BIOME study

NHS
North Cumbria Integrated Care
NHS Foundation Trust

# Patient Information Sheet for BIOME study

## Bacterial Infection: Observation & Management Evaluation

**(Prospective, single-centre, cohort study assessing the potential application of WOUNDCHEK™ diagnostics for ulcer management)**

- We would like to invite you to participate in a research study. Before you decide, you need to understand why this study is being done and what it will involve for you.
- Please take time to read the following information carefully.
- Talk to others about the study if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Take time to decide whether or not you wish to take part.

Thank you for taking the time to read this.

### Who is carrying out the study and why?

This study has been developed and is carried out by the North Cumbria Integrated Care NHS Foundation Trust (NCIC. The Chief Investigator is Grace Messenger (head of podiatry) and co-investigator is Jane Todhunter (vascular specialist nurse).

Patients with poor circulation in their legs and/or certain conditions like diabetes may develop foot or leg ulcers (a type of skin wound). There is a risk that these wounds may become infected and it is important to properly diagnose if indeed there is an infection or not.

A company called Woundchek Laboratories has developed an approved ‘bedside’ test (meaning the result is available during a patient’s clinic visit) to check what state a wound is in when it comes to checking for the presence of infection caused by bacteria. The BIOME study looks at how effective this Woundchek test is when compared to the current standard practice of a healthcare professional checking for visible symptoms of infection. The results of this study could affect how foot and leg ulcers are managed, both during the study itself and in the future.

**Why have I been invited?**

The clinical staff treating your leg(s) has determined that you have a foot or leg ulcer and that the wound needs to be checked for infection. They have identified you by screening your notes or in clinic, and will ask you if you potentially wish to take part in this study. You may already be an existing patient in podiatry or vascular surgery, or you may just have been referred into the service. If you are interested, then they will ask your verbal consent for one of the research team to talk you through the study (this may be the same healthcare professional who is treating you).

**Do I have to take part?**

You do not have to take part; it is entirely up to you to decide whether you would like to be involved in our study. Take your time, discuss things with others and ask us about anything that is not clear or if you would like more information. If you do decide to take part, you are free to withdraw at any time without explanation and this will not affect the general standard of care you receive in any way. In case of not taking part your treating clinician will continue to manage your ulcer as per standard practice and clinical guidelines.

**Timing of deciding on whether to take part or not**

You may be approached to take part in this study during your appointment with the podiatrist or vascular nurse. If you understand the nature of the study and any questions had have been answered satisfactorily then you are allowed to consent to taking part straight away.

If you wish to have more time to decide whether to take part, then you can take this patient information leaflet with you to read at your own leisure. Provided you are still eligible, the study can then be discussed at your next regular clinic appointment. If you wish to take part then, written informed consent can be obtained so you can take part in the study.

**What will happen to me if I take part?**

If you decide that you may want to take part in the study, one of the research staff, which may be the chief investigator, your regular healthcare professional, or another trained and delegated member of the study team, will take written consent from you. We ask permission to access your medical records to record data related to your foot/leg care.

The main difference between standard care and being part of this BIOME study is that a Woundchek test will be done at week 0 and week 6 (as long you still have the ulcer by that time). First the treating healthcare professional will assess the wound as they normally do, and then the Woundchek test is done. This involves a standard swab of the ulcer and then analysing that swab with a device that is similar in looks to a pregnancy test or COVID19 lateral flow test. Because the Woundchek device has a CE-mark and is approved for clinical use, the treating healthcare professional is allowed to manage your ulcer as a result of the test result. One study aim is to see how often this may happen.

Apart from doing the Woundchek test, your healthcare professional will use standard recognised ways to manage your ulcer. This may include using different types of dressings, in some cases compression bandaging, and possibly doing another ulcer swab to be sent off to microbiology.

**Figure 1, The Woundcheck bacterial status 'bedside' test (also known as a point-of-care test), involving a swab of the patient's ulcer and reading of the result on a display.**


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Your participation is completely voluntary and will be for 12 weeks. Once you have consented to taking part, you will be asked to complete some questionnaires regarding your ulcer (if you have multiple ulcers, we will only focus on one wound for the study for the collection of data). Table 1 summarises what happens when. The researcher and/or clinical staff can assist you with answering the questions if you wish. A summary of the questionnaires to be answered is summarised below. The research study visits usually coincide with standard clinic visits. At those three visits (week 0, week 6 and week 12) your ulcer will be examined. After the 12 week study period, clinical staff will recommence managing the leg as per your routine care. If your leg ulcer heals within the 12 week study period, we would still like to have the week

12 follow-up appointment to collect the relevant study data – it is very likely that you would still be seen as part of standard care anyway.

***Table 1, Timeline and overview of different study visits***

| Type of visit | Point of contact | What will happen? |
|---|---|---|
| Week 0 and week 6 | Clinic visit (to coincide with standard clinic appointment where possible) | • Written Informed Consent<br>• Collection of general information (age, general health)<br>• Woundchek test<br>• Questionnaires:<br>  ○ Quality of life (general)<br>  ○ Pain score (specific to ulcer)<br>• Ulcer assessment |
| week 12 | Clinic visit (to coincide with standard clinic appointment where possible) | • Check if leg ulcer has healed<br>• Questionnaires:<br>  ○ Quality of life (general)<br>  ○ Quality of Life (specific to leg)<br>  ○ Pain score (specific to leg)<br>  ○ Itchiness score (specific to leg)<br>• Ulcer assessment |

**What are the possible benefits of taking part?**

The study investigates if the Woundchek test is similar or different to a healthcare professional checking an ulcer for the presence of bacterial infection. We also want to know which type of patient may benefit from being tested with the test kit. If the Woundchek test detects a possible infection but a healthcare professional does not, then this may mean you get treated for this infection when otherwise you would not have been. On the other hand, if the Woundchek device is negative for infection - but the healthcare professional did think there could be an infection – then it may avoid being treated unnecessarily. However, the healthcare professional can make the decision to either act or not act on the Woundchek result. In most cases the treatment you receive will not differ from the standard treatment options available, and hence the risks are very low.

You cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research. Patients who take part can receive a copy of a summary of the study results, to inform them of the results obtained using the Woundchek device.

**What are the possible disadvantages and risks of taking part?**

There are no major personal safety risks anticipated regarding taking part in this research trial. The swab taken from the ulcer for the Woundchek test is no different from a swab that a

healthcare professional may take for a microbiology test swab. The risk of injury or bleeding is much lower than compared to standard thorough cleaning of an ulcer (called debridement). If you do decide to take part in the BIOME study, and your NHS Trust, surgeon, GP, nurse or the research team learns of important new information that might affect your willingness to remain in the study, they will tell you as soon as possible. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

**How will we use information about you?**

We will need to use information from your medical records for this research project.

This information will include your name, sex, and age. Contact details (address and phone number) are used by the clinical team for appointments and your care. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Some of your information (study outcome data) will be sent to the funder of the research, Woundchek Laboratories, based in the UK and USA. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Will my participation in the study be kept confidential?**

A member of your direct care team has screened your details to ensure you are eligible to take part in the study; these details will not be shared with anyone else in the research team. All information that you give us will be kept strictly confidential. You will be asked to give your name and contact details because we wish to match this with your medical information.

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act and General Data Protection Regulation for health and care research. Your data collected during your participation in the BIOME study will be entered into a password-

protected database and analysed – using only NHS computers and servers. For the data analyses, your study data will not be identified by your name – only by study number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor's clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor's auditors or their representatives, the NHS representatives and regulatory authorities may have direct access to the study files, but your medical records will not be accessed.

We will need to use information from you and from your hospital medical records for this research project. This information will include your name. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What if something goes wrong?**

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below). The study is covered by NHS insurance in relation to the design, management and conduct of the research, but not for no fault compensation.

**What will happen if I don't want to carry on with the study?**

Your participation in the study is voluntary. You can refuse to take part, or you can withdraw at any time. If you choose to withdraw, your clinician will continue treating you as he or she normally would and you do not have to give a reason as to why you wish to withdraw from the study. If you withdraw after signing the study consent form, you will not be able to re-enter the study. Any data collected up to the point where you withdraw will be retained for analysis as part of the study. The latter also applies if you were to lose capacity to take part during the study.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information
•at www.hra.nhs.uk/information-about-patients/

•our leaflet available from www.hra.nhs.uk/patientdataandresearch
•by asking one of the research team, further down this leaflet at 'Contact for further information'
•Within the sponsor NHS Trust for this study via the Data Protection Officer pals@ncic.nhs.uk

**Who is organising and funding the study?**

North Cumbria Integrated Care NHS Foundation Trust is the sponsor for the study, and Woundchek Laboratories will provide the test kit to the study team. Podiatry lead Grace Messenger. The study has been reviewed and given a favourable opinion by the National Ethics Research Service ([name of committee, ref number]), the Health Research Authority (reference 314595) and the NHS Trust (North Cumbria Integrated Care NHS Foundation Trust) which is one of the locations where the study is conducted.

The research team supports the clinical teams acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

**Contact for further information**

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the BIOME research team:

- Name: Mrs Grace Messenger (Chief Investigator)
- Phone number: 01228 814751
- Email: Research@ncic.nhs.uk

Generic information on taking part in clinical research can be obtained from the Patient Experience Team, tel 0800 633 5547 or PET@ncic.nhs.uk , or from websites such as the NHS Choices website, http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Independent advice can be obtained from the Patient Advice & Liaison Service (PALS)

Email: pals@ncic.nhs.uk , Telephone: 01228 814008

***Thank you for taking the time to read this information sheet***