permanent disfigurement), require systemic treatment. Few studies have evaluated the psychological and quality of life impact of IH and there is a lack of data concerning the burden of disease. The present study aims to characterize IH, and provide a comprehensive evaluation of the burden of disease on families, in Europe and in the United States.

**METHODS:** International cross-sectional study (p<0.04) conducted in children and adults diagnosed with IH, aged between 5 months at diagnosis and requiring systemic treatment. The primary caregivers were asked to complete two self-administered questionnaires on the day of the consultation at Kyushu Children’s Dermatology Family Medicine Questionnaire.

**RESULTS:** A total of 693 individuals participated in the study. Mean age ranged from 5.24 to 16.77 months with the majority of IH cases occurring in females. Approximately 80% of all cases were moderate or severe and the majority of parents (≥72.1%) received propranolol. Consistent across countries, the majority of parents (≥70%) reported a psychological impact resulting from their child’s IH but less than 10% were offered psychological support. In addition, only 11% of parents’ reports were reviewed by a mental health professional. The global HRQoL score increased significantly (p< 0.0001) with increased IH severity. The majority (≥90%) of parents were satisfied with the care of their child and their child’s IH. **CONCLUSIONS:** The present study, using the validated HFB questionnaire, provides previously unprecedented insights into the burden of IH, and highlights potential areas for future focus in assisting families.

**PS56**

**QUALITY OF LIFE AND PERSPECTIVES OF HAPPINESS IN MIDDLE-AGED AND OLDER PEOPLE WITH DYSPHAGIA**

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**OBJECTIVES:** Eating is a pleasure for most people in daily life. It involves not only the physical intake of food but also associated social, psychological and spiritual factors. However, few studies have been assessed the impact of dysphagia on quality of life (QOL). Also, the association between dysphagia and perspectives of happiness is unknown. We aimed to examine the association between QOL and perspectives of happiness in middle-aged and older people with dysphagia.

**METHODS:** We collected data from 138 dysphagia patients in university hospitals and clinics at Kyushu and Tokyo area, Japan (mean age ± SD, 73 ± 11 years; range 40–98 years). The total 12% of the subjects had tube feeding. QOL was assessed using the dysphagia-related QOL scale which consisted of 7 domains. Happiness was evaluated using one item of a questionnaire. Clinical information was provided by medical professionals. Perspectives of happiness was categorized as “very happy,” “quite happy,” “neither happy/nor unhappy,” or “not at all happy.” We computed the mean QOL scores in each domain according to the level of happiness, adjusting for age, gender and nutrient intake, by analysis of covariance. The p values for trend were calculated.

**RESULTS:** Overall, 26% reported feeling “very happy” and 46% were “quite happy”, whereas 20% were “neither happy/nor unhappy” and 8% were “not at all happy.” There was no significant relationship between age, the level of happiness and the severity of dysphagia. The scores of “Symptom” (p=0.04) and “Residential” (p=0.01) domains increased with decreasing the level of happiness. Even after statistical adjustment for activities of daily living, these associations remained significant.

**CONCLUSIONS:** Symptoms and resignation regarding dysphagia was significantly associated with happiness. The improvement of QOL may have the positive impact on perspectives of happiness in middle-aged and older people with dysphagia.

**PS55**

**THE VALUE OF ACHIEVING COMPLETE OR NEAR COMPLETE RESOLUTION OF PSORIASIS**

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**OBJECTIVES:** A 75% improvement in the Psoriasis Area and Severity Index (PASI) ≥90% of patients with psoriasis have the positive impact on perspectives of happiness in middle-aged and older people with severe psoriasis. Several analyses of clinical studies of adalimumab, infliximab, etanercept, and ustekinumab have been published recently. Three products have been also approved by the FDA. In two cases (apremilast, ustekinumab), the medical review was not available. Therefore, reasons for not including HRQoL in the label of all EMA products were reviewed.

**METHODS:** The websites of the FDA and the EMA were explored to identify all psoriasis products approved. PRO-labels were used to identify products with a PRO claim in label. All corresponding clinical reviews (FDA, and the EMA) were explored to find the reasons for not including HRQoL. The websites of the FDA and the EMA were explored to find the reasons for not including HRQoL. For the products approved by both agencies, the same clinical studies were reviewed.

**RESULTS:** Ustekinumab was mentioned in the label of all EMA products (mainly, improvement in QoL), but not the FDA’s. The Dermatology Life Quality Index (DLQI) was used for all products, and the SF-36 for six products. Among the eight EMA products with a HRQ claim, five products have been also approved by the FDA. In two cases (apremilast, ustekinumab), the medical review was not available. Therefore, reasons for not including HRQoL in the label could not be retrieved. For the three other products (adalimumab, infliximab, etanercept), the reasons mentioned in the label were reviewed.

**CONCLUSIONS:** The EMA seems to consider HRQoL as a valuable endpoint in the evaluation of psoriasis in contrast with the FDA. More harmonization between agencies might be beneficial to patients’ information.

**PS57**

**THE HEALTH-RELATED QUALITY OF LIFE EVALUATION IN PSORIASIS MATTRESS? A REVIEW OF LABELS OF PSORIASIS PRODUCTS APPROVED BY THE FDA AND THE EMA**

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**OBJECTIVES:** Psoriasis is a papulosquamous skin disease characterized by recurring thick, itchy and dry red patches covered with silvery scales. It has been shown that consumers with psoriasis have a reduction in their quality of life similar to patients with other chronic diseases, such as ischemic heart disease and diabetes. The objective of this study was to evaluate how health-related quality of life (HRQoL) was taken into consideration in the evaluation of psoriasis products approved by the FDA and the EMA.

**METHODS:** The websites of the FDA and the EMA were explored to identify all psoriasis products approved. PRO-labels were used to identify products with a PRO claim in label. All corresponding clinical reviews (FDA, and the EMA) were explored to find the reasons for not including HRQoL. For the products approved by both agencies, the same clinical studies were reviewed.

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**CONCLUSIONS:** The EMA seems to consider HRQoL as a valuable endpoint in the evaluation of psoriasis products in contrast with the FDA. More harmonization between agencies might be beneficial to patients’ information.