characteristics of an ideal cleanser have been provided in Figure 2.

### Cleanser Formulation

Cleansers can interact with skin in various ways, so mild and gentle cleansing for babies requires multiple considerations. Liquid cleansers having a mildly acidic or neutral pH (range: 5.5–7) are preferred over alkaline agents, which can disrupt the skin surface pH and lipids.<sup>18,88</sup> The addition of emollients to liquid cleansers may provide the combined advantage of hydration and protection.<sup>88</sup> Additionally, mild baby soaps made from natural oils (typically, the saponification of coconut oil) may be



#### Figure 2 Characteristics of an ideal cleanser\* for infant skin.

Notes: \*Water alone would be sufficient for newborn bathing unless concerns exist regarding the water quality. Mild cleansers are required for the removal of urine components, fecal enzymes and fat-soluble surface impurities, such as, fecal remnants.

considered for use with evidence of demonstrated safety and tolerability. Fragrance, preservatives, or dyes should be assessed like the other ingredients for their appropriate use and the full product should be demonstrated as safe and well tolerated.

### Factors Affecting Cleansers

pH: Gfatter et al studied the pH influence of three cleansing regimens (liquid detergent pH 5.5; compact detergent pH 5.5; alkaline soap bar pH 9.5), comparing each to washing with water alone (control). The alkaline bar displayed the greatest influence on the skin, with a significant increase in the pH and a higher loss of fat. This caused a disruption in the skin acid mantle, compromising the physiological protective function, and changing the resident bacterial flora. Further, the loss of fat affected the hydration of the skin, resulting in dryness.<sup>89</sup> Therefore, extra precaution should be taken in selecting the most suitable soaps (liquid or classic), or soapless synthetic detergents (syndets).<sup>90</sup> Appropriately formulated cleansers wash effectively while maintaining the skin surface pH; the skin barrier is preserved, conserving the skin microbial diversity.<sup>34,70</sup>

Type of surfactants: Surfactants act by decreasing the surface tension between water and air, and create lather, allowing emulsification and removal of oils and other fat-soluble impurities from the skin surface. The type of surfactant used in the cleanser determines foaming action and mildness.<sup>91</sup> Nonionic and amphoteric surfactants are typically milder compared to anionic components.<sup>30,90,92</sup> Surfactants in cleansers can potentially weaken the skin barrier, increase TEWL, and reduce stratum corneum hydration, which in turn can lead to skin dryness, irritation, and redness when the product is not designed considering the critical requirements of mildness and skin compatibility.<sup>30,91</sup> The micelle size and shape, nature and concentration of surfactants, and a number of free monomers determine the stratum corneum penetration and the irritation potential of cleansers. Recently introduced hydrophobically modified polymers form larger, more stable structures; these are less likely to penetrate the skin, maintaining the integrity of the barrier.<sup>30,92</sup>

Size of micelles: Nonionic surfactants result in substantial micelles with a lower micelle charge, and are considered to be mild and safe for neonates.<sup>30</sup> Anionic surfactants, such as sodium lauryl sulfate form smaller micelles; these result in skin irritation compared to amphoteric and nonionic surfactants like polyethylene glycol-80 (PEG-80) sorbitan laurate (milder due to micelle stabilization and size).<sup>30,90</sup>

Gentleness score: Anwar et al proposed a scoring system (5 stars rating for gentleness) to help differentiate the gentleness of cleansing products. This scoring system is based on formulation characteristics (presence of mildness enhancers, absence of allergens and sensitizers, and pH; each equal weightage and contributes 2.5 star out of 5 star) and in vitro assessment (surface penetration through epidermis and contributes 2.5 star out of 5 star).<sup>93</sup> The gentleness score can be estimated by checking the formulation and in vitro characteristics described above.

Hardness of water: Hard water generally contains ionized calcium and magnesium divalent cations at concentrations >120 ppm, and could cause irritation to the skin. Certain anionic surfactants like alkyl sulfates present in syndet cleansers may interact with ionized calcium and magnesium divalent cations, leading to surfactant precipitation and thus modifying the composition of the hard water and potentially reducing the available ions to bind to the skin.<sup>94</sup> Therefore, baby cleansers composed of these surfactants could be effective to reduce water hardness and can be ideal for baby bath.<sup>94</sup>

#### **Emollient Formulations**

Baby lotions and creams should maintain a mildly acidic to neutral pH and/or be shown to not alter the natural pH of the skin; specific considerations should be taken regarding their ocular and dermal safety.<sup>95</sup> Typically, an emollient consists of actives and excipients (emulsifiers, antioxidants, preservatives). The type of active ingredients (emollient, humectant, or occlusive) and how the product is formulated have been shown to determine the impact on skin barrier.<sup>96</sup>

Oils as emollients: Oils with the lower oleic acid content and the higher linoleic acid content have demonstrated beneficial effects.<sup>91</sup> Oleic acid is a skin penetration enhancer that increases TEWL, indicative of barrier disruption. Vegetable oils, such as mustard, soybean, and olive oil (with a higher oleic acid content) display an adverse effect on the maintenance of skin integrity.<sup>91</sup> An increased risk of atopic dermatitis and its exacerbation were reported with the use of olive oil.<sup>97</sup> Mustard oil is demonstrated to display adverse effects – increased cutaneous water loss, delayed functional maturation of the skin barrier, and an escalated risk for contact dermatitis due to the presence of allyl isothiocyanate.<sup>10,91,98</sup> Oils used for cooking and in the kitchen should be avoided as these are chemically heterogeneous, sensitive to oxidation and light, and possess variable biological activity; unpredictable effects may occur upon topical application.<sup>16,37</sup> Contrastingly, mineral oils possess emolliency, occlusion and substantivity and thereby maintain the hydration of the stratum corneum.<sup>37</sup> The Indian Academy of Pediatrics Guidelines for Pediatric Skin Care highlighted that mineral oil is an effective skincare moisturizer, which has limited penetration, and can be used safely in infants.<sup>18</sup> The characteristics of an ideal emollient have been provided in Figure 3.

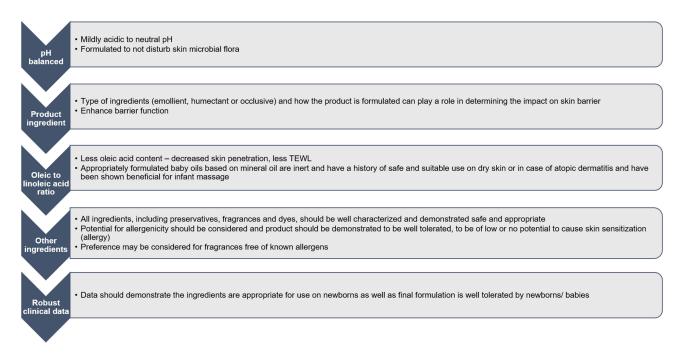


Figure 3 Characteristics of an ideal emollient for infants. Notes: TEWL, trans-epidermal water loss.

### Massage Oils

A study conducted by Sankaranarayanan et al displayed oil massage (with coconut oil and mineral oil) resulted in significantly greater weight gain velocity in the term baby group, as compared to the placebo.<sup>84</sup> In 2020, an Indian randomized controlled trial validated the efficacy of coconut oil in neonates; enhancement was observed in skin maturity, with a decreased incidence of late-onset sepsis. Thus, hypothermia and apnea were prevented, with enhanced serum vitamin D<sub>3</sub> levels and neurodevelopmental outcomes.<sup>99</sup> Mustard oil is routinely employed for infant skin massage in the Asian subcontinent; however, its use is not recommended as it slows down the skin barrier recovery, and increases the TEWL.<sup>10,100</sup> A recent community study from India did not find any difference in neonatal mortality rate between sunflower seed oil and mustard oil, except in a subgroup of infants weighing  $\leq 1500$  g. However, the study highlighted that these results might be due to low adherence to sunflower seed oil application, and further research is needed to establish newborn emollient therapy and its applicability along the continuum of care.<sup>101</sup> An abnormal epidermal lipid layering (typical of impaired barrier function), reduced stratum corneum integrity, and an enhanced TEWL following epidermal damage have been observed in neonates treated with olive oil.<sup>97</sup> Therefore, the use of olive oil for infant massage and the treatment of dry skin should be discouraged.<sup>97</sup>

# Recommendations for Industry

### Points of Discussion

### Product Ingredients

All panel members insisted on 100% ingredient transparency for baby products—including fragrances, and all ingredients used in the products should have gone through rigorous evaluation to ensure the safety appropriate for newborn use. Key criteria used to assess baby products are irritancy, pH, ocular safety, and considerations for use of preservatives and fragrance, and potential for skin sensitization (allergenicity). INCIdecoder (<u>https://incidecoder.com/</u>) is an online cosmetics database for consumers to decode the safety and benefits of ingredients present in the product.

# Approaches to Facilitate the Adoption of Neonatal Skin Care Protocols Within Hospitals

### Standardization of Quality of Care

All panel members regarded the lack of uniform guidelines regarding neonatal skin care from centralized bodies as one of the major barriers to the adoption of evidence-based protocols within hospital settings. Additionally, it was emphasized that such guidelines should be incorporated into clinical practice and the existing structure of the accreditation of the facility.

### Creating a Skincare Card

A skincare card may help new mothers follow evidence-based practices at home following discharge. All panel members proposed a need to develop specialized tools and aids, such as educational brochures, multi-vernacular information leaflets, trainings, and visual aids like video links, charts, and pictures to guide new parents and create awareness regarding scientifically documented skin care guidelines.

### Evaluating the Outcome and the Impact

The impact of integrating neonatal skin care guidelines as part of routine newborn care can be gauged on the following criteria: Skin barrier integrity parameters (eg, TEWL, stratum corneum hydration, etc.), lower frequency of skin barrier breakdown, reduced skin-related issues during follow-up out-patient department visits, diminished incidence of sepsis or infections, and enhancement in paramedical/nursing staff knowledge (tested using questionnaires).

### Literature Gaps and Scope for Future Research

There is a need to develop an appropriate core outcome set for neonatal skin research; these would include benefits over the short-term, as well as, the long-term (hydration, TEWL, skin pH, maternal satisfaction, skin colonization, erythema, etc.). Clear guidelines, with more "real-world" evidence, are needed to address concerns of parents and physicians on

skincare practices such as frequency of bathing, type of water being used, hair care, and products being utilized, in particular in the Indian context. There is a need to generate data on traditional care practices that are widely followed across India (eg, the use of turmeric, use of herbal, natural, or organic products). In addition, lack of educational material for new parents, product awareness with respect to standards, characteristics, etc., ideal compositions for cleanser, emollient, or diaper rash cream (eg, zinc oxide content), and effects of the varying quality of water on cleansing were identified among few other areas that warrant further research.

# Conclusions

Appropriate neonatal skin care practices support the skin barrier function, as well as, the development and maturation of the newborn skin during the postnatal period. The consensus recommendations may help standardize neonatal skin care in India, facilitating the adoption of evidence-based practices within hospitals. Consequently, a positive impact may be observed on neonatal health outcomes including skin barrier integrity parameters like TEWL and SCH, reduced frequency of skin barrier breakdown along with reduction in skin-related issues during out-patient department visits, and decrease in incidence of sepsis or infections. These recommendations are limited to healthy full-term infants. Future studies are warranted for the populations of preterm neonates and infants born with severe skin diseases.

# **Abbreviations**

AWHONN, Association of Women's Health, Obstetric and Neonatal Nurses; HIV, Human immunodeficiency virus; IAP, Indian Academy of Pediatrics; MoHFW, Ministry of Health and Family Welfare; NSCS, Neonatal Skin Condition Score; PEG-80, polyethylene glycol-80; TEWL, trans-epidermal water loss; UNICEF, United Nations International Children's Emergency Fund; WHO, World Health Organization.

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# **Author Contributions**

All authors made a significant contribution to the work reported, whether that is in the conception, design, execution, data analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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# Disclosure

Priti Thakor and Ankita Pandita are employees of JNTL Consumer Health (India) Pvt Ltd. Dr Ankita Pandita reports the advisory board was conducted by JNTL Consumer Health (India) Pvt Ltd. All other authors declare that they have no competing interests.

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