**PATIENT PARTICIPANT INFORMATION SHEET**

**Study title: An exploration of access to and experiences of care for patients with diabetic foot disease.**

Chief Investigator: Professor Mary Wells

Researcher: Miss Simona Racaru

**You are invited to take part in the above-named study which will be conducted through Imperial College Healthcare NHS Trust. The following information is provided to help you make an informed decision on whether to participate or not. Please read the following information carefully and ask us if you would like more information or if anything is not clear!**

1. **Purpose of and background of the research**

* **Nature and purpose of the research**

This study involves focus groups or individual interviews with patients to explore experiences of care, identify any barriers or facilitators in accessing diabetic foot services and explore any inconsistencies in treatment for patients with diabetic foot disease.

* **What is already known (or not known) and how will this study help you learn more?**

Around 50% of population with diabetes are affected by diabetic peripheral neuropathy (DPN), which leads to foot ulceration and amputation. These negatively impact on quality of life and lead to premature deaths. Four in five diabetic foot ulcers (DFUs) can be prevented with good care. Although, foot ulceration is a highly preventable disease, the number of diabetic foot ulcers is very high. In the UK, there are between 70,000 - 90,000 diabetic foot ulcers at any given time. This study endeavours to explore access to and experiences of care for patients with DPN/DFU in the Trust’s catchment area, detect possible gaps in the care pathway and find the key facilitators or barriers to access available services.

* **What interventions are additional to standard care**

Focus groups (discussions) consisting of 6 to 8 DPN/DFU participants and individual telephone interviews will be conducted when a participant will not be able to attend a focus group. A focus group will last around 90 minutes and an individual interview will last between 40 to 60 minutes.

The focus groups will cover the following main topics: access to and experiences of care in GP practices and/or hospitals.

1. **Why have I been invited and am I eligible?**

* You have been invited because you have been diagnosed with diabetes and peripheral (foot) neuropathy or have (had) a (more) diabetic foot ulceration(s), are over 18 years of age and are able to give informed consent.
* You are not eligible if your peripheral neuropathy or foot ulcer were caused by conditions other than diabetes, you have been diagnosed with severe cognitive impairment and you are not able to give informed consent.

1. **Do I have to take part?**

* Only if you want to. Participation in this study is completely voluntary. If, after reading the whole information contained in this form you decide to participate, you will be asked to sign a consent form. You can withdraw from the study at any time without giving a reason for your withdrawal.

1. **What would taking part involve**

* If you decide to be involved in this study you will take part in one focus group or telephone interview. The focus group consists of 6-8 participants with DPN/DFU. You will (discuss) share experiences of accessing primary (GP practices) and/or secondary care (hospital).
* There is no medical procedure and no medication involved. Your individual treatment will not be altered in any way; you should continue your individualised treatment provided by your care provider.
* You will only attend the focus group one time only. A focus group session will last approximately 60-90 minutes, depending on the number of participants.
* No personal information will be asked and you will only share experiences you feel comfortable sharing.
* If you consider a topic to be sensitive, you may choose not to discuss it.
* If you would like to be informed about the findings of this study, please inform the researcher/study nurse.
* The information collected during the focus groups/interviews will be participants’ experiences of and access to care in primary and secondary settings.

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

* Taking part in this study doesn’t involve a direct benefit to you, but it will help researchers understand if there are barriers to accessing care or gaps in the care pathways. Your participation in this study will be central to identify key areas for improvement (e.g. the need for more staff, more training for staff, more DFU units, etc).
* Your participation in this study may help others in better accessing care in the future.

1. **What are the possible disadvantages and risks for taking part in the research?**

* We do not recognise any physical harm associated with participation in the present study.
* Participating in a study involves a risk to confidentiality. The study team has taken all the measures to protect your confidentiality at all times. Your data will be anonymised and pseudonymised. You will be given a fictional name/ (a code) to protect your identity. Only the research & care team (trained professionals) will have access to your data.
* Psychological risk: there may be a possibility that some topics (about difficult experiences in your life such as minor/major amputation, foot ulcers, psychosocial impairment) can cause distress, although all efforts are made to minimise the chances of this happening. If this should happen, the discussion will be stopped. You will be provided with contact details of your local psychological help/support group available who will discuss with/help you.
* You must be reassured that taking part in research and in particular talking about your experiences is likely to be positive and may give you a sense of empowerment. There is patient support available such as NHS urgent mental health helpline, psychological therapies service (IAPT), support from mental health charities or Diabetes.UK forum.

1. **What if you didn’t like the way you were treated while in this study?**

* If you want to make a complaint about the way you were treated in this study, you can contact the study’s supervisor/chief investigator on the number/email provided on the bottom of this form.

1. **Will my identity be kept confidential?**

* Yes. Your identity will be protected all the time by taking the following steps:
  + The signed informed consent forms containing your details will be kept separate from other study data and safely stored in locked cabinets within the vascular unit at Charing Cross Hospital.
  + The focus groups discussions will be recorded, and you will be anonymised/pseudonymised (you will be given a fictional name (or a code) in the study). You will also be informed at the beginning of the session that the discussion is recorded.
  + Recordings will be stored in restricted-access and password protected NHS computers.

1. **Who will have access to my data?**

* Only the research team will have access to your data.
* People who have access to your medical records and trial data have appropriate professional background and training and hold scientific and ethical approval for this research.
* The research team needs to access your data to understand, for example, if there is any correlation between populations’ characteristics (such as gender, age, ethnicity and years with diabetes) and access to care.
* The name of the data controller (ICHT - named person xx)
* Anonymised/pseudonymised data from this study will be published in journals and shared through forum groups available to the public but you will be anonymised/pseudonymised (given a false name (or a code) so nobody can associate you with this research/data).

1. **What will happen if I decide to withdraw?**

* If you decide to withdraw from this study after giving informed consent, you can do so at any time without providing a reason. You can withdraw by calling the following telephone numbers 02033117422; 07375685972 or by writing at the following email addresses [simona.racaru@nhs.net](mailto:simona.racaru@nhs.net); [mary.wells5@nhs.net](mailto:mary.wells5@nhs.net). If this will happen, please be informed that collected data with your consent will be used in the study.

1. **What will happen to the study’s results?**

* The focus groups or interviews will be transcribed verbatim and analysed to find themes, patterns and associations within the data. After the study data will be published in journals and forum groups, participants (you) will be provided with a copy of the study, sent by email or post, if you request one. You will however not be identified in any publication/report.

1. **Who reviewed this study?**

* This study was reviewed by an external audit, by the sponsor, and by the Health Research Authority (HRA) & Research Ethics Committee (REC).

1. **How long this study will run for, who undertakes it and who is the funder?**

* This study will last for 1 year but your involvement in the study will be for a period of 4 weeks. The study is undertaken by Imperial Healthcare NHS Trust and was funded by Imperial Health Charity.

You will be asked to sign the consent form which states that you have read the participant information sheet and understood the information it contains.

**Contacts for further information:**

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**QUESTIONNAIRE**

**Patients’ experiences**

1. Tell me about your experience of accessing primary care (GP practices) such as:
   * making appointments for foot screening
   * quality of care from GP’s, nurses, podiatrist,
   * foot assessment/screening?
   * waiting time for referral to specialist care (how long did you wait for referral to specialist care?)
2. Tell me about your experience of care in primary care (GP practices) such as:
   * experience when receiving foot care /assessments
   * any aspect of care you liked the most/the least
3. Tell me about your experiences of accessing secondary and/or tertiary care (hospitals, diabetic foot specialist clinics) (e.g. how easy or difficult was to access it, waiting time, experience with acute/emergency care if any, services you would like to access but are not available in your area?)
4. Tell me about your experience of care in hospitals/or specialist foot clinics such as:
   * treatment while in hospital and any aspect of care you liked the most and the aspect you liked the least,
   * receiving information about your condition or the procedure (was the information clear and sufficient?)
   * waiting time to treatment.
5. What would you like to see changed or improved (regarding access to /or receiving care) in primary care (GP practices) or secondary care (hospitals)?