

### Information Sheet

A survey to establish the suitability of a quality-of-life outcome measure (QoLTEN) for adults with Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN).

#### **What is the study about?**

Survivors of SJS/TEN are left with many psychological and physiological complications leading to a substantial impact on their quality of life e.g., inability to work and relationship problems. Many survivors are afraid of taking medication, with 50% of survivors still avoiding medication five years post discharge. Patients, family carers and clinicians have noted that the general Quality of Life (QoL) outcome measures do not capture the specific experiences of these patients. Consequently, our project aims to develop and test an SJS/TEN specific QoL outcome measure to be used to assess QoL experiences for this group. We have developed a draft outcome measure, and we have named it QoLTEN.

As part of this project, we would like to invite you to participate in two round survey which aims to establish how well QoLTEN measures your quality-of-life experiences.

#### **Who is on the research team?**

This study is led by Professor Pauline O'Reilly, Department of Nursing & Midwifery, University of Limerick. In addition, the research team comprises Professors Sarah Walsh, Saskia Ingen Housz-Oro, Chris Bunker, Roni Dodiuk-Gad, Donal Fortune, Ailish Hannigan and Ms Sheila Ryan.

#### **Who can participate?**

We are inviting adults who had SJS/TEN to take part in the two round online survey.

#### **What does it involve?**

Participants will be asked to partake in the two round survey. Each survey will take approximately 20 minutes to complete. It will be held online using a GDPR compliant software (Qualtrics). If you consent to participate you will be sent a link to the survey where you will be asked to complete QoLTEN with some other questionnaires including a brief demographic and two other QoL questionnaires. Two weeks later you will be sent another link to the survey to repeat the process (as we may have made changes to QoLTEN because of your input). The findings from this study will help to finalise the development of QoLTEN. Your name, if you wish, will be entered into a draw for a voucher/gift.

#### **What are the benefits?**

It is hoped that the QoLTEN will benefit patients, into the future, when diagnosed with SJS or TEN. It is a practical step to meet SJS/TEN patients' needs and has the potential to improve care by assisting clinicians in the assessment and appropriate treatment plan of these patients. The QoLTEN should support communication between clinicians and patients in terms of discussing the impact of the condition on their lives.

#### **What are the risks?**

There are no known risks attached to this research project. Participation in this study is voluntary. At any stage should you feel that you want to stop taking part in the study, you are

free to stop and take no further part. There are no consequences for changing your mind about participating in the study.

### **How will data be protected?**

The Data Controllers are the University of Limerick, Plassey, Limerick. The information collected from the survey will be kept confidentially, with password protection of each file, on the University of Limerick computer systems. All data gathered from the research will be stored securely and safely including consent forms, by the Principal Investigator. The name of the research participant will not appear on any information, and they will be assigned a study ID code when the information is being published by the researchers. When the study is completed, the information will be kept for 7 years according to the Data Protection Act (2018) and will be erased from the electronic sources, including audio files, and any hard copies will be securely shredded.

The University will not disclose your personal data to third parties. Further information on Data Protection at the University of Limerick may be viewed at [www.ul.ie/dataprotection](http://www.ul.ie/dataprotection). You can contact the Data Protection Officer at [dataprotection@ul.ie](mailto:dataprotection@ul.ie) or by writing to Data Protection Officer, Room A1-073, University of Limerick, Limerick.

### **How are the results shared?**

The data from the surveys will be analysed and written up by Professor Pauline O'Reilly and the research team. The main purpose of the surveys is to see how well QoLTEN measures your quality-of-life experiences. In addition, the finding will be submitted for publication to a peer reviewed journal. The names of the research participants or any other identifying detail will not appear in the publications.

### **How to find out more and participate**

If you are interested in learning more about the study, or in taking part please contact Professor Pauline O'Reilly, Professor, Department of Nursing and Midwifery, University of Limerick, Email: [Pauline.OReilly@ul.ie](mailto:Pauline.OReilly@ul.ie)

Thank you for taking the time to read this. I would be grateful if you would consider participating in this study.

Yours sincerely,

Professor Pauline O'Reilly

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Professor, University of Limerick.

This research study has received Ethics approval from the Education and Health Sciences Research Ethics Committee (quote approval number).

If you have any concerns about this study and wish to contact someone independent, you may contact: Chair Education and Health Sciences Research Ethics Committee, EHS Faculty Office, University of Limerick, Tel (061) 234101

