NHS
Business Services Authority

Clinical review
Patient Dry Wipes

NHS Clinical Evaluation Team
by the NHS, for the NHS

Contents

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: **clinical.evaluationteam@nhs.net**.

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 April 2016. The team's remit 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 Patient Dry Wipes 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 Patient dry Wipes for use in future procurement activities.

It is clear from the evidence that Patient Dry Wipes, 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, culminating in the production of this report for their approval in November 2017.

Based on 2017 data supplied by NHS Supply Chain, in the NHS, over 630 million individual dry wipes are used annually with a total spend approaching £7 million. There are 15 different product codes in the category supplied via 3 different suppliers. This report covers the range of products available as of 2017.

Intelligence about Patient Dry Wipes was gathered from a variety of sources to provide background information on the current evidence available to support the way in which the products are designed and clinically evaluated.

Following this, clinical engagement sessions were held with the aim of identifying important clinical criteria for Patient Dry Wipes from frontline NHS clinicians. This information was used to develop clinical criteria for Patient Dry Wipes, 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

Patient Dry Wipes are a single disposable wipe used for single patient hygiene. During clinical conversations various uses have been raised, they may be made wet to wash the patient or used dry to dry the patient. They have in essence replaced the flannel or reusable cloth. These products are split into two distinct groups, maceratable (25%) and non maceratable (75%) being supplied in packs of 75 or 100.

This report is concerned with evaluating Patient Dry Wipes, from identification of wipe through to disposal using the clinical criteria provided by the clinicians.

The Patient Dry Wipes reviewed are limited to the products available on the current national provider framework.

2.2 Intended Clinical Use

Feedback from clinicians describe the use of Patient Dry Wipes as a single patient wipe to assist in the cleaning and hygiene needs of the patient, they may be used wet or dry.

Professional guidance and a literature review have been completed as part of the review to support the development of criteria along with establishing best practice standards to compare against.

2.3 Clinical Practice

Clinical consultation during the process has shown that Patient Dry Wipes are individual wipes used for single patient hygiene, but they may also be used for mopping small fluid spills; toilet tissues; handkerchiefs and wiping down hard surfaces.

When used for patient hygiene they may be made wet to wash the patient or used dry to dry the patient and are used across most areas of the NHS.

2.4 Clinical Impact

Selection of the correct wipe and size is important, maceratable wipes are able to be disposed of in a macerator which eliminates the need to remove all the wipes from a disposable bowl. Non maceratable wipes if disposed of in this way may block pipes and damage the macerators, leading to added costs and inconvenience to the area.

Wipes which are too harsh or not soft enough risk damaging the patients skin this can be especially noticed with the elderly or patients with already compromised skin

conditions. Furthermore wipes of not strong enough design, may not hold together and breakdown during the cleaning process.

2.5 Other Clinical Considerations

The wipe itself must feel soft and able to hold its shape when wet or dry, this may be achieved using many different materials and manufacturing techniques.

Maceratable wipes are manufactured in a different process to non maceratable wipes using different materials, this is to allow the wipe to be broken down in the macerator, these wipes are often not as soft as their non-counterparts and appear to carry the risk of breaking down easier during use, this is reflected within the matrix.

2.6 Product Technical Design

Under the NHSSC Framework, Patient Dry Wipes may consist of up to three possible material types.

- Polypropylene – Is in essence a plastic fibre woven to create a fabric like material.
- Cotton – Is a cellulose naturally occurring fibre grown from cotton plants.
- Viscose – Is also cellulose but maybe from multiple plants such as soy, bamboo etc. this cellulose will need to be treated with chemicals to soften it.

Air laid refers to the manufacturing process of laying the fibres using air rather than fluids and is not a material type.

As stated in the framework agreement specification the area of the wipe will be between 560 and 841 cm^2. This currently restricts the size the manufacturer can market and also the clinician's choice.

3 Pathway method for patient dry wipes

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: https://www.evidence.nhs.uk/Search?[text]. This suggested best practice considerations in the use of patient dry wipes.

The search terms used (see below) generated many returns:

Search criteria	Databases searched
• **Patient Dry Wipe** • **Dry Wipe** • **Patient Cleaning Wipe**	• 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 – AMED, EMBASE, HMIC, BNI, Medline, PsycInfo, CINAHL, HEALTH BUSINESS ELITE databases searched)**
Date Range	Since 1975
Language	English

However, there was little new information generated, with procedures and infection risks being repeatedly highlighted.

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 Patient Dry Wipes.

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

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

Product Material	Minimum Weight - Grams per Square Metre (gsm)	Minimum Area of an individual wipe (Square Centimetres)	Minimum Width of an individual wipe (millimetres)	Number of wipes per pack
100% Polypropylene	32	560	180	100
80% polypropylene 20% cotton	48	560	180	100
100% polypropylene	33	693	220	100
100% air laid (maceratable),	60	678	220	75
70% polypropylene 20% viscose 10% cotton	46	841	270	100

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 (https://www.gov.uk/drug-device-alerts) 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

Hierarchy 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)

4 NHS Clinical Engagement

In order to develop a shared vision of what is required from Patient Dry Wipes 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 conversation events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria.

A clinical criterion is defined for the purposes of this report as a principle or standard by which products may be evaluated. It is a 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.

The Patient Dry Wipe packet has clear product dimensions
There is a clear indication on how to open the Patient Dry Wipe packaging
Ease of opening packaging
Is this product maceratable?
It is clear this product is maceratable or not maceratable
Patient Dry Wipes can be removed individually from the packaging
The Patient Dry Wipes can be contained within the packaging for storage and easy for staff to access from full until all contents have been used
The Patient Dry Wipe in its dry state is comfortable against skin.
The Patient Dry Wipe feels soft
The Patient Dry Wipe can absorb liquid particularly water and cleaning agents for patient hygiene and patient cleansing activities
The Patient Dry Wipe in its wet state is soft and comfortable against skin.
The Patient Dry Wipe maintains its tensile strength and does not break down when used for patient hygiene and patient cleansing activities
It is clear if the packaging can be recycled

4.2.1 Criteria explanation- Inclusion (Product)

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

4.2.2 Criteria explanation- Exclusion (Product)

To capture true representation of clinical opinion, this report also aims to capture criteria that were raised, but not included as final criteria when the evaluation of patient dry wipes took place.

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 using the NHS Clinical Evaluation Team product cycle:

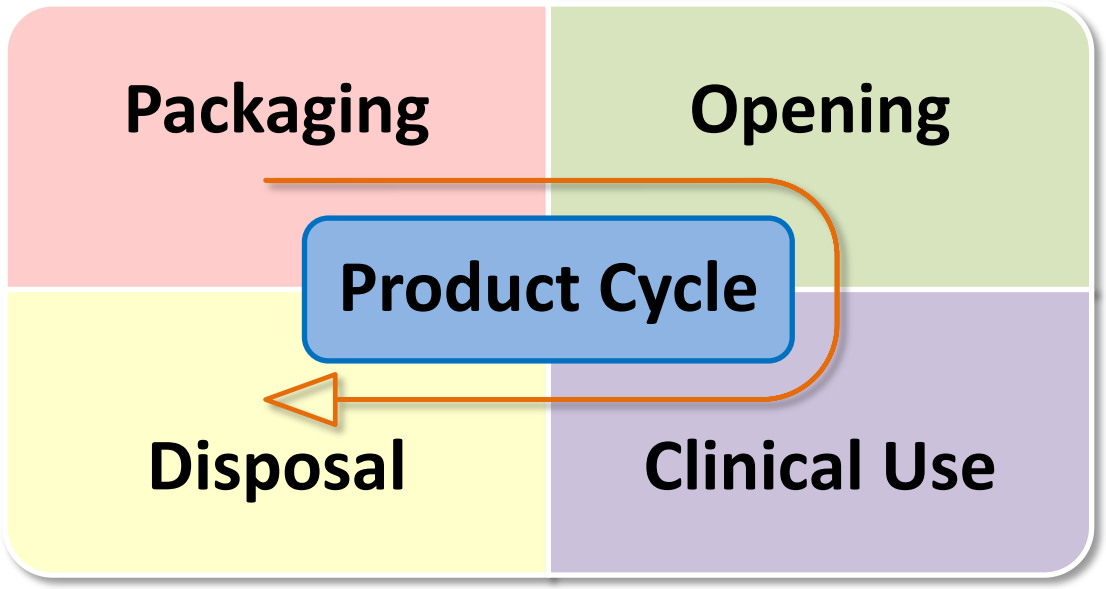

Figure 5 – NHS Clinical Evaluation Team Product Cycle

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 6 – 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 7 – 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

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

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.

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.

5 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 2017.

Results can be seen within the product matrix. Each clinical product has been given a star rating or a Yes No answer represented by a tick or cross.

6 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 will be relevant or important in all environments,

i.e. Maceratable wipes for district nurses visiting patients in their own home are unlikely to have a macerator available.
Also maceratable wipes may not be the softest and will break down easier and quicker due to their disposal requirements, which will be reflected in the matrix.

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; providing informed choice and transparency of their decision for product(s) being used.

7 Further Considerations and Recommendations

Many clinicians raised the issue of contaminating the lower wipes in the pack when removing wipes the suggestion of smaller packs for a single procedure or patient would reduce the risk of patient cross contamination and wastage in the NHS.

1. The option of smaller pack sizes to be used as a single patient pack, with minimal waste with an added area to write the patients name.
2. A reseal for packs to contain the wipes once opened and help contain the product
3. Only dispense one wipe at a time.

4. Should only be able to touch one wipe and not the wipes below

5. Instructions to open need to be clear, with written and/or understandable icons to aid opening.

The size of the wipe is very important with most clinicians stating they needed a wipe that was “Large enough to cover hands”. The size of each wipe is bound into the framework agreement but is not specified on the packaging. Manufacturers prefer to describe the product size such as standard or large rather than state actual dimensions. Clinicians mention the need for actual dimensions and various sizes on the individual packets to aid with product selection.

Reducing environmental impact of the wipes packaging were also mentioned by clinicians as important. It is also very important for route of the wipes disposal to be clear on the packaging such as maceratable or not.

7.1 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, but further information will be issued by the CET on this to stakeholders in advance.

8 Disclaimer

Reports published by the NHS Clinical Evaluation Team represent general guidance and the team's opinions on products are based on the clinical evaluations undertaken, using the information and clinical criteria generated from extensive stakeholder engagement in line with the team's requirements and evaluation pathway. Reports will be reviewed and updated at the team's discretion as deemed appropriate to reflect any changes.

You should make your own assessment and not take or rely on the opinions expressed by the NHS Clinical Evaluation Team, as contained in the reports, as recommendations or advice to buy or not buy (as the case may be) particular products.

The NHS Clinical Evaluation Team is not responsible for any errors or omissions, or for the results obtained from the use of the information contained in the reports. The reports are provided 'as is', with no guarantee of completeness, accuracy or timeliness and without representation, warranty, assurance or undertaking of any kind, express or implied, including, but not limited to fitness for a particular purpose.

The NHS Clinical Evaluation Team shall not be liable to you or anyone else for any decision made or action taken in reliance on the information contained in the reports or for any consequential, special or indirect loss.

Reports are accurate at the time of publication, any recommendations or best practice guidance should be checked for updates.

9 Acknowledgements

On behalf of the Clinical Reference Board and the NHS Clinical Evaluation Team, we would like to acknowledge the support, help and advice given by our colleagues across a range of organisations. We would particularly like to thank the Department of Health, NHS Business Services Authority and their Communications team and, most importantly, our NHS colleagues who have supported our work.

The team would also like to acknowledge the inspiration of Mandie Sunderland who saw this opportunity and who, through her personal drive and enthusiasm, has ensured that the clinical voice and the need for quality, safety and value throughout the NHS has been heard.

10 Authors and NHS Clinical Evaluation Team Information

NHS Clinical Specialist Lead author:

Roger Kirkham and Liam Horkan Clinical Specialist Leads, Department of Health

With support from NHS Clinical Evaluation Team colleagues:

Dr Naomi Chapman, RN, Clinical Programme Lead/Deputy Chief Nurse
David Newton, RN, Clinical Specialist Lead, Department of Health
Stephanie McCarthy, RN, Clinical Specialist Lead, Department of Health
Simon Hall, RN, Clinical Specialist Lead, Department of Health
Sian Fumarola, RN, Clinical Specialist Lead, Department of Health
Marc Naughton, Senior Paramedic, Clinical Specialist Lead, Department of Health
Karen Hudson, RN, Clinical Specialist Lead, Department of Health
Roger Kirkham, RN, Clinical Specialist Lead, Department of Health
Colin Iversen, RN, Clinical Specialist Lead, Department of Health
Joanna Hamilton Davies, RN, Clinical Specialist Lead, Department of Health
Maya Guerrero, RN, Clinical Specialist Lead, Department of Health
Colette Longstaffe, RN, Clinical Specialist Lead, Department of Health
Dan Lewin, Physiotherapist, Clinical Specialist Lead, Department of Health

You can find team member full biographies at: **www.nhsbsa.nhs.uk/CET**

Subscribe to the NHS Clinical Evaluation Team mailing list:

Email: **clinical.evaluationteam@nhs.net**

NHS Clinical Evaluation Team
by the NHS, for the NHS

'Quality, safety and value are at the heart of our work and it's important that we use our clinical experience to deliver high standards of care while reducing cost and waste in the NHS.'

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