U.S. dollars. Incremental cost-effectiveness ratios (ICERs) were calculated comparing the least costly alternative to the next most costly strategy. Deterministic and probabilistic sensitivity analyses were conducted. **RESULTS:** Ranibizumab demonstrated superior efficacy relative to other strategies in both BRVO and CRVO but was most costly ($26,732 and $32,850; BRVO and CRVO, respectively). Other strategy costs ranged from $10,622 (observation in BRVO) to $16,090 (dexamethasone intravitreal implant in CRVO patients). QALYs were greatest for ranibizumab (6.75 and 6.10; BRVO and CRVO, respectively) compared to a range of 4.88 (observation in CRVO) to 5.93 (laser in BRVO). Dexamethasone intravitreal implant was dominated in BRVO as was no treatment in CRVO. ICERs for ranibizumab were favorable ($19,270/QALY vs laser in BRVO; $34,204/QALY vs dexamethasone intravitreal implant in CRVO). At a threshold of $50,000/QALY, probabilistic analyses suggested ranibizumab to be cost effective in 99.7% (BRVO) and 88.3% (CRVO) of simulations. **CONCLUSIONS:** In patients with ME secondary to BRVO or CRVO, ranibizumab is a cost-effective treatment alternative.

SENSORY SYSTEMS DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PSS21
EVALUATION OF HEALTH UTILITY IN PATIENTS WITH RETINAL VEIN OCCLUSION

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OBJECTIVES: Retinal vein occlusion (RVO) is the second most common vascular disorder of the retina, affecting approximately 28,000 new patients every year in Canada, but little is known about their health utility. A Canadian Observational Utility Study was conducted to estimate utility values for RVO patients with different levels of visual acuity (VA). **METHODS:** A total of 202 participants with RVO, where 37% had CRVO and 63% had BRVO, were enrolled from 20 sites across Canada. Participantss had RVO in either their best-seeing eye (17%) or worse-seeing eye (83%). Spectacle corrected VA was measured and patient health utility was collected using the Health Utilities Index questionnaire (HUI3). VA was recorded as a fraction (Snellen Score) and the value of this fraction was expressed as logMAR. A linear regression model was used to predict utility values from logMAR in the affected eye adjusting for key clinical covariates (age, duration of disease, logMAR in fellow eye). The baseline characteristics of participants from randomized controlled clinical trials (BRAVO, CRUISE) were used to generate predicted health utilities relevant in the context of these studies. **RESULTS:** For the 202 participants (ages 39 to 92, median 72) the mean (SD) HUI utility value was 0.80 (0.20), ranging from 0.18 to 1 (n=169) and logMAR score was 0.62 (0.42), ranging from 0 to 1.60 (n=202). The correlation between VA and utility was significant (r = -0.21, p=0.004, n=169) and the regression model indicated that a one unit increase in logMAR score was associated with 0.085 unit decrease in utility. Based on the regression model, HUI-based utilities decrease from 0.87 (logMAR -0.15) to 0.74 (logMAR 1.45) for typical patients in the randomized studies (mean age=67, logMAR fellow eye=0.09, disease duration=3.4 months). **CONCLUSIONS:** RVO is a debilitating ophthalmologic condition leading to reduced health utility with worsening of visual acuity.

PSS22
IMPACT OF PATIENT SATISFACTION ON HEALTH RELATED QUALITY OF LIFE, IN PSORIASIS PATIENTS RECEIVING TRADITIONAL SYSTEMIC THERAPY

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OBJECTIVES: Despite well-documented safety and tolerability issues associated with traditional systemic therapies, many moderate and severe psoriasis patients remain on these therapies. This analysis aims to assess levels of satisfaction and quality of life in a biologic-eligible patient population currently receiving traditional systemic therapy. **METHODS:** Data were extracted from the Adelphi Real World Psoriasis Disease-Specific Programme® (DSP), a cross-sectional survey of dermatologists and their patients conducted in early 2011 in France, Germany, Italy, Spain and the UK. Each dermatologist completed a comprehensive patient record form (PRF) for their seven most recently seen psoriasis patients who met the inclusion criteria. Patients were also invited to fill out a self-completion questionnaire, which included questions on satisfaction with treatment and various validated Health Related Quality of Life (HRQoL) instruments (EQ5D and DLQI). Patients inclusion criteria were based on being eligible to receive biologic therapy; defined by Body Surface Area ever exceeding 10%, ever having moderate or severe disease (in the opinion of the physician), or ever having received a traditional systemic or biologic treatment. **RESULTS:** Patient reported satisfaction levels show 58.7% (n=261) satisfied (SAT) and 41.3% (n=184) dissatisfied (DIS) with current systemic treatment. Analyses also suggested lower QoL amongst dissatisfied patients (all reported figures have P-values <0.01; mean differences (MD) shown account for confounding factors; age, severity and BSA). EQ-5D and DLQI scores indicated poorer QoL amongst dissatisfied systemic patients, SAT 0.841 v DIS 0.672 (MD 0.124) and SAT 5.14 v DIS 9.68 (MD 3.25), respectively. **CONCLUSIONS:** The analysis conducted indicates that a number of patients remain dissatisfied with systemic treatment. This dissatisfaction is associated with lower QoL, measured by both generic and disease specific instruments. There is scope for additional investigation to determine if alternate treatment pathways could improve both treatment satisfaction and QoL for this patient group.

PSS23
PATIENT BURDEN ASSOCIATED WITH LACK OF TREATMENT SATISFACTION AMONGST PSORIASIS PATIENTS RECEIVING TRADITIONAL SYSTEMIC THERAPIES

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OBJECTIVES: Despite well-documented safety and tolerability issues associated with traditional systemic therapies, there remain barriers to biologic uptake in many moderate and severe psoriasis patients. This analysis assesses the level of treatment satisfaction with patient burden, namely work/activity impairment and emotional wellbeing, in 445 patients currently receiving traditional systemic therapy who are eligible for, but not receiving, biologic therapy. **METHODS:** Data were extracted from the Adelphi Real World Psoriasis Disease-Specific Programme®, a cross-sectional survey of 292 dermatologists and their patients conducted in early 2011 in France, Germany, Italy, Spain and the UK. Each dermatologist completed patient record forms for their seven most recently seen patients. Patients were invited to complete a questionnaire, including questions on satisfaction and validated instruments WPAI (Work Productivity and Activity Impairment) & PHQ9 (personal health questionnaire). Patient inclusion criteria were based on being eligible to receive biologic therapy defined by: Body Surface Area ever exceeding 10%, ever having moderate or severe disease (physician assessment), or ever having received a traditional systemic or biologic treatment. **RESULTS:** Patient reported satisfaction levels show 58.7% (n=261) satisfied (SAT) and 41.3% (n=184) dissatisfied (DIS) with current treatment. Results from the WPAI questionnaire (n=177) implied worse average results for those dissatisfied with current treatment, DIS 30.40 v SAT 17.12 (Mean Difference (MD) -10.53). PHQ9 (n=442) also found worse outcomes for dissatisfied patients; SAT 3.57 v DIS 6.01 (MD -1.94). All reported figures have P-values <0.05; MD incorporate confounding factors; age, severity and BSA. **CONCLUSIONS:** This analysis provides insight into the divergence in burden of disease amongst psoriasis patients, with patients dissatisfied with current systematic regimen suffering greater implied levels of burden than satisfied patients. There is scope to develop this further to better understand the implications of treatment dissatisfaction in this population.

PSS24
HOW DO GLAUCOMA PATIENTS ASSESS DIFFERENT ASPECTS OF THEIR TREATMENT: AN ELICITATION OF PATIENTS' PREFERENCES USING THE ANALYTIC HIERARCHY PROCESS

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OBJECTIVES: Patient-relevant endpoints play an important role in Health Technology Assessment (HTA). There is a need to prioritize these endpoints according to patients' preferences. Our aim was to investigate how glaucoma patients prioritize different aspects of their treatment including patient-relevant endpoints. **METHODS:** The study included a feasibility test and the completion of a specific questionnaire at the ophthalmology clinic of Bonn. Patients rated the importance of different aspects of glaucoma treatment by a pairwise comparison. Relative weights were generated for each aspect by Analytic Hierarchy Process (AHP), a multi-criteria decision analysis method using matrix algebra. . Additionally the EQ-5D was applied to stratify the patients into subgroups according to their stated utility. **RESULTS:** The AHP yielded the following results (Weight, Mean, SD, CI) by downwards order: 1. Autonomy (0.394, 0.371 ± 0.145, 0.311 - 0.431), subdivided in household chores (0.239, 0.275 ± 0.258, 0.168 - 0.381) and outdoor mobility (0.761, 0.725 ± 0.258, 0.619 - 0.832). 2. Reading and seeing details (0.229, 0.212 ± 0.123, 0.161 - 0.263). 3. Darkness and glare (0.153, 0.165 ± 0.111, 0.119 - 0.211). 4. Peripheral vision (0.089, 0.085 ± 0.058, 0.061 - 0.109). 5. Side effects (0.088, 0.115 ± 0.131, 0.060 - 0.168), and 6. Treatment-related burden (0.047, 0.052 ± 0.06, 0.027 - 0.076). The observed inconsistency reached a consistency ratio of 0.04 and did not exceed the limit of 0.1. Subgroup analyses according to the EQ-5D stratification showed adaptation effects and loss aversion. **CONCLUSIONS:** AHP can be used in HTA to give a quantitative dimension to patients' preferences for treatment aspects. Preference elicitation could provide important information at various stages of HTA and challenge opinions on the importance of treatment aspects or endpoints.

PSS25
VALIDATION OF THE PATIENT BENEFIT INDEX (PBI) FOR THE ASSESSMENT OF PATIENT-DEFINED BENEFIT IN THE TREATMENT OF PSORIASIS

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OBJECTIVES: Empirical evidence for the efficacy of drugs and therapeutic procedures has become crucial for reimbursement and for use in praxis. Beyond that, assessment of patient benefit from the patient's perspective is of particular relevance. The PBI for skin diseases is a validated instrument developed to measure patient-relevant benefits in dermatology. So far, no specific validation data on such an instrument for psoriasis have been published. Objective of this study was the validation of PBI specifically for psoriasis treatment. **METHODS:** Patient-relevant treatment needs were recorded with the "Patient Needs Questionnaire" (PNQ) and patient benefits from treatment were assessed using the "Patient Benefit Question-

naire" (PBQ), both containing identical items with different wording. Data were obtained from two studies, one being a cross-sectional study on n=2,009 patients, the other a prospective observational therapeutic study on n=93 patients. Treatment goals and benefits were used to calculate the overall preference-based Patient Benefit Index (PBI). **RESULTS:** In both studies, the PNQ showed a variety of high therapeutic needs from the perspective of the psoriasis patients. The PBQ questionnaire revealed that under routine treatment only a part of the patient-defined goal were achieved. The resulting PBI depended on the treatment applied. Higher values were observed in systemic treatments, in particular in biologics. The PBI was feasible with a rate of missing values ≤1.5% in PNQ and ≤2.0% in PBQ. The subscales of the PBI were internally consistent (Cronbach's alpha = 0.68 – 0.87). The PBI showed satisfying convergent validity with respect to correlation with changes in QoL (delta DLQI) and PASI. Moreover, correlation with separate single items on treatment benefit (anchoring variables) was markedly high (r=0.75, r=0.65, p<0.001). **CONCLUSIONS:** The Patient Benefit Index (PBI) is a valid, reliable and suitable instrument for the assessment of patient-reported benefit in the treatment of psoriasis.

PSS26

NAIL ASSESSMENT IN PSORIASIS AND PSORIATIC ARTHRITIS (NAPPA): AN INTEGRATED APPROACH OF OUTCOMES MEASUREMENT IN NAIL PSORIASIS

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OBJECTIVES: Although there are a range of established outcomes measures for psoriasis in general, there has been a lack of valid instruments for nail psoriasis (NPso). Therefore, we developed and validated the three-component tool "Nail Assessment in Psoriasis and Psoriatic Arthritis" (NAPPA) including health-related quality of life (NAPPA-QoL), patient-relevant treatment benefit (NAPPA-PBI) and clinical severity (NAPPA-CLIN). **METHODS:** The NAPPA tool was developed by a multinational expert group involving dermatologists, psychologists, statisticians, and patients. Development included the following steps: 1) Open item collection on patient-relevant impairments and needs in n=120 patients in 2 countries (D, USA); 2) item development by an expert panel including patients; 3) double forward and backward translations with subsequent translators' and developers' conferences; 4) feasibility testing of the pilot questionnaire in n=55 patients in 4 countries (D, USA, Canada, UK) with subsequent questionnaire refinement; 5) longitudinal feasibility and validation study in n=203 patients from 6 countries (Germany, USA, Denmark, Japan, Italy, Spain). **RESULTS:** Open item collection generated 692 single items with redundant content which could be condensed to 20 items for the NAPPA-QoL and 24 items for the NAPPA-PBI. Most patients rated the final questionnaires as feasible, i.e. the purpose was clear to them (95.0%), instructions and questions were comprehensible (83.6% / 89.1%), and all relevant areas were covered (87.1%). NAPPA-QoL and -PBI correlated moderately with clinical outcomes (PASI, NAPSI) but markedly with other QoL questionnaires (EQ-5D, DLQI). Sensitivity to change and internal consistency were good. Clinical severity (NAPPA-CLIN) was measured with a two-digit solution which correlated highly (r>0.9) with NAPSI but which can be assessed much more time-efficiently. **CONCLUSIONS:** With the modular NAPPA outcomes tool, clinical and patient-reported outcomes in nail psoriasis can be measured validly and reliably. Thus, it can be recommended for usage in international clinical studies and daily practice.

PSS27

DO SCARS IMPACT BEYOND JUST APPEARANCE? A REPORT OF THE CONTENT ELICITATION (CE) PHASE IN THE DEVELOPMENT OF THE PATIENT REPORTED SCAR EVALUATION QUESIONNAIRE (PR-SEQ)

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OBJECTIVES: Currently available scar assessment tools focus on the appearance and symptoms of scars but avoid the complete scar experience. Additionally, existing instruments lack evidence or documentation (or both) of their development (e.g., content validity) and performance (e.g., reliability, construct-related validity, and responsiveness), and it is unlikely they would meet current regulatory requirements for labeling. The objective of the present work was to conduct qualitative research with patients to better understand scar appearance, symptoms, and impacts, and to use those results to inform the development of a content-valid PRO instrument for use in clinical trials. **METHODS:** Eight physicians (3 dermatologists and 5 plastic surgeons) recruited subjects to participate in the CE research activities. Each subject (aged 18 to 65) was required to have a linear surgical (cosmetic or non-cosmetic) scar below the neck. Subjects with burn scars were excluded as were subjects with significant medical comorbidities. The interviews were conducted in multiple cities in the United States, transcribed, and used to derive the scar questionnaire items. **RESULTS:** A total of 43 interviews across five surgery types were conducted to elicit information regarding their experiences with their disfiguring scar. During the CE interviews, the most important and relevant concepts patients used to describe scar appearance were color, size (height, width, thickness), and texture. The most important and relevant scar symptom concepts reported were itchiness and pain. The most important, relevant, and bothersome scar impact concepts were limitations of wearing certain clothing and feeling self-conscious, sad, and less attractive because of the scar. **CONCLUSIONS:** The CE interviews provided rich information about how patients perceive and experience their scars which extends beyond the typical appearance dimensions. This work is fundamental in providing the basis for the conceptual framework of the scar experience and the first steps in the development of the PR-SEQ.

PSS28

LONG-TERM IMPROVEMENT IN PATIENT-REPORTED OUTCOMES AFTER TRANSITION FROM METHOTREXATE TO USTEKINUMAB IN MODERATE TO SEVERE PSORIASIS: TRANSIT WEEK 52 RESULTS

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OBJECTIVES: We describe Week 52 quality of life outcomes following immediate or gradual transition to ustekinumab in psoriasis patients with inadequate response to methotrexate in the Phase IV TRANSIT study (NCT01059773). **METHODS:** In this 52-week, open-label trial, 490 patients with moderate-to-severe plaque psoriasis despite treatment with methotrexate (10–25mg/week for ≥8 weeks) were randomised 1:1 to ustekinumab with immediate cessation of methotrexate (Arm1), or 4 weeks' overlap with decreasing methotrexate dose (Arm2). Ustekinumab was administered according to label: 45mg in patients ≤100kg or 90mg if >100kg. Patients ≤100kg not achieving adequate response (Psoriasis Area Severity Index decrease from baseline ≥75% [PASI 75]) at Weeks 28 or 40 were dose escalated to 90mg. **RESULTS:** A total of 244 patients were treated in Arm1 and 245 in Arm2; 92% and 90%, respectively, completed 52 weeks' therapy. Median baseline Dermatology Life Quality Index (DLQI) was 8 and 9 in Arms1 and 2, respectively, decreasing to 1 (both arms) at Weeks 16 and 52. At Week 52 in Arms1 and 2, respectively, 61% and 62% of patients had a DLQI reduction ≥5 points; 62% and 67% had DLQI 0 or 1. Median DLQI scores were low at Week 28 among patients who dose escalated; further improvements were seen by Week 52. Median EuroQOL-5D Visual Analogue Scale improved from baseline to Week 52, respectively: 70.0 (IQR 50.0–80.0) to 85.0 (IQR 70.0–95.0) in Arm1, and 70.0 (IQR 50.0–85.0) to 85.0 (IQR 79.5–95.0) in Arm2. Median Hospital Anxiety and Depression Scale (HADS) Anxiety and Depression scores also improved from baseline to Week 52. **CONCLUSIONS:** In patients with moderate-to-severe psoriasis, ustekinumab use was associated with clinically relevant improvements in patient-reported outcomes, irrespective of whether patients were transitioned with immediate or gradual cessation of methotrexate. Improvements at Week 16 were sustained to 52 weeks of ustekinumab therapy.

PSS29

ASSESSING THE CLINICAL MEANINGFULNESS OF 1-LINE AVERAGE CHANGE IN VISUAL ACUITY AMONG PATIENTS WITH DIABETIC MACULAR EDEMA: EVIDENCE FROM HEALTH-RELATED QUALITY OF LIFE CHANGES

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OBJECTIVES: To investigate whether a 1-line (5 letters) average change in best corrected visual acuity (BCVA) is associated with changes in health-related quality of life (HRQoL) in patients with diabetic macular edema (DME). **METHODS:** Data from a 12-month randomized trial of dexamethasone intravitreal implant plus laser or laser alone for DME were analyzed. HRQoL was assessed by the National Eye Institute 25-Item Visual Function Questionnaire (VFQ-25). Patients were categorized into groups based on time-weighted average BCVA change from baseline: worsened (ΔBCVA ≤-5), no change (-5 <ΔBCVA<5) and improved (ΔBCVA≥5). Average change in VFQ-25 composite score and 11 subscales were compared using ANCOVA analysis controlling for baseline BCVA and VFQ-25 scores. Proportions of patients achieving ≥5-point improvement in VFQ-25 composite score and 4 subscales closely associated with central vision (general vision, near activities, distant activities, and mental health) were also compared. Similar analyses were conducted for subgroups of better-seeing eye (BSE) and worse-seeing eye (WSE) patients, respectively. **RESULTS:** A total of 252 (18.3% BSE and 81.7% WSE) patients had a mean VFQ-25 composite score of 69.1 at baseline. Compared to the no change BCVA group, the improved group had 3.2-6.7 points (p≤0.048) greater average changes in VFQ-25 composite score and 4 subscales (general vision, near activities, dependency, and driving); the corresponding differences were greater (10.2-18.3 points, p≤0.019) among BSE patients except in general vision. The worsened, no change, and improved BCVA groups showed a statistically different (p≤0.038) and increasing trend in achieving ≥5-point improvement in the 4 VFQ-25 subscales examined except in distant activities. **CONCLUSIONS:** Previous literature based on BSE visual acuity has defined minimally important differences in VFQ-25 score ranging from 3 to 5 points. The current study suggests a 1-line average improvement in BCVA was associated with clinically meaningful changes in HRQoL among DME patients.