NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

VivaScope 1500 and 3000 imaging systems for detecting and monitoring skin cancer lesions

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 29 July 2015

THEME: EVIDENCE - ALARCON AND PELLACANI STUDIES

Comment number	Name and organisation	Section number	Comment	Response
1	Mavig	6.5	The Committee noted that the two studies (Alarcon et al. 2014; Pellacani et al. 2014) were considered most representative of NHS clinical practice for melanoma diagnosis, but that the reported specificity values differed substantially between the two studies. The reported specificity values differed in the two studies because of the different inclusion criteria. As it is explained in the paper by Pellacani et al., the results between the two studies are in fact the same in a sub-analysis of "dermoscopically positive" lesions. Details of this sub-analysis can be found on page 6, second column, within the paper.	Thank you for your comment which the Committee considered. The Committee were informed by the independent external assessment group that the two patient populations are different in terms of baseline risk, which is one of the reasons why the external assessment group decided it was inappropriate to combine the studies in a meta-analysis.
2	Private sector professional	6.5	The difference in Number Needed to Excise in the 2 studies depends on different population subset. Alarcon study is including ONLY dermoscopically positive (thus "qualified for excision") lesions (similar to the subgroup called "RCM documentation" in the study from my group), whereas we evaluated lesions with unclear diagnostic features for melanoma (the so called "RCM consultation" group). We didn't use RCM	Thank you for your comment which the Committee considered. The Committee were informed by the independent external assessment group that the two patient populations are different in terms of baseline risk, which is one of the reasons why the external assessment group decided it was inappropriate to combine the studies in a meta-

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			for saving excisions from the first group, as Alarcon et al did. On the other hand we evaluated the effect of a decision taken on RCM on the group of lesions with unclear diagnostic features for melanoma. Moreover, we made a subanalysis on the "Potential" effect of RCM also in the group of lesions "positive" for melanoma features, and results were comparable with Alarcon et. Read at Page 6, 2nd column in Pellacani et al. BJD 2014: "The apparent discordance with a recently published paper [Alarcon et al 2014], which showed the possibility to reduce the NNE from 3□.73 to 2.87, can be explained by the different study setting. In fact, the authors used RCM only in a narrow, selected population of lesions 'qualified for excision after dermoscopy', a group that is similar to our RCM documentation subgroup. When considering this subgroup, in our study 23 melanomas were identified along with the recommendation to excise 68 of 141 benign lesions. This would have led to a hypothetical NNE of 3.0. Thus, both studies prove that the NNE	analysis.

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			value can theoretically be improved, through a widened use of RCM consultation. However, the risk of missing a melanoma should always be considered in any attempt to reduce the number of excisions of benign lesions. More interestingly, RCM dramatically reduced the NNE in the RCM consultation group, which included lesions with unclear diagnostic features for melanoma at dermatoscopy, from a hypothetical 47.2 to 9.3”	

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THEME: GENERALISABILITY OF STUDIES TO THE NHS

Comment number	Name and organisation	Section number	Comment	Response
3	Department of Health	General	The evidence base contains no UK trials and impact on applicability/generalizability	Thank you for your comment which the Committee considered. The Committee noted that the studies used by the external assessment group in the analysis (Alarcon et al. (2014) and Pellacani et al. (2014),) were considered representative of practice in the UK.
4	Private sector professional	6	Lack of data coming from UK is a good point but it is important to emphasize that UK is already quite back ward compared to Australia or other European countries and should not stay backward because of a slow start.	Thank you for your comment which the Committee considered. The Committee heard that there is a higher prevalence of skin cancers in these countries compared to the UK which would account for the different care pathways.
5	MAVIG	5.8	None of the included studies was conducted in the UK. Concern seems to be primarily about equivalent care pathways. However, it should be noted that in most of the studies on melanocytic lesions the confocal examinations were performed on lesions where dermoscopic examination was performed first	Thank you for your comment which the Committee considered. The Committee noted that the studies used by the external assessment group in the analysis (Alarcon et al. (2014) and Pellacani et al. (2014),)

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			as part of the standard of care, with equivocal finding, which is not dissimilar from the standard care pathway within NHS.	were considered representative of practice in the UK.

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THEME: EVIDENCE - GENERAL

Comment number	Name and organisation	Section number	Comment	Response
6	Department of Health	General	Evidence base weaker than expected: lack of randomised controlled trials as part of the clinical effectiveness review. The evidence appears convincing enough for its use in clearly defined aspects of diagnosis/monitoring/excision but further trials would be helpful to include comparison with other technologies available for diagnostic skin scanning e.g. tomography, IR spectroscopy, and a RCT in the UK	Thank you for your comment which the Committee considered. The Committee noted that there are many technologies that may be used in the diagnosis of skin cancers and that these technologies are used at different times in the care pathway and look at different aspects of the skin cancer. The Committee concluded that a study comparing these different technologies would not be useful.
7	MAVIG	1.0	These are extremely well done, extensive and professional reports from an expert HTA team, and we thank the team for their hard work in considering these devices for inclusion in the NHS. We also appreciate this opportunity to submit comments to the committee. In response to the recommendation in Section 1.0 that the devices be recommended for research only, we have several comments that we ask you to consider. - While only six studies were ultimately considered most representative of clinical practice in the NHS, there are over 500 peer-reviewed publications spanning almost 20 years of research	Thank you for your comment which the Committee considered. The Committee heard that despite there being over 500 peer-reviewed publications the majority of these did not meet the inclusion criteria of the systematic review. The Committee noted that this assessment was comparing the use of Vivascope as an addition to and not a replacement for dermoscopy.

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			and clinical practice utilizing these devices in the scientific literature. - The publications have spanned several countries including all the core countries of the European Union, Canada, the United States, Brazil, Australia, China, Japan, Russia, Israel, Turkey demonstrating widespread use of the technology. - Of the 500 or more studies conducted world-wide, fewer than 20 were sponsored by the manufacturer in any way, and in most of those cases the sponsorship was generally limited to loan of equipment to conduct the studies. - The devices have FDA 510K clearances in the United States, CE in the European Union, TGA clearance in Australia, Health Canada, CFDA clearance in China, ANVISA registration in Brazil. - The devices have been included in the German Association of Scientific Medical Societies (AWMF) S1 Guidelines for the management of skin tumors, and in the European Dermatology Forum - Guideline on Basal Cell Carcinoma. - Efforts are currently underway with the	The Committee noted that some focussed high quality studies would be of benefit to the assessment of VivaScope. The Committee considered the German Association of Scientific Medical Societies (AWMF) Guideline and the European Dermatology Forum Guideline, and noted that the methodology used to develop the guidelines did not include full clinical and cost effectiveness analyses.

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			American Medical Association and the Centers for Medicare and Medicaid Services to obtain CPT codes for reimbursement for dermatologic applications in the United States. Final results will be disclosed in November 2015.	
8	MAVIG	3.18	We feel that the burden of evidence on RCM for evaluation of melanoma and non-melanoma skin cancers is superior to any other technology available for a dermatologic device. Dermoscopy, which is utilized and considered as part of the Association of Dermatology revised UK Guidelines, also has a huge burden of evidence; however, following 20 years of widespread use, there are still no prospective, longitudinal, interventional studies utilizing dermoscopy, and no systemic double-blinded studies demonstrating the cost-effectiveness of dermoscopy, yet it is clearly accepted as a standard of care that has not been abandoned due to lack of this evidence. Furthermore, the process for conducting studies for pharmaceuticals and therapeutics is far different than those required for devices and diagnostics and may not be practical for RCM.	Thank you for your comment which the Committee considered. The Committee noted that Dermoscopy was not the intervention being assessed in this evaluation. The Committee therefore did not make recommendations on the use of dermoscopy. The Committee recognised that Dermoscopy has been used in standard clinical practice for many years, is cheap and so the burden of evidence is less.

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Comment number	Name and organisation	Section number	Comment	Response
9	MAVIG	5.4	The report cites several instances where dermoscopy was not included in the clinical pathway. These studies were performed to evaluate RCM alone, without the bias of dermoscopy included. There are also several studies that did include dermoscopy as part of the clinical pathway that were published before 2013 that were not considered as part of the analysis.	Thank you for your comment which the Committee considered. The Committee heard that these studies did not meet the inclusion criteria of the systematic review.
10	MAVIG	5.5	In section 5.5, and elsewhere, it is mentioned that a majority of the confocal studies enrolled patients from melanoma or dermatology clinics in tertiary or university hospitals. There is an implication that these conditions potentially increase the risk of bias for these studies. We would like to point out that, due to the relative rarity of melanoma, it can be difficult to recruit statistically significant numbers of patients from other types of practices/clinics in a reasonable timeframe.	Thank you for your comment which the Committee considered. The Committee recognised the difficulty in recruiting people to all studies. The Committee discussed that section 5.5 of the diagnostics guidance document reports the setting of the included studies. The Committee had no concerns regarding the setting where people were enrolled.
11	MAVIG	6.10	Concerning the uncertainty in the evidence, we would appreciate a recommendation of the committee that would provide a level of certainty, especially considering the previous comments regarding the evidence on dermoscopy. If the committee would be	Thank you for your comment which the Committee considered. The Committee considerations refers only to evidence for interventions included in the

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Comment number	Name and organisation	Section number	Comment	Response
			willing to cite publications with examples of such evidence that have been written on other diagnostic technologies routinely used in clinical diagnosis, it would be very helpful.	assessment. NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be passed to the NICE Medical Technologies Evaluation Programme research facilitation team for the development of specific research trial protocols as appropriate. Further advice is available from the NICE Scientific Advice team.

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THEME: CARE PATHWAY

Comment number	Name and organisation	Section number	Comment	Response
12	Royal College of Physicians (RCP) on behalf of: NCRI/RCP/ACP	3.14	The NCRI/RCP/ACP are grateful for the opportunity to respond to the diagnostic consultation document. We wish to endorse the comment submitted by the BAD and make the following point. 3.14 Most skin lesions will first be examined in a primary care setting. Because melanoma is still a relatively infrequent cancer in primary care, the initial diagnosis of suspicious skin lesions in primary care should follow the British Association of Dermatologists ABCD-Easy guide to checking your moles (2011). This is not the primary care recommendation which is based on the 2005 NICE guidelines for suspected cancer in which the use of the 7 point checklist is recommended. The NICE guidelines for suspected cancer are currently being updated, so it would be sensible if this section of the VivaScope document could reflect either the 2005 or preferably the revised NICE guidelines.	Thank you for your comment which the Committee considered. The Committee decided to update section 3.14 of the diagnostics guidance document to include the NICE guideline on suspected cancer and to state that the 7 point checklist included in the guideline is used to refer patients under the 2 week rule.

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THEME: CLINICAL STANDARDS

Comment number	Name and organisation	Section number	Comment	Response
13	MAVIG	6.4	We will be very happy to provide the committee with information and access to clinical experts on the subject of the different biopsy types and clinical pathways. However, in summary, our experts have explained that the use of incisional biopsy is strongly influenced by the diagnostic confidence of the physician. In fact, the wider use of incisional biopsies for BCC and LM is first dependent on the need of a confident diagnosis before choosing alternative (less invasive/not excisional) treatment options, such as photodynamic therapy, Imiquimod cream, etc., considering that LM is usually located on the face, a cosmetically sensitive area. The physician can choose a less invasive option, or the more prudent approach; biopsy followed by radical surgical excision. It is evident that the MD experience and legal issues are the drivers for the choice more than a real clinical need.	Thank you for your comment which the Committee considered. The Committee discuss the need to understand the different types of biopsy used in UK practice, their place in the treatment pathway and the pathway that the patient follows after biopsy. The Committee noted a number of the research recommendations (recommendation 7.2 and 7.3) will help to provide information about UK practice in this area.
14	MAVIG	5.46	While we recognize that the “gold standard” for the diagnosis of melanoma (and many other disease types) is excisional biopsy followed by histopathologic analysis, it is also becoming the more mainstream	Thank you for your comment which the Committee considered. The Committee discussed the fact that histology

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			opinion that the "gold standard", histopathology, based on the most recent studies, has a concordance rate of approximately 80% for invasive melanoma and ~70% for in situ melanoma, among experts in dermatopathology (R.P.Braun 2012). As the most recent study on this topic demonstrated, even among experts with many years-experience, there is considerable variability in the range of diagnoses. If one considers that not all dermatopathologists are considered "expert", one could expect the concordance rates to be even lower. Additionally, histopathology samples about 5% of the overall lesion, while RCM has the ability to sample, in most cases, the entire epidermis and superficial papillary dermis, thus potentially providing far more pathologic information. While we agree that we must compare to some standard, and in the case of melanoma specifically that standard is histopathological examination, we should also consider that even histopathology cannot measure up to this impossible standard.	is considered the "gold standard" for diagnosis of melanoma and as such is considered 100% accurate. The Committee heard that there can be discrepancies between different histopathologists. The Committee discussed that a histopathologist has to make a decision and that it may not always be 100% accurate. The Committee also heard that unless the technology being assessed is considered better than the accepted gold standard .i.e. addresses recognised inadequacies, that it is necessary to assume that the gold standard is 100% accurate.
15	Department of	General	The reports highlight a wide variation in clinical	Thank you for your comment which the

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	Health		pathways and practice in the UK regarding diagnosis/management of skin cancer, which may or may not be appropriate and related to a localised service rather than a more concerning variation in clinical practice (not EVB or efficient)	Committee considered.

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THEME: SQUAMOUS CELL CARCINOMA

Comment number	Name and organisation	Section number	Comment	Response
16	Private sector professional	6.3 2nd sentence	Invasive SCC is a very easy clinical diagnosis. I think that improving diagnosis of this cancer is not a real unmet need in dermatology.	Thank you for your comment which the Committee considered. The Committee decided to change section 6.3 of the diagnostics guidance document to reflect that better diagnosis of in situ SCC rather than invasive SCC is an unmet clinical need. The Committee also decided to change section 6.3 to say that the VivaScope systems are not technically suitable for imaging invasive SCC.
17	Private sector professional	6.3 5th sentence	An in situ SCC, sometimes corresponding to a specific subtype called Bowen's disease, may need in some cases of a more accurate diagnosis, and this can be nicely achieved by confocal microscopy due to the lack of a consistent hyperkeratosis. Different is for nodular hyperkeratotic lesions (such as keratoacanthoma and invasive SCC) where confocal microscopy is not suitable, but there is no need of diagnostic improvement being this kind of lesions very easy to be diagnosed with an unaided eye, and being	Thank you for your comment which the Committee considered. The Committee decided to change section 6.3 of the diagnostics guidance document to reflect that better diagnosis of in situ SCC rather than invasive SCC is an unmet clinical need. The Committee also decided to change section 6.3 to say that the VivaScope systems are not technically suitable for imaging invasive SCC.

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THEME: SQUAMOUS CELL CARCINOMA

Comment number	Name and organisation	Section number	Comment	Response
			evidently rapidly growing nodules which require prompt surgery just basing on their clinical presentation.	

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THEME: EXISTING DATA

Comment number	Name and organisation	Section number	Comment	Response
18	MAVIG	6.15	Concerning the lack of available data on patients following the different clinical pathways for the diagnosis of melanoma, BCC etc., we feel that such data can be easily extracted from Pathology Department databases and claims data. Since evidence on the “number needed to excise” achievable by RCM has been demonstrated in several studies, knowing the actual NNE in the UK setting would enable an estimate of the derived benefit.	Thank you for your comment which the Committee considered. The Committee heard that this evidence could not be extracted from Pathology Department databases as the required information is about the clinical pathways that patients follow. The Committee noted a number of the research recommendations (recommendations 7.2 and 7.3 in the diagnostics guidance document) will help to provide information about UK practice in this area.
19	Private sector professional	6.15	Data can be easily extracted from Pathology Department databases. Since there are evidence on the “number needed to excise” achievable by RCM, knowing the actual NNE in the UK setting would enable to estimate the derived benefit.	Thank you for your comment which the Committee considered. The Committee heard that this evidence could not be extracted from Pathology Department databases as the required information is about the clinical pathways that patients follow.

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THEME: EXISTING DATA

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				The committee noted a number of the research recommendations (recommendations 7.2 and 7.3 in the diagnostics guidance document) will help to provide information about UK practice in this area.

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THEME: TRAINING

Comment number	Name and organisation	Section number	Comment	Response
20	Department of Health	General	Training/Training costs to use the Vivascope is not covered – is it easy to use? How about user error - experienced dermatologists vs inexperienced. It is unclear how this would impact on the cost-effectiveness or how long the initial capital costs would be realised	Thank you for your comment which the Committee considered. The Committee heard that the estimation of cost of training cost was explicitly covered in the Diagnostic Assessment Review. It included the introductory training and intensive expert training course. However, it did not take into account the substantial further time of on-going training during routine clinical practice (estimated at 3 to 5 months). The Committee also heard that the cost-effectiveness analysis assumed that VivaScope was being used by an experienced dermatologist. The purchase price of VivaScope 1500 and 3000 was annuitised over the expected lifetime of the technology, which was reported by the company to be 10 years.

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THEME: FURTHER RESEARCH

Comment number	Name and organisation	Section number	Comment	Response
21	Royal College of Pathologists	General	I have reviewed this documentation on behalf of the Royal College of Pathologists and agree entirely with its conclusions. For the foreseeable future the gold standard for the accurate diagnosis of cutaneous tumours will be based on a biopsy. Very often a diagnosis of malignancy depends on the assessment of the features of a few cells and it is difficult to envisage how such focal and often subtle features could be supplanted by this newer technology. Whilst the VivaScope may be of value in defining the extent of lesions (such as lentigo maligna) it remains at present a research tool meriting further study but I agree with the NICE recommendation that its use cannot be recommended for general introduction into the NHS.	Thank you for your comment which the Committee considered.

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THEME: WORDING

Comment number	Name and organisation	Section number	Comment	Response
22	British Association of Dermatologists	1.1	We would suggest replacing "ruling out the need" with "informing the decision" for excision and biopsy as any imaging must be carried out in the clinical context.	Thank you for your comment which the Committee considered. The Committee decided to update section 1.1 of the diagnostics guidance doument to state that VivaScope is used to inform the decision for biopsy and excision of skin lesions
23	Private sector professional	6.10	In order to favour the interest and investment for training and development of further evidence of RCM implementation into clinical practice to diagnose melanoma and BCC, it should be pointed that, although RCM looks promising, it requires further efforts. Thus I would suggest to change the conclusive sentence at 6.10 with: “Overall, the Committee concluded that although the VivaScope systems is presenting some evidence to diagnose melanoma and BCC, a burden of uncertainty remains to be confident that using the VivaScope systems represents a cost-effective use of NHS resources.”	Thank you for your comment which the Committee considered. The Committee decided to update section 6.10 of the diagnostics guidance document to state that ‘‘Overall, the Committee concluded that although the VivaScope systems are presenting some evidence to diagnose melanoma and BCC, a burden of uncertainty remains to be confident that using the VivaScope systems represents a cost-effective use of NHS resources”

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THEME: WORDING

Comment number	Name and organisation	Section number	Comment	Response
			I believe that this would push the stakeholders to invest in HTA and education in UK.	

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THEME: RESEARCH COMMISSIONING

Comment number	Name and organisation	Section number	Comment	Response
24	MAVIG	7	We greatly appreciate the Response for further research within the UK. Would this committee, or any other body within the NHS, be available to provide assistance on study design, in order to help us to better understand and meet these end points? This point becomes critical when considering the resources of a small/medium company such as ours working to incorporate a diagnostic device into clinical practice, in comparison to the large pharmaceutical and medical technology companies which routinely are able to invest orders of magnitude more money into big studies on therapeutics and more well established imaging technologies (e.g. - CT, MRI), followed by several smaller ones that should be run into different settings to address the different and various health systems. Further, a small/medium enterprise, even if it had the resources, cannot justify making big investments when there is no corresponding return expected due to the size of the given market. Therefore, all sponsored studies at this level must be extremely well designed and targeted, and your input would be most appreciated.	Thank you for your comment which the Committee considered. The Committee noted NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be passed to the NICE Medical Technologies Evaluation Programme research facilitation team for the development of specific research trial protocols as appropriate. Further advice is available from the NICE Scientific Advice team.

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THEME: OTHER

Comment number	Name and organisation	Section number	Comment	Response
25	Private sector professional		Besides a good review of the literature the final statement does not reflect the usefulness of this device . I am a dermatologist from Sao Paulo Brazil and I have a private practice in oncodermatology. I agree that there is a learning curve and there is a extra time for image acquisition that is not so long with practice,. Confocal saves time and improves costs avoiding unnecessary biopsy or/and reassuring the diagnosis	Thank you for your comment which the Committee considered. The Committee decided change the wording in section 1.1 of the diagnostics guidance document to highlight the potential of VivaScope in the recommendations.