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# **Guidance for use**

This clinical evaluation report is aimed primarily at the NHS and all those working to support patient care. If you would like to talk through how this report can be used in your setting, please contact the team by emailing: <a href="mailto:clinical.evaluationteam@nhs.net">clinical.evaluationteam@nhs.net</a>.

Please note that the product assessment results should only be read and used in conjunction with the full text of this clinical review.

# 1. Introduction

The NHS Clinical Evaluation Team was established in May 2016. The remit of the Clinical Evaluation Team is to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags across the NHS. The purpose of this report is two-fold: firstly, to provide a clinical assessment of the usability and requirements from the NHS for skin barrier films that are available to the NHS from the national procurement provider and secondly, to provide a clinical statement of desired functions and properties that the clinicians in the NHS require of skin barrier films for use in future procurement activities.

It is clear from the evidence that skin barrier films featured in this report, are everyday healthcare consumables that are found in most clinics or ward settings and would certainly be items included in any stock list to set up a new clinical service. On that basis, the project was approved by the Clinical Reference Board in June 2016, culminating in the production of this report for their approval in October 2017.

Based on 2014-16 data supplied by NHS Supply Chain the requirement for skin barrier films has increased significantly in the NHS during that time period. Combined barrier film spray and foam applicator purchases in 2014 was less than 500,000 units compared to almost 1.9 million units in 2016 representing a 388% increase in sales. There are 9 different suppliers of skin barrier films listed in the advanced wound care category of the catalogue. This report covers the range of products available as of August 2017.

Intelligence about skin barrier films was gathered from a variety of sources to provide background information on the current evidence available to support the way in which the devices are designed and clinically evaluated.

Following this, clinical engagement sessions were held with the aim of identifying important clinical criteria for skin barrier films from frontline NHS clinicians. This information was used to develop clinical criteria for skin barrier films against which all brands available from the national procurement provider were reviewed.

Findings from these clinical reviews are collated into a product assessment report to allow users to identify products and see how they performed against the agreed clinical criteria.

A more detailed description of the team and our pathway approach can be found in the NHS Clinical Evaluation Team operating manual which can be found on our website at: www.nhsbsa.nhs.uk/cet.

# 2. Clinical Context

# 2.1 Clinical definition and scope for skin barrier films

Skin barrier films are liquid formulations designed to protect skin from the effects of mechanical or chemical injury. Skin barrier films are also used in the prevention of moisture-associated skin damage (MASD), protecting skin from excessive moisture due to incontinence, perspiration or wound drainage. Products form a transparent protective coating on the skin and can be safely applied to intact or broken skin without stinging, they may be formulated from a variety of substances including acrylates, polymers both organic and inorganic, and silicone. Following application, the liquid part of the barrier evaporates and leaves a transparent, breathable protective coating.

Skin barrier films are available in a wide variety of packaging and dispensing options including foam applicator, wipe, and spray container. Application of liquid skin protectants is often the final step in a comprehensive skin care protocol for the prevention of pressure ulcers including the process of cleansing, moisturising and protecting the genital and rectal areas to prevent skin breakdown.

Skin barrier films are designed for external use only and contraindicated for use on open wounds or in deep puncture wounds. Studies have shown that silicone barrier films reduce erythema and skin stripping following removal of adhesives in various patient populations, including neonates (Campbell et al 2000, Irving 2001, Shannon and Chakravarthy 2009). Using products that are alcohol-free is recommended, as the alcohol component can cause pain when applied to skin that is excoriated, such as can be seen with peristomal or peri-wound care. The products represented in this report are all alcohol free and therefore intended not to sting on application. One study involving 60 premature infants greater than 33 weeks gestation used a barrier film to reduce trans-epidermal water loss (TEWL) and improve skin integrity and found it as beneficial as petrolatum ointment in this population (Brandon et al 2010). However, The Association of Womens Health (2013) state that further research is needed in NICU patients before widespread use of skin barrier films is endorsed in this population.

Clinical indications for the use of skin barrier creams and ointments show some similarities to barrier films however the formulations and diversity of application are different and so for the porpose of this report barrier creams and ointments will remain out of scope.

#### 2.2 Intended clinical use

Skin barrier film is depicted in the literature to feature the following general performance properties and attributes:

- Provides protection from adhesive trauma.
- Helps to prevent maceration of periwound skin (wound margins).
- Promotes dressing adhesion and atraumatic dressing removal.
- Helps to prevent skin excoriation associated with incontinence of urine and faeces.
- Helps to prevent excoriation associated with excess moisture for example in skin folds.

# 2.3 Clinical practice

Skin barrier films are available in different volumes and application modes, including applicators, pump action sprays and aerosol sprays. This enables the clinician to choose the best option for their patient and their clinical environment.

# 2.4 Clinical impact

Selection of the most appropriate product for the clinical indicators will enhance patient comfort and clinical outcomes.

#### 2.5 Other clinical considerations

It must be recognised that the clinical understanding of wound care and knowledge of product(s) will vary amongst healthcare professionals in any given clinical environment.

# 3 Pathway method for skin barrier films

# 3.1 Intelligence gathering

In preparation of the criteria, account has been taken of academic and related clinical evidence, known guidance and nationally recognised publications as further described in this Section 3.

#### 3.1.1 Literature search

A literature search has been undertaken to establish what current academic knowledge exists on the products for evaluation. It should be noted that the team have not conducted a comprehensive or systematic review of literature. However, the team have interrogated the information to look for common themes which supported the development of the clinical criteria.

Initially, an evidence search was performed across the NICE service: <a href="https://www.evidence.nhs.uk/Search/skin-barrier-films">https://www.evidence.nhs.uk/Search/skin-barrier-films</a>. This suggested best practice considerations in the use of skin barrier films.

The search terms used (see below) generated many returns, however, there was little new information generated.

Search criteria	Databases searched		
<ul> <li>Skin barrier films</li> <li>No sting barrier films</li> <li>No sting skin barrier films</li> <li>Skin barrier products</li> <li>Liquid skin protectants</li> <li>Skin protectant</li> </ul>	NICE website evidence search https://www.evidence.nhs.uk/      NICE website journals and databases https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases (using Healthcare databases advanced search tool – Ovid, Medline, CINAHL, databases searched)		
Date Range	Since 1975		
Language	English		

Figure 1 Literature and other sources searches – Skin barrier film

## 3.1.2 National Procurement Provider Specification

As the national procurement provider, NHS Supply Chain manages a framework of suppliers who are then listed in the national catalogue. The framework covers a wider selection of products than just skin barrier films.

The specification used by the national provider (NHS Supply Chain) has been reviewed to understand what has previously been asked of suppliers for these devices.

The specification, as used by the NHS national procurement provider (NHS Supply Chain, 2016), provides insufficient detail relating to the clinical criteria relevant for this product group, but are considered in the process for the development of such criteria.

### 3.1.3 National and International Safety and Quality Standards

Account has also been taken of appropriate international and other standards as they pertain to the devices (e.g. from the International Organisation for Standardisation (ISO), European Standards (EN) and/or British Standards Institution (BSI). A review of Medicines & Healthcare products Regulatory Agency (MHRA) alerts has also been performed.

The MHRA website (<a href="https://www.gov.uk/drug-device-alerts">https://www.gov.uk/drug-device-alerts</a> ) returned no product alerts relating to this product category against the search terms previously described.

Medical Device Directive 93/42/EEC as amended, currently in transition to the new Medical Device Regulation MDR 2017/745

 All products classified as a Medical Device must have their CE marking clearly evident on the product and/or packaging and meet the requirements set out within the standard(s) related to labelling.

## 3.1.4 Product Suppliers and Manufacturers

All suppliers listed within the national framework were invited to submit relevant evidence, product information and testing data to help support the review. All suppliers provided some level of information from product brochure through to technical datasheets and compliance with standards.

# 3.1.5 Quality of evidence

Levels of evidence sometimes referred to as hierarchy of evidence are assigned to studies based on the methodological quality of their design, validity, and applicability to patient care.

Hierarchy ranking	Description
Level 1	A systematic review of all relevant randomised controlled trials (RCT) or evidence based clinical practice guidelines based on systematic reviews of RCT evidence
Level 2	Evidence from at least one well designed RCT
Level 3	Evidence from well-designed controlled trials; non-randomised, quasi experimental
Level 4	Well-designed case-control & cohort studies
Level 5	Systematic reviews of descriptive and qualitative studies
Level 6	Evidence from a single, descriptive or qualitative study
Level 7	Evidence from the opinion of authorities and/or reports of expert committees

Figure 2 – Hierarchy ranking: Evidence based practice in nursing & healthcare: a guide to best practice" (B.M. Melnyk & E. Fineout-Overholt; 2005; p10)

## 3.2 Best Practice Guidelines

The National Institute for Health and Care Excellence (NICE) has published no medical technology guidance related to skin barrier films at this time however skin barrier preparations are advocated by NICE (2014) to help prevent skin damage, such as moisture lesions for people who are incontinent. The guideline does not however specify the formulation of the barrier product for example barrier cream, ointment or film.

Beeckmann et al in The Best Practice Principles for Incontinence–Associated Dermatitus (2015) state that "IAD represents a significant health challenge worldwide and is a well-recognised risk factor for pressure ulcer development." The Global Expert panel set out specific requirements for products designed to prevent and manage IAD, including skin barrier films:

	General characteristics of the ideal product for prevention and management of IAD
>	Clinically proven to prevent and /or treat IAD
>	Close to skin pH (note that pH is not relevant to all products e.g those that do not contain hydrogen ions, including some barrier films
>	Low irritant potential/hypoallergenic
>	Does not sting on application
>	Transparent or can be easily removed for skin inspection
>	Removal/cleansing considers caregiver time and patient comfort
>	Does not increase skin damage
>	Does not interfere with the absorption or function of incontinence management products
>	Compatible with other products used (e.g. adhesive dressings)
>	Acceptable to patients, clinicians and caregivers
>	Minimises number of products, resources and time required to complete skin care regime
>	Cost effective

The best practice statement "Principles of wound management in paediatric patients" (2014) advises that barrier preparations should be used to prevent faeces coming into contact with skin, so reducing humidity and maceration and minimising transepidermal water loss. The document does not recommend any specific type of barrier formulation over another.

The All Wales Best Practice Statement "Prevention and Management of Moisture Lesions" (2014) advocates the use of film barrier products stating that they can be applied to broken or irritated skin without stinging and should dry quickly to provide a waterproof protective barrier against irritants such as faeces and urine. The guidance states that the product should be allowed to dry completely before applying pads or clothing as they may stick.

McNichol et al (2013) in a Consensus Statement for the Assessment, Prevention and Treatment of Adhesive-Related Skin Injuries (MARSI) state that these injuries have a significant, negative and costly impact on patient safety. The expert panel recommend the use of skin barrier films prior to adhesive product application.

# 4. NHS Clinical Engagement

In order to develop a shared vision of what is required from skin barrier films several methods of engagement were used. These events were used to formulate thoughts, ideas and needs from differing clinicians, familiar with these products; identifying their own expectation(s) of the product for their given patient group, and intended patient outcome, being used in a variety of differing clinical environments.

Mapping exercises were undertaken to determine personnel that should be involved and/or consulted regarding these products. This stage of the report focused on clinical staff that are:

- a) recognised as subject experts, and/or
- b) recognised regular users of the devices in their clinical practice.

Various methods of engagement were undertaken to ensure these clinical opinions were robust, and validated by peers from around the country, options of engagement included:

- Regional and national face-to-face events with NHS clinical colleagues
- Focussed visits to NHS clinicians regional and national face-to-face events
- Website subscription
- Attendance at specialist network events
- Attendance at NHS Business Services Authority events
- Web-based surveys and e-engagement tools (e.g. email, WebEx, portal based surveys)

#### 4.1 Clinical Conversations

To build a broad caucus of attendees at our events letters were sent inviting Trusts to nominate clinical colleagues to attend a series of regional group events. These were hosted by NHS organisations throughout England to enable the widest possible access for all invited. This ensured to set aside any pre-existing regional variance.

Details of the discussion outcomes were recorded in workbook form from the open events, transcribed and then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product has been tested.

## 4.2 Clinical criteria

The data received from all the NHS clinical engagement events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria.

A clinical criterion is defined as a principle or standard by which products may be evaluated. It is an objective statement which describes the clinician's requirements for the product.

The proposed criteria were validated by workshop attendees and all other clinical experts engaged in the development process. In addition, other clinical experts who are likely to add further useful insight were also included, leading to the finalised clinical criteria listed below.

## Clinical Criteria – Skin barrier films

#### **PACKAGING**

The product type is clearly visible

The volume of liquid contained in the packaging is clearly visible

Area available on the pump action/ aerosol container to apply the patients name label/ write the patients name

The pump action bottle and aerosol bottle should be clearly labelled for single patient use.

The cap on the pump action bottle should be smooth and not contain grooves

Product flammability warning is clearly visible

The product life once opened is clearly identified on the packaging. (Pump action and aerosol spray.)

The expiry date, EN standards and CE marking are clearly visible

The information is in English and clearly explains what is in the box

Contra –indications for use are clearly displayed on the packaging

The product information leaflet can be easily read and understood.

Figure 3 - Defining the clinical criteria for [text] – NHS Clinical Criteria skin barrier film

#### **OPENING & PREPARATION FOR USE**

Foam applicator packaging should have a clearly marked 'tear line', or a tab to enable ease of opening

Foam applicator packaging should tear cleanly along the indicated line to allow access to the product

Shrink-wrapped (tamper-proof) packaging applied to pump action spray bottles should be perforated for and clearly marked for opening

Shrink-wrapped (tamper-proof) packaging applied to pump action spray bottles should be clearly marked for opening

Pump action spray bottles and aerosol bottles should have a lid that can be easily replaced and maintained

#### **CLINICAL USE**

The product dries on application to the skin within 30 seconds

The product is clear on the skin (no pigment)

The product does not leave a tacky residue on the skin when dry.

The product has no odour 30 seconds after application

The product can be applied to the skin at diverse angles from a pump action or aerosol container

The product should be suitable for application to paediatric skin

The product does not prevent successful application of adhesive dressings to the skin.

# 4.2.1 Criteria explanation- Inclusion

To enhance the readers understanding of this report, and to provide value to the results, an explanation for the defined clinical criteria is captured.

PACKAGING CRITERIA				
The product type is clearly visable	Displaying the product category clearly ensures health professionals know that the product being selected is a skin barrier film			
The volume of liquid contained in the packaging is clearly visible	There is a range of volume options available, it is important that clinicians select the correct product.			
Area available on the pump action/ aerosol container to apply the patients name label/ write the patients name	Multi-dispensing, single- patient use products must be clearly labelled to prevent cross contamination between patients and support infection prevention policy.			
The pump action bottle and aerosol bottle should be clearly labelled for single patient use.	As above			
The cap on the pump action bottle should be smooth and not contain grooves	The dispensing bottle will come into close contact with potentially contaminated tissue and body fluids. Multi-dispensing units should be easily cleaned to prevent cross contamination			
Product flammability warning is clearly visible	To enable correct product storage			
The product life once opened is clearly identified on the packaging. (Pump action and aerosol spray.)	Clinicians are unclear about product life once open. Suppliers have stated that pump action and aerosol containers are safe to use until empty. Clinicians said that there was limited awareness and that product was often discarded early leading to wastage.			
The expiry date, EN standards and CE marking are clearly visible	Clinicians are required to check this information prior to applying to the patients skin			
The information is in English and clearly explains what is in the box	The product will be stored together with multiple items in any clinical setting. The clinician must be able to quickly and clearly identify the product.			
Contra-indications for use are clearly displayed on the packaging.	Clinicians are required to understand the mode of application and to consider any indications and contra indication for use prior to application to the patients skin			
The product information leaflet can be easily read and understood.	As above			

OPENING AND PREPARATION FOR USE			
Foam applicator packaging should have a clearly marked 'tear line', or a tab to enable ease of opening	To enable efficient and rapid identification of the appropriate access to the product.		
Foam applicator packaging should tear cleanly along the indicated line to allow access to the product	To enable efficiently access to the product and/or using a sterile non-tough technique.		
Shrink-wrapped (tamper-proof) packaging applied to pump action spray bottles should be perforated for and clearly marked for opening	To enable efficient and rapid identification of the appropriate access to the product.		
Shrink-wrapped (tamper-proof) packaging applied to pump action spray bottles should be clearly marked for opening	To enable efficient and rapid identification of the appropriate access to the product.		
Pump action spray bottles and aerosol bottles should have a lid that can be easily replaced and maintained	To protect the dispensibng portal, and ensure that the lid remains with the bottle and does not become easily detached presenting a potential hazard to the patient, particularly in seating or in the bed area.		

CLINICAL USE			
The product dries on application to the skin within 30 seconds	Skin barrier film is often applied prior to application of a dressing or paper continence product. Extended drying time is problematic during clinical procedure.		
The product is clear on the skin (no pigment)	It is important that the colour of the skin remains visible to determine tissue perfusion and potemtial tissue injury.		
The product does not leave a tacky residue on the skin	Tachy residue is uncomfortable on the skin, particularly when wound dressings or contimnence products are in use.		
The product has no odour 30 seconds after application	Clinicians said that patients find odour to be unacceptable and the literature confirms that odour negatively impacts patients quality of life and experience of illness.		
The product can be applied to the skin at diverse angles from a pump action or aerosol container	Skin barrier film is applied in diverse clinical situations and environments. Spray applicators are often the most appropriate dispensing modality in these circumstances.		
The product should be suitable for application to paediatric skin	Clinicians require clear guidance about suitability of prodcuts in babies and children		
The product does not prevent successful application of adhesive dressings to the skin.	Skin barrier films are often used inconjunction with medical adhesives.		

# 4.2.2 Criteria explanation – exclusion

PROPOSED CRITERIA	EXPLANATION FOR EXCLUSION	
Function and performance of the product over time following application to the skin	The formulations of barrier products vary by supplier making any direct comparison difficult.  Skin lipid contect varies between individual patients and ethnic groups effecting the barrier performance of the product.  Transepidermal water loss from the skin will be effected by multiple variables, including age, medication, medical condition and skin barrier function.	
	Clinical areas have diverse process, procedure and product availability for skin cleansing which will impact erosion and removal of the product from the skin.	
Shear reduction at the skin surface	There is no clinical evidence or advice with regards to the use of barrier films for the reduction of shear forces in Best Practice Statements	
Chlorhexidine Gluconate compatibility	This feature will be included in the product indications and will be selected by the clinician when using under vascular access dressings.	

#### 4.3 Product evaluation

Evaluation methodologies are defined for each and every clinical criterion. They reflect a simulated clinical environment.

Wherever possible, products were supplied in a 'ward ready' unit of issue as would be found by clinical staff on accessing a store area in their clinical environment. Where this has not been possible it was acknowledged as part of the product assessment results matrix.

The tests were formulated to move through the key aspects of product use using the NHS Clinical Evaluation Team product cycle:

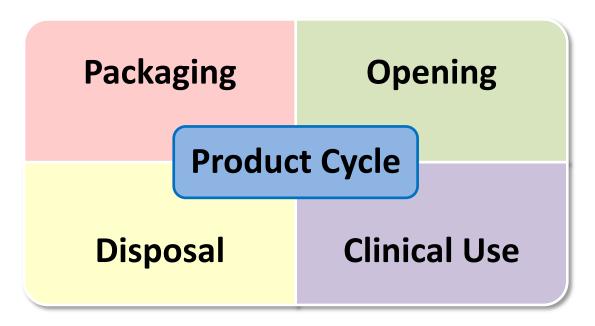


Figure 4 - NHS Clinical Evaluation Team Product Cycle

The evaluation product was ordered and picked from the NHS distribution centres. Products evaluated have been stored post evaluation for a period of three months after publication of this review.

Practicing NHS clinical staff were invited to review the products in accordance with the developed criteria. It was not possible to 'blind' the evaluations; in the sense that the evaluators were aware of the product brand; however, the product to be evaluated was independently picked in accordance with the product selection criteria in Section 2 and prepared for evaluation by colleagues who were not otherwise involved in the process.

Each clinical evaluator entered data independently and without inter-rater comparison into their own workbook. These were then collated, reviewed and summarised by the clinical specialist lead for the project.

As part of the evaluation preparation, each evaluator was given a more detailed and product specific definition for each of the scores

The defined criteria either prompted a 'yes/no' answer, or a score was given between 0 and 2 or 0 and 3 as follows:

Score	Meaning
0	This does not meet the criteria
1	This partially meets the criteria
2	This meets the criteria
3	This exceeds the criteria

Figure 5 – NHS Clinical Evaluation Team scoring methods

These numerical scores across all evaluators were totalled and a mean value determined. This mean value has then been converted into a star rating (see matrix below).

The mean values convert to a star rating in accordance with the following table:

Point scored		Star value		
0	to	0.99	0	stars
1	to	1.24	1	Star
1.25	to	1.74	1.5	Stars
1.75	to	2.24	2	Stars
2.25	to	2.74	2.5	Stars
2.75	to	3	3	Stars

Figure 6 - conversion of mean scores to star rating

The above scoring mechanisms will not be followed where the criterion identified by the CET cannot reasonably exceed expectations. For example, if the clinical criterion was whether the removal of an adhesive dressing was atraumatic and with the individual patient reporting no pain or skin damage, then it cannot reasonably be expected that a product could exceed that criteria. Therefore, in such circumstances, the relevant criteria will be based on the scoring regime of:

A) If the criterion is a Yes/No response, the responses will be converted into aggregate percentages and then star ratings as follows:

Percentages	Star value
0% to 24.99%	0 star
25% to 49.99%	1 star
50% to 74.99%	1.5 stars
75% to 100%	2 stars

Figure 7 - Percentage scores to star rating

B) For other subjective criteria, the responses will be converted into mean scores and then star ratings as follows:

Point scored	Star value
0 to 0.49	0 star
0.5 to 0.99	1 star
1 to 1.49	1.5 stars
1.5 to 2	2 stars

Figure 8 - Points scores to star rating

On the basis that clinical evaluators will be providing scores as follows:

- 0 stars Does not meet the criteria
- 1 star Partially meets the criteria
- 2 stars Meets the criteria

All supplemental products used in the evaluation are in use in the NHS and available through the national catalogue (e.g. clinical waste containers, gloves). Evaluators were also encouraged to record comments where they felt it necessary to provide rationale for their scoring and answers.

The results obtained have been validated by the NHS Clinical Evaluation Team moderation committee for consistency of scoring and interpretation. These results are presented in the product assessment reports herein.

# 6 Product Assessment Results

The following product assessment results pages show the tested clinical criteria listed horizontally on the left-hand side of the page with the tested device found vertically across the top of the matrix. The accompanying photographs were taken during evaluation. These photographs are of sample products provided for evaluation. Lot numbers were recorded and samples have been retained in storage following the completion of evaluation.

The products represented are the range of suppliers and brands available through the NHS national procurement provider's framework as of August 2017.

Results can be seen within the product matrix. Each clinical criterion has been awarded a score displayed in the matrix.

# 7 Using the Product Assessment Results Matrix

The clinical criteria displayed are designed to capture key clinical elements that health professionals may wish to consider when reviewing/selecting products for their own clinical practice. The report is intended as a guidance tool to aid product selection and is not intended to be a universal determination of the clinical effectiveness of any particular product. Each clinical practitioner should therefore make their own assessments taking into account all relevant considerations for their particular situation.

Not all clinical criteria cited in the report will be relevant or important in all environments,

i.e. pump action and aerosol sprays dispensed on prescription to the patient in the community setting will be labelled with the patients name by the dispensing pharmacy, and is unlikely to be shared with other patients. In the hospital setting the item is unlikely to be dispensed via prescription.

Likewise not all clinical criteria will be relevant or important for all patient groups;

i.e. suitable for paediatric use in an adult unit/hospital

Clinicians may identify the criteria that most represent their clinical environment and patient demographic, and may choose to build their own hierarchy of importance to aid product(s) selection for patient outcome goals using the matrix presented in this report, their own clinical knowledge, as well as any other resources (including publications) to provide informed choice and transparency of their decision for product(s) being used.

# 8 Further Considerations and Recommendations

## 8.1 Future recommendations

## 8.1.1 Packaging

Clear identification of product contra-indications should be visible on the individual product packaging.

The product should be clearly identified as 'single patient use' where appropriate, with space to add a patient identity label or write the patients name and date of opening. This must be achievable without obscuring product information on the package.

Guidance is required on safe shelf life once multi-use dispensers are opened. All suppliers states that the product is safe to use once open until the pack is empty regardless of the time-line, however clinicians were unaware of this and said that product was therefore disposed of unnecessarily.

Multiple units of issue i.e. a pack of 12 spray bottles should contain an instruction for use leaflet.

## 8.1.2 Opening

Re-design of the 28ml pump action bottle lid/cap which is small and easily misplaced. Clinician described incidences where the lid/cap had accidentally fallen into a patients bed and caused skin injuries. Clinicians requested an attached or telescopic cap/lid.

#### 8.1.3 Clinical Use

Clinicians requested that the product should be dry on the skin within 30 seconds to enable timely facilitation of adjunct processes, for example the application of wound dressings, adhesives or continence products. Irritant contact dermatitis may result from not allowing skin barriers to dry effectively (Bryant 2012)

Product odour should be minimal on application and odourless once dry on the skin. Clinicians said that patients found product odour unacceptable, and studies confirm that odour may have a negative impact on both mood and pain perception particularly when associated with other sensory loss. (Marchand and Arsenault 2002, Schifferstein and Desmet 2007)

#### 8.1.4 Disposal

Clear labelling for recycling.

## 8.2 Barcodes

The CET are aware of the Scan4Safety project and are aligned with the ambitions of the programme, which will deliver significant benefits in terms of patient safety and efficiency, to the NHS. The adoption of standards, driven by Scan4Safety, enables patient, product and location identification and traceability from the supply chain to the patient.

Adoption of these standards has also been shown to improve the quality of care by minimising the risk of human error.

The CET will be considering the inclusion of an evaluation criteria relating to the presence of GS1 compliant barcodes in future reports, as following our clinical conversations we have seen clinical staff asking for it to be included. Further information will be issued by the CET in due course.

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Mandie Sunderland Chair, Clinical Reference Board (Governing body of the NHS Clinical Evaluation Team)