

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Sarah Bradshaw, Dr Allan Wood"/>
Job title:	<input type="text" value="Chair of Dermatology in Podiatry Specialist Advisory Group RCPod (Dermatology Specialist Podiatrist) / Chair of the Independent Practice Group Specialist Advisory Group RCPod (Independent Practice Specialist Podiatrist)"/>
Organisation:	<input type="text" value="Royal College of Podiatry"/>
Email address:	<input type="text" value="Sarah.bradshaw1@icloud.com, allanrobertwood@aol.com"/>
Professional organisation or society membership/affiliation:	<input type="text" value="Royal College of Podiatry, Faculty of Podiatric Medicine, Specialist Advisory Groups (Dermatology and Independent Practice)"/>
Nominated/ratified by (if applicable):	<input type="text" value="Click here to enter text."/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="HCPC CH35869 , HCPC CH06384"/>

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.


Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see [our privacy notice](#).

I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

 Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

<p>1 Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?- Is this procedure/technology performed/used by clinicians in specialities other than your own?- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	<ul style="list-style-type: none">• No personal use of infrared laser* use in the treatment of Onychomycosis.• *The term infrared laser may wish to be exchanged to the laser medium such as Nd:YAG (neodymium-doped yttrium aluminium garnet) (or other laser types) for greater clarity as procedures and efficacy will be different between the different types of lasers.• Nd:YAG lasers are established within dermatology departments and deal with many skin conditions including pigmented lesions, vascular lesions and hair removal. Onychomycosis is currently unlikely to be treated within the NHS using this type of laser. Some private clinic environments offer Nd:YAG laser treatment for onychomycosis.
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2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	No involvement in research on this procedure.
3	<p>Does the title adequately reflect the procedure?</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<ul style="list-style-type: none"> • The term infrared laser may wish to be exchanged to the laser medium such as Nd:YAG for greater clarity as procedures and efficacy will be different between the different types of lasers. • A novel approach • Definitely novel and of uncertain safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	<ul style="list-style-type: none"> • No, it is not a replacement to current standard care • For patients who are unsuitable for oral Terbinafine or who do not wish to take medication.

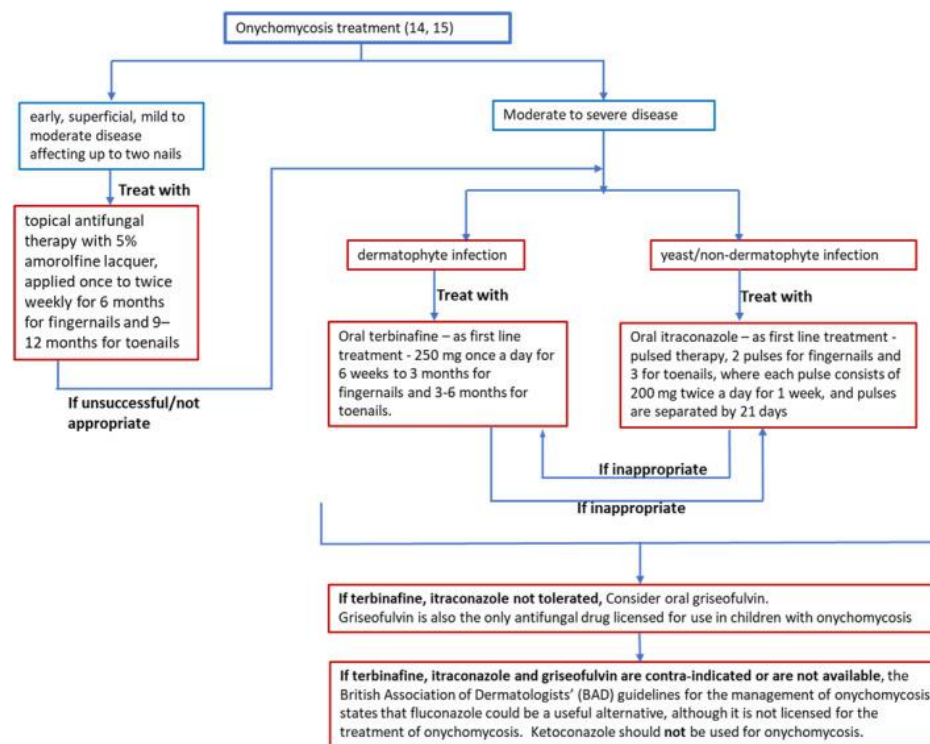
<p>5 Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p>	<ul style="list-style-type: none"> • Certain Nd:YAG lasers have been approved by the FDA in USA for Onychomycosis but only for temporary effect, not cure. • There is limited evidence that lasers eradicate pathogenic fungi, there is a lack of quality randomised controlled trials and trials with comparison to existing accepted therapies are needed before lasers are deemed a standard in onychomycosis treatment. <p>Please see,</p> <ul style="list-style-type: none"> ○ Bristow, I.R. The effectiveness of lasers in the treatment of onychomycosis: a systematic review. <i>J Foot Ankle Res</i> 7, 34 (2014). https://doi.org/10.1186/1757-1146-7-34 ○ Liddell LT, Rosen T. Laser Therapy for Onychomycosis: Fact or Fiction? <i>J Fungi (Basel)</i>. 2015 Apr 3;1(1):44-54. doi: 10.3390/jof1010044. PMID: 29376898; PMCID: PMC5770012. ○ Gupta AK, Stec N, Summerbell RC, Shear NH, Piguet V, Tosti A, Piraccini BM. Onychomycosis: a review. <i>J Eur Acad Dermatol Venereol</i>. 2020 Sep;34(9):1972-1990. doi: 10.1111/jdv.16394. Epub 2020 Jun 5. PMID: 32239567. ○ Foley K, Gupta AK, Versteeg S, Mays R, Villanueva E, John D. Topical and device-based treatments for fungal infections of the toenails. <i>Cochrane Database of Systematic Reviews</i> 2020, Issue 1. Art. No.: CD012093. DOI: 10.1002/14651858.CD012093.pub2. Accessed 14 June 2023.
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Current management

6 Please describe the current standard of care that is used in the NHS.

Please refer to,

- NICE (2023), Fungal Nail Infection: Scenario: Management of Fungal Nail Infection. Available at: <https://cks.nice.org.uk/topics/fungal-nail-infection/management/management/>
- Ameen, M., et al. (2014) British Association of Dermatologists' guidelines for the management of onychomycosis 2014, *British Journal of Dermatology*, Volume 171, Issue 5, 1 November 2014, Pages 937–958, <https://doi.org/10.1111/bjd.13358>



Treatment of onychomycosis as recommended by NICE and BAD from Sajeed M, Wei L, Murdan S. What can GP data tell us about the treatment of onychomycosis in the UK? *Skin Health Dis.* 2021 Dec 16;2(1):e84. doi: 10.1002/ski2.84. PMID: 35665209; PMCID: PMC9060066.

<p>7 Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	<p>“A similar off-label therapy to laser treatments is photodynamic therapy (PDT). PDT works by irradiating specific wavelengths of light onto topically applied photosensitisers...these sensitisers get excited and produce highly reactive oxygen specie which cause apoptis in fungal cells. Not many studies have been reported using PDT for the treatment of Onychomycosis”</p> <p>Gupta AK, Stec N, Summerbell RC, Shear NH, Piguet V, Tosti A, Piraccini BM. Onychomycosis: a review. J Eur Acad Dermatol Venereol. 2020 Sep;34(9):1972-1990. doi: 10.1111/jdv.16394. Epub 2020 Jun 5. PMID: 32239567.</p> <p>“More randomised controlled studies of device-based therapies (e.g. 1064-nm Nd:YAG, photodynamic therapy, iontophoresis) are needed.”</p> <p>Foley K, Gupta AK, Versteeg S, Mays R, Villanueva E, John D. Topical and device-based treatments for fungal infections of the toenails. Cochrane Database of Systematic Reviews 2020, Issue 1. Art. No.: CD012093. DOI: 10.1002/14651858.CD012093.pub2. Accessed 14 June 2023.</p>
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Potential patient benefits and impact on the health system

<p>8 What do you consider to be the potential benefits to patients from using this procedure/technology?</p>	<p>Temporary improvement may be possible but there is a low level of evidence in the published data with varying outcome measures and no clear evidence of long-term efficacy</p>
<p>9 Are there any groups of patients who would particularly benefit from using this procedure/technology?</p>	<p>Those that are unsuitable for oral anti-fungal treatments.</p> <p>Patients who do not wish to take medication.</p>
<p>10 Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?</p> <p>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?</p>	<p>No, there is a low level of evidence in the published data with varying outcome measures and no clear evidence of long-term efficacy.</p>

11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A large, multi-centre trial using the same protocol would be advantageous for further studies.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes

Safety and efficacy of the procedure/technology

13	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Side effects from Nd:YAG laser treatment include:</p> <ul style="list-style-type: none"> • Pain, • Redness, swelling and itching immediately after the procedure • Blistering • Hyperpigmentation / hypopigmentation • Bruising • Infection <p>Ranaweera, A. (2014) Neodymium YAG laser treatment, Available at: https://dermnetnz.org/topics/ndyag-laser-treatment</p>
14	Please list the key efficacy outcomes for this procedure/technology?	Temporary improvement may be possible but there is a low level of evidence in the published data with varying outcome measures and no clear evidence of long-term efficacy
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There is a low level of evidence in the published data with varying outcome measures and no clear evidence of long-term efficacy.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There is uncertainty about long-term efficacy.

17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present. Private clinics.
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Abstracts and ongoing studies

18	<p>Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).</p> <p>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.</p>	<ul style="list-style-type: none"> ○ Bristow, I.R. The effectiveness of lasers in the treatment of onychomycosis: a systematic review. <i>J Foot Ankle Res</i> 7, 34 (2014). https://doi.org/10.1186/1757-1146-7-34 ○ Liddell LT, Rosen T. Laser Therapy for Onychomycosis: Fact or Fiction? <i>J Fungi (Basel)</i>. 2015 Apr 3;1(1):44-54. doi: 10.3390/jof1010044. PMID: 29376898; PMCID: PMC5770012. ○ Gupta AK, Stec N, Summerbell RC, Shear NH, Piguet V, Tosti A, Piraccini BM. Onychomycosis: a review. <i>J Eur Acad Dermatol Venereol</i>. 2020 Sep;34(9):1972-1990. doi: 10.1111/jdv.16394. Epub 2020 Jun 5. PMID: 32239567. ○ Foley K, Gupta AK, Versteeg S, Mays R, Villanueva E, John D. Topical and device-based treatments for fungal infections of the toenails. <i>Cochrane Database of Systematic Reviews</i> 2020, Issue 1. Art. No.: CD012093. DOI: 10.1002/14651858.CD012093.pub2. Accessed 14 June 2023.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	No
20	Please list any other data (published and/or unpublished) that you would like to share.	Elmorsy, E., Khadir, N. and Taha, A. (2020) Laser Treatment of Onychomycosis: An Overview and our Experience. Lambert Academic Publishing (Mauritius)

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Onychomycosis is the single most common disorder of the nail unit worldwide and the cause of half of all nail dystrophy disorders. Treatment in an acute or in the early phase of the appearance of onychomycosis is needed.
22	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: 	<p>Beneficial outcome measures:</p> <ul style="list-style-type: none"> • Onychomycosis Scoring Index (Start / End) • Dermatology Quality of Life Index (Start / End) • Mycological Cure Rate • Complete Cure Rate • Type of Onychomycosis • Follow up at 12-24 months post procedure. • Outcome should be person based rather than individual nail based <p>Adverse outcome measures:</p> <ul style="list-style-type: none"> • Nail dystrophy • Redness, swelling and itching immediately after the procedure • Blistering • Hyperpigmentation / hypopigmentation • Bruising • Infection / Paronychia

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	<ul style="list-style-type: none"> • There is need for clear guidance on the Nd:YAG laser variables including but not limited to: <ul style="list-style-type: none"> ○ Short Pulsed Nd:YAG / Long Pulsed Nd:YAG / Q Switched Nd:YAG ○ Wavelength ○ Pulse Duration ○ Repetition Rate ○ Spot Size • A firm diagnosis of onychomycosis is essential prior to treatment.
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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the [NICE policy on declaring and managing interests](#) as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	<input type="text" value="Sarah Bradshaw, Dr Allan Wood"/>
Dated:	<input type="text" value="16 June 2023"/>