National Institute for Health and Clinical Excellence

Medical Technologies Evaluation Programme

EP 050 – Ambulight PDT for the treatment of non-melanoma skin cancer

Consultation Comments table

MTAC date: 17 February 2011

There were 75 consultation comments from 13 consultees.

The comments are reproduced in full.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1.	Consultee 2, Consultant Dermatologist	1	Was the comment "in place of conventional PDT" appropriate? I agree the evidence is not there to support it as a replacing technology. Was this the remit of this assessment?	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intends to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
2.	Consultee 2, Consultant Dermatologist	1	Also Question that the reason was that other therapies are complex? and that many NMSC patients do not need any treatment. The majority of dermatologists would in my view disagree with both these points.	Thank you for your comment. A brief explanation, informed by expert advice to the Committee, of why some patients may receive no treatment for their small low-risk skin lesions has been added to section 2.8 of the guidance.

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3.	Consultee 2, Consultant Dermatologist	1	Also NICE assessed PDT in 2006!	Thank you for your comment. Related NICE guidance is listed in section 8 of the guidance. Ambulight PDT was outside the scope of all related NICE guidance at the time of this medical technology guidance publication
4.	Consultee 2, Consultant Dermatologist	1	The concluding sentance seems reasonable	Thank you for your comment.
5.	Consultee 3, Consultant Dermatologist, Expert Adviser	1	Treatment of NMSC is rarely "conservative" - in which the trem here is used to mean no treatment. This would be exceptional to not treat these lesions. The term conservative is misleading as I consider that PDT is a conservative treatment - ie. non-surgical.	Thank you for your comment. The evidence submitted on Ambulight PDT suggests that it may be of most benefit to patients with NMSC lesions ≤ 1.5 cm diameter. For this specific lesion size the Committee was advised that treatment may not always be offered. The use of the term ‘conservative’ has been changed in the guidance. A brief explanation of why some patients may receive no treatment for their small low-risk skin lesions has been added to section 2.8 of the guidance.

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6.	Consultee 1, Consultant Dermatologist	1	I agree that this is mostly an appropriate recommendation. I do suggest considering re-wording. I am puzzled by the reasons given here for supporting "Ambulight PDT in place of conventional PDT". The main reasons must relate to the fact that so far there have been limited studies, with in particular no large comparative (comparing with conventional PDT) study, including cost effectiveness measures as well as measures of pain and clinical efficacy as outcome measures. I suggest re-wording to something like: "The Ambulight PDT offers a means of delivering photodynamic therapy in an ambulatory care setting for patients with small non-melanoma skin cancers. Its use may be associated with less pain than conventional photodynamic therapy. The case for adoption for using the Ambulight PDT in place of conventional photodynamic therapy could not be supported at this stage because there is insufficient available comparative data assessing the outcomes of efficacy, pain and cost-effectiveness. The Ambulight PDT is one option available to treat non-melanoma skin cancer".	Thank you for your comment. The guidance does not support the use of Ambulight PDT over conventional PDT. Sections 3.14 and 4.5 of the guidance have been amended to state that Ambulight PDT is a treatment option.
7.	Consultee 3, Consultant Dermatologist, Expert Adviser	1	The intention would newver have been for Ambulight PDT To replace conventional PDT asof course the evidence base at this stage is small and the devices only for small lesions. It should however be AN option for PDT - agree with last sentence but preceding statements are misleading.	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intended to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.

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8.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	1	Consideration needs to be given to patients presenting with multiple basal cell carcinomas, i.e. Gorlin Syndrome (Nevoid Basal Cell Carcinoma Syndrome). NICE Guidelines Improving outcomes for people with skin tumours including melanoma state Protocols should cover the management of care for people in high risk or special groups. Â Gorlin Syndrome patients are identified as high risk and included as a special group. Despite the guidelines many Gorlin patients experience lengthy waiting periods for treatment, thus resulting in subsequet, extensive surgery. Â Ambulight PDT would offer patients another treatment option and be of benefit for the treatment of superficial basal cell carcinomas associated with the condtion.	Thank you for your comment. The scope for Ambulight PDT was for single lesions only, in line with the manufacturer's notification of this product to NICE. The treatment of patients with Gorlin syndrome is therefore outside the scope of this evaluation. However, the manufacturer could, if they wish, promote the use of the Ambulight PDT in this patient group.
9.	Consultee 6, Device Manufacturer	1	During the evaluation process neither the manufacturer, nor the MTAC team suggested that the Ambulight PDT should be considered as a replacement to any therapy, but that it should be offered for particular patient groups who would benefit from it. If the 'replacement' aim of the guidance is removed we are in full agreement with the statement," Ambulight PDT remains one of the options available for non-melanoma skin cancer."	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intended to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
10.	Consultee 6, Device Manufacturer	1	NMSC treatment is complex, NICE and the BAD have published guidelines to establish treatment parameters. Given these guidelines, we do not agree that the complexity surrounding NMSC is a barrier to consideration of the Ambulight.	Thank you for your comment. Guidance has been issued by NICE and the British Association of Dermatologists on the use of PDT for NMSC. The Committee was advised that despite these guidelines, variation in practice still exists in England.

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11.	Consultee 6, Device Manufacturer	1	Peer reviewed, published data to support the claims relating to pain were submitted. This evidence has not been factored into the recommendation. MTAC encouraged the manufacturer to submit the Ambulight to this elective process which is aimed to assist market entry and deliver support for adoption of new technologies. Using the words “could not be supported” has led to commercially damaging publicity for the company. The manufacturer requests that this phrase is removed.	Thank you for your comment. The data on pain are reported in sections 3.4 and 3.5 with a Committee consideration on these data included in section 3.9.
12.	Consultee 7, Killing Cancer Charity, Director	1	I find the above confusing. Yes, Ambulight should be an available option. To say that that choice of treatment is complex is unhelpful. It is also not accurate. There are many in dermatology who will only offer what they do and where they are specialists. It is quite true that for some parts of the body, surgery is a quick option and any scar is of little consequence to the patient. But where cosmetic outcome is deemed important by the patient, PDT is the most obvious answer.	Thank you for your comment. Guidance has been issued by NICE and the British Association of Dermatologists on the use of PDT for NMSC. The Committee was advised that despite these guidelines, variation in practice still exists in England.
13.	Consultee 1, Consultant Dermatologist	2	I was initially puzzled by 2.10. On re-reading I suspect this is because "ambulatory care setting" is variably defined, to include outpatient treatment (as for conventional PDT) and home treatment (as with the Ambulight device).	Thank you for your comment. Section 2.10 referred to by the consultee is now section 2.9 in the final guidance document. This section has been changed to describe the ambulatory care settings that conventional PDT is currently offered in.
14.	Consultee 3, Consultant Dermatologist, Expert Adviser	2	again term "conservative" taken to mean no treatment whereas most dermatologists would consider non-surgical treatment, including PDT to be conservative.	Thank you for your comment. The use of the term ‘conservative’ has been changed in the guidance.

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15.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	2	With regard to 2.10 - not sure that this is the case. Â Gorlin patients should have access to all available treatment options (other than radiotherapy which is not recommended), whether that be locally, in secondary care or at a specialist centre. Ambulight PDT for the treatment of superficial basal cell carcinomas in Gorlin Syndrome has the potential to be delivered locally by trained GPs of Skin Cancer Specialist Nurses thus reducing the burden on secondary care costs.	Thank you for your comment. The scope for the assessment of Ambulight PDT was for single lesions only, in line with the manufacturer's notification of this product to NICE. The treatment of patients with Gorlin syndrome is therefore outside the scope of this evaluation.
16.	Consultee 6, Device Manufacturer	2	From existing NICE guidance, clinicians are able to use PDT and are not restricted in their choice of light source required. The Ambulight is simply one light source available to clinicians. The views presented by [redacted] at the committee meeting were surprising. For example taking the following extract, 'that practice varies substantially, that many of the skin lesions suitable for this type of treatment can be managed conservatively.' This view would seem to contrast with the BAD guidelines for the treatment of NMSC, the DoH systematic review, and the PCDS guidelines.	Thank you for your comment. A brief explanation of why some patients may receive no treatment for their small low-risk skin lesions has been added to section 2.8 of the guidance. Both these sections were informed by expert advice to the Committee. In addition, section 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.

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17.	Consultee 6, Device Manufacturer	2	The existing NICE guidelines state 'failure to diagnose early and/or inadequate treatment can result in tumours that destroy important anatomical structures. Such tumours are very challenging to treat, making it difficult to obtain a good cosmetic result or resulting in the tumour becoming inoperable.' This view also seems to contradict the publicly stated views of the other clinical experts used for this review. We would therefore ask if there was an official clinical report written for this review. We would also like to ask why the views expressed differ so markedly with the existing clinical consensus.	Thank you for your comment. Expert advice is sought in line with the draft process guide. No clinical report is written, but the opinions of all the Expert Advisers are presented in full to the Committee at each stage of a products evaluation.
18.	Consultee 7, Killing Cancer Charity, Director	2	The options offered by hospitals are based on the skills set in the unit - not by any other consideration. A unit not offering PDT will be generally unable by the PCT to refer out of area. This technology offers the chance for the NHS to use less expensive staff to undertake the rapidly increasing numbers of skin cancer patients. Using this technology will allow more patients to be treated without bed or area blocking, and reduce the need for staff to wear goggles.	Thank you for your comment. Section 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
19.	Consultee 1, Consultant Dermatologist	3	No comments	Thank you for your comment.
20.	Consultee 2, Consultant Dermatologist, co-inventor of device	3	See above comments	Thank you for your comment.

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21.	Consultee 3, Consultant Dermatologist, Expert Adviser	3	I agree there is evidence for use as an option for PDT of skin cancer but it should never have been remit to consider it as a replacement for conventional PDT at this stage of its development.	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intended to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
22.	Consultee 3, Consultant Dermatologist, Expert Adviser	3	NB. Ibbotson S paper in press does not state that second treatments are more painful - incorrect statement regarding this in press article.	Thank you for your comment. The Medical Technologies Evaluation Programme team had sight of the Ibbotson paper in press during public consultation. This paper did not contain all data included in the manufacturer's submission and was also not referenced in the submission. It has therefore been removed from the guidance and the raw data from the submission referenced in its place. The statement on second treatments referred to by the consultee was an observation by the Medical Technologies Evaluation Programme team will be removed from the guidance.
23.	Consultee 6, Device Manufacturer	3	Patient 'selection' would appear to contradict the recommendations from Kinsy, NICE, DoH and current NHS thinking where patient choice is the expectation.	Thank you for your comments. Before being given a choice of treatment options, patients do need to be selected for appropriate treatments by clinicians and this is important in PDT. The Committee considered that Ambulight PDT is only appropriate for use in selected patients. The Committee's considerations on patient preference are reflected in section 3.10 of the guidance.

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24.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	3	Is it the case that Ambulight PDT were looking to replace Â current management? Surely this new techology offers patients another treatment option for superficial basal cell carcinomas.	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intended to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
25.	Consultee 6, Device Manufacturer	3.2	3 studies where submitted.	Thank you for your comment. The External Assessment Centre considered that 2 studies using Ambulight PDT were included in the submission. However, section 3.2 of the guidance has been changed to remove this statement.
26.	Consultee 6, Device Manufacturer	3.5	The data is presented as a range of values, but omits the point relating to the mean score. This is significantly lower than typical PDT pain scores.	Thank you for your comment. The consultee refers to the last table of data in section 3 of the submission appendix. Mean pain scores were not presented in the submission. The guidance will not be changed.

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27.	Consultee 6, Device Manufacturer	3.7	The issues of lesion size and efficacy are separate, but appear to be linked in this statement. This contrasts with the scope to undertake evaluations with an emerging or 'thin' evidence base. The reference to a lack of evidence disregards a clinical report that was commended by MTAC for its approach. In this report PDT was examined as a combination therapy of drug + light. This report claims that the main advantages extend beyond pain and include factors such as the ambulatory nature of the device and its ability to be used in primary/home settings. These claims have benefits to certain patients, those with limited mobility, those from rural areas, pain intolerant or time poor people. The experts opinions differ, but there is consensus that some patients experience extreme pain with PDT.	Thank you for your comment. The Committee considered this comment and decided not to change section 3.7 of the guidance. Section 3.8 of the guidance has been changed to further describe the Committee's considerations on the use of Ambulight PDT for patients with impaired mobility and those patients for whom accessing treatment may be difficult. The Committee's considerations on pain are included in sections 3.9 and 3.12 of the guidance.
28.	Consultee 7, Killing Cancer Charity, Director	3	Unless NICE and others encourage the development of devices like this, then the treatment options will struggle to move forward. This device can be adapted for PDT in vulval and penile cancer, and to discourage this development would be unhelpful. In situations like this, surely NICE should focus on the evidence of reduced discomfort for patients, less inconvenience for patients being treated, the opportunity to treat more patients in a clinic day. It works. Its safe. It would be the option that patients would prefer IF GIVEN THE OPTION.	Thank you for your comment. The aim of medical technologies guidance is to promote the uptake of new and innovative technologies where they offer value for money and patient and system benefits over existing options. Patient choice is an important and integral part of a clinician's overall management plan (this is reflected in Committee consideration 3.10). The use of PDT for different indications is outside the scope of this evaluation.
29.	Consultee 1, Consultant Dermatologist	4	No comments	Thank you for your comment.

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30.	Consultee 3, Consultant Dermatologist, Expert Adviser	4	Misleading to consider that most dermatologists would not treat these lesions at all - this would be the exception.	Thank you for your comment. A brief explanation of why some patients may receive no treatment for their small low-risk skin lesions has been added to section 2.8 of the guidance.
31.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	4	Staff training -v- quality of live for many!	Thank you for your comment.
32.	Consultee 6, Device Manufacturer	4.4	Current NICE guidance states that all lesions should be biopsy tested prior to deciding on treatment options therefore this is common for any NMSC treatment. The cost for training would be comparative to the introduction of any new treatment to the NHS (or indeed could be lower for Ambulight PDT v.s static lamp PDT given the simplicity of applying the device to a patient). The introduction of such a new technology is the purpose of MTAC.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
33.	Consultee 6, Device Manufacturer	4.5	This contradicts current NICE guidance which states that all patients should be offered the full range of treatment choices regardless of age, location or disability. The Ambulight would open up PDT to patients with particular needs such as those with low mobility.	Thank you for your comment. Section 4.5 of the guidance states that 'Ambulight PDT is one treatment option for NMSC for carefully selected patients'. Section 3.8 of the guidance has been changed to further describe the Committee's considerations on the use of Ambulight PDT for patients with impaired mobility and those patients for whom accessing treatment may be difficult.

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34.	Consultee 7, Killing Cancer Charity, Director	4	When the DH starts to promote PDT for skin cancer, demand is going to increase. Our own marketing is going to heighten awareness. Of course training in its use will be required. And the savings in the short term are obvious. What I find hard to comprehend in this section that no thought is given to the patients and what they might prefer. It will very rapidly become the treatment of choice for many groups - including professional people that all the reports seem to ignore.	Thank you for your comment. Section 4.2 of the guidance describes how an ambulatory PDT treatment could be an attractive treatment option for some patients. Section 3.10 of the guidance includes a Committee consideration on patient preference in the decision to treat low-risk NMSC.
35.	Consultee 1, Consultant Dermatologist	5	No comments	Thank you for your comment.
36.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	5	Patient need and preference also need to be considered when calculating / reviewing costs. Â Many Gorlin Syndrome patients travel excessive distances to specialist centres for PDT, often requiring them to take a full day out of paid employment and impacting on individual finances.	Thank you for your comment. Section 3.10 of the guidance includes a Committee consideration on patient preference in the decision to treat low-risk NMSC. The scope for the assessment of Ambulight PDT was for single lesions only, in line with the manufacturer's notification of this product to NICE. The treatment of patients with Gorlin syndrome is therefore outside the scope of this evaluation.
37.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	5	Whilst recognising there will always be a Â need for a full range of treatment options for Gorlin Syndrome patients in both primary and secondary care it is worth noting that prompt treatment in the community for superficial basal cell carcinomas could reduce the cost of secondary care services.	Thank you for your comment. Prompt treatment is important, but the scope for Ambulight PDT was for single lesions only, in line with the manufacturer's notification of this product to NICE. The treatment of patients with Gorlin syndrome is therefore outside the scope of this evaluation.

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38.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	5	Too often patients are experiencing lengthy delays in treatment and requiring extensive surgery for the removal of basal cell carcinomas.	Thank you for your comment. Use of Ambulight PDT may reduce waiting times, although there is no evidence at this stage to support this.
39.	Consultee 6, Device Manufacturer	5	Many of the training costs highlighted in this report as proving to be a barrier to the Ambulight are already covered elsewhere by the NHS. For a clinician to be offering any PDT service in primary care, NICE guidelines state they must suitably trained in the requisite skills. The Ambulight is simply another light source for use with PDT.	Thank you for your comment. Staff training does need to be taken into account, particularly as Ambulight PDT may be used in different settings to conventional PDT.
40.	Consultee 6, Device Manufacturer	5	Clinicians are encouraged to offer PDT as part of the NICE guidelines and as such must use a light source. The cost scenarios show that the use of the Ambulight is likely to reduce PDT treatment costs for the NHS.	Thank you for your comment. The uncertainty in the models presented was too great for any firm conclusions on potential cost savings to be determined. This is reflected in section 5.7 and 6.1 of the guidance.
41.	Consultee 6, Device Manufacturer	5.6	However 5 out of 7 scenarios showed a reduction in costs and included total service provision costs.	Thank you for your comment. The uncertainty in the models presented was too great for any firm conclusions on potential cost savings to be determined. This is reflected in section 5.7 and 6.1 of the guidance.
42.	Consultee 6, Device Manufacturer	5.8	This is contradictory to the MTAC report who also agreed with the manufacturer that this was a considered and transparent method of presenting cost comparative data. The DoH have also commented on the lack of transparency in coding PDT treatments and have commissioned a report to better understand costing in PDT so as to eventually create specific codes as part of a systematic review.	Thank you for your comment. The uncertainty in the models presented was too great for any firm conclusions on potential cost savings to be determined.

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43.	Consultee 7, Killing Cancer Charity, Director	5	How much do we value time? Do we feel is acceptable to have a patient away from work, the family etc having a lamp treatment that is regarded as more painful and slows the efficient use of limited space in a clinic? There seems to be no consideration in the costings of the greater efficiency of a PDT skin clinic using the light patch which encourages patients not to hang around the clinic, but to go home, back to the office or use the hospital cafe.	Thank you for your comment. The uncertainty in the models presented was too great for any firm conclusions on potential cost savings to be determined.
44.	Consultee 8, Medical Physicist	5	In the cost analysis, the matter of waste disposal does not seem to have been considered explicitly. Â This can be distictively different for the Ambulight devices compared with other skin PDT methods. Â A used Ambulight is an awkward combination of clinical waste and electronic/electrical waste (i.e. WEEE). Â The liability for safe waste disposal and the appropriate procedure may vary depending on the treatment setting, but may well involve an additional and cost-able amount of time to thorougly clean and decontaminate the device prior to consigning to a WEEE disposal route. Â Although this is a fairly minor consideration, it should be included for completeness.	Thank you for your comment. The issue of waste disposal is outside the scope of the guidance. However, the notification submitted by the manufacturer states that Ambulight PDT ‘complies fully with the WEEE regulations relating to the disposal of electrical goods’.

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45.	Consultee 1, Consultant Dermatologist	6	Regarding 6.1, I am unclear of the relevance of some points here. Everyone treating non-melanoma skin cancers is aware of the wide range of treatment options (including occasionally [for example for someone with an expected life expectancy of 1 year and a tumour not currently causing problems nor growing rapidly] conservative management). Here surely the main issue is assessing this way of delivering PDT compared with other ways of delivering PDT.	Thank you for your comment. Section 6 of the guidance has been changed to improve clarity.
46.	Consultee 1, Consultant Dermatologist	6	Section 6.2 is, I think, a good summary of the current place of Ambulight PDT.	Thank you for your comment.
47.	Consultee 2, Consultant Dermatologist, co-inventor of device	6	See above comments	Thank you for your comment.
48.	Consultee 3, Consultant Dermatologist, Expert Adviser	6	Conclusions misleading that most NMSC best left untreated and contradicts previous NICE support of PDT. Conclusions also not correct that treatment complex - several optuons available but none are complex and Ambulight PDT is one of these options.	Thank you for your comment. Section 6 of the guidance has been changed to improve clarity.
49.	Consultee 4, Patient	6	As I am not qualified to agree or disagree, I am unable to advise. However, I think it is necessary to educate patients in the use of PDT. My local Surgery had no knowledge of PDT, and were, at best a hindrance, as were other NHS staff.	Thank you for your Comment. NICE guidance is supported with lay translations for patients to help them learn about medical conditions and the treatments available to them. A lay description of the technology will be published alongside the final guidance for Ambulight PDT.

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50.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	6	Its disappointing to note that the committee feel it inappropriate to support Ambulight PDT as a treatment option for basal cell carcinomas. Â Many treatments options are available for Gorlin patients but still patientss experience excessive delays in treatment in secondary care settings resulting in more extensive surgery than should be necessary.	Thank you for your comment. Section 3.14 and 4.5 of the guidance states that 'Ambulight PDT is one treatment option for NMSC for carefully selected patients'. The scope for Ambulight PDT was for single lesions only, in line with the manufacturer's notification of this product to NICE. The treatment of patients with Gorlin syndrome is therefore outside the scope of this evaluation. However, the manufacturer could, if they wish, promote the use of the Ambulight PDT in this patient group.
51.	Consultee 5, Patient Support Group (Gorlin Syndrome Group)	6	Â Timely and appropriate treatment needs to become a priority.	Thank you for your comment.
52.	Consultee 6, Device Manufacturer	6	The Ambulight weighs the same as a mobile phone and comes with a belt clip, therefore some of the clinical advantages of the Ambulight such as the ambulatory nature of the device and its ability to be used in primary care are self evident, and as such do not require clinical evidence.	Thank you for your comment. If a product claims to offer greater convenience to its users (for example, ambulatory treatment), evidence on its clinical effectiveness is still essential in reaching a balanced conclusion about its clinical utility.

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53.	Consultee 6, Device Manufacturer	6	The clinical advantages relating to mobility offer significant benefits to specific patient groups, particularly for those where mobility is an issue. BAD, DoH, PCDS and NICE guidelines do not support a conservative treatment approach to these indications (see section 3 above). During the evaluation process neither the manufacturer, nor the MTAC team suggested that the Ambulight PDT should be considered as a replacement to any therapy, but that it should be offered for particular patient groups who would benefit from it.	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intends to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients. Section 3.8 of the guidance has been changed to include further Committee considerations on the potential to make treatment more convenient for certain patients.
54.	Consultee 6, Device Manufacturer	6	NICE and the NHS recognise that there are issues relating to transparent costing of treatment in primary care. The evaluation of any new treatment in a primary care setting would have identical issues with costing. Ambicare would welcome the opportunity to work with NICE and MTAC on further evaluation of costs in a primary care setting, as suggested in the original MTAC scope.	Thank you for your comment. The uncertainty in the models presented was too great for any firm conclusions on potential cost savings to be determined. NICE welcomes the development of evidence in relation to this technology, as stated in section 5.2 of the guidance.

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55.	Consultee 7, Killing Cancer Charity, Director	6	Do we consider that the NHS should be encouraging innovation? Should we be looking at ways of increasing the efficiency of the service in a service area that is going to come under escalating demand? Does the DH from the top level support the greater development of PDT? We can all stay in the past, allowing clinicians to treat in the way they have for decades without addressing new options that perhaps dont require their skills set. Are we to ignore the fact that devices like this offer the NHS the opportunity to be more efficient, offer a more popular modality, and to improve cosmetic outcomes. I have read the evidence presented, and I believe that the members of the Committee should take greater heed of the views of the expert witnesses.	Thank you for your comment. The Medical Technologies Evaluation Programme is designed specifically to promote the uptake of new and innovative technologies where they offer value for money and patient and system benefits over existing treatment options. As stated in section 7 of the guidance 'more evidence is required on both clinical and cost benefit to support the routine adoption of Ambulight PDT in the NHS'.
56.	Consultee 3, Consultant Dermatologist, Expert Adviser	7	Would suggest conclusions should be that Ambulight PDT is an option for the management of some NMSC lesions - not appropriate to compare it with conventional PDT at this stage of its development.	Thank you for your comment. Section 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients. At scoping stage, conventional hospital-based PDT was considered the most appropriate comparator by the NICE team and the Expert Advisers.
57.	Consultee 1, Consultant Dermatologist	7	No comments	Thank you for your comment.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
58.	Consultee 7, Killing Cancer Charity, Director	7	As suggested in previous sections, the guidance above does not really serve the interests of the patients. Those are the people the NHS serves, and not hospital managers and the personal interests of clinicians not prepared to be more open in their review of the options for the future. I urge the Committee to do one thing. Talk to [redacted]. His view is probably more valuable than all the other opinions expressed. It will be fair and balanced.	Thank you for your comment. The views of patients and carers are important and section 3.8 of the draft process guide describes how patient and carer organisation views are sought. NICE's Patient and Public Involvement Programme supports the Medical Technologies Evaluation Programme in continually improving its processes. The Department of Health is a consultee for medical technology guidance. Comment number 9 contains the Department's response on this topic.
59.	Consultee 9 Consultant Dermatologist	General	A co-author of the BAD evidence-based guidelines on topical PDT, I read with interest your evaluation of the ambulight that I came across in preparing another manuscript. I am impressed by the detail of the analysis, although am disappointed at the summary, which appears to pull a number of different arguments together to derive the proposed non-approval.	Thank you for your comment. The recommendations are a reflection of Medical Technologies Advisory Committee's discussions and conclusions.
60.	Consultee 9, Consultant Dermatologist	General	PDT in the UK has approvals for actinic keratoses, Bowen's disease and certain basal cell carcinomas. Conservative management is considered appropriate in a small group of patients with actinic keratoses, but standard practice is to actively treat the remaining majority, plus Bowens and BCC lesions.	Thank you for your comment. Section 1.1 of the guidance has been changed and a brief explanation of why some patients may receive no treatment for their small low-risk skin lesions has been added to section 2.8 of the guidance. Both these sections were informed by expert advice to the Committee. In addition the term 'conservative' has been removed from the guidance.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
61.	Consultee 9, Consultant Dermatologist	General	PDT offers an effective choice for therapy, with a substantial evidence-base. Granted, the evidence specific to ambulight is limited by small study sizes, but much of the argument for use can reflect the body of existing evidence.	Thank you for your comment. PDT is listed as a current treatment option in section 2.8 and 2.9 of the guidance. The aim of medical technologies guidance is to promote the uptake of new and innovative technologies where they offer value for money and patient and system benefits over existing options. The evidence on conventional PDT is outside the scope of this evaluation.
62.	Consultee 9, Consultant Dermatologist	General	I do consider the system to offer a useful option for the delivery of PDT in certain patients and is a useful technology to have available. It should sit alongside services providing conventional PDT.	Thank you for your comment. Section 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
63.	Consultee 9, Consultant Dermatologist	General	It is hoped we will see refinements to this technology that will facilitate its wider use in the NHS and beyond.	Thank you for your comment. Section 6.2 of the guidance states that Ambulight PDT is a novel development in the area of PDT that shows some promise.
64.	Consultee 9, Consultant Dermatologist	General	Price evaluations suffer from the difficulty in reflecting the real life situation in the NHS. A lower unit cost for the ambulight would doubtless increase the amount of use - PDT is already perceived as expensive on account of the drug costs plus staff/facility costs, but evaluations against other therapies find this differential diminishes if reduced costs for managing adverse reactions from conventional therapies are included.	Thank you for your comment. The manufacturer provided a range of detailed cost models in which all the direct and indirect costs were included and these formed the basis of the Committee's considerations on cost. The uncertainty in the models presented was too great for any firm conclusions on potential cost savings to be determined.
65.	Consultee 10, Consultant in clinical oncology	General	I am a consultant in clinical oncology at the Christie Hospital in Manchester. I have used the Ambulight on several occasions.It has produced excellent tumour resolution and is therefore an acceptable treatment for small superficial non melanoma skin cancers.	Thank you for your comment.

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66.	Consultee 11, Chairman of the Therapy and Guidelines Sub-Committee, British Association of Dermatologists	General	The Therapy and Guidelines Sub-Committee of the British Association of Dermatologists has reviewed this consultation document, and agrees with the draft recommendations made by the Medical Technologies Advisery Committee of NICE that the case for adopting the Ambulight PDT for the treatment of non-melanoma skin cancer in the NHS could not, at this stage, be supported over current management. In so doing, the sub-committee feels that the relevant available evidence for clinical effectiveness and resource savings has been taken into account, that there has been reasonable interpretation of the evidence, that the recommendations are sound and a suitable basis for guidance to the NHS, and that there are no relevant equality issues.	Thank you for your comment.
67.	Consultee 12, Department of Health	General	Thank you for the opportunity to comment on the draft guidance for the above Medical Technology. I wish to confirm that the Department of Health has no substantive comments to make regarding this consultation.	Thank you for your comment.

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68.	Consultee 13, The Registrar, Royal college of physicians	General	I write on behalf of the National Cancer Research Institute (Melanoma Clinical Studies Group, non-melanoma skin cancer subgroup)/Royal College of Physicians/Royal College of Radiologists/Association of Cancer Physicians/Joint Collegiate Council for Oncology. We are pleased to be asked to comment on the above consultation and would like to make the following joint response. Overall, we believe that the comments made by NICE are reasonable. As stands, there is very limited data on this therapy, especially when compared to conventional PDT. This should be revisited when there is data on safety and efficacy.	Thank you for your comment.
69.	Consultee 13, The Registrar, Royal college of physicians	General	We have also had sight of and would like to endorse the response submitted by the British Association of Dermatologists.	Thank you for your comment.
70.	Consultee 13, The Registrar, Royal college of physicians	General	Our experts would also like to raise the following points: • This therapy is only used to treat small areas. That being the case, pain can be adequately and easily managed and is therefore less of an issue.	Thank you for your comment. Data on pain are reported in sections 3.4 and 3.5 with a Committee consideration on these data included in section 3.9 of the guidance. The view of the clinical experts in the consultees comment reflects the advice given to the Committee in section 3.12 of the guidance.

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71.	Consultee 13, The Registrar, Royal college of physicians	General	Our experts would also like to raise the following points: • The intention with the development of Ambulight is not to replace hospital-based PDT. Rather, it would be an available option for use in the community, where desirable, and where the condition being treated is suitable for Ambulight. We feel strongly that the final wording in the NICE document should make this intention clear.	Thank you for your comment. The intention of the Committee was not to evaluate Ambulight PDT so it can replace hospital-based PDT, instead it intends to guide treatment choice when faced with multiple options for NMSC. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
72.	Consultee 13, The Registrar, Royal college of physicians	General	Our experts would also like to raise the following points: • Further to the use of Ambulight in the community - There are strict guidelines regarding which GPs with a special interest (GPSIs) can treat basal cell carcinomas (BCCs) in the community. It may therefore be challenging for this to be adopted as the GPSIs will require accreditation, training, on-going CPD etc to treat these patients. Patient selection is often the most important part of the process and the clinical issues around the management of this patient group must not be ignored. Clinical experience is required to interpret biopsy results and to put this in the clinical context of the lesion. Our experts feel that this important aspect should be addressed with the NICE document.	Thank you for your comment. Section 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients. Section 3.10, 3.14 and 4.5 of the guidance have been changed to improve clarity on patient preference and patient selection. No further changes will be made to the guidance.

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73.	Consultee 13, The Registrar, Royal college of physicians	General	Our experts would also like to raise the following points : • Ambulight can offer a useful alternative option, to be adopted by secondary care, if the dermatologist feels this is indicated in preference to conventional PDT or if conventional PDT is not available.	Thank you for your comment. Sections 3.14 and 4.5 of the guidance state that Ambulight PDT is a current treatment option for selected patients.
74.	Consultee 13, The Registrar, Royal college of physicians	General	Our experts would also like to raise the following points : • Some experts are unsure as to whether this would be cost neutral (once training etc is considered).	Thank you for your comment.
75.	Consultee 9, Consultant Dermatologist	General	I trust that these comments are of assistance in moving towards more positive overtones to this evaluation,	Thank you for your comment. All comments submitted have been discussed by the Committee and changes made to the guidance as considered appropriate.