National Institute for Health and Clinical Excellence

Medical Technologies Evaluation Programme

The MIST therapy system for the promotion of wound healing

Consultation comments table

There were 34 consultation comments from 9 consultees (6 NHS professionals, 2 manufacturers and 1 other). The comments are reproduced in full, arranged in section order with general comments at the end.

Comment Number	Consultee Number and Organisation	Section Number	Comments	Response
1	Consultee 2, Private Sector Professional	1	The Wound Healing Centre in Eastbourne cares for up to 700 patient contacts per month and all our nurses are experienced Tissue Viability Nurses and we also have a multidiscplinary team and, although we are a private company, our patients are funded by the local PCT.	Thank you for your comment
2	Consultee 2, Private Sector Professional	1	We requested the opportunity to use MIST to establish if we should purchase. We have been extremely impressed with the difference it makes to the wounds. We treated 4 patients with very complex and intractable wounds. All of them greatly improved during treatment and all but 1, developed slough again once treatment was discontinued. The machine is expensive, but, if we can find a way to afford it, we will definitely purchase. All patients in our evaluation will be willing to report the findings and have agreed that their photographs may be used to demonstrate the changes. I would highly recommend its use.	Thank you for your comment

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			[redacted] Tissue Viability Consultant. [redacted]	
3	Consultee 5, Healthcare Other	1	There is clearly an abundance of peer reviewed published articles. As stated in the meta-analysis this represents 444 patients. While only 2 of these trials are randomized controlled trials, the evidence presented identifies the real issue of healing chronic wounds in the community hospital setting. I	Thank you for your comment. The meta-analysis was not considered robust evidence with regard to the efficacy/effectiveness of MIST Therapy in the treatment of chronic wounds because of lack of control groups; lack of clearly defined patient population and comparator; lack of sufficient description of the characteristics of the patients/wounds; lack of assessment of the methodology of included studies; and the short duration of the studies. The Committee considered this comment and decided not to change the guidance to include the meta-analysis mentioned because of the low quality of the studies which it analysed.
4	Consultee 5, Healthcare Other	1	It appears that the assessment of the MIST Therapy system really hinges around the quality not quantity of evidence.	Thank you for your comment
5	Consultee 2, Private Sector Professional	2	The technology is simple and easy to use. The patients all commented that there was no pain associated with the ultrasound.	Thank you for your comment
6	Consultee 2, Private Sector Professional	3	In the Wound Healing Centre, we undertake our own clinical evaluations, based on the experience of the Tissue Viability Nurses, Wound Care Podiatrist and consultants. However, the evidence detailed above is impressive and certainly agrees with our own findings.	Thank you for your comment
7	Consultee 3, NHS Professional	3	I am inclined to agree with the committee in that there is potential but the evidence is limited by small patient numbers. My own experience of using this device, while also limited to small	Thank you for your comment

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			numbers, does mirror what is said above.	
8	Consultee 3, NHS Professional	3	The patients I have been involved with have been very positive about the benefits of reducing wound size and to some degree reduction of pain.	Thank you for your comment
9	Consultee 4, Business Development Manager	3	3.6 contains a number of errors a) 1) medical charts of 210 patients were reviewed, not the 163 patients stated b) the intervention group should state163, whereas it currently states n 116.	Thank you for your comment. The Committee considered this comment and decided to change the total number of patients to state 210 and the number of patients in the intervention group to state 163 in section 3.6 of the guidance
10	Consultee 4, Business Development Manager	3	3.14. states the study was judged to be of “poor quality” as the data this reflects provides healing rates of 40% in the intervention group this is a strong term to use and would suggest that “not substantial quality” would be more appropriate.	Thank you for your comment. The External Assessment Centre recommended that the recognised categorisation of evidence quality described in the ECRI Institute guidance would be appropriate to use in this context. The committee considered this comment and decided to change the reference in section 3.14 to ‘low quality’ instead of ‘poor quality’.
11	Consultee 4, Business Development Manager	3	There are a number of factual inaccuracies within the clinical evidence: 3.4 States 18% of wounds healed in the intervention group. This should actually state 40% which in fact does provide a statistical significance p0.0366.	Thank you for your comment. The 40% wound closure and p value of 0.0366 cited here was based on the 'efficacy population' (a subset of 55 patients), which was defined post hoc and excluded more than half of patients originally randomised. It was decided that it would be misleading in citing results from the subset of 55 patients rather than from the total number of 133 patients that were in the study. Therefore the figure used of 18% in the intervention group is correct. The evidence was assessed by an independent external assessment centre; their advice to the Committee stated that the analysis based on 'intention to treat (ITT)' principle (which includes all randomised patients) provides better (less biased) estimates of treatment effect. The Committee considered the

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				comment and decided the 40% figure should not be included but it was agreed to change section 3.4 to clarify that the figures are based on the intention to treat analysis only. The Ennis et al (2005) intention to treat analysis reported 26% (18/70) of wounds healed in the intervention group compared with 22% (14/63) in the control group (not 18% and 14% as stated in the draft guidance). The Committee considered this and agreed these percentages should be changed to state 26% and 22% respectively in section 3.4 of the guidance.
12	Consultee 5, Healthcare Other	3	Section 3.6 There are numerical errors There was a total of 210 patient records, the intervention group was 163 patients, the control group was 47 patients.	Thank you for your comment. The Committee considered this comment and decided to change the total number of patients to state 210 and the number of patients in the intervention group to state 163 in section 3.6 of the guidance
13	Consultee 5, Healthcare Other	3	3.17 Recurrence:Kavros/Schenck(2007) specifically looked at suvivorship at 30 months post healing. 83% of subjects had NO further incidence of ulceration. 12% developed an ulceration, but at a different location.	Thank you for your comment. In Kavros and Schenck (2007), long-term follow up (30 months) was conducted by distributing a questionnaire to all 51 patients in this case series, for which the inclusion/exclusion criteria and whether the cases were consecutive patients were not clearly described. Responses to the questionnaire were received from 43 survivors (there were 8 deaths), with 38 respondents (88%) stating that they did not have an incident of further ulceration. 5 patients (12%) developed a subsequent ulcer but at a different location. Wound closure was reported to occur with MIST therapy in 26 out of the 51 cases in the study but it is not clear how many of the 38 respondents had their wound closed, and thus the 88% figure does not reflect the true rate of no recurrence after healing. The committee considered this comment; it was stated that

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				the figures quoted were the results of a question in the discussion part of the paper. As there is no way of verifying the data, the Committee decided not to change the guidance.
14	Consultee 5, Healthcare Other	3	Section 3.4 The article specifically states that 40% of the wounds healed in the intervention group wth a statistical significance of p0.0366. (18% without stitistical significance is incorrect)	Thank you for your comment. The 40% wound closure and p value of 0.0366 cited here was based on the 'efficacy population' (a subset of 55 patients), which was defined post hoc and excluded more than half of patients originally randomised. It was decided that it would be misleading in citing results from the subset of 55 patients rather than from the total number of 133 patients that were in the study. Therefore the figure used of 18% in the intervention group is correct. The evidence was assessed by an independent external assessment centre; their advice to the Committee stated that the analysis based on 'intention to treat (ITT)' principle (which includes all randomised patients) provides better (less biased) estimates of treatment effect. The Committee considered the comment and decided the 40% figure should not be included but it was agreed to change section 3.4 to clarify that the figures are based on the intention to treat analysis only. The Ennis et al (2005) intention to treat analysis reported 26% (18/70) of wounds healed in the intervention group compared with 22% (14/63) in the control group (not 18% and 14% as stated in the draft guidance). The Committee considered this and agreed these percentages should be changed to state 26% and 22% respectively in section 3.4 of the guidance. See response to comment no. 11

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15	Consultee 2, Private Sector Professional	4	Given that the patients that were provided with the MIST therapy in the Wound Healing Centre were all non-healing prior to MIST, then we would certainly agree that the treatment is cost effective and clinically effective.	Thank you for your comment
16	Consultee 3, NHS Professional	4	I also agree with point 4.5, could it be this willingness to embrace treatments rather than MIST that hs had positive outcomes?	Thank you for your comment. In developing its recommendations, the Committee considered published and unpublished evidence and expert advice. The Committee considered this comment and decided not to change the guidance.
17	Consultee 3, NHS Professional	4	I can confirm that MIST therapy can easily be performed in a community setting.	Thank you for your comment.
18	Consultee 2, Private Sector Professional	5	Agreed	Thank you for your comment
19	Consultee 4, Business Development Manager	5	The economic analysis took into account the symposium data provided at Wounds UK, Harrogate, 2010. The data from Dr Driver and Ray Norris is being published in wounds UK journal. A copy has been forwarded to NICE to provide further information on the presentations carried out.	Thank you for your comment. The publication in the Wounds UK journal is a meeting report summarising the plenary session held at the Wounds UK conference. It included a presentation of one case study of one patient and a presentation on the use of MIST therapy in the US. The committee considered this comment and decided not to include the study suggested in the final guidance.
20	Consultee1, nurse from US	6	I work as a nurse, in wound care, in Minnesota. I used this therapy, in a clinical setting, on a variety of wounds and in a variety of patients with different concurrent disease and compliance. I found it to be high priced, clumsy, time consuming and in my opinion, it did not speed wound healing, decrease infection rates or make the day to day quality of	Thank you for your comment. In developing its recommendations, the Committee considered published and unpublished evidence and expert advice. The Committee considered this comment and decided not to change the guidance.

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			life better for the patients.	
21	Consultee1, nurse from US	6	I was always frustrated when the MD ordered this treatment, which he did on nearly every wound care patient we saw. I cant say WHY he ordered it for every one as i cannot read his mind but in my opinion it was not because it helped the patients. [redacted]	Thank you for your comment
22	Consultee 2, Private Sector Professional	6	I absolutely do not agree with the call for good quality studies as there are excellent centres in the UK with many very highly qualified people providing experienced wound care and they are never listened to when examining the efficacy of a product. It is almost impossible to undertake good studies in wound care due to the very high variables that face the researcher. if 2 or 3 Tissue Viability Consultants examine a product and all agree on its efficacy, then that should be evidence enough	Thank you for your comment. In developing its recommendations, the Committee considered published and unpublished evidence and expert advice. The Committee was advised that good quality studies could be undertaken. The Committee considered this comment and decided not to change the guidance.
23	Consultee 2, Private Sector Professional	6	In pharmacy, evidence in the form of RCT, is requisite. Everytime that NICE calls for evidence in wound care, it costs the company money to undertake the trial and this is put back on the product. MIST has evidence of its efficacy as demonstrated by all of the above studies, and, it will not harm a patient, so why are we so hung up on evidence. Use the people who know wound care and stop this uneccessary drain on resources. MIST works and works well, take it from an experienced clinician.	Thank you for your comment. In developing its recommendations, the Committee considered published and unpublished evidence and expert advice and considered that the quality and quantity of evidence available did not support the case for adoption. The Committee considered this comment and decided not to change the guidance.
24	Consultee 4, Business	6	It has been highlighted in the document that in the area of wound care the evidence is generally poor	Thank you for your comment. The Committee considered changing section 6 but judged that section

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	Development Manager		and that the committee stated that the evidence for MIST was equal to or better than evidence for many other wound care interventions in current use in the NHS.	3.15 was sufficiently clear about this point. The Committee considered this comment and decided not to change either section 3.15 or section 6. The response to comment 25 is also relevant to this issue.
25	Consultee 4, Business Development Manager	6	There is also a growing debate in Europe about evidence for medical device. MIST has a large amount of evidence and we (the distributors) believe the following statement : “The quality of that evidence and consequent uncertainty about its effectiveness in healing wounds compared with standard care alone meant that the case for routine adoption in the NHS could not be supported at the time of writing” would be more appropriate.	Thank you for your comment. Section 6.1 states that the evidence available is 'low quality'. The Committee considered this comment and decided not to change the guidance. The response to comment 10 is also relevant to this issue.
26	Consultee 2, Private Sector Professional	8	The Wound Healing Centre would be happy to be part of the development of guidance.	Thank you for your comment
27	Consultee 4, Business Development Manager	8	Within the documentation the BSI certification had a short period of time remaining before its renewal, the technical file since been reviewed (Q1 2011) and will next be reviewed in 5 years.	Thank you for your comment
28	Consultee 3, NHS Professional	General	I have been using MIST therapy on trial for the last 3 months to decide if it would be a worth while piece of equipment to purchase. My use of it has been limited to two patients one with ischaemic diabetic foot ulceration and one with neuropathic diabetic foot ulceration.	Thank you for your comment
29	Consultee 5, Healthcare Other	General	I am currently the VP of Clinical Affairs or Celleration, Inc the manufacturere of this technology. My primary responsibilities are for the	Thank you for your comment

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			research agenda of the corporation.	
30	Consultee 6, Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make regarding this consultation.	Thank you for your comment
31	Consultee 7, Healthcare	General	MIST therapy has had a tremendous impact on healing of wounds, reduction in bacteria and has been a cost Effective alternative. When we first evaluated MIST for large complex wounds, we showed a 40 to 50 % reduction in Negative Pressure Wound Therapy use in the long term acute care setting. It is painless for patients and safe to use since there is no splatter like with pulsatile lavage. Treatment times are usually less than ten minutes so it is very time and cost efficient. Bottom line is it works to clean up wounds and stimulate healing and it is one of the few wound technologies that actually has randomized clinical trials to demonstrate its efficacy.	Thank you for your comment. In developing its recommendations, the Committee considered published and unpublished evidence and expert advice. The Committee considered this comment and decided not to change the guidance.
32	Consultee 8, Healthcare	General	I have used MIST therapy in complex diabetic foot wounds as a part of a five patient evaluation, whilst this is by no means strong evidence the positive anecdotal results achieved including speed of healing and reduction in pain for patients were impressive. The research undertaken in the USA is of a reasonable standard and is far more convincing than for any other wound care product (see the draft Diabetic Foot guidelines 2011) and I would advise this is recommended for complex hard to heal diabetic foot ulcers as an adjunctive therapy.	Thank you for your comment. In developing its recommendations, the Committee considered published and unpublished evidence and expert advice. The Committee considered this comment and decided not to change the guidance.

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33	Consultee 8, Healthcare	General	The cost of long standing complex wounds which are failing to heal are soaring, the use of this therapy would prove cost effective.	Thank you for your comment
34	Consultee 9, RCN, Healthcare	General	The evaluation for this medical technology was circulated to nurses caring for people in this area for their views. There are no comments to make at this stage on behalf of the RCN.	Thank you for your comment