South West London Collaborative Medicines Optimisation Group

Title	**Wound Care Product Evaluation Standard Operating procedure**
Aim and purpose of document	**To provide a framework for evaluating wound care products for South West London**
Authors	**Tissue Viability Services and Medicines Optimisation representing Croydon, Kingston, Merton, Richmond, Sutton, Wandsworth**
Review date	**May 2020**
Group accountable for review	**SWL Collaborative Wound Care Steering Group Approved May 2018 by SWL MOG**
Issue date	**May 2018**

Contents Page

WOUND CARE PRODUCT EVALUATION

Aim

- To support clinical and cost-effective wound care for all patients within South West London.
- To provide robust evaluation tools to demonstrate clinical and cost effectiveness of wound care products.
- To demonstrate transparency in the decision making process of wound care product selection.
- To develop a list of evidence-based products for inclusion in the South West London wound care formulary.
- To provide a consistent methodology of product evaluation for formulary development.

Wound Care Product Screening

The product may be identified via new clinical evidence, literature, education, pricing or indicated by EPACT 2 data. The SWL wound care steering group will decide upon the subgroup, which will screen products for subsequent evaluation areas. Formulary products will be identified from the current BNF, Wound Care Handbook, Drug Tariff and company literature.

The initial screening tool (Appendix 1) will be used by the subgroup to establish if:

- There is evidence that the product may provide a clinical equivalence and cost advantage to a product already in use in South West London.
- The product may be considered as an addition to the formulary to benefit patient care.

The screening tool will also establish 'fitness for purpose' of the product:

1. **Size/**range available.
2. **Recommended** wear time
3. **Cost per day**.
4. **Quality** – CE mark is mandatory.
5. **Availability** of product established i.e. drug tariff, NHS supply chain, direct from manufacturer.
6. **Clinical evidence** to support the effectiveness of the product.
7. **Functionality** of the product against screening criteria i.e. non-patient examination and handling of the product to mimic its use in the clinical situation.

Outcome of Screening

Depending on the outcome, the product will either be recommended to proceed to clinical evaluation in the nominated evaluation sites or the product will not be successful.

Following screening of each wound care product category a maximum of four products will progress to evaluation unless there are exceptional circumstances.

Wound Product Evaluation Following Screening

Aim

To establish the clinical effectiveness of the product in clinical use.

Process

- Request manufacturing company to provide sufficient supplies of dressings, ideally for a minimum of 10 patients.
- Clinical evaluation time period will be 2-6 weeks dependant upon wound care product and setting.
- A product range for evaluation will be allocated to one or more local care settings.

The site for evaluations will be agreed by the local subgroup. Patient inclusion criteria will be defined by local subgroups. As part of good clinical practice all patients should be informed of the purpose of the wound care product being used, its properties and functions.

The Wound Product Evaluation Tool (Appendix 2) will be completed at suitable intervals for the products evaluated.

Evaluation Sites

The subgroup will identify evaluation sites where there are clinicians who are sufficiently involved in wound care provision. Wherever possible, an even distribution of evaluation sites will be used to minimise any bias, however, this may not be practical depending upon the product category. Evaluation sites may include: acute hospitals, community hospitals, patient homes, NHS clinics, GP surgeries and care homes.

Variations to the Process

Whilst the minimum number of evaluations that are performed is defined as 10, it is acknowledged that this is a subjective number agreed on which a decision regarding the evaluation of a product will be made. However, other variables that will need to be taken into account include:

- The number of specialist sites suitable to evaluate the product
- The availability of suitable wound types and/or wound characteristics (as assessed by the clinician performing the evaluation) that meet the criteria of indications for use of the product.

Identifying Suitable Patients

When deciding to undertake a wound product evaluation, the clinician must ensure that they have selected a wound suitable for the product. Patients' views and opinions are valued and should be reported on the completed evaluation tool.

During all the processes of wound evaluation codes of good practice relating to privacy, dignity, confidentiality, information sharing and capacity will be adhered to.

Clinicians should ensure they are aware of any ethical considerations or diversity issues associated with the product that may be of relevance to inform the patients' decision making.

The Product

Evaluation stock will be requested as per local policy.

Manufacturing Company Representatives

In addition to responsibilities above, manufacturing company representatives may be asked to support training on evaluation product use. Manufacturing company representatives are advised not to contact evaluation sites unless requested to do so for a specific purpose.

Responsibilities of Subgroup

- To have representation at South West London wound care steering group meetings.
- To co-ordinate screening and evaluations on suitable patients.
- Ensure the team of clinicians are aware of the purpose and process of the evaluation.
- To co-ordinate responses and provide a timely response to the SWL wound care steering group.
- To declare any member of their team of clinicians' interests.

Evaluators' Responsibilities

- Identify potential patients/wounds.
- Adhere to the evaluation process – including completion of patient evaluation forms using the Wound Care Product Evaluation Tool (Appendix 2).
- Ensure product is used for whole of evaluation period (if appropriate).

Ending Evaluation

The use of the evaluation wound care product should be discontinued:

- At the patient's request
- If there is any deterioration and/or reaction that is attributed to the wound product, it should be stopped immediately and if appropriate, reported via The Suspected Adverse Drug Reactions MHRA (yellow card system) and an incident form completed.
- If the wound product is found to be inferior to an existing product on the current wound formulary it must be discontinued, detailed on the evaluation form and an alternative product prescribed.
- If the evaluation period has been completed the product used should be discontinued. However, if there are improved outcomes for the patient then the product can be continued, although further supplies must be prescribed and/or ordered in the usual manner for that service.
- The products supplied for the purpose of the evaluation must not be used on any other than the identified patients.

Any unused wound products should be returned to the manufacturer's representative.

All feedback regarding the evaluation and the completed evaluation forms should be given to the subgroup. The results will be correlated by the South West London wound care steering group. At no point should any separate manufacturing company evaluation tool be completed nor should any verbal feedback or a copy of the evaluation tool be given to the manufacturing company.

Decision

The final decision rests with the South West London wound care steering group regarding the outcome of the evaluation. The evaluating subgroup can submit an opinion based upon the evaluations completed.

The SWL wound care steering group will make a recommendation to decision making committees based upon the clinical effectiveness, service provision and cost of the product, as to whether it will be included in the South West London Joint Wound Care Formulary.

All decisions made to include products in the formulary will be submitted for ratification by the relevant Local / Trust / Prescribing Committee.

APPENDIX 1 - Wound Care Product Screening Tool

Date **Company**	
Product	**Formulary Category**
Key Functions and Aim of Product (See Manufacturers Information Form)	
Quality Does the product carry a CE mark in accordance with the Medical Devices Directive (93/43 EC)? **Yes/No**	
Availability Drug Tariff □ Available via hospital/pharmacy □ Other □	
Education to use the product Is any training/ education required to support the use of the product? If so what level of support from the manufacturer is available? See manufacturers information form	

APPENDIX 1 Continued

Fitness for Purpose of Wound Product	Details
Functionality (state e.g. adherence, absorption)	
Strength of Clinical Evidence Summary*	
Any special precautions/ethical considerations (e.g. any constituents derived from animal or blood products, latex or nuts)	
Size range available	
Recommended wear time	
Estimated cost per day (average cost of 7 days wear time using 10 x 10cm dressing if possible)	
Ease of use/handling	
Additional qualities depending on category (state)	

Is the product to proceed to patient evaluation? Yes/No

Rationale…….....
……
……
……

***HIERARCHY OF EVIDENCE FOR USE DURING SCREENING PROCESS**

Levels of evidence for intervention studies (NICE 2008)

Level Source of evidence

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1− Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2− Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies (for example, case reports, case series)

4 Expert opinion, formal consensus

NICE (2008) Surgical site infection prevention and treatment of surgical site infection. National Collaborating Centre for Women's and Children's Health
Commissioned by the National Institute for Health and Clinical Excellence

APPENDIX 2 – Wound Care Product Evaluation Tool – Page 1
On completion of evaluation send completed patient forms to:

Product:				
Evaluator:				
Organisation:				
Site/health centre/care home:				
Speciality:	Hospital nurse Community nurse Podiatrist TVN Practice nurse Nursing home	☐ ☐ ☐ ☐ ☐ ☐		
Date evaluation commenced:				
Clinical evaluation must be returned by:	**(Date of completion)**			
Size of dressing……	Adhesive ☐	Non Adhesive ☐		
Duration of wound:	Less than 2 weeks 2 – 4 weeks 1 – 2 months 2 – 3 months	☐ ☐ ☐ ☐	3 – 6 months 6 – 12 months 12 – 24 months Over 24 months	☐ ☐ ☐ ☐

Wound Type
Pressure Ulcer ☐ Leg Ulcer ☐ Trauma ☐ Burn ☐ Fungating Lesion ☐
Surgical ☐ Diabetic Foot Ulcer ☐ Other ☐ state ……

Compression in situ **Y/N**

Predominant Tissue Type (please indicate %)
Necrotic ……% Slough ……% Granulating ……% Epithelialisation ……%
Healed/Intact ……% Surrounding skin condition ……

Reason for using dressing (tick all applicable)
Absorption ☐ Hydration ☐ Odour Control ☐ Minimise pain ☐ Non adherence ☐
Control bleeding ☐ Desloughing ☐ Protection ☐ Reduce bacterial load ☐
Other ☐ state……

Was the product used as: Primary ☐ or Secondary ☐ dressing?

Was the product used in combination with any other dressing? **Y / N** (If yes, please state)

Wound Care Product Evaluation Tool – Page 2
TO BE COMPLETED AT EACH DRESSING CHANGE
Please score the wound care product effectiveness using the following criteria:

0 =Does not do this at all, 1 = Partially does this, 2 =Mostly does this, 3 = Completely does this, N/A = not applicable.

Date of dressing change								
Absorbed exudate and locked it away from the surrounding skin								
Hydrated the wound bed								
Visual removal of slough								
Conformed to wound bed								
Controlled odour (where applicable)								
Controlled bleeding (where applicable)								
Surrounding skin remained healthy								
Pain on application (0-5)								
Pain on removal (0-5)								
Acceptable to patient								
Product met expected performance								

	Yes	No
Were the instructions for use clear/understandable?		
Was the dressing easy to apply?		
Did the dressing detach prematurely?		
Did the dressing need additional fixation?		
Did the dressing cause any skin damage on removal?		
Did the dressing need hydration to aid removal?		

Would you consider this product for inclusion in the wound formulary? Y/N
Reasons:

Would you recommend this product replace the existing product within its category in the wound formulary? Y/N
Reasons:

If the evaluation had to be discontinued please state date and reason why.

Evaluation completed by: **Designation:** **Date evaluation completed:**

Appendix 3 -Wound Product Final Evaluation – Summary of Evaluation

Company	
Product	
	Comments
Summary of screening (Refer to Appendix 1)	
Summary of evaluation (Refer to Appendix 2)	
The above product has been evaluated with the recommendation that it **will** ☐ **will not** ☐ be included within the SWL Joint Wound Formulary **Rationale:**	
Signed: **Print name:** **Designation:** **Date:**	