National Institute for Health and Clinical Excellence

Medical Technologies Evaluation Programme

moorLDI2-BI: a laser doppler blood flow imager for burn wound assessment

Consultation comments table

There were 26 consultations comments from 6 consultees (5 NHS professionals and 1 manufacturer). The comments are reproduced in full, arranged in section order with general comments at the end.

No.	Consultee	Section no	Comments	Response
1	Consultee 2, NHS Professional	1	The treatment of patients with significant or complex burn injury is a specialised service (as part of the NHS specialised services definition set). Treatment for patients with complex burn injury should only be undertaken by specialised burn care clinicians who work within specialised burn care services.	Thank you for your comment. The Committee changed the guidance by inserting section 2.5 referring to the role of the specialised burn care services (comprising burn centres, burn units and burn facilities) in the treatment of patients with significant or complex burn injury in the UK.
2	Consultee 4, NHS Professional	1	Agree	Thank you for your comment.
3	Consultee 3, NHS Professional	2	Excision and skin grafting does NOT prevent the formation of hypertrophic scarring and does not guarantee a better scar than spontaneous healing!	Thank you for your comment. Expert advice to the Committee agreed that excision and skin grafting does not prevent the formation of hypertrophic scarring and may well create worse scars than a burn that healed spontaneously. The Committee was advised that where a burn is excised and skin is grafted this will always form a scar, and will often form a hypertrophic scar if some areas take longer than 21 days to heal. The Committee changed the end of section 2.9 to clarify this.
4	Consultee 4, NHS Professional	2	Agree	Thank you for your comment

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5	Consultee 1, NHS Professional	3	Despite being available internationally for a number of years, this technology has not gained universal support. many surgeons remain frustrated by the time lapse between injury and when the scan becomes sensitive and specific enough to be relied upon. The move to early surgery, within the first day of injury, in many international centres renders this technology obsolete.	Thank you for your comment. Expert advice to the Committee was that decisions about which areas to excise in the immediate post-injury days are normally based on clinical assessment. The Committee considered this comment and decided not to change the guidance.
6	Consultee 1, NHS Professional	3	There remain no scientific studies comparing LDI on a properly cleaned burn wound (with dead epidermis and non-viable tissue scrubbed off) and clinical observation. Similarly there are no studies comparing LDI with wounds managed with Biobrane - a biological dressing that should be applied to a clean burn within 48 hrs of injury. Biobrane is thought to be able to "support" the burn wound allowing areas of intermediate burn to heal primarily in a reasonable time period. Failure of biobrane to adhere to a wound is also a clinical sign that the burn is deep and requires further surgical debridement. This sign is apparent by the same time that LDI becomes useful and therefore may also yield the same improvement in shortening hospital stay.	Thank you for your comment. Expert advice to the Committee was that publications using moorLDI2-BI state in their methodology that dead epidermis and non-viable tissue has been scrubbed off (as recommended by the manufacturer in the user guide). Failure to do so results in erroneously low flow. Expert advice to the Committee was that Biobrane can be applied up to 5 days post-burn provided there has been adequate cleansing of the wound and it is also possible to use moorLDI2-BI through applied Biobrane. In some units, moorLDI2-BI and application of Biobrane happen on the same day (between 48 hours and 5 days post-burn). The Committee added a consideration to section 3.16 of the guidance about the use of moorLDI2-BI with biological and semi-biological wound dressings.
7	Consultee 4, NHS Professional	3	Agree	Thank you for your comment.
8	Consultee 2, NHS Professional	4;4.8	Might suggest to some readers that specialist assessment of the burn wound image by an experienced clinician can only take place in a "Burn Centre". It should be noted that "Burn Units" are also specialised burn care services - but they are commissioned to deal with a lower level of complex burn severity than "centres".	Thank you for your comment. The Committee changed section 5.2 of the guidance to clarify the relationship between “burn centres” in the cost model and the specialized burn care services.

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9	Consultee 2, NHS Professional	4;4.8	It should also be made explcit whether ot not "Burn Care Facilities" (This level of in-patient burn care equates to a standard plastic surgical ward for the care of non-complex burn injuries) would or would not benefit from this technology.	Thank you for your comment. Expert advice to the Committee was that burn care facilities treat non-complex burn injuries and they would benefit from the moorLDI2-BI if they have sufficient patients requiring scanning and if a specialist burn care clinician is available to interpret the scan. The Committee changed the guidance to clarify this issue in section 5.7.
10	Consultee 4, NHS Professional	4	Agree	Thank you for your comment.
11	Consultee 3, NHS Professional	5	Excision and grafting DOES NOT reduce the incidence of post-burn hypertrophic scarring (several reports in the literature) therefore you cannot extrapolate the evidence that by LDI assessment, we will accelerate the healing and reduce scarring and hence reduce cost of scar management and prohylactic antiscar therapy!	Thank you for your comment. See response to comment no. 3.
12	Consultee 1, NHS Professional	5	Additionally, the time between burn and the point at which the Moor LDI becomes both sensitive and specific puts the burn wound beyond the point at which biological dressings become useful. The use of dressings such as Biobrane are considered the gold standard therapy for both superficial and intermediate burns in some international centres and are thought to reduce the grafting and subsequent scarring rate. Insisting on waiting for a scan would make this valuable therapeutic technique no longer useful or available and may infact increase the number of skin grafts required.	Thank you for your comment. See response to comment no. 6.

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13	Consultee 3, NHS Professional	5	Operating time of one hour for all patients is not appropriate as the surgical time varies with the extent of the injury and the availability of donor sites.	Thank you for your comment. This value used in the cost model represents an average operating time across all types of burn wounds. Expert advice to the Committee was that this is a conservative estimate since many skin graft operations take longer than this. The Committee considered this comment and decided not to change the guidance.
14	Consultee 1, NHS Professional	5	Some of the burn units and centres treating adult and paediatric populations do so at geographically separate sites within the same city. Use of this technology would probably involve the use of 2 machines + associated housing and technical staff. How does this affect the "cost savings"	Thank you for your comment. The External Assessment centre investigated the effect of separate adult and paediatric centres on the cost savings. Their results are summarised in Table 9 and 10 p 40 (External Assessment Report).The base case of the cost model shows that for the costs and cost savings of moorLDI2-BI to break even, the minimum annual number of burns patients treated in an adult centre is 26 and 16 in a paediatric centre. Assuming 400 patients are treated in each centre the cost savings are £1344 per adult patient and £2176 per paediatric patient. The Committee considered this comment and decided not to change the guidance..
15	Consultee 2, NHS Professional	5	Is there any information on cost saving and patient benefits in relation to rehabilitation and psycho/social aspects of Burn Injury?	Thank you for your comment. This is beyond the scope of this guidance.
16	Consultee 4, NHS Professional	5	Agree	Thank you for your comment.
17	Consultee 5, NHS Professional	6	I manage a Moor Instruments based LDI Burns Assessment service for the Newcastle RVI Regional Burns Unit. The technology is excellent for visualising microvascular blood flow across a vast range of body sites and tissue.	Thank you for your comment.

No.	Consultee	Section no	Comments	Response
18	Consultee 5, NHS Professional	6	The training element, which can be provided by the company, is excellent and arguably a must for clinical governance purposes. Production of images can be made by a trained nurse / technologist and then suitably annotated to note any measurement factors needed for consideration subsequent interpretation by the clinical burns specialist.	Thank you for your comment.
19	Consultee 5, NHS Professional	6	Overall, it is an excellent system for specialist burns centres to routinely use to benefit patient care.	Thank you for your comment.
20	Consultee 4, NHS Professional	6	Agree	Thank you for your comment.
21	Consultee 4, NHS Professional	7	Agree	Thank you for your comment.
22	Consultee 3, NHS Professional	General	LDI assessment is useful to determine the vascularity of the burn as an indirect method of burn depth. However, its use is of limited benefit in the presence of infection moreover, assessment of the burn depth at a single point of care does not negate conversion of depth at later stage and should be made very clear in the guidelines if adopted. I believe this is included in the guidelines.	Thank you for your comment. Section 2.7 recognises that burn wound conversion is a factor which needs to be taken into account when assessing the burn injury. Expert advice to the Committee was that all methods of burn depth assessment can be affected by later conversion. Section 3.15 of the guidance refers to the importance of having a trained burns clinician to take and interpret the scan to avoid difficulties in reading which may be caused by infected wounds, tattoos etc. Expert advice to the Committee is that LDI scans may be used on an infected burn. However if infection intervenes after the LDI has been performed (and interferes with healing) the LDI result is invalidated. This is the case for all methods of burn depth assessment. The Committee considered this comment and decided not to change the guidance.

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23	Consultee 3, NHS Professional	General	The use of the LDI will only inform the burn depth at point of assessment. It is erroneous to assume that excison and skin grafting will reduce the quality of scarring and reduce development of hypertrophic scarring because there is ample evidence to the contrary. It is also erroneous to assume that by excising and grafting a burn it always reduces the time to complete healing: Cubison et al have reported the contrary and you do need to take into consideration the time it takes for the donor site to heal.	Thank you for your comment. Expert advice to the Committee was that surgery where clinically indicated will result in a better outcome, provided skin graft, ungrafted areas of the burn and donor site are all healed within 21 days. The Committee was advised that surgery where clinically unnecessary will always produce a scar. The Committee considered this comment and decided not to change the guidance.
24	Consultee 3,NHS Professional	General	I am unsure as to how there is an assumption that using LDI will reduce the cost of dressings????	Thank you for your comment. There is no assumption in the cost model that use of moorLDI2-BI reduces the cost of dressings.
25	Consultee 6, Manufacturer	General	The manufacturer's team, who have been involved in the instrument development and its clinical evaluation over a 12 year period, strongly support the NICE provisional recommendations. The team agree there is evidence of benefit for patients, and evidence that significant cost savings can be made, if the system is used routinely to assess clinical assessment of burn wounds.	Thank you for your comment.

No.	Consultee	Section no	Comments	Response
26	Consultee 6, Manufacturer	General	**Has all of the relevant evidence been taken into account?** We believe the available evidence has been taken into account. **Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?** Yes **Are the provisional recommendations sound, and a suitable basis for guidance to the NHS?** Yes **Are there any equality issues that need special consideration and are not covered in the medical technologies consultation document?** The Moor Instruments team are not aware of any.	Thank you for your comment