

# **Protocol for e-Delphi consensus study to agree diagnostic criteria for plaque psoriasis in children**

## **STUDY BACKGROUND INFORMATION AND RATIONALE**

Psoriasis is recognised by the World Health Organisation as a serious non-communicable disease which can affect both adults and children. The prevalence of childhood psoriasis (<18 years) is reported between 0-2.15% globally and the incidence of psoriasis in children may be increasing over time. The natural history and long-term outcomes for children with psoriasis are largely unknown; however studies of adult psoriasis patients have shown that approximately 30% first develop psoriasis in childhood. Synthesis of existing epidemiological research is limited by variation in methodology and definition of psoriasis. Therefore, the development of diagnostic criteria for childhood psoriasis will benefit future epidemiological studies. Clinically, diagnostic criteria will help the early diagnosis of psoriasis by non-dermatologists.

Currently there are no recommended diagnostic criteria for psoriasis in adults or children. Diagnosis is based on a clinical assessment by a dermatologist and rarely a biopsy is performed. Outside dermatology, misdiagnosis and difficulties diagnosing childhood psoriasis have been demonstrated. Specific diagnostic criteria for childhood psoriasis are needed because: i) greatest diagnostic uncertainty is observed in this age group ii) the clinical presentation is often different to adults.

Age, gender ethnicity may affect the clinical presentation of psoriasis, however further studies are needed to explore this further.

The development of diagnostic criteria will aid the early and accurate diagnosis of psoriasis by non-dermatologists. Identification of psoriasis will allow psoriasis specific treatment and monitoring for associated conditions to be started. In particular it will help identify children at risk of psoriatic arthritis and assist rheumatologists to accurately classify juvenile idiopathic arthritis.

## **STUDY OBJECTIVES AND PURPOSE**

To develop diagnostic criteria for plaque psoriasis in children to be used in primary and secondary care and epidemiological studies.

**Primary objective:** To develop expert derived diagnostic criteria using e-Delphi consensus methodology.

## **STUDY DESIGN**

e-Delphi consensus

## **Primary endpoint**

≥70% consensus on included diagnostic criteria

## **Secondary endpoint**

≥70% consensus on list of important criteria

≥70% consensus on number of criteria required to make a diagnosis

## **STUDY MANAGEMENT**

The study will be co-ordinated by Dr Esther Burden-Teh from Centre of Evidence Based Dermatology, University of Nottingham. The study will be managed through a research group who will involve experienced researchers and a statistician. The group will contribute to the design and finalise the study protocol, provide advice and feedback on progression of the study and specific problems as they arise, assist with interpretation and dissemination of the study findings.

## **DURATION OF THE TRIAL / STUDY AND PARTICIPANT INVOLVEMENT**

### **Study Duration:**

The study will involve three rounds of the e-Delphi consensus. During each round participants will be given a two week period for each round and reminders to non-responders sent at 7, 10 and 14 days. A further feedback round will be planned.

The first three rounds will be conducted over a three month period.

The full study will aim to be completed within 9-12 months.

### **Participant Duration:**

Participants will be involved during the active rounds of the e-Delphi. In total this will be eight weeks.

### **End of the Trial**

The end of the study will be the last submission of feedback by the last participant in round four.

## **SELECTION AND WITHDRAWAL OF PARTICIPANTS**

### **Recruitment**

Participants will be recruited through the membership of the International Psoriasis Council (IPC) paediatric committee. Invitation will be by email from Dr Ruth Murphy, IPC councillor.

Email invitation outlining aims of the e-Delphi, purpose of the diagnostic criteria, design of the study, participation details and level of commitment. Participants will be specifically asked for their consent to take part in the study. Only those willing to complete all round of the e-Delphi will be asked to participate.

### **Eligibility criteria**

#### **Inclusion criteria**

Member of the IPC

Practising dermatologist with clinical experience of diagnosing and managing psoriasis in children  
Capability to give informed consent

**Exclusion criteria**

Unable to commit to all four rounds of the e-Delphi

**Participant Withdrawal**

Participants who fail to respond to an e-Delphi round despite three email reminders will be defined as a withdrawal. Participants can also withdrawal at their own request. Data collected up to that point cannot be erased.

**Informed consent**

All participants will be contributing to the study in their role as a medical professional.

Participants will be asked to respond to the email invitation and further information about the study will be sent in a follow-up email. It will be explained that completion of the surveys will provide agreement to participate in the eDelphi study.

**STATISTICS****Methods**

Dr Esther Burden-Teh will evaluate the findings with methodological support from the research group. The approach to the statistical analysis will involve calculating the average responses for the group to feedback to individual participants in the following e-Delphi round. Consensus will be reached when  $\geq 70\%$  of participants agree. The definition of consensus will be applied to both the primary and secondary outcomes.

**Sample size and justification**

No sample size calculation is required for e-Delphi methodology.

**ETHICS COMMITTEE AND REGULATORY APPROVALS**

Participants will be contributing to the e-Delphi within their role as a health professional.

**DATA PROTECTION**

All study members will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The questionnaire which forms each round of the e-Delphi will only collect the minimum required information for the purposes of the survey. The coordinator (Dr Esther Burden-Teh) will be required to know the participants details for administrative purposes. The study will otherwise be conducted anonymously. The e-Delphi will be conducted using the online software Survey Monkey. Access to the software requires a secure password. Paper documentation will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the coordinator and immediate study investigators. Computer held data

will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

## **STUDY FINANCES**

### **Funding source**

No funding has been received for this study

The salary of Dr Esther Burden-Teh is paid for by the University of Nottingham

### **Participant stipends and payments**

Participants will not be paid to participate in the study.