NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG2: moorLDI2-BI: a laser Doppler blood flow imager for burn wound assessment

This guidance was issued in March 2011.

Consultation on the review proposal is planned for May 2017.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Review decision

Amend[1] the guidance and do not consult on the review proposal and proposed amendments to the guidance (shown in detail in appendix 3).

Publish a summary of the updated cost model.

Consider producing a MIB on the moorLDLS-BI.

2. Original objective of guidance

To assess the case for adoption of moorLDI2-BI: a laser Doppler blood flow imager for burn wound assessment.

3. Current guidance

1.1 The case for adopting the moorLDI2-BI in the NHS is supported when it is used to guide treatment decisions for patients in whom there is uncertainty about the depth and healing potential of burn wounds that have been assessed by experienced clinicians.

1.2 There is evidence of benefit for patients and for the NHS when the moorLDI2-BI is used in addition to clinical evaluation compared with clinical evaluation alone, in

[1] See Appendix 1 for an explanation of this option

burn wounds of intermediate (also known as indeterminate) depth. By demonstrating which areas of any burn wound require surgical treatment and which do not, the moorLDI2-BI enables decisions about surgery to be made earlier and for surgery to be avoided in some patients.

1.3 The estimated average cost saving when the moorLDI2-BI is used in addition to clinical evaluation is £1248 per patient scanned (if the equipment is purchased) or £1232 per patient scanned (if the equipment is leased). This is based on an assumption of a 17% reduction in the number of skin graft operations at a cost of £2043 each.

4. Rationale

Evidence published since the original guidance supports the recommendations and there has been no change in the care pathway or in technology availability, mode of action or regulatory status. However, the price of the product, and some NHS resource costs have changed. Using these parameters, an updated cost model shows an increase of £33 (purchasing option) and £42 (leasing option) in the estimated per-patient saving. It is therefore proposed that this guidance should be amended (proposed amendments shown in Appendix 3). The landing page of the guidance will link to a summary of the updated cost savings.

5. New evidence

The search strategy from the original assessment report was re-run on Medline, Embase, PubMed and CINAHL. References from August 2010 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company provided information on changes relating to the regulatory approval, indications, uses, costs and claimed benefits of the technology as well as important new evidence. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

6.1 Technology availability and changes

MoorLDI2-BI has had a number of hardware and software changes to improve connectivity and usability since March 2011. None of these has required an updated CE mark and the technical specification of the laser Doppler imaging used for burn assessment is unchanged. The UK end user price in 2011 was £49,950 and the current price is £53,942. The price adjustment is mainly in line with inflation rate. Also, the current price includes a training cost of £1198. A new laser Doppler burn imager, moorLDLS-BI has been developed which uses a line scanning approach to minimize scan time.

6.2 Clinical practice

There is no NICE clinical guideline on burn management. MoorLDI2-BI is linked to the skin conditions NICE pathway. NICE has published MTG 21: the ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury which relates to a different stage in the care pathway. Expert advice was received from three clinicians with experience of using moorLDI2-BI, one of which who acted as an Expert Adviser to the committee during the development of MTG2. Two experts felt the NICE published guidance on this technology has been helpful, although both experts stated some surgeons caring for patients with burns are not convinced by the reliability of the technology in determining healing time. One expert considered that this technology is particularly helpful for burn wounds with a very pale appearance, usually an indication of a deep wound that requires grafting, however moorLDI2-BI will often show good blood flow, so that surgery and scarring can be avoided.

6.3 NICE facilitated research

No research has been commissioned by NICE on this technology.

6.4 New studies

The updated literature searches identified 14 studies using the moorLDI2-BI for assessment of burn injuries published since the guidance was issued. Seven of the 14 studies were excluded; 2 study protocols, 1 systematic review which includes evidence already included here or in the original evaluation, 3 not assessing the clinical utility of moorLDI and 1 where moorLDI was not the focus of the study. The remaining 7 studies are relevant to the current review. Three studies (Hoeksema et al. (2011), Hoeksema et al. (2014), Holland et al. (2014)) compared performance of the 2 moorLDI devices; 2 studies compared the technology with other methods of burn assessment (Burke-Smith et al. 2015 and Seki et al. 2014) and the remaining 3 studies compared the technology with clinical assessment which was the comparator in the scope (Stewart et al. 2012 and Hop et al. 2014). All studies support the current recommendations.

Hoeksema et al. (2011), published preliminary results (see Hoeksema et al. 2014 for full results) in a conference abstract comparing moorLDI2-BI with a laser Doppler line scanner (LDLS) which is a burns assessment imager that covers a smaller area (15cm x 20cm compared to 50cm x 50cm), but takes less time to assess the burn (4 to 8 seconds compared to up to 120 seconds). The aim of the study was to assess the accuracy and convenience of the LDLS to help predict healing times and to compare this with the moorLDI2-BI. Images using moorLDI2-BI and LDLS were obtained at 2-5 days post burn and assessment of healing took place 14-21 post burn. Burns were categorised into healing within 14 days, with 14-21 days and not healed within 21 days. 120 burns from 44 patients were included in the study and

the results showed an overall accuracy of 92% was found with use of the LDLS compared with 94% with moor LDI2-BI.

Hoeksema et al. (2014) is an updated publication of Hoeksema et al. (2011). 596 burns from 204 patients were included in the analysis. An accuracy of 94.2% was found with use of the LDLS compared with 94.4% for the moorLDI2-BI. The results showed that the accuracy LDLS line-scan imager was comparable to that of the moorLDI2-BI. The authors concluded that higher scan speed was particularly beneficial for scans in paediatric patients.

Holland et al. (2014) conducted a prospective study comparing a LDLS with moorLDI2-BI to assess burn wound healing potential was performed in 50 paediatric patients presenting to a Australian burns unit between February 2010 and March 2011, as part of a multi-centre, international trial. One of the 50 patients enrolled was excluded from the analysis as they were unable to present for wound reviews at 14 and 21 days. Ninety scans were performed of 59 burn wounds in the remaining 49 patients. Overall accuracy was 94.5% for moorLDI2-BI and 95% for LDLS. The authors concluded that LDLS was found to be as accurate as the moorLDI2-BI in predicting burn wound healing potential in children. The LDLS scan resolution was lower, with more scans of larger burns required, its smaller size and greater scan speed proved valuable in children.

Burke-Smith et al (2015) carried out a UK based observational study assessing the accuracy of infrared thermography (IRT) and spectrophotometric intracutaneous analysis (SIA) for burn depth assessment compared with moorLDI. Burn regions were grouped according to burn wound healing: group A healed within 14 days, group B within 14–21 days, and group C took more than 21 days or underwent grafting. Both LDI and IRT accurately determined healing potential in groups A and C, but failed to distinguish between groups B and C ($p > 0.05$). Results for SIA were 100% consistent with clinical outcome across all groups.

The Seki et al (2014) study included 14 patients with a total of 50 burns (mean age 54, 8 males). The study assessed if regional tissue oxygen saturation (rSO2) measured by near-infrared spectroscopy (NIRS) in burn injuries correlated with regional tissue blood flow (rTBF) measured by moorLDI. The results indicated that the rSO2 (%; range, 52-82) by NIRS and the rTBF (perfusion unit; range, 61-704) by LDI in burn lesions were positively correlated ($r=0.755$, $p<0.001$). This statistically positive correlation still remained significant ($r=0.678$, $p<0.001$) after the rSO2 values were standardised.

Stewart et al (2012) conducted a blinded observational study comparing moorLDI with clinical assessment for the decision to operate. Immunohistochemistry and real-time reverse transcription polymerase chain reaction was performed to determine whether there is a correlation between histological assessment of burn depth and LDI, and the presence of fibrocytes was detected using confocal microscopy. The

results showed that moorLDI was >90% accurate at predicting the need for excision and grafting. The accuracy of the decision to debride deep dermal burns to avoid hypertrophic scarring using both clinical parameters and LDI was supported by histological and biochemical measurements.

Hop et al (2014) conducted an RCT to assess the effects of the introduction of moorLDI on therapeutic decisions, clinical outcomes and costs compared with clinical assessment alone on 202 patients. The primary outcome was time to wound healing. The results showed that mean time to wound healing was 14.3 days (95 % CI, 12.8 to 15.9 days) in the laser Doppler imaging group and 15.5 days (95 percent CI, 13.9 to 17.2 days) in the standard care group ($p = 0.258$). On the day of randomisation, clinicians decided significantly more often on operative or non-operative treatment in the laser Doppler imaging group, instead of postponing their treatment choice ($p < 0.001$). Analyses in a subgroup of admitted patients requiring surgery showed a significant earlier decision for surgery and a shorter wound healing time in the laser Doppler imaging group. Mean total costs per patient were comparable in both groups. In 2016 Hop et al published a full paper based on the Hop et al (2014) conference abstract (see above). Additional information highlighted although mean total costs per patient were comparable in both groups, this was due to theatre access. The subgroup of admitted patients requiring surgery showed a significant earlier decision for surgery in the laser Doppler group. If patients had been operated on at the time of the decision making, potential cost savings could be €875 per scanned patient.

7. Summary of new information and implications for review

The new clinical evidence on the moorLDI2-BI device supports the original recommendations of MTG 2.

The original cost model was revised to incorporate:

- the increased technology price;
- updated NHS resource costs. Where these were not readily available, the original cost was inflated to 2015 prices using HCHS index (Curtin & Burns 2015). The main changes relate to the cost of an adult bed day for skin grafts, and the revision of unit staff costs;
- a more accurate method of estimating the annual equipment cost. In the original submission the purchase cost of the equipment was divided by its lifespan to estimate the annual cost. The equipment costs have been annuitizing in the updated model. The updated unit costs and source of the costs are presented in appendix 2.

The proposed amendments to the guidance are presented in appendix 3.

8. Implementation

The company has stated that moorLDI2-BI is being used in approximately 16 NHS burns centres in the UK, with multiple imagers in use within some trust and that clinical diagnostic use has increased since the NICE guidance was produced. Some of the centres who previously only used the system occasionally have trained more staff in order to use the system as a routine aid; there has been a large increase in the number of NHS staff trained to use the system since 2011. . The Adoption and Impact team is aware of the use of moorLDI2-BI at 2 of the 16 NHS organisations listed by the company.

9. Equality issues

In the original guidance the Committee was advised of the usefulness of this technology for people with dark skin whose burns are often more difficult to evaluate using clinical assessment. The Committee noted this information and agreed it should be included as a consideration.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequence	Selected – 'Yes/No'
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	No
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – EAC updated unit costs

Table 1: Updated unit costs

Cost Parameter	Unit Cost (Original model)	Updated unit cost	Source(Updated cost)

moorLDI Leasing cost	£ 22,000	£ 22,000	Manufacturer
moorLDI purchasing cost	£ 50,000	£ 53,942	Manufacturer
Servicing cost	£ 8,000	£ 8,301	Manufacturer
Nurse(Band 5) hourly rate*	£ 45	£ 105	Unit cost of Health and Social Care 2015
Clinician(surgeon) hourly rate	£ 170	£ 186	Unit cost of Health and Social Care 2015
Registrar hourly rate	£ 61	£ 81	Unit cost of Health and Social Care 2015
Administration cost	£ 15	£ 16	Inflated to 2015 prices using HCHS index
NHS staff training cost	£ 3,416	£5,160	2 days (16 hours)training for 1 clinician, 2 registrars and 3 nurses(Unit cost of Health and Social Care 2015)
Cost of day bed adult	£ 378	£ 387	Weighted average National Schedule of Reference Costs Year: 2014 -2015 (codes JB30A - JB33C)
Cost of day bed child	£ 794	£ 866	Inflated to 2015 prices using HCHS index
Cost of operation/hour	£ 2,043	£ 2,319	Updated unit costs in the original EAC estimation

* The increase in nursing cost is mainly because of an increase in qualifications and overheads costs that goes into the costing methodology. The original model used estimates from PSSRU 2009 http://www.pssru.ac.uk/archive/pdf/uc/uc2009/uc2009.pdf (page 159) and the revised model used more recent estimates http://www.pssru.ac.uk/project-pages/unit-costs/2015/ (page 236).

Appendix 3 – Proposed amendments to original guidance

Table 2: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
Page 1, 1.3	The estimated average cost saving when the moorLDI2-BI is used in addition to clinical evaluation is £1248 per patient scanned (if the equipment is purchased) or £1232 per patient scanned (if the equipment is leased). This is based on an assumption of a 17% reduction in the number of skin graft operations at a cost of £2043 each.	The estimated average cost saving when the moorLDI2-BI is used in addition to clinical evaluation is £1281 per patient scanned (if the equipment is purchased) or £1274 per patient scanned (if the equipment is leased). This is based on an assumption of a 17% reduction in the number of skin graft operations at a cost of £2319 each. [2017]
Page 2, 2.4	The moorLDI2-BI can be purchased at a cost of approximately £50,000 with an annual servicing cost of approximately £8000, or it can be leased at an inclusive cost of approximately £22,000 per year.	The moorLDI2-BI can be purchased at a cost of approximately £53,942 with an annual servicing cost of approximately £8301, or it can be leased at an inclusive cost of approximately £22,000 per year. [2017]
Page 10, 5.3	The cost model assumed that 70% of the admitted patients were likely to have intermediate burn wounds and be scanned. To calculate a per patient cost in the base case, each burns centre was assumed to have one imager with annual staff training costs of £3416. Nurse scanning time per patient was 1 hour and clinician time per patient for interpreting results was 15 minutes. The cost savings included were based on a reduction of 17% in the number of skin graft operations and a 2-day reduction in the length of hospital stay. These parameter values were based on evidence from clinical studies. In the model the cost per hour for an operation to treat burn wounds was £4593, based on the figures presented in Hemington-Gorse et al. (2009). Expert advice to the External Assessment Centre was that this	The cost model assumed that 70% of the admitted patients were likely to have intermediate burn wounds and be scanned. To calculate a per patient cost in the base case, each burns centre was assumed to have one imager with annual staff training costs of £5160. Nurse scanning time per patient was 1 hour and clinician time per patient for interpreting results was 15 minutes. The cost savings included were based on a reduction of 17% in the number of skin graft operations and a 2-day reduction in the length of hospital stay. These parameter values were based on evidence from clinical studies. In the model the cost per hour for an operation to treat burn wounds was £4593, based on the figures presented in Hemington-Gorse et al. (2009). Expert advice to the External Assessment Centre was that this

	hourly cost was high, so it derived a lower figure of £2043 per hour.	hourly cost was high, so it derived a lower figure of £2043, this has been adjusted for inflation to £2319 per hour. [2017]
Page 10, 5.4	A range of scenario analyses were done, including best- and worst-case scenarios using the ranges for the proportion of patients scanned, number of bed days saved and operating time. Additional analyses were done by the External Assessment Centre to assess the impact of changing the hourly cost for an operation to £2043.	A range of scenario analyses were done, including best- and worst-case scenarios using the ranges for the proportion of patients scanned, number of bed days saved and operating time. Additional analyses were done by the External Assessment Centre to assess the impact of changing the hourly cost for an operation to £2043, this has been adjusted for inflation to £2319. [2017]
Pages 11, 5.5	The cost saving per patient scanned from using the moorLDI2-BI in addition to clinical evaluation compared with clinical evaluation alone for the base case was £1248 for the purchase option and £1232 for the lease option (both based on an hourly cost of £2043 per operation). The worst-case scenario for the purchase option resulted in a cost saving of £734 per patient and the best-case scenario resulted in a saving of £2860 per patient scanned. All analyses presented in the assessment report showed that the total cost saving from reducing length of hospital stay and number of operations was greater than the costs associated with the purchase and operation of the moorLDI2-BI.	The cost saving per patient scanned from using the moorLDI2-BI in addition to clinical evaluation compared with clinical evaluation alone for the base case was £1281 for the purchase option and £1274 for the lease option (both based on an hourly cost of £2043 per operation). The worst-case scenario for the purchase option, based on 2011 prices resulted in a cost saving of £734 per patient and the best-case scenario resulted in a saving of £2860 per patient scanned. All analyses presented in the assessment report showed that the total cost saving from reducing length of hospital stay and number of operations was greater than the costs associated with the purchase and operation of the moorLDI2-BI. [2017]

Additional information

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