



# Recommendation for hygiene and topical in neonatology from the French Neonatal Society

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## Abstract

We sought to establish guidelines for hygiene care in newborns based on a systematic review of the literature and grading of evidence using the Groupe de Réflexion et d'Évaluation de l'Environnement des Nouveau-nés (GREEN) methodology. We examined 45 articles and 4 reports from safety agencies. These studies recommend a tub bath (rather than a sponge bath) for full-term infants and a swaddle bath for preterm newborns. They also recommend against daily cleansing of preterm infants. The literature emphasized that hygiene care must consider the clinical state of the newborn, including the level of awareness and behavioral responses. Hospitalized newborns treated with topical agents may also experience high exposure to potentially harmful excipients of interest. Caregivers should therefore be aware of the excipients present in the different products they use. In high-resource countries, the available data do not support the use of protective topical agents for preterm infants.

**Conclusions:** We recommend individualization of hygiene care for newborns. There is increasing concern regarding the safety of excipients in topical agents that are used in neonatology. A multidisciplinary approach should be used to identify an approach that requires lower levels of excipients and alternative excipients.

## What is known:

- Hygiene care is one of the most basic and widespread types of care received by healthy and sick newborns worldwide.
- There is no current guideline on hygiene for preterm or hospitalized term newborn.

## What is new:

- The French Group of Reflection and Evaluation of the environment of Newborns (GREEN) provided here guidelines based on the current body of evidence.
- Caregivers should be aware of the many issues related to hygiene care of newborns including newborns' behavioral responses to hygiene care, exposition to excipients of interest, and the potential risk of protective topical agents in a preterm infant. provided here guidelines based on the current body of evidence.
- Caregivers should be aware of the many issues related to hygiene care of newborns including newborns' possible behavioral responses to hygiene care, exposition to excipients of interest and the potential risk of protective topical agents in a preterm infant.

**Keywords** Excipient of interest · Hygiene · Newborn · Preterm · Topical

All the authors are members of the GREEN study group from the French Neonatal Society.

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## Introduction

Full-term and preterm newborns receive hygiene care and treatment with topical agents. These interventions are applied to hospitalized newborns and to healthy full-term newborns in maternity wards and at home.

A topical agent is a treatment that acts where it is applied, on the skin or mucous membranes. These medications also contain excipients, which facilitate administration, preservation, or action. However, some excipients (excipients of interest) have

potentially adverse effects. Thus, professional associations such as the European Study of Neonatal Exposure to Excipients (ESNEE) [53] and user associations such as the Women in Europe for a Common Future (WECF) [12, 44] have raised concerns about the daily use of hygiene products and cosmetics in newborns. Kuhn et al. [30] identified great variability in the use of hygiene care and topical agents in newborns, with the number of times a newborn was exposed to such agents widely varying among the units surveyed.

The aim of the present study was to summarize data from the literature on skin care and hygiene of preterm and full-term newborns who were hospitalized in neonatal intensive care units or maternity wards.

The specific questions regarding hygiene procedures were: What hygiene care was provided to newborns? What procedures were used for bathing? What was the timing of bathing?

The questions regarding the use of topical agents were: What topical agents were applied to newborns? What was the tolerance and impact of topical agents? Is there a place for nutritive and/or protective topical agents in newborns?

Thus, the aim of this manuscript was to examine the types of hygiene care provided to newborns, identify the problems associated with the use of certain compounds and excipients, determine which topical agents are most used, and assess interest in the use of nutritive and/or protective topical agents. We did not address the issues of antiseptics, umbilical cord care, massage, and therapeutic topics.

## Methods

The literature search was conducted according to the Groupe de Réflexion et d'Évaluation de l'Environnement des Nouveau-nés (GREEN) Committee guidelines [31]. The MEDLINE database (PubMed) was searched for publications on hygiene and topical care for newborns using the following phrase: (neon \* OR preterm OR newborn) AND "skin care"; (neon \* OR preterm OR newborn) AND emollient; (neon \* OR preterm OR newborn) AND clean \* AND skin; (neon \* OR preterm OR newborn) AND bath \*; (neon \* OR preterm OR newborn) AND swaddled bath \*; "neonatal nursing" AND skin. The search for excipients and endocrine disruptors used the following phrase: (neon \* OR preterm OR newborn) AND "excipients of interest"; (neon \* OR preterm OR newborn) AND "endocrine disruptor." The filters were "human," "newborn: birth-1 month," "publication date: from 2000/01/01" and "clinical trial." Only articles in English and French were included.

A single reader selected the articles after reading the title and summary. Additional articles of interest were identified by examination of the references listed at the end of selected articles. A level of evidence (LE) was assigned to each study, as described by the Haute Autorité de Santé. According to the French Haute Autorité de Santé, the "experts' agreement"

corresponds, in the absence of available scientific data, to the approval of at least 80% of the members of the working group [27]. Only studies with the highest level of evidence were selected [27], and articles with any major methodological bias were excluded.

The search for protocols and practical guidelines for the hygiene care of neonates examined the websites of the French Hospital Hygiene Society [45], the Agence Nationale de Sécurité du Médicament (ANSM) et des produits de santé (National Agency of Security of Medications and health products) [1], and the Scientific Committee on Consumer Safety (SCCS) of the European Commission Health and Food Safety [49].

Documents on this subject from societies of pediatric dermatology (Société Française de Dermatologie Pédiatrique [51] and the European Society for Paediatric Dermatology [20] were examined. Documents of interest from the Association of Women's Health website, Obstetric and Neonatal Nurses (AWHONN/NANN) [4], and from user associations (WECF and [www.projetnesting.fr](http://www.projetnesting.fr)) were also examined [12, 44].

## Results

The last PubMed search was on May 24, 2018. There were 38 eligible articles on hygiene and topical agents and 7 eligible articles on excipients (Figs. 1 and 2). There were no eligible documents on hygiene from the French Society of Hospital Hygiene, the Société Française de Dermatologie Pédiatrique, or the European Society for Pediatric Dermatology. Eligible documents on the composition of excipients were available from the ANSM [21], the SCCS [49], the European Commission [11], and the user associations [44].

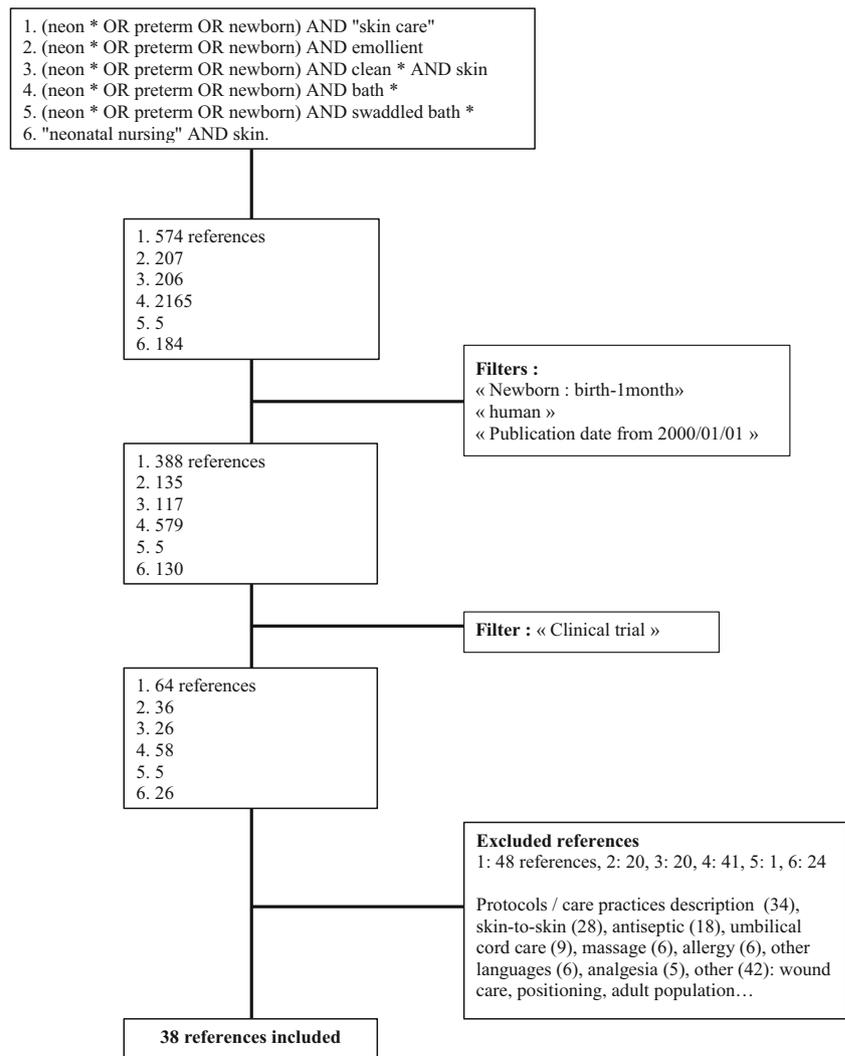
### What hygiene care was provided to newborns?

#### What procedures were used for bathing?

Eleven studies examined the topic of bathing [7–9, 17, 23, 24, 34, 36, 37, 39, 50] (Table 1).

Studies of full-term or near-term newborns (35–36 weeks gestational age) favored the use of tub baths rather than non-woven compresses (sponge bath) because they allowed better regulation of the infant's behavior [7] (LE 2) and body temperature [37, 39] (LE 3). The tub baths were also associated with better maternal experiences, and the mothers perceived no particular difficulty with the procedure [7] (LE 2). The tub bath and sponge bath had comparable effects on the physicochemical properties of the skin (transepidermal water loss [TEWL], skin pH, corneal layer thickness, and stratum corneum) and the process of postnatal skin maturation [24] (LE 2).

**Fig. 1** Flow chart of study selection for hygiene and topical care



Studies of preterm newborns favored the use of a “swaddle bath” rather than a regular bath because it allowed better temperature regulation and reduced crying times and manifestations of stress and discomfort [9, 17] (LE 2). Data were similar in a population of hospitalized full-term newborns [8] (LE 2). Bathing remained a potentially stressful event for newborns, with vegetative manifestations (variation in vagal tone and heart rate) and behavior, especially at the time of immersion [34, 36] (LE 3).

### What was the timing of bathing?

Five studies examined the timing of bathing [22, 35, 40, 46, 55] (Table 2).

Two studies evaluated the impact of early bathing of full-term newborns using traditional practices [40] or practices arising from concerns about the risk of pathogen transmission (from the caregiver to the newborn and from the newborn to the caregiver), and the effect of bathing on reducing this risk [55]. The

criteria used in these two studies were not in accordance with current international recommendations, particularly those of the World Health Organization (WHO), regarding the timing of bathing [5, 58]. These studies also did not address issues concerning preterm or sick newborns. Full-term newborns seemed to tolerate early bathing in terms of temperature regulation (LE 3), but the WHO does not recommend early bathing.

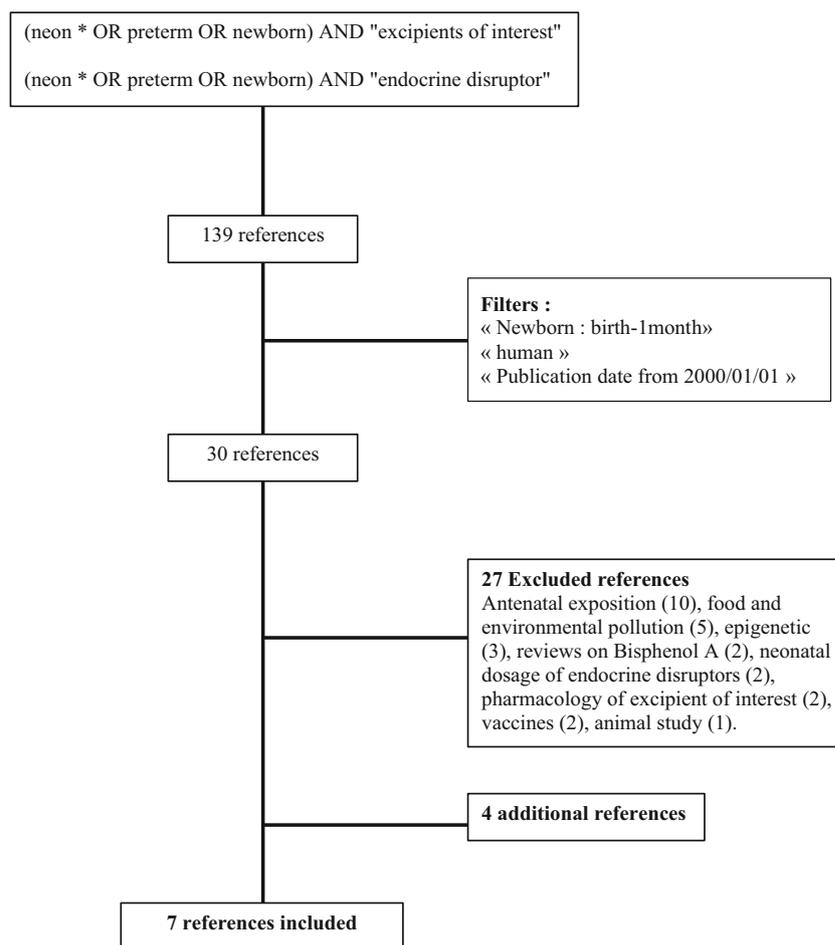
Studies of preterm infants reported that a change in the rhythm of bathing from daily to every 4 days did not appear to alter the composition of cutaneous flora or affect the risk of infections [22, 35, 46] (LE 3).

### What topical agents were applied to newborns?

#### What were the active compounds and excipients?

The skin of newborns, especially those who are preterm, is more permeable than the skin of children and adults. The buttocks is a special area, because it is often covered, and

**Fig. 2** Flow chart of study selection for excipients and endocrine disruptors



the external genitalia in particular have thin skin. Furthermore, exposure to topical agents may be repeated 6 to 8 times a day, depending on the diaper changing regimen. The excipients used in topical agents may have greater toxicity in newborns than adults. Indeed, the ratio of body surface to body mass is more than two times greater in newborns than that in adults, and newborns also lack functionally mature metabolic systems. Thus, the ANSM concluded its April 2010 assessment report on the safety of cosmetic products for children under 3 years old [21] as follows: “Considering the permeability and the metabolic immaturity of the skin of preterm babies (...) the group of experts considers that cosmetic products are not intended for them (...). This population however requires hygiene care and should be considered in order to specify toilet protocols and define the quality criteria to which the products applied to it must respond.”

A European practice survey of 89 centers in 21 countries examined exposure to excipients of interest in hospitalized preterm infants, with a focus on seven potentially toxic excipients [42]. At least one of these seven excipients was found in 27% of the products used topically, orally, or parenterally, and 63% of newborns were exposed to these products. Excipients were more common in oral and topical products than parenteral

products. For example, benzalkonium chloride (BKC; an antimicrobial preservative that could potentially irritate the skin and eyes) was present in 85% of the topical agents that were used. The authors also found that exposures to excipients varied among countries, suggesting that some formulations do not contain excipients of interest [43] (LE 3). Two observational studies found significant exposure to ethanol, propylene glycol, and sorbitol in preterm and full-term infants who were hospitalized [54, 57]. These exposures had a greater impact on newborns who were clinically unstable [57], and doses were higher than the recommendations of the European Medicines Agency in more than 51% of cases [54] (LE 3). A French study showed that the daily frequency of hygiene care varied significantly among hospital units; in particular, buttocks care using soap or cream varied from one per day to twelve times per day depending on the unit [30] (LE 3).

These data demonstrated that preterm and full-term hospitalized newborns are exposed to many potential toxic excipients.

### What was the tolerance and impact of topical agents?

Nine studies (8 randomized trials and 1 prospective study) examined the use of topical agents in hygiene care for

**Table 1** Studies evaluating the type of toileting

Articles	Study design	Population	Assessments	Results	Level of evidence comments
Lee 2002 (South Korea)	Single-center descriptive study	Preterm Mean GA 33.1 GW N = 40	RR interval variability (vagal tone), HR, and SpO2 variation during sponge bathing.	Loss of RR interval variability and increased HR during the procedure ( $p = 0.0005$ ). No significant difference in SpO2 or newborn behavior.	LE 3
Bryanton 2004 (Canada)	Single-center randomized controlled trial	Healthy term newborns N = 102	Tub bathing vs. sponge bathing.	Newborn behavior (NBAS 4.5 vs. 5.3) and self-evaluated pleasure for mother (4.5 vs. 3.7/5) in favor of the tub bath ( $p < 0.05$ ). Maternal confidence evaluation was similar in both groups.	LE 2 No blind assessment.
Medves 2004 (Canada)	Single-center randomized controlled trial	Healthy term newborns N = 111	First bath within 5 h of life: nurse vs. parents and nurse.	No significant difference between the 2 groups in term of thermoregulation.	LE 3 The toileting protocol was different between the 2 groups.
Liaw 2006 (Taiwan)	Single-center descriptive study	Preterm Mean postnatal term 32.8 GW N = 12	65 filmed tub baths to assess newborn behavior.	Distress and state behavior increased during immersion ( $p < 0.001$ ). Less stress manifestation during drying.	LE 3 Non standardized behavioral assessment
Garcia Bartels 2009 (Germany)	Single-center randomized controlled trial	Healthy term newborns N = 57	Tub bathing vs. sponge bathing, twice weekly	No significant difference between the 2 groups at postnatal day 7 and 28 for skin pH, TEWL, and skin condition (NSCS). Higher stratum corneum hydration in the bathing group at day 28 ( $p < 0.05$ ).	LE 2
Loring 2012 (USA)	Single-center randomized controlled trial	Preterm 35–36 GW N = 100	Tub bathing vs. sponge bathing.	Better thermoregulation with less temperature variability and higher body temperature at 10 and 30 min after bath in the tub bathing group ( $p = 0.024$ ).	LE 2
Edraki 2014 (Turkey)	Single-center randomized controlled trial	Preterm, mean GA 31 GW Postnatal age 20 j N = 50	Swaddled bathing vs. conventional bathing	Mean temperature loss and crying time significantly less in swaddled bathing group (5.8% vs. 43.4% of the mean bath time, $p < 0.001$ ).	LE 2
So 2014 (South Korea)	Single-center randomized controlled trial	Healthy term newborns N = 62	Trunk to head bathing vs. head to trunk bathing	Decrease in body temperature of 0 °C and 2 °C in both groups; body temperature recovery was faster in the trunk to head bathing group ( $p < 0.01$ ). No significant differences for HR, SpO2 between groups.	LE 2
Çaka 2018 (Turkey)	Single-center randomized controlled trial	Hospitalized term newborns BW > 2500 g N = 80	Swaddled bathing vs. Tub bathing	Shorter crying time (17.58 ± 18.58 vs. 99.23 ± 38.5 s, $p = 0.001$ ), better body temperature, and lower NIPS score after the swaddled bath (0.35 ± 0.62 vs. 1.65 ± 1.12, $p = 0.001$ ).	LE 2
Ceylan 2018 (Turkey)	Single-center randomized controlled trial with crossover	Preterm 33–37 GW BW > 1500 g N = 35	Swaddled bathing vs. Tub bathing	Better thermoregulation and shorter crying time during the bath (0.28 ± 1.17 vs. 51.14 ± 67.5 s, $p < 0.001$ ) and after the bath (0.8 ± 0.37 vs. 8.8 ± 10.78 min, $p < 0.001$ ). Stress (NSS) and pain (ALPS-Neo) scores were significantly lower during and after the bath.	LE 1 Video recording with an independent observer.
de Freitas 2018 (Brazil)	Single-center randomized	Preterm (32–36 GW) N = 43	Swaddled bathing vs. Tub bathing		LE 2

Table 1 (continued)

Articles	Study design	Population	Assessments	Results	Level of evidence comments
	controlled trial with crossover			No significant differences between the 2 groups for HR, SpO <sub>2</sub> , body temperature, sleep-wake states, and salivary cortisol levels.	
<i>HR</i> , heart rate; <i>SpO<sub>2</sub></i> : transcutaneous oxygen saturation; <i>NBAS</i> , Brazelton Neonatal Behavioral Assessment Scale; <i>NSS</i> , Neonatal Stress Scale; <i>TEWL</i> , transepidermal water loss; <i>NSCS</i> , Neonatal Skin Condition Score; <i>LE</i> , level of evidence (according to the referential from the Haute Autorité de Santé (HAS)); <i>BW</i> , birth weight; <i>GW</i> , gestational weeks; <i>GA</i> , gestational age					

newborns [3, 13, 25, 26, 32, 33, 38, 47, 56]. Four studies focused on the use of topical agents for diaper care [3, 26, 32, 56] (Table 3), and five studies evaluated the use of topical cleansers for newborns [13, 25, 33, 38, 47] (Table 4).

The use of a commercial wipe for diaper care, rather than cotton and water, provided no physicochemical or cutaneous benefits to full-term [26, 32] or preterm newborns [56] (LE 2). These studies compared wipes of different compositions. However, some of these studies had significant biases because many participants were lost to follow-up and because of conflicts of interest among the researchers [56].

Studies that compared bathing using a washing solution with water alone found that the cutaneous tolerance (clinical skin condition score) was comparable in full-term newborns [25, 33] (LE 2). The use of a washing solution, rather than water alone, did not appear to alter the quantity or quality of skin flora in a population of full-term [38] (LE2) and preterm newborns [13] (LE 2). Data comparing these routines on cutaneous maturation in full-term newborns were discordant [25, 33, 47].

#### Is there a place for nutritive and/or protective topical agents in newborns?

Thirteen publications (12 randomized controlled trials and 1 Cochrane Database meta-analysis) examined the use of topical preventives in newborns, primarily preterm infants. The assessment criteria varied among the different countries where these studies were performed, reflecting concerns with different issues.

Seven randomized trials were conducted in low-resource countries [2, 14–16, 19, 41, 48]. These studies are not detailed in the present study but were described in Cleminson's meta-analysis [10]. Five studies [6, 18, 28, 29, 52] were conducted in high-resource countries, and these studies assessed the use of different preventive topical agents in preterm newborns (Table 5).

Some data suggest that the use of topical agents, rather than standard care, improved skin conditions [29] (LE 2), but Kanti et al. [28] reported the rate of TEWL in newborns treated with sunflower oil (rather than usual care) indicated delayed skin maturation (LE 3). The main argument against using preventative topical agents in preterm infants is from the Edwards et al. [18] study. They found that infants receiving Aquaphor® rather than standard care had no differences in the composite criteria of death/sepsis during the first 28 days of life. However, when considering sepsis alone, the use of Aquaphor was associated with an adjusted relative risk (RRa) of 1.27 (95% CI, 1.03 to 1.54), and this association was stronger for infants with birth weights of 500 to 750 g (RRa = 1.43; 95% CI, 1.05 to 1.86) (LE 1). In high-resource countries, the use of some protective topical agents in preterm infants was associated with an increased risk of infection

**Table 2** Studies evaluating the rhythm of toileting

Articles	Study design	Population	Assessment	Results	Level of evidence comments
Nako 2000 (Japan)	Single-center controlled trial	Healthy term newborns <i>N</i> = 187	Immediate bath after birth vs. drying alone	Lower rectal temperature (0.3 °C) at 30 min in the bathing group ( <i>p</i> < 0.05). No significant differences between the 2 groups for HR, SpO <sub>2</sub> , BP.	LE 3
Varda 2000 (USA)	Single-center randomized controlled trial	Healthy term newborns <i>N</i> = 80	Bathing at 1 vs. 2 h of age.	No significant differences between the 2 groups for body temperature.	LE 2
Franck 2000 (USA)	Single-center prospective study	Preterm Mean GA 31 GW Postnatal age 14 to 30 days <i>N</i> = 59	Impact of the toileting rhythm on skin flora: daily vs. 1×/4 days toileting.	Significant increase in CFU number on day 2, then the number of CFU stabilized. No significant differences in skin flora composition (pathogens).	LE 3
Quinn 2005 (USA)	Single-center randomized controlled trial	Preterm Mean GA 31 GW Postnatal age 14 days <i>N</i> = 53	Daily toileting for 7 days then randomization: daily vs. 1×/4 days toileting.	At 1 month, mean CFU 18.4 (daily) vs. 4170 × 10 <sup>5</sup> (every 4 days) (NS). No infection reported, no detail on skin flora composition.	LE 3 Lost to follow-up (30 newborns participated for analysis on 53 included)
Lee 2018 (Korea)	Single-center randomized controlled trial	Preterm Mean GA 32 GW Postnatal age 8.5 days <i>N</i> = 32	Bathing every 2 days vs. every 4 days.	No significant differences for skin condition (NSCS) and skin colonization between the 2 groups.	LE 2

HR, heart rate; SpO<sub>2</sub>, transcutaneous oxygen saturation; BP, blood pressure; LE, level of evidence (according to the referential from the Haute Autorité de Santé (HAS)); GA, gestational age; GW, gestational weeks; CFU, colony forming unit; NSCS, Neonatal Skin Condition Condition Score; NS, non significant

(coagulase-negative *Staphylococcus* sepsis), especially in infants with low birth weight (< 750 g). Data on the possible trophic benefits of certain topical agents were contradictory, and the composition of the topical agents and excipients of interest must be considered.

## Discussion

### Recommendations

Regarding the importance of mother and child close contact during the first moments of an infant's life for the establishment an emotional relationship and the fact that early bathing of newborns provides no benefit in terms of protection from infectious diseases, early bathing of newborns is therefore not recommended (experts' agreement).

Full-term newborns should receive tub baths rather than sponge baths (grade B). Preterm infants should receive swaddle baths (grade B). Daily cleansing of preterm infants is not recommended (grade C). The specific procedures used for bathing a newborn must consider the infant's clinical state, level of awareness, and behavioral responses (experts' agreement).

Caregivers must be aware of potentially harmful excipients of interest in the different topical, enteral, and parenteral products they use. Given the complexity of identifying harmful excipients of interest, care teams must work in close collaboration with the hospital pharmacy (experts' agreement). The selection of topical agents used for hygiene care must consider the presence of potentially harmful excipients of interest, and these pharmacy personnel should systematically search for alternatives that contain no excipients or fewer excipients (experts' agreement).

Wipes are non-rinse products that contain a number of different excipients, depending on the brand. Because of the risk of over-exposure to excipients and the precautions stated in the excipient part, the risk-benefit balance is not in favor of their use in neonatology units (experts' agreement).

When using a washing solution, it is important to consider its composition. For most topical agents used in neonatology, there are alternatives that have fewer excipients. Particular attention should be devoted to products that are not rinsed off after application due to the risk of accumulation of potentially harmful excipients (experts' agreement).

For high-resource countries, the literature does not support the use of protective topical agents for preterm

**Table 3** Studies evaluating topical for diaper care

Article	Study design	Population	Assessment	Results	Level of evidence comments
Visser 2009 (USA)	Single-center randomized controlled trial	Hospitalized newborns (term and preterm). Mean GA 33 GW Mean BW 2280 g Mean postnatal age of 4.6 weeks. N = 130	Diaper care regimen 8×/day 3 groups: diaper wipes with emollient and cleanser A vs. wipes B vs. cloth and water.	Lower perineal erythema at day 5, 7, 10, and 14 in wipes groups A and B compared with cloth and water ( $p = 0.03$ ) Lower TEWL at day 7, 10, and 14 in wipes groups A and B compared with cloth and water ( $p < 0.05$ ).	LE 3 More than 50% of lost to follow-up. Study funded by Procter & Gamble®
Garcia Bartels 2012 (Germany)	Single-center randomized controlled trial	Healthy term newborns N = 44	Diaper care regimen 8×/day Wipe vs. cloth and water.	Lower TEWL on the buttock in the group with wipes vs. water ( $p = 0.007$ ). No significant differences for other outcomes (TEWL on non diapered skin, skin pH, skin hydration, skin flora, and skin condition (NSCS)).	LE 2
Lavender 2012 (England)	Single-center randomized controlled trial	Healthy term newborns N = 280	Diaper care regimen with wipe vs. cloth and water.	No significant differences between the 2 groups at day 14 for TEWL, skin pH, skin hydration, skin flora, and skin condition (NSCS).	LE 1 More frequent diaper changes in the wipe group ( $p = 0.028$ )
Alonso 2013 (Spain)	Single-center randomized controlled trial	Hospitalized newborns (term and preterm). Mean GA 37 GW Mean BW 2800 g Mean postnatal age 3 days. N = 229	Standard diaper care regimen vs. diaper care with petrolatum jelly.	No significant differences between the 2 groups for diaper rash.	LE 2

LE, level of evidence (according to the referential from the Haute Autorité de Santé (HAS)); BW, birth weight; GW, gestational weeks; TEWL, transepidermal water loss (perte hydrique transcutanée); NSCS, Neonatal Skin Condition Score

infants (grade A). In fact, the use of certain topical agents may increase the risk of infection (coagulase-negative *Staphylococcus* sepsis), especially in newborn infants with birth weights below 750 g. In addition, the use of these products will expose newborns to potentially harmful excipients (grade A).

### Limitations

The main limitation of this study was the use of only one database (Pubmed) and that a single reviewer did the research, selection, and level of evidence assignment. However, the levels of evidence were assigned according to the French Haute Autorité de Santé Guidelines, and all were discussed by the GREEN committee during working sessions. Once achieved, the manuscript has been sent to external reviewers with expertise in the field of hygiene and topics for validation (methods, level of evidence assessment, and recommendations).

### Strategies to implement the guidelines

It is important to train and sensitize health care teams on the appropriate methods of hygiene care to be used for preterm and full-term newborns with different health status. A multi-disciplinary approach with the hospital pharmacy team should be used to address the issue of excipients of interest, so that there is informed selection of the products to be used for hygiene care.

### Opportunities for research

Future research should address the following unresolved issues:

- Short-term, medium-term, and long-term impact of different excipients on full-term and preterm newborns
- Benefits of swaddled bath wrapped for full-term newborns with a neonatal abstinence syndrome or cerebro injured

**Table 4** Studies evaluating the use of topical for toileting

Article	Study design	Population	Assessment	Results	Level of evidence comments
Medves 2001 (Canada)	Single-center randomized controlled trial	Healthy term newborns <i>N</i> = 127	First bath: water vs. soap and water	No significant differences between the 2 groups for skin bacterial colonization.	LE 2
Da Cunha 2005 (Brazil)	Single-center randomized controlled trial	Preterm Mean GA 31 GW <i>N</i> = 73	Daily toileting with water vs. soap and water.	Significant decrease in the number of GPB and GNB CFU between the samples taken before and after the toileting. No significant differences between the 2 groups for the number of CFU or the skin flora composition.	LE 2 Important antibiotics exposure (42 to 48%)
Garcia Bartels 2010 (Germany)	Single-center randomized controlled trial	Healthy term newborns <i>N</i> = 64	4 groups: WG, wash gel; C, water and emollient; WG + C; B, water alone	No significant differences between the 4 groups at week 8 for skin condition (NSCS) and skin bacterial colonization TEWL: B > WG + C > C ( $p < 0.05$ ). Skin pH: B > WG + C ( $p < 0.05$ ). Skin hydration: C > WG + C > B ( $p < 0.05$ ).	LE 2
Lavender 2013 (England)	Single-center randomized controlled trial	Healthy term newborns <i>N</i> = 307	Toileting 3 times a week Water vs. wash gel and water.	No significant differences between the 2 groups at day 14 for TEWL, skin hydration, skin pH, and skin condition (NSCS) No significant differences in mother's satisfaction.	LE 2 Lost to follow-up (only 71% of the patients included were analyzed)
Raboni 2014 (Italia)	Single-center prospective study	Healthy term newborns <i>N</i> = 94	Water vs. wash gel, water, and emollient.	Water alone group had a significant lower TEWL than the wash gel and emollient group.	LE 3

CFU, colony forming unit; TEWL, transepidermal water loss (mesure de la perte transcutanée en eau); NSCS, Neonatal Skin Condition Condition Score; LE, level of evidence (according to the referential from the Haute Autorité de Santé (HAS)); GA, gestational age; GW, gestational weeks; GPB, Gram-positive bacteria; GNB, Gram-negative bacteria

- Hygiene cares for children with prostheses, such as a central venous catheter
- Benefits of parental involvement in hygiene care for preterm newborns and identification of types of support that the parents require
- Roles and potential effects of topical application of breast milk
- Excipients in neonatology, with emphasis on the transcutaneous passage, metabolism, and elimination (currently in progress by the ESNEE)
- Value of using the neonatal skin condition scale (NSCS) during routine care of newborns
- Diaper care regimen, including type of diaper, use of topic, and prevention and treatment of diaper related issues (rash, fungal infection, etc.).

## Conclusion

Hygiene care is one of the most basic and widespread types of care received by healthy and sick newborns worldwide. Studies on hygiene care in newborns emphasized that caregivers should be trained and sensitized to the techniques they use, and they should also consider the level of awareness and behavioral responses of the newborn. Protective topical agents should not be used for preterm infants, because these agents may increase the risk of infection. A multidisciplinary approach should be used to address the growing issue of potentially harmful excipients of interest in products used in neonatology. There should also be a search for alternatives that have lower levels of excipients, and further research to examine the potential toxicity of different excipients in newborns.

**Table 5** Studies evaluating nutritive and/or protective topicals in the newborn

Article	Study design	Population	Assessment	Results	Level of Evidence Comments
Cleminson 2016 (USA)	Meta-analysis	18 randomized controlled trial (RCT)	Preterm newborns Use of topical preventives vs. Standard care.	8 RCT ( $n = 2086$ ): in high-resource countries - Death RR 0.87; 95%CI, 0.75, 1.03 - Sepsis RR 1.13; 95%CI, 0.97, 1.31 with an increased risk for the newborns with a GA under 32 GW (RR 1.25; 95%CI 1.04, 1.50). 11 RCT ( $n = 1184$ ) with 9 RCT in low-resource countries, comparing the use of vegetable oil - Death RR 0.94; 95%CI, 0.81, 1.08 - Sepsis RR 0.71, 95%CI, 0.51, 1.01 - Better growth in the topical group. No significant differences between the 2 groups for the death/nosocomial infection before day 28 criteria. Increased risk for sepsis in the Aquaphor group (aRR 1.27; 95%CI, 1.03, 1.54), especially for newborns with a birth weight between 500 to 750 g (aRR 1.43; 95%CI, 1.05, 1.86). Better skin condition score (Skin Condition Grading Scale) in the emollient groups compared with no emollient group (control) ( $p < 0.001$ ). Better skin condition score in the olive oil and lanolin group vs. Bepathen® at 2, 3, and 4 weeks ( $p < 0.05$ ).	LE 1
Edwards 2004 (USA)	Multicenter randomized controlled trial (53 centers)	Preterm Mean GA 26.2 GW Mean BW 770 g $N = 1191$	Standard care vs. emollient (Aquaphor®) twice a day on the whole body for 14 days		LE 1
Kiechl-Kohlendorfer 2008 (Austria)	Single-center randomized controlled trial	Preterm Mean GA 30 GW Mean BW 1550 g $N = 173$	3 groups: - Bepanthen®. - Cream with olive oil (30%) and lanolin (70%) - No emollient. Emollient on the whole body, twice a day for 4 weeks		LE 1
Brandon 2010 (USA)	Multicenter randomized controlled trial (2 centers)	Preterm Mean GA 28.6 GW Mean BW 1117 g $N = 63$	No Sting® (one application on day 1 and 7) vs. Aquaphor® (twice a day)		LE 3
Kanti 2014 (Germany)	Single-center randomized controlled trial	Preterm $N = 22$	Sunflower oil 6×/day for 10 days vs. standard care	No significant differences between the 2 groups for TEWL. Better skin condition (NSCS) in the Aquaphor® group ( $p = 0.04$ ). NSCS was considered as normal ( $< 4$ ) in both groups. No significant differences between the 2 groups for TEWL, skin pH, skin hydration, skin condition (NSCS) and skin flora. For the sunflower oil group, TEWL increased until day 11 and then decreased, suggesting a delay in skin maturation.	LE 3
Strunk 2018 (Australia)	Single-center randomized controlled trial	Preterm GA < 30 GW $N = 72$	Coconut oil (5 ml/kg) 2×/day from day 1 to 21 vs. standard care	No variation for skin condition (NSCS) in the coconut oil group. Decreased of the NSCS for the control group between day 1 and 21 (3 vs. 4, $p 0.01$ ). No adverse effect observed.	LE 2

LE, level of evidence (according to the referential from the Haute Autorité de Santé (HAS)); BW, birth weight; GA, gestational age; GW, gestational weeks; aRR, adjusted relative risk; 95%CI, 95% confidence interval; TEWL, transepidermal water loss; NSCS, Neonatal Skin Condition Score

**Authors' contribution** L. Renesme selected and reviewed the articles, and wrote, drafted, and reviewed the manuscript. The members of the GREEN committee listed in the appendix participated in the assignment of level of evidence and reviewed the manuscript.

### Compliance with ethical statement

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** This article does not contain any studies with human participants or animals performed by any of the authors.

**Abbreviations** LE, Level of evidence; TEWL, Transepidermal water loss

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