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ABSTRACT

This retrospective open study evaluating the efficacy of Sudocrem Antiseptic Healing Cream (SAHC) in infantile nappy rash (NR) was based on real-world evidence collected using an online questionnaire that included Likert scales. Participants who had used SAHC in the past (n=2159) were recruited via social media and email. A total of 1818 respondents who had treated NR in the previous 6 months were asked to take part in the study. Over 50% of respondents saw an improvement in NR on the same day that treatment was started, and within 3 days 94.5% of respondents reported an improvement in NR. Of 1804 subjects who answered the question, 72.5% indicated that the NR had completely healed within 3 days of starting treatment and by the fifth day, 94.7% said that the NR had completely healed. A total of 71% of 1793 respondents said that an episode of NR had either no or minimal impact disrupting their normal lives, but 29% reported a noticeable impact, even though evidence suggests that mild to moderate nappy rash can be treated quickly. Based on this real-world retrospective study, the evidence suggests SAHC is rapidly effective, reduces signs and symptoms of inflammation, and heals NR.

Key words: Nappy rash ■ Dermatitis ■ Inflammation ■ Real-world evidence

Current healthcare practice needs interventions to be delivered in a cost-effective manner based on best available evidence. Typically nurse practice may include not only evidence but also information from case studies involving small numbers of people and well-established legacy practice based on sources that do not stand up to contemporary scrutiny. Clinical trials typically have inclusion and exclusion criteria, and much has been written about the possibility that patients who participate in clinical studies may not be truly representative of those that actually use a product (Goldacre, 2012). While some clinical studies are sufficiently large to permit the reader to conclude that findings can be extrapolated, sometimes it is so difficult to find suitable patients that conclusions and predictions are based on relatively small numbers (of selected patients). Opportunities for formal clinical trials in busy nurse practice areas are limited and increasingly the information is based on analysis of outcomes from health records. One future possibility for increasing nurse knowledge resources is the outcome of nurse-led real world evidence studies.

Sudocrem Antiseptic Healing Cream (SAHC) is a licensed medicine authorised for the treatment of nappy rash, which has been available for over 80 years (Sudocrem, 2016). The evidence for the efficacy of healthcare interventions is typically based on the outcome of controlled clinical trials, and the gold standard is the double-blind prospective comparative study where neither the patient nor the investigator knows which patient receives which medication.

Nappy rash (NR), also known as diaper rash and diaper dermatitis, is primarily an irritant incontinence-associated contact dermatitis caused by several interacting factors, which can cause a breakdown of the integrity of the skin, particularly in the perineum, groin, thighs and buttocks (Lund, 1999; Shin, 2005). The majority of newborns display some skin breakdown in the nappy area by 1 week of age, with increasing severity by 3 weeks. NR most commonly occurs in the first year of life, but can occur up to 2 years of age as this is the most common time for wearing nappies. Approximately half of all children will have rash at some time during years of nappy-wearing (BMJ, 2015) and advice on management is typically from nurses and health visitors.

Factors that cause NR include contact of the skin with a soiled nappy and friction/shearing between the nappy and skin. Sitting in a urine-soaked nappy does not on its own cause NR but makes the skin moist, more permeable and susceptible to injury, and enhances the possibility of microbial/fungal infection. The faecal enzymes, alkaline pH and bile salt content may enhance stratum corneum breakdown (Scowen, 2000; Adam, 2008). Other risk factors include formula milk feeding, diarrhoea, frequency of nappy changing (Scowen, 2000) and age. Most cases seem to occur between 9–12 months of age (Jordan et al, 1986; Singalavanija and Frieden, 1995).

Strategies for prevention involve a gentle cleaning regime, keeping the skin in the nappy area as dry as possible and the use of hydrophobic partially-permeable creams to limit contact between the skin and nappy contents (Shin, 2005). Some infants seem more prone to NR and possible factors include having an atopic constitution, and possibly familial or genetic tendency (Scowen, 2000).

Treatments include the use of bland barrier creams, to permit natural healing, the use of steroid-containing topical treatments

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to reduce inflammation, and the administration of topical anti-infectives to eliminate complicating infection, e.g. by candida yeast infections, which can cause an intense inflammation that is bright red and sharply demarked (Prasad et al, 2003; Humphrey et al, 2006). Not all rashes and skin breakdown in the nappy area are simple NR, and may be related to other more serious conditions (e.g. trauma, bullous disorders such as bullous impetigo, Crohn's disease) as has been reviewed by Halbert and Chan (2002) and Humphrey et al (2006).

Advice on the management and prevention of NR is frequently the responsibility of practice nurses and health visitors who may have a better rapport with parents and more time than hospital doctors and GPs (Redsell et al, 2007). However, advice offered may be based on personal experience, case studies and anecdote rather than evidence. The study described in this article involved reports from users of SAHC and offers a methodology that can be extrapolated to other nurse-led interventions.

Method

A protocol for the collection of retrospective data was agreed with input from medical, pharmacovigilance, marketing and social media expertise from Actavis UK Ltd and Allergan Limited and an independent expert in clinical research and real-world evidence (MG). As the study was retrospective and involved no randomisation, intervention, or access to medical records, it did not need ethical approval or regulatory submission.

The protocol was designed to collect information on four components of inflammation that participants could evaluate, their perception of the healing of NR, and the speed of action. There was also a question relating to the impact on daily life of NR. All respondents were asked all questions.

Data were collected using a bespoke internet platform SurveyGizmo application configured for use on home computers, tablets and smart phones. The cohort size was set at a minimum of 200 respondents (thought to be the lowest credible number to be able to draw meaningful conclusions) up to a maximum of 2000 (considered to be representative of the population in general). The subjects confirmed that they had used SAHC for the treatment of an episode of NR in a child, and the questionnaire asked for details of how it was used and the outcome experienced.

A pilot study preceded the main study to confirm the viability of the methodology and resolve any ambiguity of the questions. These data were not included in the results, but the sequencing of questions was modified to eliminate non-logical progression through the questionnaire.

Patients were recruited via Facebook, Twitter and a mailing list from the Bounty Bag 'parenting club' mailing list with 100 000 members. The participants included mothers, fathers, grandparents, and other carers (as long as they were over 18 years old) who cared for infants. The prophylactic use of the product was not permitted for entry into this study, in line with the product's marketing authorisation.

On entry into the Sudocrem Real-World Evidence (SURE) study, the participants were informed of the objectives of the study and they agreed that their data could be used for research and marketing purposes. As this was not a prospective clinical study, formal informed consent was not necessary. The key criteria for entry into the study was a diagnosis of NR either from a health professional or carer in a child, and the use of

Table 1. Time since using SAHC to treat an episode of nappy rash

When did you use SAHC to treat NR?	Number (%)
In the last 4 weeks	1346 (74.0)
Between 1 and 3 months* ago	344 (18.9)
Between 3 and 6 months* ago	128 (7.0)
Total	**1818**

SAHC: Sudocrem Antiseptic Healing Cream; NR: nappy rash

Table 2. Age of child

Age (months)*	Number (%)
0–3	131 (7.2)
3–6	149 (8.2)
6–9	156 (8.6)
9–12	175 (9.6)
12–15	170 (9.4)
15–18	114 (6.3)
18–21	132 (7.3)
21–24	137 (7.5)
24–27	275 (15.1)
27–30	116 (6.4)
30–33	81 (4.5)
33–36	182 (10.0)
Total	**1818**

*Range from lower limit to just under the upper age in months

Table 3. Perceived redness of skin affected by nappy rash

n=1816	% before starting SAHC	% day after starting SAHC
No redness	2.3%	41.4%
Slight redness	24.7%	39.7%
Slightly less than moderate redness	19.1%	13.1%
Moderate redness	35.5%	3.5%
Slightly more than moderate redness	10.4%	1.8%
Severe/very severe redness	8.1%	0.6%

Table 4. Perceived swelling of skin affected by nappy rash

n=1816	% before starting SAHC	% day after starting SAHC
No swelling	57.6%	90.6%
Mild swelling	30.9%	6.6%
Slightly less than moderate swelling	4.7%	1.8%
Moderate swelling	4.8%	0.7%
Slightly more than moderate swelling	1.1%	0.3%
Severe swelling	0.7%	0.1%
Very severe swelling	0.2%	0.0%

Table 5. Subjective hotness of skin affected by nappy rash

n=1816	% before starting SAHC	% day after starting SAHC
Not hot	23.9%	83.3%
Slightly hot	48.7%	12.8%
Slightly less than moderately hot	11.2%	2.4%
Moderately hot	10.9%	1.1%
Slightly more than moderately hot	3.2%	0.4%
Severely hot	1.7%	0.1%
Very severely hot	0.6%	0

Table 6. Apparent discomfort of infant

n=1816	% before starting SAHC	% day after starting SAHC
No discomfort	13.4%	73.2%
Mild discomfort	42.2%	19.7%
Slightly less than moderate discomfort	13.2%	4.1%
Moderate discomfort	15.4%	1.9%
Slightly more than moderate discomfort	7.5%	0.7%
Severely uncomfortable	6.1%	0.3%
Very severely uncomfortable	2.3%	0.2%

SAHC to treat NR. The study evaluated one episode of NR.

Consistent with the real-world evidence methodology, there were no exclusion criteria. There were no excluded co-medications or treatments.

This was a study of efficacy only, and did not address safety apart from inefficacy. Although the results in this article include participants who reported the product to be ineffective, inefficacy was treated as an adverse event and the carer was redirected to a function that resulted in an adverse event report to the marketing authorisation holder. As this was not a clinical trial in the conventional sense there were no audits or inspections. Participants completed an online questionnaire, and the SurveyGizmo system provided summary descriptive statistics of the results. The questionnaire covered demographic details, details of the episode of NR, and an evaluation of the response to treatment with SAHC. Other treatments being used at the same time were permitted and did not mean participants were excluded from the study, and this meant the responses evaluated looked at the holistic approach used to manage NR rather than just SAHC.

Results

A total of 2159 respondents aged 18 to 85 years who had used SAHC on an infant that they cared for in the past completed an online questionnaire during a 9-day period. An estimated 1070 of these were from the Bounty mailing list, recruited in a 2-day period, after which recruitment was closed. There were 140 male and 2019 female respondents.

Of these, 1818 had used the product within the previous 6 months (74% had used the product within the previous 4 weeks) (*Table 1*). In order to minimise recall bias, the responses of these 1818 people were included in the analysis for this study. Not all respondents answered all questions. The average age of the infants being cared for by the respondents was 17.9 months, standard deviation (SD): 9.4 months (*Table 2*). A total of 1784 responses gave the infants' gender: there were 873 males and 911 females. Using a series of guidance pictograms, only 94/1816 (5.2%) of respondents judged the NR to be worse than mild to moderate, and the remaining 94.8% judged the condition to be mild to moderate.

In order to assess the severity and treatment effect on inflammation, participants were asked to rate redness, heat, swelling and apparent discomfort (as a surrogate for pain) before treatment and 1 day after, using a Likert scale. It was not possible to rate loss of skin function, the final component of inflammation. Participants were asked to judge the redness of the skin affected by NR before the first application of SAHC and 1 day later using a Likert scale(*Table 3*).

Similarly, participants were asked to rate skin swelling before and 1 day after using SAHC (*Table 4*). They were also asked to rate how hot the affected skin felt before starting SAHC and 1 day after starting treatment using a Likert scale (*Table 5*).

As there was no easy way to measure the pain or other unpleasant sensation that the children experienced from NR, it was decided to use the concept of discomfort. This may present as crying, lack of sleep, general irritability and fussing in infants, and is something that can cause distress to carers. The results are shown in *Table 6*.

Two questions were used to ascertain the efficacy of SAHC. The objective of treating NR is to decrease the rash (in area and intensity), with an ultimate aim of healing the skin, i.e. when all of the signs and symptoms of the condition have resolved.

For those respondents reporting that the condition did not improve at all, an interpretation of inefficacy was made, and the respondents were redirected to report this as an adverse event (reported in this study as there being no improvement).

A total of 38.7% of the respondents (703/1818) indicated that, in their opinion, the NR had completely healed or completely disappeared. A total of 99.3% indicated that the NR had improved (ranging from a very small amount to completely healed/disappeared) (*Table 7*).

Speed of healing

Respondents (n=1805) were asked how rapidly the NR improved (*Table 8*) and how rapidly, in their opinion, the NR completely healed after they started using (first application of) SAHC for the episode of NR (*Table 9*).

In total 99.4% (1793/1804 respondents) indicated that the NR had healed. The number of respondents answering this question was slightly lower than the previous question as people who had not responded to the question were removed automatically by the web interface questionnaire.

Impact on daily life

Of the 1793 carers, 71% said that an episode of NR had either no or minimal impact on their lives, but 29% reported a noticeable impact, even though the results suggests that mild to moderate NR can be treated quickly.

Discussion

SAHC is a licensed medicinal product with several indications, including the treatment of NR. It is a water-in-oil emulsion and its active ingredients are: zinc oxide, benzyl alcohol, benzyl benzoate, benzyl cinnamate, and lanolin (hypoallergenic).

Zinc oxide is used in dermatology for its astringent, soothing, and protective properties. Benzyl alcohol is a local anaesthetic and has disinfectant properties. Benzyl benzoate and benzyl cinnamate are the principal esters of Peru Balsam (Balsam of Peru), which is classed as having mild antiseptic properties. Lanolin resembles the sebaceous secretions of human skin, and the grade used in SAHC is manufactured so as to exclude many sensitising substances usually present in the lanolin (Forest Laboratories UK Ltd, 2014).

The barrier properties of SAHC are related to its excipients of waxes and paraffin oil. The efficacy of SAHC was established in two legacy studies (Mitchell and Reid, 1982; Anthony et al, 1987), but these did not specifically address the healing of infantile NR.

While well-controlled prospective clinical trials have been the gold standard for establishing efficacy of a healthcare intervention, they are increasingly difficult to undertake and complete, ethically problematic, and may be difficult to interpret in light of highly selected populations of patients (Goldacre, 2012). Current thinking (Annemans et al, 2007; Association of the British Pharmaceutical Industry, 2011; Cziraky and Pollack, 2015) is that efficacy should be categorically defined by randomised clinical trials, but real-world evidence is a reflection of what happens in a population that accesses a treatment, and may be more relevant to nurse-led practice.

Real-world evidence studies examine how existing medicines and treatments are working in the healthcare system. Unlike controlled clinical trials, real-world evidence studies use observational data such as electronic medical records, insurance claims information and patient surveys. Real-world data can provide a structured snapshot of patient experience, but on their own they do not permit recommendations in the clinical setting because it is recognised that they fall short of the conventional required robust scientific analysis (Annemans et al, 2007; Association of the British Pharmaceutical Industry, 2011; Cziraky and Pollack, 2015).

What makes this study of treatment of NR unique is that the methodology is used for a scenario where medical records

Table 7. Perceived improvement in nappy rash

Did the rash improve?	Number (%)
It didn't improve at all	12 (0.7)
It only improved a very small amount	40 (2.2)
It improved a small amount	85 (4.7)
It improved a fair bit	313 (17.2)
It improved more than a fair bit	233 (12.8)
It almost disappeared	432 (23.8)
The nappy rash completely healed/completely disappeared	703 (38.7)
Total	**1818**

Table 8. Speed of perceived improvement

How quickly did you see any improvement to the nappy rash AFTER the first application of SAHC?	Number (%)
Next nappy change	319 (17.7)
Same day	606 (33.6)
Next day or the day after	779 (43.2)
3 to 5 days later	87 (4.8)
5 to 7 days later	10 (0.6)
More than a week afterwards	2 (0.1)
I didn't see any improvement	2 (0.1)
Total	**1805**

Table 9. Perceived timing of healing

When complete healing occurred	Number (%)
Next nappy change	78 (4.3)
Same day	210 (11.6)
Next day or the day after	1021 (56.6)
3 to 5 days later	400 (22.2)
5 to 7 days later	64 (3.5)
More than a week afterwards	20 (1.1)
It did not heal/I had to seek alternative treatment	11 (0.6)
Total	**1804**

are very rarely kept. Conditions commonly self-diagnosed and treated with over-the-counter medicines rarely generate medical records. Therefore the collection of data from medical records for minor self-treated (or carer-treated for children) ailments even when planned prospectively would be unachievable, necessitating the use of retrospective survey methods. By examining data associated with the delivery of care, even from over-the-counter products, real-world analyses can assess how various treatments impact the cost of care and other key evidence-based outcomes. Data about real-world patient experience also has the potential to improve the quality and delivery of medical care, reduce overall costs and improve outcomes by accelerating the understanding of how best to incorporate new therapies and technologies into everyday clinical practice. Essentially, these data help fill the knowledge gap between clinical trials and actual clinical practice.

Social media

The method of real-world evidence is particularly appropriate to nurse-led healthcare interventions. Often these are based on historical precedent and lack contemporary evidence. The method, which may be based on existing records of patients or on a social-media approach, is well suited to research into the nursing environment and deserves further investigation into its wider applicability. This may be a significant advance on the case-report led literature, where numbers are often small, and the opportunity for larger cohorts seems promising.

The use of social media for collection and collation of medical information is now widespread. There is no existing literature on the use of social media for systematic collection of efficacy data, but it seem likely that because of the ease of use, speed of collection and low budget needed, this method will become widely accepted.

Recruitment

In this study, the problems of recruiting adequate numbers of young infants (with the inherent ethical issues), protracted recruitment period, and confounding factors (such as concomitant therapies, other medical conditions, missing data, inclusion and exclusion criteria, age restrictions) are eliminated by taking participants on an almost all-comers basis. The only criteria for participation were living in the UK, needing treatment for NR, having used SAHC to treat it and that the NR occurred on a child under 3 years old.

Thus the study took all comers and all interpretations of NR. There were no restrictions on diet, use of disposable or re-usable nappies, intercurrent illnesses and other therapies. There were no conditions on the use of the product, and thus the quantity used per application was not a factor and neither was the frequency of application. This means that the results are more likely to represent an overall picture of what might happen to the larger population, but no study can cover all possibilities.

Accounting for participants

The oversight that is part of the quality-management systems inherent in clinical trials is absent in real-world evidence, and one inherent problem is accounting for participants. In this study, as one of the criteria for participation was use of the product, then the equivalent of the intention-to-treat group is the same as the number recruited. It is not typical to demonstrate a per-protocol group, and it was found in this study that data did not exist for all respondents, and the sequential display of questions may not have prevented failure to answer a particular question. Nevertheless, the numbers did not dip below 1804/1818 (99.2% of respondents) suggesting that the data set was almost complete.

Questionnaire development

The questions were developed on a pragmatic basis, and answered using a 7-point scale. Where the response rate to any option was zero, these data have not been presented. It was expected that there would be sufficient sensitivity for discrimination of change. The questionnaire was not validated, but was subjected to a trial period involving volunteers associated with the project (employees of the sponsor company and the subcontractors to the project), and the wording and order of questions were fine-tuned based on their responses.

Influencing factors

Issues that could have influenced the prevalence of NR include diarrhoea, bottle-feeding rather than breast, nappy type and frequency of changing nappies (Scowen, 2000; Atherton and Mills, 2004). While NR may be regarded as a self-limiting condition (Frazier and Drzymkowski, 2016), it is unlikely to go untreated, and the question becomes whether the active treatment produces a rapid response.

Demographics

The population recruited was heterogeneous, including infants who were born prematurely, by caesarian section, and infants who may have had other coexisting illnesses and may have been on other treatments. This reflects more accurately the real-life situation of treating an infant with NR than limiting these variables.

While the consensus view is that most NR occurs between 9 and 12 months, the demographics of the study population identifies secondary peaks between 24–27 and 33–36 months (*Table 1*). This may represent children learning to live out of nappies, but having accidents or wearing nighttime nappies.

It was not possible to deduce the association between NR and issues such as teething, immunisations or weaning. The majority of the analysed population (74%) had experienced NR in the previous 4 weeks. This suggests that the outcome was not corrupted by recall bias and to all intents and purposes the retrospective nature of this analysis does not differ from patient-derived data in clinical trials.

User engagement

There were no particular reasons why either a satisfied or dissatisfied user should preferentially enter the study, but as most communications from a consumer to a brand relates to dissatisfaction (Richins, 1983; Curren and Folkes, 1987) , it would have been reasonable to expect the questionnaire to be

used as a method of indicating that the treatment did not work. At several stages, inefficacy could be documented, and it was consistently reported as less than 1% of respondents. In line with EU legislation, reports of inefficacy of the product were documented and reported to the relevant competent authority.

Treatment outcomes

As NR is inflammation associated with incontinence, the typical features of inflammation are present: redness, heat, swelling, pain and loss of skin function. Thus a perceived response and healing of skin are marked by reduction of signs and symptoms of inflammation. There was no accessible way of assessing loss of skin function in a real-world setting, so the other four parameters were assessed. As the infants could not be conventionally rated for pain, a surrogate of apparent discomfort was used, as this is what was witnessed by the carers. The data indicate that the treatment reduced the apparent severity of components of inflammation within 1 day of starting treatment with SAHC. The resolution of signs of inflammation and return to normality of skin is conventionally recognised as healing of the NR.

Response to SAHC

In this study, the signs and symptoms were recognised by the respondents and 38.7% of respondents considered the condition to have been healed or to have completely disappeared, with only 0.6% considering that there had been no response to treatment with SAHC. It is not possible to discern why there was a lack of response to the product, but may have included those who used the treatment infrequently (21.6% of respondents used SAHC once a day or less frequently). Further research is needed to establish whether more frequent use is associated with a better outcome.

NR might be a self-limiting condition, however, it is unlikely that a carer would leave it untreated unless they were in a position to leave the affected skin completely exposed without a nappy, which is unlikely in Western cultures. The study revealed that when mild to moderate NR is treated using SAHC, the response was rapid; 51.3% of respondents reported an improvement the same day the treatment was started, including 17.7% who noticed improvement by the next nappy change.

While there is an excess of 'expert' (unregulated and non-peer-reviewed) opinion available on the internet on treating NR, there is a dearth of information on the speed of action of treatments and how long to expect it to take to treat/heal the condition. This study is the first to consider speed of response to a treatment for NR. It is noteworthy that of 1805 respondents, 94.5% reported improvement the same day, the next day or the day after (i.e. within 3 days of starting treatment) and 72.5% of 1804 respondents reported healing within the same time frame and 94.7% within 5 days of starting treatment.

These self-selected subjects include those not only with mild to moderate NR, but also those with more difficult cases and misdiagnosis. (They may not have had nappy rash by strict diagnostic criteria, or it also may have been misdiagnosed by health professionals. However, in a real world study, you derive the outcome of use of therapy independent of the accuracy of diagnosis). Thus it seems fair to say that 50.1% of users can expect to see improvement at the next nappy change or the same day, 15.9% can expect healing at the next nappy change or the same day and 95% of users can expect improvement within 3 days and healing within 5 days of starting treatment. A previous study of SAHC in geriatric incontinence dermatitis (Anthony et al, 1987) showed that SAHC was superior to a bland zinc oxide cream. This suggests that the combination of ingredients in SAHC gives some superiority over a simple barrier cream. There is a positive effect on resolution of inflammation and healing of skin affected by NR and this suggests that the product is not simply acting as a barrier cream in NR (Anthony et al, 1987).

Impact of NR

Around 50% of parents said NR is the skin complaint they worry about most (Scowen, 2000). Responses in this study indicated 71% of 1793 carers said that an episode of NR had either no or minimal impact disrupting their normal lives, but 29% reported a noticeable impact, even though this study suggests that mild to moderate NR can be treated quickly. This suggests that the concern may exceed the reality of the situation, and with effective treatment, the impact on daily life is small for the majority of people. For some carers, a child with NR is a significant issue and these data will bring reassurance that the condition can be treated in the vast majority of cases effectively and rapidly.

Real-world evidence

The method of real-world evidence is an effective way of collecting significant amounts of data from users of over-the-counter treatments in conditions that may not always be seen by medical professionals, and where medical records may not exist. This study supports the widespread anecdotal information about the efficacy of SAHC and the speed of action in a real-world environment. There are numerous published reviews (Boiko, 1999; Lund, 1999; Scowen, 2000; Atherton and Mills, 2004; Borkowski, 2004; Humphrey et al, 2006) advocating ideal treatments for NR, but few offer data as opposed to judgement indicating the logic for choice. The study was not a comparative study, and does not indicate the efficacy compared to other treatments.

Real-world evidence is the outcome of interventions in the wider population, and this study indicated that in a sample bigger than that which would normally be recruited into a clinical trial, meaningful outcomes data can be generated using social media. A review of the fuller cohort of 2159 respondents showed only minimal difference to the smaller cohort, but to exclude the possibility of recall bias, only the 1818 respondents who had treated an episode of NR in the previous 6 months were included in this analysis. Of the 1818 respondents, 1346 had used SAHC in the previous 4 weeks.

Limitations

The method of real-world data collection has never been tried for the evaluation of the efficacy of an intervention for NR. The outcome measures were not been validated formally. The retrospective reporting of efficacy is not as resilient as real-time

KEY POINTS

- Clinical trials for common self-treated conditions are difficult
- Real-world evidence provides retrospective information about the way that conditions have been treated and is a potentially valuable method in nursing practice for evaluating established and new healthcare interventions
- The methods are simple, can be implemented with the minimum of administrative oversight, are very cheap to apply and may produce meaningful results much more rapidly than a clinical trial
- Social media platforms can be a novel way of collecting data from large numbers of patients

clinical endpoint reporting by a health professional and may be subject to recall bias. There was no comparator product and no data on the consequence of no active intervention.

Conclusions

Much of the published information on NR is in the form of reviews, case reports and non-clinical data extrapolated to the clinical world. Real-world evidence studies using social media platforms can be used to generate user-based relevant efficacy data for healthcare interventions. This method is ideally suited for nurse-led interventions where a formal clinical trial would be impractical. Most nurses will be working in environments where good clinical research practice cannot be implemented as the dedicated resources needed are huge and most will not have received the annual training needed in good clinical research practice.

Of 2159 respondents recruited to the online study of the efficacy of SAHC, using Likert scales, 1818 had used the product within the previous 6 months to treat an episode of NR and their responses were included in this analysis. The majority of users found the product rapidly effective at reducing the signs and symptoms of inflammation associated with NR, 94.5% reporting improvement the same day, the next day or the day after and 72.5% of 1804 respondents reported healing within the same time frame.

Based on these real-world data, SAHC can be considered rapidly effective at reducing the inflammation associated with NR and healing the affected skin. **BJN**

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