

A protocol for the specialist use of topical steroidpreparations on wound beds within the community of Oxfordshire

**With thanks to:-**

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**At a glance summary**

* **Topical Corticosteroids are not products licensed for direct application to wound beds.**
* **Topical steroids are not recommended as a wound bed management agent unless instigated and overseen by a specialist service (e.g. Leg Ulcer Clinic, Community Tissue Viability Service or Podiatry).**
* Steroid use for wound care management has been classified as brown for restricted use and Trimovate for wound care management will be added to the black list (i.e. Should not be used) as per Area Prescribing Committee Oxfordshire (APCO) March 2013.
* **Specialist care plans should be explicit regarding the key treatment objectives and provide clear guidance on where, when and how often the treatment should be applied. A treatment period with prescribed end dates should be made clear.**
* **Each prescription should be for single-patient use only.**
* **The choice of steroid should be Dermovate, reducing down to Elocon ointment.**
* **The use of topical corticosteroids is not indicated as first line treatment for the following:-**
	+ **Wound-related Pain**
	+ **Hypergranulation**
	+ **Reducing wound bed bacterial loading**
	+ **Delayed wound healing secondary to a prolonged inflammatory process**
	+ **Clinicians needing support with hard to heal wounds should refer the patient to community tissue viability service.** tissueviability@oxfordhealth.nhs.uk **or** oxfordhealth.tissueviability@nhs.net

This protocol has been devised based on consensus sought from a consortium of specialist services within secondary and primary care trusts. It has been developed to support primary care healthcare professionals in the safe application of prescribed topical steroid formulas to wound beds. The prescription of such treatment remains the responsibility of a specialist service and should not be instigated within the community without prior consultation.

**What are topical Corticosteroids?**

* Topical steroids have been used within dermatology practice since they were introduced in the late 1950s. They are effective anti-inflammatory preparations used to control skin conditions including Eczema and Dermatitis. They are often called topical corticosteroids or cortisone.
* Topical Corticosteroids work by suppressing the inflammatory reaction during use. They are not considered curative and often the condition can re-occur following discontinuation (British National Formulary (BNF), accessed 19/12/12). They are generally used for the purpose of relieving symptoms and therefore maintaining skin integrity where emollient therapy alone is not sufficient.
* Within wound bed management it is thought topical corticosteroids can increase cytokines, such as platelet derived growth factor (required for epidermal proliferation), and T cell growth factor (required for keratinocyte migration in the maturation phase of healing). Any reports of an improvement to wound healing status can be believed as it is likely this is due to the steroidal agent reducing local wound bed inflammation.
* The Dermatology team within Oxford University Hospitals advocate the application of Tetracycline-based formulations such as Trimovate® on wound beds. Although primarily used in healthcare as an antimicrobial therapy (contains an antibiotic) for the treatment of infected skin conditions, dermatology often implement this treatment for wound-related pain management due to Oxytetracycline, a constituent of Trimovate® having an anti-inflammatory effect.
* Outside dermatology practice the routine use of combination (contain antibacterial/antifungal properties) topical steroid formulations such as Fucibet, Fucidin H, Daktacort are not advocated for use on wound beds.

**Summary**

* Trimovate® cream and other topical steroids are not recommended for use as a wound bed management agent within the primary care setting of Oxfordshire unless instigated and overseen by a specialist service (e.g. Leg Ulcer Clinic, Community Tissue Viability Service or Podiatry.

**Before implementation have you considered:-**

* Topical Corticosteroids are not products licensed for direct application to wound beds.
* Treatment must be instigated and prescribed by a specialist service
* Each prescription should be for single-patient use only.
* Has the patient provided informed consent for the treatment and is this documented on the patient’s treatment plan?
* The use of topical corticosteroids is not indicated as **first line** treatment for the following:-
	+ Wound-related Pain
	+ Hypergranulation
	+ Reducing wound bed bacterial loading
	+ Delayed wound healing secondary to a prolonged inflammatory process
* There are localised and systemic risks associated with long-term use of topical steroid preparations
* Specialist care plans should be explicit regarding the key treatment objectives and provide clear guidance on where, when and how often the treatment should be applied. A treatment period with prescribed end dates should be made clear (DermNet NZ, 2012, accessed 23rd November 2012)

**The clinical evidence relating to the mode of action of topical steroids within wound bed management is limited. The following protocol has been developed by applying national dermatology guidelines relating to topical formulas on skin, to wound bed management. Specialist consensus has been sought in order to promote safe nursing practice within the community.**

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| Action | Rationale |
| **Clear treatment objectives and rationale for use:-**Is there evidence of a holistic patient assessment with a clear diagnosis requiring this specialist treatment?Could treatment objectives be managed through the application of licensed ONPOS dressing products and by optimising underlying disease processes/patient health?The prescribed steroid preparation is for single-patient use only. | * Liability for prescribing an unlicensed product lies with the prescriber and the dispenser or supplier ((Nursing and Midwifery Council (NMC), 2007). Although as an accountable practitioner you should be satisfied that you have sufficient information to administer an unlicensed drug safely and where possible acceptable published evidence to support product use (NMC, 2007)
* You must exercise you professional judgement and apply your knowledge and skill in the given situation to ensure safe administration of medications (NMC, 2007) and contact the prescribing specialist teams in order to obtain this information prior to implementation.
* If a non-medical prescriber chooses to change the specification for use of a prescribed product they are responsible for their actions. This includes being accountable for any harm that the patient may experience following the application (Griffiths, 2007).
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| **Ensuring safe administration:-**Where possible gain and document patient informed consent for treatment.Application of medication should be in line with a Patient-Specific Direction (PSD) (pink sheet)  | * As a registered nurse, where possible, you are responsible for gaining patient informed consent prior to instigating treatment. It is important the patient has a clear understanding of the purpose of treatment.
* Patient allergies should be checked and clearly documented prior to administration (NMC, 2007)
* A practitioner should administer an unlicensed product against a Patient-Specific Direction and not against a Patient Group Direction (NMC, 2007)
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| **What topical steroid should be applied:-** **Examples include:*** Potent- Mometasone furoate 0.1% (Elocon)
* Very Potent -  Clobetasol Propionate (Dermovate)

**The choice of formulation will be guided by a specialist service** | * Blood vessels become more permeable during the inflammatory phase of wound healing. This increased vascular activity at the surface of the wound bed may mean topical steroids are absorbed more rapidly when compared with absorption rates on thinner tissue types such as skin on the eyelid or face. Absorption rate via the eye lids is thought to be higher (30%) than that of the palm of a hand (0.1%) (DermNet NZ, 2012, accessed 23rd November 2012))
* Occlusion of the wound bed with conventional dressings and compression therapy will enhance the absorption of the formulation therefore potent corticosteroids may significantly increase the risk of side effects

(British Association of Dermatologists (BAD), 2008, accessed 24th November 2012)* Topical corticosteroids are often classified in the UK as mild, moderate, potent, or very potent. For further information regarding topical steroid formulas for the treatment of dermatology conditions, please refer to the British National Formulary (BNF) (December 2012)
* Specialist consensus advocate the use of topical corticosteroid ointment formulations rather than creams on wound beds as they contain less preservatives therefore reduce the likelihood of contact allergy
* Topical corticosteroids containing antimicrobials such as Fucibet, Fucidin H, Daktacort are not advocated for use on wound beds unless under the supervision of a specialist service.
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| **How should the preparation be applied:-**Using a sterile gloved fingertip. The topical steroid should be applied gently in a thin layer directly to the wound bed (BNF, accessed 19/12/12) in line with treatment objectives and dressing regime. If the wound is too painful to tolerate direct contact, thinly spread the steroid ointment onto a non-contact dressing and place directly over the wound site. | * The recommendations for application primarily relate to those preparations applied to skin. In order to minimise the side-effects, the preparation should be applied thinly to intended affected area only. The application of such preparations within wound management is likely to be in line with dressing changes however generally should not be applied more often than twice a day (BNF, accessed 19/12/12).
* A fingertip unit describes the amount of ointment squeezed out of its tube onto the end of the finger. It is a convenient way to measure how much formulation should be applied in relation to a specific surface area of skin. See <http://www.dermnetnz.org/> or <http://www.patient.co.uk> for further guidance
* Within wound care such guidance may be adapted to enable accurate dosing (depending on potency, 1 fingertip dose = 0.5g of steroid and is sufficient to cover a surface area of two adult palms)

.**E.G**. If the average adult palm measures = 60cm2 then one fingertip unit dose would be sufficient to cover a wound bed surface area of 120cm2* The use of the fingertip guidance will be at the discretion of the specialist team implementing the treatment and clinicians should seek confirmation within the care plan.
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| **A clear treatment period and end date-**Depending on the potency of application and the frequency of dressing change, the maximum treatment period for the use of topical steroids is four weeks (BNF, 2012). In the management of skin conditions, daily applications should be applied for a maximum of two weeks and if within this time there are signs of improvement, application frequency or steroid potency should be titrated accordingly (BNF, 2012).In wound care, an application of a topical steroid to the wound bed is required less frequently and is often in line with dressing changes. The prescribing specialist is responsible for advising clinicians on the frequency and treatment timescale.It is suggested that a step down approach is used when using steroids on wound beds, with a very potent steroid (Dermovate ointment) being applied initially for 2 weeks then stepping down to a potent steroid (Elocon) for a following 2 weeks. | * If the wound is occluded with conventional dressings or compression therapy the rate of absorption is increased therefore the need for daily application is reduced (BAD, 2008).
* The direct action of topical steroids on long-term wound and patient health is not clear. Therefore the controlled use of such treatment is deemed necessary in order to reduce the risk of potential side-effects (Table 1).

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| Skin thinning (atrophy)  | Easy bruising and tearing of the skin. |
| [Allergy](http://www.dermnetnz.org/dermatitis/corticosteroid-allergy.html) to the steroid cream. | Enlarged blood vessels (telangiectasia). |
| Susceptibility to increased bacterial loading | Masked inflammatory markers therefore disguising infection  |

Table 1: - common side effects of topical steroid use (DermNet NZ, 2012) |

**Supporting Guidance**

* The administration of medicines is an important aspect of the professional practice of registered nurses. It is not considered a mechanistic task to be performed in strict compliance with the written prescription of a medical or nursing practitioner, it also requires the professional judgement of the healthcare professional towards safe application (Nursing and Midwifery Council (NMC), 2007)
* The community tissue viability service do not currently advocate the use of Trimovate® or any other topical steroid preparation in wound management without specialist team input. This is mainly due to the lack of scientific evidence or consensus regarding the effects of their prolonged use on wound and patient health.
* The products are not licensed for this purpose and therefore the prescription of which remains the responsibility of a specialist service such as Dermatology or Tissue Viability.
* Historically topical steroids have also been used to reduce hypergranulation within the wound bed. This is no longer advocated as it is thought that this is caused by the exaggerated angiogenesis (development of new blood vessels) secondary to mismanaged bacterial load, exudate levels or dressing irritation. These can be managed successfully with conventional dressings however Haelen tape is widely used and is licensed for this purpose. We would recommend you seek advice from tissue viability prior to implementing this treatment.

**What does off-licence product mean?**

* This term relates to the use of a prescribed medicine in a different way to that set out in the product specification (Griffith 2007). For example it may be the product is administered using a different dose or route to that set out in the licensing specification.

**What are the implications of this in practice?**

* If a non-medical or nurse prescriber chooses to change the specification for use of a licensed product they are responsible for their actions. This includes being accountable for any harm that the patient may experience following the application (Griffiths, 2007)
* In local dermatology services topical steroids such as Trimovate® are often favoured within wound/ulcer management for the purpose of pain management despite the product not being licensed for this. It is felt that Tetracycline within the product has anti-inflammatory properties thought to help reduce pain symptoms. Topical corticosteroids are licensed and therefore often prescribed for the specialist treatment of dermatology skin conditions such as Varicose Eczema.
* Specialist care plans should be explicit regarding the key treatment objectives and provide clear guidance on where, when and how often the treatment should be applied. A treatment period with prescribed end dates should be made clear prior to implementation.
* Caution should be exercised if the rationale for the implementation of such treatment is not made clear by the specialist service and individual practitioners should be mindful of their professional accountability when implementing such a treatment plan.

**The use of Trimovate® cream in wound management**

Although this is an off-licence product there have been a number of case studies (Hofman et al, 2007) where Trimovate® application has shown to be effective in the management of painful, inflammatory wounds. This is thought to be due to oxytetracycline, a constituent of Trimovate® having a known anti-inflammatory effect.

* There are many reasons why wounds fail to progress and the development of tools to help clinicians identify and manage the biological causes are currently in place together with guidance on alternative therapies to address any abnormalities. Please refer to the Oxford Health Guidelines for direction on the assessment and management of wounds available at:-
* There are licensed topical wound dressings available on local formularies that have the potential to achieve similar results in a timely and safe manner. Practitioners should be working to local Oxford Health guidelines and considering these products as first line.
* The use of hydrocolloid or occlusive dressings during the use of topical corticosteroids will increase the uptake of the steroid and also increase the systemic/localised side effects of the product. Therefore these dressings should only be used under specialist supervision or a short period of time.
* You might also consider that hydrocolloid dressing products can also increase the probability of hypergranulation at the wound bed. The application of topical steroids to wound beds is not advocated for the treatment of such a condition. Often hypergranulation is secondary to mismanaged bacterial loading, exudate levels and/or dressing irritation. Consider whether changing the dressing regime and overall management plan might improve this.
* Please refer to the Nursing and Midwifery standards for medicines management available at:- http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf towards ensuring safe administration of medicines.

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