

Appendix B4: Stakeholder consultation

2019 surveillance of [Diabetic foot problems: prevention and management \(2015\)](#)

Stakeholders were consulted on the surveillance proposal not to update for 2 weeks. Consultation dates: 25 April 2019 to 8 May 2019

Themes from stakeholder comments

Overall, 20 stakeholders commented. Seven stakeholders agreed with the proposal not to update the guideline, 10 disagreed and 3 did not answer

Wound dressings

Stakeholders raised concerns about recommendation 1.5.10 as they felt that the wording prevented interactive dressings such as UrgoStart being used. No modelling had taken place and little evidence was available in this area at the time of guideline development. Although one RCT on UrgoStart was identified through the surveillance review, additional evidence from comparative trials is needed in this area. No evidence was found at this review that was deemed to impact on the existing recommendation, which allows the most clinically appropriate dressing to be used, including interactive dressings. Additionally, the UrgoStart

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dressing is covered by MedTech guidance MTG42 UrgoStart for treating diabetic foot ulcers and leg ulcers, which is linked within the diabetic foot pathway, highlighting the benefits of this dressing to service users.

Amputations

Stakeholders highlighted that minor amputations may be avoidable, in relation to new technologies such as rheophoresis and neuromuscular electronic stimulation. No new evidence was found at this surveillance review relating to these technologies. Studies highlighted by stakeholders did not meet the inclusion criteria for this review. This issue will be noted for consideration at the next surveillance review.

Time to assessment

Increasing time to diagnosis and review times for diabetic foot problems were highlighted by 2 stakeholders. Review times were highlighted in relation to a 2018 audit which found not all new cases of diabetic foot ulcer required an urgent referral. Since consultation on this surveillance review closed, the 2019 version of the audit has published which is in support of the existing recommendations that suggest a rapid referral is made for all new diabetic foot ulcers. No new evidence was found to suggest a change to recommendations, with studies provided by stakeholders not meeting the inclusion criteria for this review.

Peripheral artery disease

Several stakeholders raised issues relating to peripheral artery disease (PAD) including interventions to address ischaemia, lack of evidence around the 10 g monofilament test for diabetic peripheral neuropathy, increase in diagnostic sensitivity when the

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monofilament test was combined with Neuropad and more information requested on PAD and diabetes. Studies provided by stakeholders in this area did not meet the inclusion criteria for this review. NG19 has several cross referrals to NICE guideline CG147 – peripheral arterial disease: diagnosis and management, which were considered sufficient for signposting service users to CG147 for further information.

Antimicrobial prescribing guideline (APG)

An APG is in progress for diabetic foot infection which also had a consultation period at the same time as this guideline. The APG will replace recommendations 1.6.6 – 1.6.15. Through the consultation for the APG, a number of stakeholder comments were raised that are relevant to the other areas of NG19. A number of these are areas that have already been considered as part of this surveillance review.

Comments were also raised about terminology such as including more emphasis for the clinical urgency of Charcot arthropathy and more detailed definitions for ischaemia. As no new evidence was put forward during consultation, highlighted by topic experts or found during the surveillance review, we will log these issues and consider them again at the next surveillance review.

Several stakeholders highlighted a reliance on the results of wound swabs for changing antibiotics and noted that these results may not always be representative of the causative organism. A topic expert highlighted an ongoing [NIHR trial](#) which compares wound swab diagnosis to that of tissue sampling which we hope will provide new evidence in this area. When the results are available, we will assess them against the current guideline recommendations.

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Stakeholder consultation comments table

Do you agree with the proposal not to update the guideline?			
Stakeholder	Overall response	Comments	NICE response
Urgo Medical	No	<p>We believe this guideline should be updated specifically with reference to the section discussing Wound care (section 1.5.10) – “When deciding about wound dressings and offloading when treating diabetic foot ulcers, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances.”</p> <p>Recent high quality RCT evidence has been published (for example the ‘Explorer Trial’ – Edmonds et al 2018*) demonstrating the efficacy of using TLC NOSF dressings to increase wound healing and accelerate wound closure in DFU. Such new evidence (especially strong evidence from a very robust trial) should be considered when deciding on the guideline of treatment for DFU and the clinical pathway.</p> <p>In addition, the recent Medical Technology guidance MTG41 states that “using UrgoStart to treat diabetic foot ulcers increases wound healing compared with non-interactive dressings.” This guidance published in January 2019 recommends the use of UrgoStart (=TLC NOSF dressing) in DFU across the NHS as it is associated with</p>	<p>Thank you for your comment.</p> <p>We have reviewed the evidence for wound dressings and found it to be consistent with current guideline recommendations.</p> <p>The wording for recommendation 1.5.10 was chosen carefully by the guideline development group to allow the use of the most appropriate dressing for the clinical need, and this could include interactive dressings. The recommendation currently permits the use of any clinically appropriate dressing. MedTech guidance MTG42- UrgoStart for treating diabetic foot ulcers and leg ulcers is linked within the diabetic foot pathway in order to highlight this technology guidance to service users.</p> <p>The evidence identified in the surveillance review on UrgoStart compared the intervention with a control, which is just one comparison, and ideally we would require a comparison of all available options to consider any impact on the current recommendation, which allows the most clinically appropriate dressing to be used, including interactive dressings.</p> <p>Thank you for highlighting the Explorer trial, this RCT was identified in our search and has already been included in the summary of new evidence.</p>

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	<p>faster wound healing, improved patient quality of life, and cost savings for the NHS.</p> <p>It also states that “using UrgoStart dressings to treat diabetic foot ulcers is associated with a cost saving of £342 per patient after 1 year”. Keeping the original statement about using the ‘lowest acquisition cost dressing’ seems to be in direct contradiction to this.</p> <p>It also contradicts the published statements by NICE which illustrate the cost savings available which are up to £19m per year for the NHS. All the published resources (such as the Resource Impact model, Resource Impact report and the published findings of both the EAC and the Committee) illustrate that the use of an innovative but inexpensive TLC NOSF dressing (average price £4.28 vs. a non-interactive dressing £2.38) will improve clinical outcomes and save money to the overall system due to reduced healing time, fewer amputations etc.</p> <p>Table 1 Estimated annual saving of implementing the guidance for diabetic foot ulcers for England.</p> <table border="1"> <thead> <tr> <th>Scenario</th> <th>Per 100,000 population (£)</th> <th>In England (£)</th> </tr> </thead> <tbody> <tr> <td>Scenario 1 - Future uptake of UrgoStart 25%</td> <td>9,900</td> <td>5,455,000</td> </tr> <tr> <td>Scenario 2 - Future uptake of UrgoStart 50%</td> <td>22,200</td> <td>12,273,000</td> </tr> <tr> <td>Scenario 3 - Future uptake of UrgoStart 75%</td> <td>34,500</td> <td>19,091,000</td> </tr> </tbody> </table> <p>https://www.nice.org.uk/guidance/mtg42/resources/resource-impact-report-pdf-6663141613</p>	Scenario	Per 100,000 population (£)	In England (£)	Scenario 1 - Future uptake of UrgoStart 25%	9,900	5,455,000	Scenario 2 - Future uptake of UrgoStart 50%	22,200	12,273,000	Scenario 3 - Future uptake of UrgoStart 75%	34,500	19,091,000	
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		<p>We believe this statement is confusing for Clinicians, driving them toward lower priced but less effective dressings, and should therefore be amended accordingly.</p> <p>*Edmonds, M. et al., 2018. Sucrose octasulfate dressing versus control dressing in patients with neuroischaemic diabetic foot ulcers (Explorer): an international, multicentre, double-blind, randomised, controlled trial. <i>Lancet Diabetes Endocrinol</i>, 2018 Mar;6(3):186-196.</p>	
East Midlands Diabetic Foot Group	No	<p>The National Diabetes Foot Care Audit of England and Wales was launched in 2014 and has now assembled details of links between the time to referral and clinical outcomes of almost 40,000 foot ulcer episodes. While the annual Audit reports affirm the need for expert referral, the data have not produced evidence that all new foot ulcer episodes should be referred as stipulated in 1.4.2. The conclusion from the national diabetic foot audit (NDFA) data is that all people with new foot ulcers which do not need to be seen as an emergency should be assessed by an expert member of an MDT within two weeks.</p>	<p>Thank you for highlighting the NDFA. The most recent version published after this consultation had closed, as such it was not previously included in our evidence summary, it has now been summarised and added to the section on intelligence gathering</p> <p>The report frequently links to NICE guideline NG19 and has time to first expert consultation as a primary aim for improving care for people with diabetic foot problems. It also states that a quick or urgent referral pathway should be in place to facilitate this. The findings from the care structures assessment found next working day appointments were available in over 80% of sites. However, it did also highlight that around 50% of participants had no urgent referral pathway in place.</p> <p>The NDFA goes on to make recommendations including the following:</p> <p>'Providers should ensure that people with diabetic foot ulcers are referred promptly for early specialist assessment, in line with NICE guidance'. We feel that this supports recommendation 1.4.2 encouraging a quick referral to be made for expert assessment.</p>
Neurocare Europe Limited	No	No comments provided	Thank you for your response.

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Mölnlycke Health Care	No	<p>On page 21 of the current guidance document, under the heading 'Treatment', bullet point 1.5.4 lists a number of things to offer as standard of care for treating diabetic foot ulcers, i.e. offloading, control of foot infection, control of ischaemia, wound debridement and wound dressings. Further guidance on these interventions are given in subsequent bullet points, with the exception of the control of ischaemia. As approximately half of all patients with a diabetic foot ulcer have co-existing peripheral artery disease (Brownrigg, J.R., Schaper, N.C., Hinchliffe, R.J. Diagnosis and assessment of peripheral arterial disease in the diabetic foot. <i>Diabetic Medicine</i> 2015;32(6):738-747), we feel that more guidance on the control of ischaemic is required. For example, we would like to see applicable interventions that address ischaemia included, e.g.</p> <ul style="list-style-type: none"> - Revascularisation, which is linked to a decreased risk of ulcer recurrence (Elgzyri, T., Larsson, J., Nyberg, P., Eriksson, K.F., Apelqvist, J. Reconstructive vascular surgery and the extent of tissue damage due to diabetic foot ulcers relates to risk of new ulceration in patients with PAD. <i>Journal of Wound Care</i> 2015;24(12):592-597) - Oxygen-based therapies (de Smet, G.H.J., Kroese, L.F., Menon, A.G., Oxygen therapies and their effects on wound healing. <i>Wound Repair and Regeneration</i> 2017;25(4):591-608) 	<p>Thank you for your comment.</p> <p>NG19 does not contain recommendations on management of limb ischaemia as this is covered by NICE clinical guideline CG147 - Peripheral arterial disease. We will add a cross referral from recommendation 1.5.4 to CG147 to direct service users to further information in this area. We will also log your comments on CG147 for consideration at the next surveillance review for that guideline.</p> <p>Thank you for supplying the 3 references, however they do not meet the inclusion criteria for this review for the following reasons:</p> <ul style="list-style-type: none"> • Brownrigg et al – this study is not an RCT or Cochrane review and as such does not meet the strict study type criteria for this review • Elgzyri et al – this reference is unclear on study type and inclusion criteria for participants • DeSmet et al – this study has a lack of data presented in the abstract and as such cannot be included
Neuropad UK	No	<p>The incidence of diabetes related foot ulcers and amputations in England has been increasing at a rate of between 15-20% per annum for the past 3-4 years and shows no sign of decreasing. (1)</p>	<p>Thank you for your comment.</p> <p>No new evidence was identified at this surveillance review regarding foot assessment. Examination was not raised as an area of concern by topic experts. Unfortunately, the studies highlighted during stakeholder consultation do not meet the required search date or</p>

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	<p>NG19 guideline does not appear to have been effective enough in preventing the devastating consequences of diabetes related foot disease nor huge cost to the NHS.(2)</p> <p>“New data from the Diabetes Foot Care Profiles, published by PHE’s National Cardiovascular Intelligence Network, shows that the number of major lower limb amputations (above the ankle) continues to rise – with 7,545 major amputations over the past 3 years between 2015 to 2018, compared with 6,957 between 2012 to 2015.” (2)</p> <p>The current guideline recommends only one standard device for the detection of what it states are early signs of diabetic peripheral neuropathy (DPN). That device is the 10g Semmes Weinstein monofilament examination (SWME) despite, as the Guidelines Development Group (GDG) stated, the lack of evidence for its use and that it results in a high rate of false positives:</p> <p>“The GDG considered the predictive accuracy of the different scores and tools. The group agreed that they would be prepared to accept lower specificity in exchange for higher sensitivity in order to ensure all patients at risk are included in the correct risk categories. The group felt that false positives were preferable to false negatives given the impact that foot ulcer can have on a person’s life.” (3)</p> <p>The principal problem with the SWME is that it is a test not for early signs of neuropathy but for advanced neuropathy as it is a test which speculatively measures the presence or absence of vital protective sensation in the feet of people with diabetes. This is as a result of large rather than small nerve fibre denervation. Loss of vital protective sensation</p>	<p>study type criteria for this surveillance review. We appreciate that improving diagnosis is an important issue. We identified related NICE guidance when conducting the NG19 surveillance review, which included the recent MedTech guideline MTG38 - Neuropad for detecting preclinical diabetic peripheral neuropathy from September 2018. However, MTG38 stated a number of areas of uncertainty such as cost modelling and clinical importance in the current NHS pathways. As such we have insufficient evidence to suggest making a change to recommendation 1.3.4 at this time. We will log your comments for consideration at the next surveillance review.</p>
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		<p>cannot be reversed and is a serious complication not a moderate one.</p> <p>Relying on only a single test to diagnose DPN does not lead to accurate risk stratification as an active foot ulcer cannot reasonably be described as high risk as the person in fact has a lesion. Nor is a person who has lost vital protective sensation at moderate risk but at high risk and a person who has protective sensation is not at low risk as a percentage of those people will have some evidence of early nerve fibre damage. A combination of two different tests is required that screen for early signs of DPN (sudomotoric dysfunction) as well as more advanced signs of neuropathy (lack of protective sensation). These two tests (SWME + Neuropad) combined provide surrogates for both small and large nerve fibre damage permitting a more accurate risk stratification to take place. This is evidenced by a recent independent prospective study (4) in 263 patients with a median follow up 42 months which concluded that sudomotor function testing (SFT) using a Neuropad is a simple, objective, inexpensive and early diagnostic tool for the diagnosis of diabetic neuropathy that could be added in a care setting where accurate categorisation of risk is required. The results of the test are independent from the response of the patient and highly qualified professionals are not required to perform the test. The SFT demonstrated a sensitivity of ~100% when combined with SWME.</p> <ol style="list-style-type: none"> 1. Public Health England. Preventing amputations major concern as diabetes numbers rise. Published online 2 April 2019. 	
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		<p>https://www.gov.uk/government/news/preventing-amputations-major-concern-as-diabetes-numbers-rise</p> <ol style="list-style-type: none"> 2. M. Kerr E. Barron P. Chadwick et al. The cost of diabetic foot ulcers and amputations to the National Health Service in England. Diabetic Med. April 2019 https://onlinelibrary.wiley.com/doi/abs/10.1111/dm.e.13973 3. National Institute of Health and Care Excellence. Guideline NG19 Diabetic foot problems: prevention and management (Updated January 2016). Table 17 p 63. 4. Sanz-Corbalán I, Lázaro-Martínez JL, García-Morales E, et al, Advantages of early diagnosis of diabetic neuropathy in the prevention of diabetic foot ulcers, Diabetes Research and Clinical Practice (2017). doi: https://doi.org/10.1016/j.diabetes.2017.12.018 	
South Sefton Clinical Commissioning Group	Yes	No comments provided	Thank you for your response.
Interaction	No	<p>Medical technologies guidance published 31st January 2019, states: Evidence supports the case for adopting UrgoStart dressings to treat diabetic foot ulcers and venous leg ulcers in the NHS, because they are associated with increased wound healing compared with non-interactive dressings</p> <p>This new guidance has helped develop a pathway for treating PWD and lower limb problems and has not only considerably reduced healing time but has notably 'healed'</p>	<p>Thank you for your comment.</p> <p>We have reviewed the evidence for wound dressings and found it to be consistent with current guideline recommendations.</p> <p>The wording for recommendation 1.5.10 was chosen carefully by the guideline development group to allow the use of the most appropriate dressing for the clinical need, and this could include interactive dressings. The recommendation currently permits the use of any clinically appropriate dressing. MedTech guidance MTG42- UrgoStart for treating diabetic foot ulcers and leg ulcers is linked within the diabetic foot pathway in order to highlight this technology guidance to service users.</p>

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		<p>patients who have endured the debilitating effects of a DFU for months and in some cases years.</p> <p>The NG19 guideline currently states:</p> <p>1.5.10 When deciding about wound dressings and offloading when treating diabetic foot ulcers, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances.</p> <p>This is now obviously outdated by the above technology guidance, so it should be updated to reflect this recommendation.</p> <p>It has proved to not only reduce healing time but also save money across various services.</p>	<p>The evidence identified in the surveillance review on UrgoStart compared the intervention with a control, which is just one comparison, and ideally we would require a comparison of all available options to consider any impact on the current recommendation, which allows the most clinically appropriate dressing to be used, including interactive dressings.</p> <p>Thank you for highlighting the Explorer trial, this RCT was identified in our search and has already been included in the summary of new evidence.</p>
Manchester Metropolitan University	No	<p>With regards to wound dressings, particularly the sucrose octasulfate dressing. The Intelligence gathering on page 20 states that “NG19 does not currently specify what type of wound dressing should be used, however MTG42 is linked within the diabetic foot pathway.”</p> <p>In section 1.5.10 of NG19 clinicians are instructed to use “dressings with the lowest acquisition cost appropriate to the clinical circumstances” this is in direct opposition to MTG42, which includes evidence showing that the sucrose octasulfate dressing improves outcomes for patients;</p>	<p>Thank you for your comment.</p> <p>We have reviewed the evidence for wound dressings and found it to be consistent with current guideline recommendations.</p> <p>The wording for recommendation 1.5.10 was chosen carefully by the guideline development group to allow the use of the most appropriate dressing for the clinical need, and this could include interactive dressings. The recommendation currently permits the use of any clinically appropriate dressing. MedTech guidance MTG42- UrgoStart for treating diabetic foot ulcers and leg ulcers is</p>

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		<p>despite not being the dressing with the lowest acquisition cost.</p> <p>Therefore, MTG42 and NG19 are in direct opposition with each other and the reference to acquisition cost in NG19 ought to be removed, qualified with a reference to the sucrose octasulfate dressing, or changed to “a cost-effective dressing”.</p>	<p>linked within the diabetic foot pathway in order to highlight this technology guidance to service users.</p> <p>The evidence identified in the surveillance review on UrgoStart compared the intervention with a control, which is just one comparison, and ideally we would require a comparison of all available options to consider any impact on the current recommendation, which allows the most clinically appropriate dressing to be used, including interactive dressings.</p> <p>Thank you for highlighting the Explorer trial, this RCT was identified in our search and has already been included in the summary of new evidence.</p>
Ethical Medicines Industry Group	No	No comments provided	Thank you for your response.
Cardiff and Vale University Health Board	Yes	No Comments provided	Thank you for your response.
The British Orthopaedic Foot and Ankle Society	Yes	<p>The British Orthopaedic Foot and Ankle Society (BOFAS) is committed to improving the quality of care offered to diabetic foot patients.</p> <p>We strongly support caring for these patients in a multidisciplinary setting with orthopaedic foot and ankle surgeons central to the Multidisciplinary Foot Service (MDFS) in all hospitals. We would support regular MDFS meetings to include orthopaedic foot and ankle surgeons in all hospitals. We believe that this is critical to the early implementation of effective treatment to these patients.</p> <p>We believe that surgery on the diabetic foot is complex and has higher complication rates than surgery on the non-diabetic foot. Therefore, surgery on the diabetic foot should be undertaken in an appropriate MDFS, which</p>	<p>Thank you for your comment.</p> <p>We recognise the support for the recommendations on the provision of a multidisciplinary foot care service such as 1.1.3, 1.2.1 and 1.2.3, and appreciate that this is an important part of the patient pathway.</p> <p>However no new evidence or intelligence was identified through surveillance to suggest these recommendations should be updated at this time. We will log this issue for consideration at the next surveillance review.</p>

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		<p>should fall within a Trauma and Orthopaedic Department's Audit and Governance structure to ensure the maintenance of standards. This should be the case whether the operating surgeon is an Orthopaedic surgeon, or a Podiatrist Practicing Surgery.</p> <p>BOFAS in association with the British Orthopaedic Association, The Vascular Society, Diabetes UK, The Association of British Clinical Diabetologists, Foot in Diabetes UK and the British Association of Prosthetists and Orthotists produced Guidelines for the Operational Delivery of the Multidisciplinary Care Pathway for Diabetic Foot Problems in April 2016 (https://www.bofas.org.uk/Portals/0/news-files/DiabeticFoot%20FINAL.pdf?ver=2016-05-23-204311-560). BOFAS believes that the introduction of such a structure in all hospitals Trusts in the United Kingdom would reduce variability of care across.</p> <p>Prevention is important and BOFAS supports a community based, Foot Protection Service (FPS) led by a non-surgical podiatrist, The FPS should have ready access to the MDFS.</p> <p>We recognise ulceration, Charcot neuroarthropathy and infection as being some of the main complications that diabetic foot patients may develop. We strongly support research and education in order to allow early detection and effective treatment.</p>	
NHS England	Not answered	No comments provided	Thank you.
Fresenius Medical Care	No	Fresenius Medical Care recommends the inclusion of rheopheresis as a research recommendation, as a rescue therapy for non-responding diabetic foot ulcers. It can bring about health economic benefits through effective	<p>Thank you for your comment.</p> <p>No new evidence has been found at this surveillance review which indicates a change is necessary to the recommendations on treatment of diabetic foot problems. Rheopheresis would be a new</p>

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	<p>removal of target molecules, acceleration of wound healing, reduced need for amputation, pain relief and improvement in quality of life. Examples of published evidence for rheopheresis therapy for patients with ulcerative wounds and diabetic foot include:</p> <ul style="list-style-type: none"> • Blaha M, Rencova E, Maly R, et al. The importance of rheological parameters in the therapy of microcirculatory disorders. <i>Clinical Hemorheology and Microcirculation</i>. 2009; 42(1):37-46. • Ferrannini M, Vischini G, Staffolani E, et al. Rheopheresis in vascular diseases. <i>Int J Artif Organs</i>. 2007; 30(10):923-929. • Klingel R, Mumme C, Fassbender T, et al. Rheopheresis in patients with ischemic diabetic foot syndrome: results of an open label prospective pilot trial. <i>Therapeutic Apheresis and Dialysis</i>. 2003; 7(4):444-455. • Klingel R, Erdtracht B, Gauss V, et al. Rheopheresis in patients with critical limb ischemia—results of an open label prospective trial. <i>Therapeutic Apheresis and Dialysis</i>. 2005; 9(6):473-481. • Lumlertgul D, Suteeka Y, Tumpong S, et al. Double filtration plasmapheresis in different diseases in Thailand. <i>Therapeutic Apheresis and Dialysis</i>. 2013; 17(1):99-116. • Vass M, Dioszegi A, Nemeth N, et al. Rheopheresis in vascular diseases. <i>Clinical Hemorheology and Microcirculation</i>. 2016; 64:977-987. 	<p>area for NG19, as there are currently no recommendations on the removal of blood components to improve blood flow, it is not within the remit of surveillance to add or change the research recommendations at this time</p> <p>Thank you for highlighting the 6 studies, unfortunately these did not meet our strict inclusion criteria for this review for the following reasons:</p> <ul style="list-style-type: none"> - Blaha M et al, Ferrannini M et al, Klingel R et al 2003, Klingel R et al 2005 and Lumlertgul et al could not be included as they are outside the search dates for this surveillance review. - Vass M et al is within the search dates for this review, however as it is a conference abstract rather than an RCT or Cochrane review, it is unfortunately outside of the study type criteria for this review. <p>We will log this issue for consideration at the next surveillance review.</p>
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<p>St Helier Hospital, Threatened Limb Service</p>	<p>No</p>	<p>We should be looking to update the Guidelines for Diabetic Foot problems.</p> <p>We could improve the way we prevent and manage Diabetic Foot problems.</p> <p>We still see major and minor amputations occurring in Diabetic patients, many of which are avoidable.</p> <p>There is a huge discrepancy between various trusts in the United Kingdom in the way Diabetic Foot problems are managed. Where some trusts treat Diabetic Foot problems as the clinical emergencies that they often are, other trusts do not have the knowledge or guidance to act quickly and appropriately and prevent unnecessary amputations.</p> <p>There has been an increase in the number of clinicians and teams who specialise in the management of Diabetic feet, however, when these teams are not supported by the wider Medical, Surgical and nursing disciplines, we still routinely see suboptimal care for patients with Diabetic Foot pathology. There is often little accountability for Medical and Surgical teams if a Diabetic patient goes on to have an amputation. We see Doctors and Surgeons very quick to consider lower limb amputation as a normal and feasible result for Diabetic patients and there is definitely not a generalised attitude that we should be 'trying to do everything possible to prevent amputation' from Medical and Surgical teams outside of the Diabetic Foot MDT.</p>	<p>Thank you for your comment.</p> <p>We appreciate the feedback on implementation of the guideline, however we do not currently have any uptake data to drive any changes in this area. We will pass on this feedback to our implementation team for further consideration.</p> <p>During this consultation we have been made aware of the national diabetic foot audit (NDFa) in England and Wales (May 2019), which highlighted that around 50% of those surveyed did not have an urgent referral pathway in place, however the figure for next working day referrals was much higher at 80%. Having assessed the report from the NDFa, we feel that it supports our current guideline recommendations which encourage a quick referral, particularly for inpatient care as set out in recommendations 1.1.1-1.1.4. There has been no evidence received which suggests the strength of these recommendations should be changed or additional recommendations be added.</p> <p>Recommendation 1.1.3 specifically states that the multidisciplinary foot care service should be notified within 24 hours of initial assessment and that care should be transferred to a consultant from that team if the diabetic foot problem is the main reason for admission.</p> <p>Recommendation 1.2.1 also sets out the services that should be provided by commissioners in relation to multidisciplinary working such as:</p> <ul style="list-style-type: none"> • A foot protection service for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community. • A multidisciplinary foot care service for managing diabetic foot problems in hospital and in the community that cannot
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	<p>We need to be doing everything that we can to change this and get Medical, Surgical, Nursing and Allied Health professionals to take Diabetic Foot problems more seriously.</p> <p>Diabetic Foot teams do the best that they can to educate their colleagues and try to spread understanding that amputations can often be avoidable, and amputation greatly increase a patient's mortality rate. Diabetic foot teams need help to enforce this message and improve the care for their patients. By improving the NICE guidelines, we can send a clearer message and give a direct, consistent message regarding protocols to follow in managing Diabetic foot pathology. Without improvement we will continue to see avoidable Diabetic foot pathology including amputation and our patients will continue to have poor prognoses. We will additionally continue to see experienced Diabetic Foot clinicians / Podiatrists leave the profession due to lack of understanding and support from the wider Medical profession.</p> <p>The current guidelines state: <i>It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives</i></p> <p>Recommendation for NICE to update guidelines</p> <p>As multiple studies report this percentage to be higher.</p> <p>The current guidelines state: <i>Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation and</i></p>	<p>be managed by the foot protection service. This may also be known as an interdisciplinary foot care service.</p> <ul style="list-style-type: none"> • Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including emergency care and general practice. The protocols should set out the relationship between the foot protection service and the multidisciplinary foot care service. • Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit.
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		<p><i>around 50% dying within 5 years of developing a diabetic foot ulcer.</i></p> <p>Recommendation for NICE to update guidelines as multiple studies report mortality rate to be higher.</p> <p><i>The current guidelines state: Care within 24 hours of a person with diabetic foot problems being admitted to hospital, or the detection of diabetic foot problems (if the person is already in hospital)</i></p> <p>The above frequently does not occur. Diabetic patients admitted to hospital or reviewed by any clinical in primary care often do not have their feet reviewed and therefore diabetic foot problems are not detected, and the Diabetic Foot team not notified. Diabetic patients are seen to be admitted to hospital, at times septic, and their feet are still not checked.</p> <p>Recommendation for NICE to update guidelines' Diabetic patients who are admitted to hospital should have their feet reviewed within 24hours by any health care professional. (So, as they can then be referred to the diabetic foot team if detection of pathology) Any Diabetic patient who is systemically unwell with unknown source of infection must have their feet reviewed.</p>	
British Society of Interventional Radiology (BSIR)	Yes	Very comprehensive and largely uncontroversial guidance.	Thank you for your comment.

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Royal College of Nursing		This is just to let you know that the feedback I have received from nurses caring from people with diabetes suggests that there is no additional comments to submit to inform on the consultation of the above draft guidelines.	Thank you for your comment.
Royal College of Paediatrics and Child Health (on behalf of the British Society of Paediatric Endocrinology and Diabetes)	Yes	The reviewer was happy with the proposal to not update this guideline	Thank you for your comment.
Association of British Clinical Diabetologists	Yes	<i>We wish to say that the 2019 surveillance of 4 diabetes guidelines is welcomed and that there has obviously been a lot of thought and work put in to identifying areas ripe for updating. We are supportive of all areas annotated in the document.</i>	Thank you for your comment.
Royal College of Physicians		We would like to endorse the responses submitted by the Diabetes Technology Network (DTN) and the Association of British Clinical Diabetologists (ABCD).	Thank you for your comment.
Diabetes UK	Yes	While we agree with the decision not to update this guideline, this is specifically because we have submitted our comments on the <i>Diabetic foot infection: antimicrobial</i>	Thank you for your comment. You are correct that the antimicrobial prescribing guideline on diabetic foot infection will be incorporated into NG19. It will replace

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		<i>prescribing</i> guideline consultation and understand that this guideline will be incorporated into NG19 when published.	recommendations 1.6.6 – 1.6.15 on treatment of diabetic foot infection.
Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	Overall response	Comments	NICE response
Urgo Medical	No	No comments provided	Thank you for your response.
East Midlands Diabetic Foot Group	No	No comments provided	Thank you for your response.
Neurocare Europe Limited	Yes	<p>Neuromuscular Electronic Stimulation (NMES) is used elsewhere to treat diabetic ulceration particularly in limb salvage cases. It is not used in the UK despite supporting clinical evidence.</p> <p>Amputations now exceed 8000 per annum and foot care for diabetics with none/slow healing is extremely costly. It is surely grossly negligent to ignore a therapy with proven potential to transform the prospects of healing and achieve major cost reduction.</p>	<p>Thank you for your comment.</p> <p>Thank you for highlighting the issue of treatment with NMES, unfortunately this is not an area where any new evidence was found during this surveillance review, with no additional studies highlighted by stakeholders during consultation.</p> <p>We are monitoring an ongoing NIHR funded study on different treatments for diabetic foot ulcers which will be assessed once the results are available. We hope this will provide more evidence on the most effective treatment methods for diabetic foot ulcers.</p>
Mölnlycke Health Care	No	No comments provided	Thank you for your response.
Neuropad UK	Yes	<p>Early signs of DPN can be treated and small nerve fibre damage can be reversed. There is much evidence in the literature that the treatment for early neuropathy is tight (normoglycaemic) control of blood sugar levels in appropriate patients (1,2,3,4).</p>	Thank you for your comment.

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		<ol style="list-style-type: none"> 1. Ishibashi F, Taniguchi M, Kosaka A, Uetake H, Tavakoli M. (2018) Improvement in Neuropathy Outcomes With Normalizing HbA1c in Patients With Type 2 Diabetes. <i>Diabetes Care</i>. 1-9 https://doi.org/10.2337/dc18-1560. 2. Martin CL, Albers JW, Pop-Busui R, DCCT/EDIC Research Group (2014) Neuropathy and related findings in the diabetes control and complications trial/epidemiology of diabetes interventions and complications study. <i>Diabetes Care</i> 37(1): 31-8. 3. Stratton IM, Adler AI, Neil AW et al (2000) Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. <i>BMJ</i> 321(7258): 405-12. 4. Tavakoli M, Mitu-Pretorian M, Petropoulos I. (2013) Corneal Confocal Microscopy Detects Early Nerve Regeneration in Diabetic Neuropathy After Simultaneous Pancreas and Kidney Transplantation. <i>Diabetes</i>, 62. 254-60. 	<p>Thank you for highlighting the studies on control of blood sugar levels. Unfortunately, they did not meet our strict inclusion criteria for this review:</p> <ul style="list-style-type: none"> • 1. This study is not an RCT or Cochrane review so does not meet our study type criteria for this review. • 2. This study is outside the search dates for this review and is not the correct study type • 3. This study is outside the search dates for this review • 4. This study is outside the search dates for this review <p>We appreciate that tight glucose control is an important factor in people with diabetic foot problems, however glucose control is covered by the following guidelines:</p> <ul style="list-style-type: none"> • NICE guideline NG17 Type 1 diabetes in adults: diagnosis and management • NICE guideline NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management • NICE guideline NG28 Type 2 diabetes in adults: management <p>These guidelines are all included in the diabetic foot pathway and there are also cross referrals from recommendations in NG19. We would need further evidence in order to add recommendations on tight blood glucose control to NG19, specifically regarding the impact on diabetic foot problems, so as not to repeat guidance stated in the above guidelines.</p>
South Sefton Clinical Commissioning Group	No	No comments provided	Thank you for your response.

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Interaction	Yes	Our work with patients with (DFU) Diabetic Foot Ulcers and (LU) Leg Ulcers has highlighted not only the debilitating impact of the condition but also the <u>psychosocial impact</u> of lengthy treatment. The successful treatment of many of these patients with the above recommended dressings has in many cases transformed them, and given hope helping to negate the threat of subsequent amputations.	<p>Thank you for your comment.</p> <p>Thank you for highlighting the emotional impact of diabetic foot ulcers, we appreciate that this is an important aspect of care. Unfortunately, no new evidence has been found at this surveillance review which indicates a change is necessary to the current recommendations. We appreciate the studies highlighting new dressings however they were outside of the search dates for this review, additionally they were not RCTs or Cochrane reviews which are our required study types for this review. We are tracking an ongoing study regarding treatment of diabetic foot ulcers and will assess the results for impact on the guideline once available.</p>
Manchester Metropolitan University	Yes	Page 22: "The evidence found supports the use of wound dressings as an intervention rather than highlighting a specific product". UrgoStart is the only product to have received an MTG recommendation for use and has therefore been highlighted as a specific product to use.	<p>Thank you for your comment.</p> <p>We have reviewed the evidence for wound dressings and found it to be consistent with current guideline recommendations.</p> <p>The wording for recommendation 1.5.10 was chosen carefully by the guideline development group to allow the use of the most appropriate dressing for the clinical need, and this could include interactive dressings. The recommendation currently permits the use of any clinically appropriate dressing. MedTech guidance MTG42- UrgoStart for treating diabetic foot ulcers and leg ulcers is linked within the diabetic foot pathway in order to highlight this technology guidance to service users.</p> <p>The evidence identified in the surveillance review on UrgoStart compared the intervention with a control, which is just one comparison, and ideally we would require a comparison of all available options to consider any impact on the current recommendation, which allows the most clinically appropriate dressing to be used, including interactive dressings.</p>

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			Thank you for highlighting the Explorer trial, this RCT was identified in our search and has already been included in the summary of new evidence.
Ethical Medicines Industry Group	Yes	<p><i>Page 26 ('context'): lines 1-6 discusses the incidence rate of diabetic foot ulceration, as well as this being a pre-cursor to diabetic foot amputation in 80% of cases. The addition of the risk callus poses to people with diabetes should also be included here, as studies have found that the presence of callus is highly predictive of diabetic foot ulceration, and can be found in up to 80 % of cases¹. The earlier identification and treatment of callus through the use of available topical products (e.g. urea-based emollients) and their role in reducing the risk of foot ulceration / re-ulceration) should also be included. Urea-based products have been cited as the most effective emollients for the diabetic foot, which show positive benefits when compared to other emollients². Studies have also concluded that the use of urea-based creams be recommended in the treatment and prevention of the diabetic foot, and both 10% and 25% urea creams were also found to significantly increase skin hydration³. Furthermore, the use of urea-based emollients also aids daily foot checking for people with diabetes, allowing earlier identification of changes to foot health. In a survey of 1000 patients with</i></p>	<p>Thank you for your comment.</p> <p>Thank you for highlighting the 3 studies, unfortunately these did not meet the strict inclusion criteria for this review for the following reasons:</p> <ul style="list-style-type: none"> • Rosen et al, Harkness et al and Bristow et al- these studies are outside the search dates for this review. <p>Thank you for highlighting the use of urea-based emollients. This was not an area we have found any evidence for at this surveillance review, and unfortunately the evidence submitted at stakeholder consultation did not meet the inclusion criteria. We will however, note this issue for consideration at the next surveillance review.</p> <p>We appreciate that daily foot care and foot checking is important, and with a lack of new evidence in this area, we feel that this is sufficiently highlighted in recommendations in section 1.3.</p>

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	<p>diabetes³ only 18% of people who check the condition of their feet, did so every day. Within this same survey however, 83% indicated that having a simple daily foot care routine as well as having expert advice from a healthcare professional on how and why to check their feet regularly would make people with diabetes check the condition of their feet every day.</p> <p>In addition to the above, the total expenditure on healthcare related to foot ulceration in people with diabetes is stated as costing the NHS up to £1.06 billion per annum⁴; with a burden to a patient with diabetes with a diabetic foot ulcer resulting in a health-related quality of life index being lower than that for people with Chronic Obstructive Pulmonary Disease or on Haemodialysis⁴. This therefore, highlights the importance of preventing diabetic foot ulceration through earlier intervention via implementing daily foot checking and treating callus appropriately (e.g. with a urea-based emollient), given the aforementioned incidence rate of callus prior to diabetic foot ulceration.</p> <p>1Rosen RC, Davids MS, Bohanske LM, Lemont H (1985) Hemorrhage into plantar callus and diabetes mellitus. <i>Cutis</i> 35(4): 339-41; Harkless LB, Dennis KJ (1987) You see what you look for and recognize what you know. <i>Clinics in Podiatric Medicine and Surgery</i> 4(2): 331-9</p> <p>2Bristow, Emollients in the care of the diabetic foot. <i>Diabetic Foot</i></p>	
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		<p><i>Journal, 2013. 16: p. 63- 66.)</i> 3 Survey of 1000 people with diabetes – data on file (available on request) 4 Improving footcare for people</p>	
Cardiff and Vale University Health Board	No	No comments provided	Thank you for your response.
The British Orthopaedic Foot and Ankle Society	Yes	As above	Thank you for your response.
NHS England	Yes	<p>On page 23 it says: “They discussed the limited evidence on antibiotic course length, which compared 6 weeks with 12 weeks in adults with diabetic foot osteomyelitis. The committee agreed that for people with a moderate or severe diabetic foot infection (which includes osteomyelitis), a 7-day course would be a minimum, with antibiotic treatment for up to 6 weeks if people have osteomyelitis.” The reference quoted for this is <i>Tone et al. Diabetes Care 2015</i>, which has been interpreted as suggesting that there is no significant benefit of extending antibiotic duration to 12 weeks for osteomyelitis. However, another legitimate interpretation of the trial by Tone et al is that it was underpowered to show statistical significance but suggested a 70% remission rate with 12 weeks antibiotics vs. 60% remission rate with just 6 weeks (so better outcomes with 12 weeks duration). It would therefore be appropriate to be less prescriptive about the 6 weeks duration and acknowledge the poor evidence base.</p>	<p>Thank you for your comment.</p> <p>Thank you for highlighting issues with antibiotic duration. The recommendations on antibiotics were excluded from this surveillance review due to an in development antimicrobial prescribing guideline (APG) in this area. The APG will be incorporated into NG19 section 1.6 on treatment, replacing recommendations 1.6.6 – 1.6.15. We will pass your comment on to the appropriate team so that they can consider these issues when reviewing comments on the consultation draft of the APG guideline.</p>

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		<p>Interestingly, in the document sent out yesterday from NICE on diabetic foot disease, it is indeed less prescriptive, and under point 1.6.15 says “Offer prolonged antibiotic treatment (usually 6 weeks) to people with diabetes and osteomyelitis, according to local protocols.” – this seems much more appropriately balanced, given the paucity of evidence. (JV)</p> <p>This is not an area of specialty within the team, we would be keen for NICE to engage with the College of Podiatry regarding this consultation, we do have some concerns regarding the podiatry workforce which is a small, vital and vulnerable profession essential in the delivery of this pathway. (SC)</p>	
Fresenius Medical Care	Yes	<p>As detailed in ID1, Fresenius Medical Care recommends the inclusion of rheopheresis as a research recommendation, as a rescue therapy for non-responding diabetic foot ulcers. It can bring about health economic benefits through effective removal of target molecules, acceleration of wound healing, reduced need for amputation, pain relief and improvement in quality of life. Examples of published evidence for rheopheresis therapy for patients with ulcerative wounds and diabetic foot include:</p> <ul style="list-style-type: none"> • Blaha M, Rencova E, Maly R, et al. The importance of rheological parameters in the therapy of microcirculatory disorders. Clinical Hemorheology and Microcirculation. 2009; 42(1):37-46. 	<p>Thank you for your comments.</p> <p>No new evidence has been found at this surveillance review which indicates a change is necessary to the recommendations on treatment of diabetic foot problems. Studies presented by stakeholders did not meet the inclusion criteria for this review due to study date or study type.</p> <p>Thank you for highlighting the technology rheophoresis. Unfortunately, the studies provided do not meet the strict inclusion criteria for this review for the following reasons:</p> <ol style="list-style-type: none"> 1. Blaha et al – this study is outside the search dates for this review 2. Ferrannini et al - this study is outside the search dates for this review 3. Klingel et al (2003 & 2005)- these studies are outside the search dates for this review

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		<ul style="list-style-type: none"> • Ferrannini M, Vischini G, Staffolani E, et al. Rheopheresis in vascular diseases. <i>Int J Artif Organs</i>. 2007; 30(10):923-929. • Klingel R, Mumme C, Fassbender T, et al. Rheopheresis in patients with ischemic diabetic foot syndrome: results of an open label prospective pilot trial. <i>Therapeutic Apheresis and Dialysis</i>. 2003; 7(4):444-455. • Klingel R, Erdtracht B, Gauss V, et al. Rheopheresis in patients with critical limb ischemia—results of an open label prospective trial. <i>Therapeutic Apheresis and Dialysis</i>. 2005; 9(6):473-481. • Lumlertgul D, Suteeka Y, Tumpong S, et al. Double filtration plasmapheresis in different diseases in Thailand. <i>Therapeutic Apheresis and Dialysis</i>. 2013; 17(1):99-116. • Vass M, Dioszegi A, Nemeth N, et al. Rheopheresis in vascular diseases. <i>Clinical Hemorheology and Microcirculation</i>. 2016; 64:977-987. 	<ol style="list-style-type: none"> 4. Lumlertgul - this study is outside the search dates for this review 5. Vass et al – this is not an RCT or Cochrane review and as such does not meet the study type criteria.
St Helier Hospital, Threatened Limb Service	Yes	<p>1.As mentioned above, Diabetic Foot Team spend a great deal of time trying to convince Medical and Surgical teams of the severity of Diabetic Foot problems and the need to act quickly.</p> <p>Recommendation for NICE to include in guidelines:</p> <p>'Diabetic patients with High Risk Feet are likely to display a reduced clinical response and reduced signs and symptoms of infection. We will have a reduced ability to monitor infection based on clinical signs. In patients with High Risk feet any problem can result in a major amputation. The monitoring of inflammatory markers can assist in monitoring infection and allows clinicians to change the</p>	<p>Thank you for your comment.</p> <p>We appreciate the frustration experienced with time to treatment or even time to consultation. However, at this time there has been no evidence found at this surveillance review or presented at stakeholder consultation which suggests a change to the guideline recommendations is needed.</p> <p>The recommendations in sections 1.1 and 1.2 strongly emphasise the need for multidisciplinary working, rapid referral and the role of commissioners in providing these services. For further information please see strength of recommendations.</p>

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	<p>management plan quickly should there be any signs of deterioration. Diabetic foot infection can deteriorate rapidly and become limb threatening very quickly, sometimes in the absence of clinical signs. Patients with Diabetic foot problems and any concerns of infection should have blood tests to monitor inflammatory markers on a regular basis. Patients with High Risk feet and Active Diabetic Foot infection should have blood tests and inflammatory markers reviewed daily while an inpatient.’</p> <p>2. Patients are not being referred to Vascular Surgeon despite Critical Limb Ischaemia and Necrosis. We see repeat occurrences of Diabetic patients admitted to hospital (particularly if over the weekend) with foot necrosis present. Patients are not referred to the Vascular team on discovery of necrosis or signs of CLI. Patients are eventually referred to the Diabetic Foot team where on review we escalate to the Vascular team urgently and arrange vascular investigations. At this point the limb is usually less salvageable than it may have been 1-3 days ago when patient was first reviewed by a clinician.</p> <p>Recommendation for NICE to include in guidelines:</p> <p>‘All Diabetic patients with foot necrosis must be referred immediately (within 12 hours) to the Vascular team. The Vascular on call team at the closest hospital / service must be contacted for an opinion as soon as any clinician identifies necrosis or any signs of critical limb ischaemia.</p> <p>3. The current guidelines state:</p> <p><i>A foot protection service for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community.</i></p>	<p>Unfortunately we have no evidence to support the suggestion of a 12 hour referral to vascular surgical team, however we will log this issue for consideration at the next surveillance review.</p> <p>Thank you for the suggestion about including diabetic foot care information into education and advice for people with type 1 and type 2 diabetes. This is broadly covered by NICE guidelines NG17 – Type 1 diabetes in adults and NG28 Type 2 diabetes in adults, both of which have sections of education and cross referrals to NG19. This guidance is also linked together in the foot care for people with diabetes pathway.</p> <p>In relation to the suggestion about including retinopathy/neuropathy and eye disease/chronic kidney disease, these are also covered by NG17 and NG28 above, with eye disease in particular being an area considered for update.</p> <p>Thank you for the detailed comments regarding wound care, availability of wound healing options, treatment, timing and need for X-rays and charcot arthropathy. We appreciate the concerns raised; however these appear to be an implementation issue. The NDFA 2019 supports our recommendations in sections 1.5-1.7, and we feel the strength of recommendations are appropriate at this time. As we have not received any evidence to contradict this during consultation, we will log it as an issue for consideration at the next surveillance review.</p>
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	<p><i>A multidisciplinary foot care service for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service. This may also be known as an interdisciplinary foot care service.</i></p> <p>Despite more of the above services being available, we see a large portion of Diabetic Patients who do not access these services. It is very common for patients to present to a hospital MDT/ Diabetic Foot team service with High Risk feet and active pathology who have had Diabetes for multiple years and who have never been reviewed by a Podiatrist / Foot protection team. These patients often are seen to have very poor knowledge of how Diabetes can affect the lower limb and have no self footcare practices in place to help reduce their risk of foot pathology.</p> <p>Recommendation for NICE to include in guidelines:</p> <p>'All Type 1 and Type 2 Education courses should include information on Diabetic Foot pathology and how to reduce the risk of foot pathology. This information should be presented by a clinician who is part of a MDT Diabetic Foot Service or a Foot Protection Team.'</p> <p>The current guidelines state: Once patients are out of the 'Active' pathology stage and are no longer attending a multidisciplinary foot care service for in the hospital setting, they will likely be stepped down to the Foot Protection Service in the Community setting.</p>	
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	<p>We very regularly see patients who have been discharged to from the MDT service, only to re-present with active pathology months or years later having never been reviewed by the Foot Protection service.</p> <p>Recommendation for NICE to include in guidelines changes include more robust recommendations similar to recommendations relating to Eye Disease and Kidney Disease.</p> <p>Recommend changing the advice for frequency of risk assessment advise to specify review by the Diabetic Foot Team or Foot Protection service:</p> <p>'On diagnosis of Type 1 or Type 2 Diabetes, GPs should immediately refer adults to the Community Podiatry / Foot Protection Service for a Diabetic Foot Assessment and Categorisation of Risk Status.</p> <p>All patients with Type 1 or Type 2 Diabetes should be reviewed at least annually by the Community Podiatry / Foot Protection Service.'</p> <p>Recommendation for NICE to include advice regarding the links between developing: Neuropathy, Retinopathy and Nephropathy.</p> <p>'If patients are found to have Neuropathy OR Retinopathy OR Nephropathy, they should be referred for screening of the other two pathologies.'</p>	
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		<p>4. 1.5 Diabetic Foot ulcer.</p> <p>Recommendation for NICE to change guidelines relating to 1.5.4:</p> <p>'Offer as standard care for treating diabetic foot ulcers ALL of the following:</p> <p>Offloading, control of infection, control of ischaemia, wound debridement</p> <p>If the service cannot provide treatment related all the above aspects of care, patients should be referred to a service that does. Unless all four aspects of wound management are addressed, care will be suboptimal.'</p> <p>5. Guideline 1.5.5 relating to offloading of ulceration.</p> <p>Recommendation for NICE to change guidelines to include:</p> <p>'forefoot, midfoot AND HINDFOOT diabetic ulcers'</p> <p>6. Guideline 1.6.2</p> <p>Consider an X-ray of the person's affected foot (or feet) to determine the extent of the diabetic foot problem.</p> <p>Recommendation for NICE to change guidelines to include:</p>	
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		<p>... If a Diabetic patient with High Risk feet presents with unilateral pathology consider bilateral foot and ankle x-rays as both feet are, and always will be, at a High Risk of serious pathology and amputation. The way in which we treat and manage a complaint for one limb will have an effect of the contralateral limb. In offloading an affected limb, we are changing the pressure distribution of the other limb. In patients with neuropathy and reduce slinci response, there is always a chance of underlying bony pathologyoccurring bilaterally which may change the management plan. Patient with High Risk feet, (particularly those who have not had regular review from the Diabetic Foot / Foot protection team) and have not have recent foot x-rays, should be considered for bilateral foot and ankle Anterior-Posterior, Lateral and Oblique x-rays.</p> <p>Daibetic patients may have poor bone integrity including osteoporosis. This may limit or change the offloading plan. Often, the bony integrity of a Diabetic patient is discovered on imaging and therefore patients with High Risk feet should be considered for bilateral x-rays to help direct the most appropriate level of offloading/ weightbearing.</p> <p>7. Guidline 1.7 Charcot Arthropathy. Recommendation for NICE to change guidelines to inlcude:</p> <p>‘consideration that bilateral Charcot can occur concurrently and remain suspicious if clinical signs present WITHOUT temperature differnce to contralateral limb.’</p>	
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		<p>Recommendation for NICE to change guidelines to include: If acute Charcot arthropathy is suspected, arrange a weight-bearing X-ray of the affected foot and ankle. Consider an MRI if the X-ray is normal but Charcot arthropathy is still suspected.... 'If x-ray is normal but clinical suspicion remains, continue to offer treatment with a non-removable offloading device until further imaging can confirm or disprove diagnosis.'</p> <p>Recommendation for NICE to change guidelines to include:</p> <p>Once the Acute phase has resolved the Charcot Arthropathy remains chronic and can reactivate. Patients should be educated that they are not 'cured' from the Charcot, it has just resolved to a chronic state and they still require treatment in the form of monitoring and offloading, as the form and structure of their foot will not return to normal. The aim is to prevent further activity, changes and deformity.</p> <p>'Once the active Charcot phase has resolved, patients should be referred for custom offloading and review with an Orthotist. The majority of patients will require long term custom footwear and insoles to accommodate deformity and reduce risk of re-activation. If the residual deformity is severe or cannot be accommodated in custom footwear, or, if the patient is experiencing recurrent ulceration, a referral to the Orthopaedic team should be made to assess the need for surgical options.'</p>	
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		'If the service does not have an Orthopaedic team experienced in the management of High Risk Diabetic feet, including experience with Charcot reconstruction, a referral to a service which provides this level of expertise should be made.'	
British Society of Interventional Radiology (BSIR)	No	No comments provided	Thank you for your response.
Royal College of Nursing	Not answered	No comments provided	Thank you.
Royal College of Paediatrics and Child Health (on behalf of the British Society of Paediatric Endocrinology and Diabetes)	No	No comments provided	Thank you for your response.
Association of British Clinical Diabetologists	Yes	<p><i>There are however some areas where ABCD believes there is evidence to warrant updating, expanding or which have been overlooked, namely;</i></p> <ul style="list-style-type: none"> ○ <i>Ultrafast acting insulins</i> 	<p>Thank you for your comment.</p> <p>Thank you for highlighting these areas of interest. These are largely outside the scope of NG19 and are instead covered by other NICE guidelines in the diabetes theme, NG17, NG18 and NG28 as follows:</p>

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		<ul style="list-style-type: none"> ○ <i>Management of renal complications in light of CREDENCE trial data</i> ○ <i>Low/ v low calorie diets</i> ○ <i>Potential risks of SGL2 inhibitors: Fournier's gangrene, diabetic ketoacidosis & increased risk of lower limb amputation</i> 	<ul style="list-style-type: none"> ● Ultrafast acting insulins – NG17 – type 1 diabetes in adults, section 1.6 blood glucose management, type 2 diabetes in adults section 1.7 – insulin therapy ● Renal complications – NG17 section 1.15 complications ● Low/v low calorie diets – this was raised during consultation for NG28, please see their response to stakeholder comments for further information.
Royal College of Physicians		We would like to endorse the responses submitted by the Diabetes Technology Network (DTN) and the Association of British Clinical Diabetologists (ABCD).	Thank you for your comment.
Diabetes UK	Not answered	No comments provided	Thank you.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Urgo Medical	No	No comments provided	Thank you for your response.
East Midlands Diabetic Foot Group	No	No comments provided	Thank you for your response.
Neurocare Europe Limited	No	No comments provided	Thank you for your response.
Mölnlycke Health Care	No	No comments provided	Thank you for your response.

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Neuropad UK	Yes	<p>The current guideline recommendation for primary care testing for DPN with 10g SWME, which requires a skilled healthcare professional to carry out the examination, discriminates against people with diabetes who cannot respond to the SWME test because of cognitive, mental health, speech, inadequate understanding, language or other impediments and disabilities that would prevent them responding to the SWME. In addition, relying on SWME also discriminates against the >500,000 people in NHS England alone who for whatever reason do not have an annual diabetic foot examination (1) which therefore puts them at high risk for a future first presentation in a hospital A&E department because a lesion on the foot has developed. This would appear to be a very significant oversight and it needs addressing.</p> <p>Mayor S. A quarter of diabetic patients miss out on annual foot checks, Diabetes UK survey warns. BMJ 2011;343:d7405. doi: https://doi.org/10.1136/bmj.d7405</p>	<p>Thank you for your comment.</p> <p>We consider related NICE guidance when conducting a surveillance review, which included the recent MedTech guideline MTG38 - Neuropad for detecting preclinical diabetic peripheral neuropathy from September 2018. However, MTG38 stated a number of areas of uncertainty such as cost modelling and clinical importance in the current NHS pathways. As such we have insufficient evidence to suggest making a change to recommendation 1.3.4 at this time. We will log your comments for consideration at the next surveillance review.</p> <p>When the committee for MTG38 discussed the evidence, they took potential inequalities into account, particularly as you mention, that this test does not rely on a patient response. MTG38 recommendation 1.1 states 'There is insufficient evidence to support the use of Neuropad in patients in whom 10 g monofilament testing for diabetic peripheral neuropathy is not possible.'</p> <p>Thank you for providing the study by Mayor, unfortunately it was outside the search dates for this surveillance review and as such cannot be included.</p>
South Sefton Clinical Commissioning Group	No	No comments provided	Thank you for your response.
Interaction	No	No comments provided	Thank you for your response.
Manchester Metropolitan University	No	No comments provided	Thank you for your response.

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Ethical Medicines Industry Group	No	No comments provided	Thank you for your response.
Cardiff and Vale University Health Board	No	No comments provided	Thank you for your response.
The British Orthopaedic Foot and Ankle Society	No	No comments provided	Thank you for your response.
Fresenius Medical Care	No	No comments provided	Thank you for your response.
St Helier Hospital, Threatened Limb Service	Not answered	No comments provided	Thank you
British Society of Interventional Radiology (BSIR)	No	No comments provided	Thank you for your response.
Royal College of Nursing	Not answered	No comments provided	Thank you.
Royal College of Paediatrics and Child Health (on behalf of the British Society of Paediatric Endocrinology and Diabetes)	No	No comments provided	Thank you for your response.

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Association of British Clinical Diabetologists	No	No comments provided	Thank you for your response.
Royal College of Physicians		We would like to endorse the responses submitted by the Diabetes Technology Network (DTN) and the Association of British Clinical Diabetologists (ABCD).	Thank you for your comment.
Diabetes UK	Yes	<p>Language throughout the whole of NG19 should be amended to reflect the NHS England position statement 'Language Matters'. This should help to ensure that all children living with diabetes are able to access the best possible care available regardless of their age, sex, gender, disability, religion, race, ethnicity or socio-economic status.</p> <p>NHS England (2018) https://www.england.nhs.uk/publication/language-matters-language-and-diabetes/</p>	<p>Thank you for your comment about the language used within NICE guideline NG19.</p> <p>All NICE guidelines and related products are developed with editors to ensure they are written and presented in a way that is clear and accessible to a range of different audiences. Further details can be found on the Language page of the NICE website.</p>

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