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Mapi Values Session Overview on Workshops, Presentations and Posters



ISPOR 12th Annual European Congress
Health Care Decision Making in Europe: From Patients to Populations

24 - 27 October 2009
Le Palais des Congrès de Paris, Paris, France

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W11: Assessing Treatment Satisfaction During A Product's Lifecycle To Facilitate Market Access: Definitions, Frameworks, And Measurement

WORKSHOPS AND ISPOR CHAPTER FORUMS - SESSION II, 26 October 2009 between 16:30 and 17:30

Discussion leaders: Rofail D¹, Regnault A², Baladi JF³, Berdeaux G⁴

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PURPOSE: To show how the assessment of treatment satisfaction can demonstrate the 'added value' of a product from patients' perspectives by capitalising on product differentiation, providing a competitive edge, and ultimately facilitating market access and the product uptake of a pharmaceutical therapy.

DESCRIPTION: This workshop will consider reasons for conducting satisfaction studies and address conceptual issues related to treatment satisfaction including definition of the concept, and how satisfaction relates to expectations, preferences, and adherence to treatment regimens. The patients' experience will be emphasised and associated factors such as medication characteristics, convenience, and presence and impact of side effects. The theoretical models framing satisfaction will be presented with empirical evidence supporting them.

Implications on scientific research and clinical practice such as the choice of the assessment type (generic versus disease-specific or treatment-specific assessments), identification of appropriate time points to assess treatment satisfaction during a product's lifecycle, and designing studies (either as part of clinical trials or as independent cross-sectional or longitudinal studies), will be a focus of the discussion.

Case-studies from various application fields (e.g. iron chelation therapy, anticoagulant treatment, and glaucoma treatment) will illustrate the definitions, conceptual frameworks, and measurement issues related to treatment satisfaction. This will include aspects related to research aims, study designs, development and validation of treatment satisfaction instruments, implications for protocols and statistical analyses, as well as interpretation of results.

This will be an interactional workshop and participants' contributions will be encouraged throughout. This session is directed at individuals who design and conduct outcomes research, and those in charge of interpreting study results, but will provide a useful overview for those who analyse outcomes data to support communicating key messages to local and national key stakeholders.

W16: Assessing Patient Adherence For A Positive Change In Health Behaviour

WORKSHOPS AND ISPOR CHAPTER FORUMS - SESSION III, 27 October 2009 between 08:30 and 09:30

Discussion leaders: Dias Barbosa C¹, Abetz L², Cotté FE³, Arnould B¹

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PURPOSE: Discuss the added value of evaluating adherence to optimise patient management.

DESCRIPTION: Adherence is recognised as a primary determinant of the effectiveness of treatment; poor adherence has direct consequences such as disease complications, impact on patients' quality of life and increased use of healthcare resources. Social and economic impact of poor adherence can be great in chronic diseases. With increasing 'risk-sharing' requirements by local authorities and payers, adherence becomes an ever-more important issue for pharmaceutical industry. However, adherence is a complex and multifaceted concept that is challenging to understand, measure and improve. Accurate measurement of adherence is nevertheless necessary for efficient assessment of health care interventions and positive change in patient behaviour is critical for optimal management. This workshop is composed of four parts. The first part will define adherence, as opposed to other similar concepts, and will describe the behavioural mechanisms explaining adherence. The second part will demonstrate the social and economic impact of poor adherence and the benefits for pharmaceutical industry of improving adherence to treatment. Third, different methods for measuring adherence will be described and the consistency of these methods discussed. Finally, methods for improving patient adherence will be presented, including development of interactive tools to identify reasons for lack of adherence and physician patient educational material for use in clinical practice. Both aim to change patients' illness perception and behaviour. This workshop will address these different points using examples from the presenters' experiences and from the literature. In particular, the development of specific PRO tools for assessing or improving adherence will be presented and discussed. Participants (academics, policy makers, researchers from the pharmaceutical industry and healthcare programmes) will be invited to debate how to improve patient behaviour in order to optimise disease management.

W24: Post-Reimbursement Studies Assessing Good Medication Use In Real Practice: French Situation

WORKSHOPS AND ISPOR CHAPTER FORUMS - SESSION IV, 27 October 2009 between 14:45 and 15:45

Discussion leaders: Préaud E¹, Longin J², Tcherny S³, Woronoff-Lemsi MC

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PURPOSE: The purpose of this workshop is to present and discuss studies assessing compliance and real-life practice, focusing mainly on the way such studies should be conducted. Examples are based on studies requested by the French Transparency Committee following reimbursement decisions.

DESCRIPTION: French Haute Autorité de Santé (HAS) reimbursement decisions are increasingly completed by real-life data requests. Hundreds of requests have been addressed, focusing on outcomes like impact on the healthcare system, real-life tolerability, and especially real-life conditions for drug prescription and use in addition to real benefits to patients. These data on prescription and especially patients' experiences and compliance are essential to assess the true benefit provided by new pharmaceutical products. They are generally requested for reimbursement status re-evaluation, to complete information from clinical development programs with evidence from real practice. One of the main challenges in addressing these requests is how to collect valid and reliable information to reflect real-life practice and impact of a new drug. Key data sources are patients and physicians, but many discussions are currently underway regarding the best way to assess such outcomes. Despite the significant number of requests, HAS has issued no clear recommendations on how these studies should be conducted. Some studies use either existing studies or bibliographic references, while some pharmaceutical companies try to develop and conduct ad-hoc studies. The aim of this workshop is to propose a framework to provide relevant answers to HAS's real-life data requests. The starting point will be the analysis of existing studies provided to the HAS, thoroughly appraising the way they have been performed using leaders' expertise in patient-reported outcomes. Leaders will also discuss their experiences with two study protocols recently accepted by the HAS, in addition to the audience's own experiences.

EE4: Market Access In Germany: Where Next?

PODIUM SESSION II, 26 October 2009 between 14:00 and 15:00

Zoellner YF¹, Schaefer M²

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BACKGROUND: HTA has become the key tool to control market access for new technologies in Europe. This development has been mirrored in Germany through institutions such as DIMDI and, later, IQWiG at federal level, paralleled by similar tools at sickfund level. Furthermore, bilateral market access agreements appear to bloom.

OBJECTIVES: To explore the foundation and trends of future healthcare decision making in Germany. To formulate recommendations to manufacturers seeking market access for new technologies in Germany with respect to a number of key launch parameters.

METHODS: We reviewed the development of allocative decision making in Germany with particular attention to IQWiG (methods, international collaboration, decisions to date, impact). Furthermore, the role of other routes was examined (EVITA, rebate contracts, risk sharing).

RESULTS: IQWiG assessments have had a crucial impact on some products, eg clopidogrel and the fastacting insulin analogues, and other manufacturers can learn from these decisions. While IQWiG will most likely cooperate with NICE and HAS on a number of issues such as evidence synthesis, a harmonized set of methods, leave alone decisions, cannot be expected in the near future. The future significance of other access routes still needs to be determined.

CONCLUSIONS: Manufacturers must be prepared for IQWiG assessments to be used for pricing purposes. Evidence must stem from randomized controlled trials wherever possible. Cost-effectiveness analysis will remain a second step of the appraisal, to which a new technology will only be admitted after having overcome a standalone effectiveness assessment. Neither QALYs nor a cost per QALY threshold will be used for decision making. Germany will continue to grant high rewards to innovation, but careful thought must be given by manufacturers on how to present the added value of such innovations – be it via the IQWiG, a potential EVITA, or a direct contracting route.

MO5: The Use Of Survival Analyses For Cost-Effectiveness Models: An Evaluation Of Methods Used In NICE Appraisals

PODIUM SESSION III, 26 October 2009 between 15:15 and 16:15

Guyot P¹, Ouwens M²

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OBJECTIVE: In the area of oncology and cardiovascular disease, treatments often affect overall survival, progression, free survival and other time-to-event outcomes. For such treatments, the evaluation of cost-effectiveness often implies an extrapolation of trial results to periods beyond the trial length. The choice of extrapolation function may have a substantial impact on the mean survival: in some of our projects, the mean survival using the log-normal and log-logistic distribution was more than 1.5 times larger than the mean survival using the Weibull distribution. This triggered us to perform an evaluation of methods used for extrapolation in NICE submissions, in order to know which methods were accepted.

METHODS: CEAs published between 2004 and 2008 by the NICE Technology Appraisal programme, which included failure-time outcome(s), were systematically reviewed with respect to curve fitting procedures used for extrapolation.

RESULTS: In the HTA reports, exponential, Weibull, log-logistic or log-normal curves were fitted. The distribution was chosen based on face-value, by comparing it with the Kaplan-Meier Curve. The quality of the graphical methods is limited, especially because the three curves often have a comparable fit. In the reports, the proportional hazard assumption was used to compare the treatment arm with the comparator arm, often without assessing the validity of the assumption.

CONCLUSION: The choice of methods used to extrapolate survival curves in HTA reports has been inadequately justified, and has underestimated uncertainty. In our opinion, researchers should: assess the validity of proportional hazards and use different methodology when the assumption is violated; evaluate goodness-of-fit more appropriately. Consider using a generalized distribution, for which the Weibull, log-logistic and log-normal are special cases.

PR3: Fibromyalgia Fatigue – Development Of A Conceptual Model Based On Qualitative Patient Interviews

PODIUM SESSION III, 26 October 2009 between 15:15 and 16:15

Mease P¹, Humphrey L², Arbuckle R², Williams DA³, Danneskiold-Samsøe B⁴, Gilbert C⁵

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OBJECTIVE: Although fatigue is increasingly recognized as an important symptom in fibromyalgia (FM), qualitative evidence regarding how patients describe this and the impact it has on their daily lives is limited. We conducted qualitative research to better understand what individuals with FM mean by 'fatigue', assessed the impact it had on their lives, and developed a conceptual model to represent these findings.

METHODS: Open-ended, qualitative interviews were conducted with 40 FM patients (US (n=20), Germany (n=10) and France (n=10)) using open-ended questions and creative tasks to elicit unbiased information about FM and FM fatigue. Transcripts were analysed using qualitative methods based on grounded theory.

RESULTS: Participants were 70% female; mean age 48.7 years (range 25 - 79) with a range of education levels. Thirty-one (77.5%) spontaneously described experiencing fatigue/tiredness/lack of energy due to FM. The conceptual model developed depicts key elements of FM fatigue from a patient perspective, which was discussed as being more severe than normal tiredness, constant/persistent and unpredictable. In the model it is defined as: an overwhelming feeling of tiredness (n=17, 42.5%), not relieved by resting/sleeping (n=14, 35%), not proportional to effort exerted (n=25, 62.5%), associated with a heavy feeling in their body (n=16, 40%) or a weak feeling in their muscles (n=9, 22.5%), makes it difficult to motivate themselves to do things (n=23, 57.5%), affects things they want to do (n=27, 67.5%), or makes tasks take longer to do (n=15, 37.5%), and makes it difficult to concentrate (n=21, 52.5%), think clearly (n=12, 30%) or remember things (n=9, 22.5%).

CONCLUSIONS: The majority of individuals with FM experience fatigue and describe how it is more severe than normal tiredness. The qualitative data supported development of a conceptual model of key elements of FM fatigue from the patient perspective which will be used to construct an FM specific fatigue measure

PCN01: Cost-Effectiveness Of Short-Acting Opioids For Breakthrough Pain In Cancer Patients, A Scottish-Based Decision-Analysis Model

POSTER SESSION I, 25 October 2009 between 12:00 and 19:30

Visser D¹, Stam W¹, Tolley K², Sendersky V³, Jansen JP⁴

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OBJECTIVE: A decision-analysis model parameterised for Scotland was used to evaluate the cost-effectiveness of intranasal fentanyl spray (INFS, Instanyl®) compared with oral transmucosal fentanyl citrate lozenge (OTFC, Actiq®) and oral transmucosal fentanyl buccal tablet (FBT, Effentora®) for the treatment of BTCP.

METHODS: The model estimated costs and benefits associated with INFS, OTFC and FBT. Relative analgesic efficacy of the interventions was derived from a meta-analysis of six randomised controlled trials. The percentage of BTCP avoided was estimated from the pain intensity (PI) course of a BTCP episode with and without treatment. Resource use and quality of life gains were estimated based on reductions in PI. The relationship between PI and utility was derived from a time-trade off study in the UK general population. Resource use and unit cost data were obtained from the literature and validated by clinical experts. Uncertainty in the source data was incorporated by means of one-way sensitivity analyses, probabilistic sensitivity analyses and different scenario analyses.

RESULTS: For the base-case scenario, 3 BTCP episodes/day, a background PI of 2, a time-horizon of 365 days and equal prices for INFS and OTFC irrespective of dosage were assumed. With INFS, 55% of BTCP (95% Uncertainty Interval: 45–66%) was avoided, greater than expected with OTFC (29%; 21–39%) or FBT (31%; 25–39%). INFS was dominant versus OTFC and cost-effective versus FBT. Despite the uncertainty in the source data, there is a >99% probability that INFS is the most cost-effective intervention. Sensitivity and scenario analyses did not change the main conclusion.

CONCLUSION: Greater efficacy of INFS in pain reduction is expected to reduce medical resource use and result in cost-savings for healthcare providers and quality of life gains for patients. INFS is a cost-effective treatment for BTCP compared with OTFC and FBT in Scotland.

PCN137: Oncology Patient-Reported Claims: Maximising The Chance For Success

POSTER SESSION I, 25 October 2009 between 12:00 and 19:30

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OBJECTIVES: To review PRO labelling claims achieved in oncology in Europe and in the US, and consider the benefits and challenges faced.

METHODS: PROLabels database was searched to identify oncology products with PRO labelling approved in Europe since 1995 or in the US since 1998. FDA and EMEA websites and guidance documents were reviewed. PubMed was searched for articles on PRO claims in oncology.

RESULTS: Among all oncology products approved, 19 were identified with PRO claims; nine in the US, five in Europe and five in both. The language used in the labelling was limited to benefit (eg '...resulted in symptom benefits by significantly prolonging time to deterioration in cough, dyspnoea, and pain, versus placebo') and equivalence (e.g. 'no statistical differences were observed between treatment groups for global QOL'). Seven products used a validated HRQL tool; two used symptom tools; two used both; seven used single-item symptom measures (one was unknown). The following emerged as likely reasons for success: ensuring systematic PRO data collection; clear rationale for pre-specified endpoints; adequately powered trials to detect differences and clinically significant changes; adjusting for multiplicity; developing an a priori statistical analysis plan including primary and subgroup analyses, dealing with missing data, pooling multiple-site data; establishing clinical versus statistical significance; interpreting failure to detect change. End-stage patient drop-out rates and cessation of trials due to exceptional therapeutic benefit pose significant challenges to demonstrating treatment PRO improvement.

CONCLUSIONS: PRO labelling claims demonstrate treatment impact and the trade-off between efficacy and side effects ultimately facilitating product differentiation. Reliable and valid instruments specific to the desired language, claim, and target population are required. Practical considerations include rationale for study endpoints, transparency in assumptions, and attention to subtle variations in data.

PCN140: Impact Of Tumor Response On Health-Related Quality Of Life (HRQOL) In Newly Diagnosed Multiple Myeloma Patients Treated With Velcade/Melphalan/Prednisone (V-Mp): Results From The Vista Trial

POSTER SESSION I, 25 October 2009 between 12:00 and 19:30

Meunier J¹, Regnault A¹, Robinson D², Rosa K³, San Miguel JF⁴, van de Velde H⁵, Richardson PG⁶, Cakana A⁵, Dhawan R⁷

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OBJECTIVES: To describe the impact of best tumor response to therapy (Complete Response [CR], Partial Response [PR], and Minimal Response [MR]) on HRQoL using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 scores.

METHODS: The VISTA trial was a randomized, open-label, multicentre study designed to compare the efficacy and safety of V-MP to melphalan/prednisone (MP) in subjects with previously untreated multiple myeloma. Patients were followed over a 9 cycle period (54 weeks) and for a post-treatment follow-up phase. Response to therapy was defined according to the European group for Blood and Marrow Transplant criteria. The EORTC QLQ-C30, a HRQoL questionnaire commonly used in multiple myeloma, was administered at screening, day 1 of each cycle and every 8 weeks until progression during follow-up. Change in HRQoL scores from best response were analyzed by response (CR, MR or PR).

RESULTS: By 3 cycles after best response, CR patients of the V-MP arm experienced an average, clinically relevant (5 point or more; Dubois et al, JCO 2006; 24:976-82) improvement in 'Physical Functioning' (n = 63); this benefit was delayed for PR patients and rarely occurred for MR patients. A similar pattern was found for 'Pain'; for CR patients the mean, clinically relevant improvement was reached after 3 cycles in the VMP arm (n=62). At 4 cycles after CR onset, the improvement in all the EORTC QLQ-C30 scores in the V-MP arm (n=53-55) except 'Cognitive Functioning', 'Diarrhea' and 'Financial problems', was greater than 5 points.

CONCLUSIONS: Overall, CR produced improvement in patient-reported HRQoL but gains were also observed with PR. MR was infrequently and inconsistently associated with HRQoL benefits. These results could not be reliably replicated in the MP arm because of the few patients in the CR group. Also results were limited by the short follow-up period after achieving best response.

PRS34: Item Selection And Scoring Definition Of A Disease-Specific Instrument To Assess The Handicap In Chronic Obstructive Pulmonary Disease (COPD) Patients, For Use In Clinical Routine Practice

POSTER SESSION I, 25 October 2009 between 12:00 and 19:30

Regnault A¹, Mueser Ruphin M², Dias-Barbosa C¹, Aguilaniu B³, Bonnefoy M⁴, Gonzalez-Bermejo J⁵, Granet G⁶, Similowski T⁵, Arnould B¹

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OBJECTIVES: To finalise and establish the scoring algorithm of the 12-item 'COPD and activities of daily living (ADL)' questionnaire, a tool specifically developed to help in the detection of handicap in COPD patients and determine the handicap level, thus optimising COPD management in the primary care setting.

METHODS: The 'COPD and ADL' questionnaire was developed and tested with patients and clinicians. It was included for finalisation and validation in a multi-centre, cross-sectional, observational study involving 100 French lung specialists. Patients with COPD stage II to IV according to the GOLD classification were included. Finalisation of the questionnaire included: assessment of the quality of completion, verification of the unidimensionality hypothesis using principal component analysis (PCA) and Rasch modelling (Partial Credit Model).

RESULTS: Sixty lung specialists each included at least one patient. Two hundred and eighty-two COPD patients were included, of whom 272 (96%) returned the 'COPD and ADL' questionnaire. The quality of completion was very good (91% of questionnaires with no missing data), confirming the good acceptability of the items. In the PCA, the first factor explained 58% of the total variance, confirming the a priori unidimensionality hypothesis. The items 'Impact of COPD on sexual life' and 'Overall perception of handicap due to COPD' were considered for deletion from the score because they had high residual values in the Rasch analysis. After reduction to a 10-item score, the fit of the Rasch model was acceptable (2=27.452; p=0.599).

CONCLUSIONS: The 'COPD and ADL' questionnaire is a short instrument assessing the handicap level among COPD patients, specifically designed as a clinical tool to contribute to patient management. The next step will be the validation of this instrument, including the assessment of its relationships with other measures of health impairment in COPD patients.

PIH30: Symptoms And Impact Of Premenstrual Dysphoric Disorder (PMDD): Concepts And Measurement

POSTER SESSION I, 25 October 2009 between 12:00 and 19:30

Rofail D¹, Abetz L¹, Lindemann M², Filonenko A², Colligs A², Endicott J³

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OBJECTIVES: To investigate the symptoms and impact associated with premenstrual dysphoric disorder (PMDD), and the appropriateness of the patient-reported Daily Record of Severity of Problems (DRSP) as an instrument to assess PMDD.

METHODS: A review of 47 published peer-review articles and conference presentations was conducted to aid the development of a PMDD conceptual model. The content of the DRSP was then compared to the conceptual model to assess face and content validity. The DRSP's reliability and responsiveness was also assessed.

RESULTS: Studies showed women with PMDD experience severe physical and emotional symptoms at the luteal stage of the menstrual cycle (five days before menses), primarily as a result of hormonal fluctuations associated with ovulation. Physical symptoms include: aches/pains; breast tenderness/swelling; bloating; weight gain; increased appetite/cravings; sleep problems; fatigue and difficulties concentrating. Emotional symptoms include: mood swings; depressed mood; anxiety/tension; anger; irritability; decreased interest; and feelings of being overwhelmed. The experience of these symptoms contributes to functional impairment in women with PMDD, particularly in terms of: social functioning; work/school functioning; productivity; role functioning; relationships; and activities of daily living. A review of DRSP item content revealed all symptoms and impacts of PMDD are captured by the DRSP, supporting the face and content validity of the instrument. Studies also showed the DRSP to have acceptable internal consistency (Chronbach's alpha 0.7), test-retest reliability (ICC correlations 0.67-0.99) and responsiveness to improvements following treatment (effect sizes 0.64-1.71).

CONCLUSIONS: PMDD is associated with physical and emotional symptoms which can have a significant impact on patients' lives. The DRSP is a valid, reliable and responsive patient-reported tool for assessing PMDD-related symptoms and their impact. The DRSP could be useful for clinicians during general practice, or for clinical trials in identifying PMDD populations or the impact during treatment.

PSY45: Development Of A Questionnaire To Evaluate Treatment Satisfaction Of Patients With Severe Crohn's Disease: Qualitative Steps

POSTER SESSION II, 26 October 2009 between 08:00 and 19:00

Arnould B¹, Marrel A¹, Marant C¹, Spizak C¹, Colombel JF², Hagege H³, Faure P⁴, Lemann M⁵, Nahon S⁶, Tucac G⁷, Vandromme L⁸, Thibout E⁹, Goldfarb G⁹

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OBJECTIVES: Severe Crohn's disease management includes anti-Tumour Necrosis Factor (anti-TNF) drugs. These drugs differ from the treatments used in early stages of the disease in terms of efficacy, safety and convenience. This can modify the impact of the disease and its treatment on patients' lives. The objective of the study was to develop a questionnaire assessing patients' satisfaction with anti-TNF treatments in Crohn's disease.

METHODS: A literature review, 3 clinician interviews and 3 interviews with nurses were carried out as a preparation step. Semi-directive patient interviews (16) were then conducted using a specific interview guide. Transcripts were analysed using thematic analysis to extract concepts related to satisfaction with treatments and to organise them into a model. Items were generated for each concept of interest using patients' words. The resulting test version of the questionnaire was tested for relevance and comprehension with 7 patients and revised accordingly; the new version was tested on a second set of 5 patients and revised to provide the pilot version. A clinician advisory board was involved at each milestone of the questionnaire development for validation.

RESULTS: The test questionnaire assessed treatment satisfaction through 49 questions and 67 items, organised into 5 sections: treatment efficacy, side-effects, convenience and constraints, global impact, and satisfaction. Conceptual content of the questionnaire includes comparison to prior state and to expectations, satisfaction, acceptability, and intentions. The questionnaire was globally well-accepted by patients during the tests; few modifications were made in the structure and some items were reformulated. The pilot version (62 items) was finalised after the second round of comprehension tests.

CONCLUSIONS: The questionnaire is a unique tool to assess treatment satisfaction in patients with severe Crohn's disease treated by anti-TNF. A scoring and validation study is currently being completed before the questionnaire can be included in clinical research and epidemiological studies.

PCV143: Exploring Patients' Satisfaction With Anticoagulant Treatment By Applying Structural Equation Models To The Perception Of Anticoagulant Treatment Questionnaire (PACT-Q)

POSTER SESSION II, 26 October 2009 between 08:00 and 19:00

Regnault A¹, Gilet H¹, Carita P², Arnould B¹

¹Mapi Values France, Lyon, France; ²Sanofi Aventis R&D, Paris, France

OBJECTIVES: To explore the process of patients' satisfaction with anticoagulant treatment using Structural Equation Modeling (SEM).

METHODS: The Perception of AntiCoagulant Treatment Questionnaire (PACT-Q) includes 2 modules: a 7-item module assessing patient expectations of anticoagulant treatment and a 20-item module assessing treatment convenience and patient satisfaction. It was completed by deep venous thrombosis, atrial fibrillation and pulmonary embolism patients in 3 clinical trials assessing anticoagulant treatments. The first module was administered at baseline (BL) and the second after 3 (M3) and 6 months (M6). SEM was applied to pooled data from the three trials. SEM specifications were supported by the questionnaire conceptual model, satisfaction theory and the scoring rules of the instrument. The goodness of fit of the models was assessed using a set of commonly used fit indices including the Root Mean Square of Approximation (RMSEA). Association between latent variables was assessed using Standardized Path Coefficients (SPC).

RESULTS: A total of 986 patients had fully completed PACT-Q at BL, M3 and M6. PACT-Q items allowed good measurement of Convenience (RMSEA=0.054) and Satisfaction (RMSEA=0.028) at M3. The 7 expectation items were kept independent. An overall model involving two expectation items (expectations of symptom relief, worries about making mistakes) and both Satisfaction and Convenience at M3 and M6 was estimated (RMSEA=0.032). In this final model, Convenience had a stronger impact on Satisfaction at M3 than at M6 (respective SPC: 0.57 vs 0.48). Convenience at M6 was very strongly related with Convenience at M3 (SPC: 0.80) while the relationship between Satisfaction at M3 and M6 was weaker (SPC: 0.52).

CONCLUSIONS: The application of SEM to the PACT-Q data allowed the prominent role of patients' expectations and perception of treatment convenience in the process of anticoagulant treatment satisfaction to be highlighted. Convenience was also shown to be more stable over time than satisfaction.

PIN68: Psychometric Evaluation Of The Functional Assessment Of HIV Infection (FAHI) Questionnaire In Two Clinical Programmes

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: To evaluate the psychometric properties of the Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) questionnaire, a 47-item disease-specific instrument evaluating Health-Related Quality of Life (HRQL) in Human Immunodeficiency Virus (HIV) patients, and show its usefulness for the evaluation of new antiretroviral therapy.

METHODS: Treatment-experienced HIV patients included in two independent clinical programmes completed the self-administered FAHI questionnaire at Baseline and after 24 weeks of treatment. The FAHI questionnaire includes five scales (physical well-being, emotional well-being, functional and global well-being, social well-being, cognitive functioning) and a total score, with higher scores indicating better HRQL. Psychometric properties of the FAHI questionnaire were assessed independently in both trial populations (N=565, 1096). A range of minimal important differences (MID) was provided using anchor-based and distribution based methods. The link between HRQL and biological endpoints was explored by regression analysis.

RESULTS: Internal consistency reliability was good, with Cronbach's alphas ranging from 0.72 to 0.94. Most items met both convergent and discriminant validity criteria, demonstrating good construct validity of the scores. Clinical validity was demonstrated by better FAHI scores, indicating better HRQL for patients in earlier HIV stages. Changes in scores were significantly linked to the change in EQ-5D score, demonstrating their responsiveness. MID ranged from 3.2 to 14 for the FAHI Total score. Regression analyses between the FAHI Total score and CD4 cell count and viral load showed poor relationships between HRQL and biological parameters (square<3%).

CONCLUSIONS: The FAHI questionnaire demonstrated robust psychometric properties in two independent clinical trial populations. The assessment of HRQL enabled the detection of changes in patients' health status not revealed by traditional clinical parameters of efficacy.

PIN70: Perception And Acceptance Of Intradermal Influenza Vaccine Measured By The Vaccinee's Perception Of Injection (VAPI©) Questionnaire

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: During the clinical development of a new intradermal influenza vaccine given using a microinjection system, in parallel with the conventional evaluation of vaccine reactogenicity, perception and acceptability of injection site reactions (ISRs) were assessed using the VAPI[®] self-administered questionnaire developed and validated as previously described (Chevat et al, Health and Quality of Life Outcomes 2009, 7:21).

METHODS: The questionnaire was specifically developed and validated according to recommended methods to assess vaccinees' perception of ISR. It was completed 21 days after intradermal or intramuscular vaccination by elderly and non-elderly participants in two European, randomised, controlled, phase III trials. It was divided into 4 dimensions: 'bother' (6 items), 'arm movement' (4 items), 'sleep' (4 items), 'acceptability' (2 items), and 5 individual items: anxiety before and after vaccination, bother by pain during injection, satisfaction with injection system and willingness to be vaccinated again. Scores range from 1 to 5 (1 being the most favourable opinion).

RESULTS: Of the 5562 trial participants, 5305 returned the questionnaire with at least one item completed. Mean scores were low (≤ 1.68 in non-elderly, ≤ 1.48 in elderly) in both vaccine groups, indicating that ISR did not bother participants or affect their sleep or arm movement (at least 75% were not at all affected). In the ID group, among those who answered the questions, 96% of non-elderly and 97% of elderly participants considered ISRs caused by vaccination as being 'totally' or 'very' acceptable; 96% of both non-elderly and elderly participants were 'very satisfied' or 'satisfied' with the injection system; and 85% of non-elderly and 89% of elderly participants wanted to be vaccinated again.

CONCLUSIONS: ISRs were well accepted by participants, and were generally not a cause for concern. The level of satisfaction of the participants with the injection system was high, as was the willingness to be vaccinated again.

PMS69: Item Reduction And Validation Of A New Adherence Questionnaire In Osteoporotic Postmenopausal Women: The Adherence Evaluation Of Osteoporosis Treatment (ADEOS) Questionnaire

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: To reduce and validate the ADEOS questionnaire, an instrument specifically developed to evaluate treatment adherence by women with post- menopausal osteoporosis

METHODS: The ADEOS questionnaire has been developed with clinicians and patients. Before item reduction, it included 45 items covering 5 distinct themes related to adherence (personal characteristics, beliefs, perceptions, behaviour and information received). It was included for finalisation and validation in a cross sectional observational study in French general practitioners. The study sample was randomly divided into 2 subsamples: one for item selection, one for validation. The item selection procedure was performed according to the association of the items with a generic measure of compliance, the Morisky Medication Adherence Scale (MMAS). The validity of the score derived from these items was scrutinised by assessing its correlation with MMAS score. Its ability to separate compliant patients from non-compliant patients according to MMAS was studied using area under receiver-operating characteristic curve (AUC).

RESULTS: Five hundred and sixty osteoporotic women were included, of whom 348 (62%) returned the ADEOS questionnaire. Patients who did not return the questionnaire were comparable to those who did in terms of demographics and medical parameters. The questionnaire quality of completion was very good, confirming its good acceptability. Twelve items of the questionnaire showed a statistically significant relationship ($p < 0.05$) with the MMAS in the 'item selection sample' (N=200) and were retained to derive the ADEOS score. In the 'validation sample' (N=148), the ADEOS score was noticeably correlated with MMAS score (Spearman correlation coefficient: 0.58) and showed good discriminant validity according to MMAS (AUC: 0.84).

CONCLUSIONS: The 12-item ADEOS questionnaire is a short validated instrument specific to osteoporosis, whose score can easily be calculated by hand. Therefore, it might be particularly useful in daily practice to detect patients at risk of being poorly adherent to their osteoporosis treatment.

PMS70: Use Of Qualitative Research To Elicit Patient-Reported Outcome Approaches In Osteoporosis

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: Recent anti-osteoporotic treatments are characterised by monthly or even yearly administration. These treatments may challenge the prescription of daily-administered drugs. The objective of this qualitative research was to explore patients' perception as well as clinicians' views on the frequency of anti-osteoporotic treatment administration.

METHODS: A health psychologist carried out face-to-face interviews with six patients treated on a daily basis and six patients treated with a monthly-administered drug. The patients' perception, behaviour and expectations regarding anti osteoporotic treatment were assessed. Clinicians who recruited the patients, comprising a general practitioner and specialists, were also interviewed. Information on factors driving their treatment choice decision and on the importance of patients' feedback and perception in their decision was collected.

RESULTS: Patients perceived osteoporosis as a sign of premature ageing and a disease of secondary importance. They reported that a daily administration was not a problem per se if it did not modify their lifestyle. They raised concerns about lower frequency of drug administration that clinicians did not: the difficulty of remembering to take the treatment; the worry about the treatment being too concentrated, with the thought of a possible irregular efficacy of the drug over the time and a harmful effect. They did not feel involved in the choice of treatment. Clinicians believed monthly administration to be more convenient than daily administration. They declared choosing the treatment according to the patient's characteristics, in particular concomitant diseases, lifestyle, and dosing preference.

CONCLUSIONS: Discrepancies exist between clinicians' perception and reality for patients regarding anti-osteoporotic treatment. Consequently, possible patient-reported outcomes approaches to improve treatment decision would consist in 1) educating patients on osteoporosis, and clinicians on their patients' perception and expectations, and 2) promoting shared decision-making. This is likely to contribute to a better persistence of the patients with regard to their treatment.

PMC10: How To Make Use Of Available Survival Evidence In An Indirect Comparison

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: Therapies for oncology often affect time-to-event statistics like overall survival and progression-free survival. In the literature, these time-to-event statistics are summarized by median time-to-event, percentage of people having had the event at a specific point in time and hazard rates, among others. Although pooling based on individual patient data would be preferred, we still encounter situations where only aggregated data are available. For these situations, the hazard ratios can be pooled. However, many high quality papers would be ignored, if publications were only regarded once the hazard ratio is presented. We therefore searched for methods to transform the different outcomes to the same scale and to pool based on as much information as possible.

METHODS: A review was performed with respect to the pooling of different time-to-event outcomes. Mixed Treatment Comparisons were performed using the methods to assess their usability.

RESULTS: For cost-effectiveness models, a distribution (exponential, Weibull, among others) of the time-to-event statistic is often used to obtain the average of the time-to-event statistic for the comparator arm. This distribution can also be used to transform the median and the 'percentage having had an event at a specific time point' into hazard rates. Comparing the transformed medians with the hazard rates for publications in which both are presented implied a way to check the validity of assumptions.

CONCLUSIONS: Although the way information about time-to-event statistics is presented may differ across publications, it is often possible to pool the different types of information. This implied the inclusion of papers which otherwise couldn't be used and a reduction of the uncertainty in the cost-effectiveness outcomes.

PMC72: Development Of The Accept[®] Questionnaire To Assess Acceptability Of Long Term Treatments: Qualitative Steps

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: Patient-Reported Outcomes (PRO) are routinely used to measure disease severity, perceived treatment impact, or patient attitude toward treatment. However, adherence can only partially be explained by clinical and these PRO variables alone.

Our objective was to develop a generic Acceptability measure assessing how patients balance out between advantages and disadvantages of long-term treatments. It could be used in future adherence studies.

METHODS: A literature review was conducted in biomedical databases using keywords related to acceptability, perceptions, motivations and barriers linked to treatment, allowing the initial conceptual model of Acceptability to be developed. Exploratory interviews were performed with 5 pharmacists and 18 patients. They were recorded, transcribed word-for-word and systematically analysed in order to complete the initial conceptual model. Items of the ACCEPT[®] questionnaire were generated in French for each concept identified, using patients' words. The resulting test version was tested for relevance and comprehension with 5 patients, and revised accordingly; the new version was tested on a second set of 5 patients and revised to create the pilot version of the ACCEPT[®] questionnaire.

RESULTS: In the test version, items generated for each concept identified were organised into 6 sections: drug characteristics, duration, constraints, side-effects, efficacy and global acceptability of treatment. Except for a few items that were modified or deleted following patients' suggestions and some minor modifications in the answer choices, the questionnaire was globally very well accepted, easy to complete, and considered relevant and appropriate by patients. The pilot version of the ACCEPT[®] questionnaire contains 32 questions divided into the same 6 sections as the test version.

CONCLUSIONS: The comprehension tests confirmed the existence of the previously hypothesised concept of treatment Acceptability. The ACCEPT[®] questionnaire will allow the Acceptability of a great variety of long-term treatments to be assessed, while being a specific instrument making sense to each individual.

PMS73: Content Validity Of The Fibromyalgia Syndrome Burden Assessment (FMBA[®])

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: To test the comprehension of the FMBA[®] in France, Germany and Spain

METHODS: The FMBA[®] was tested to assess ease of comprehension, cultural equivalence, clarity, wording and acceptability of the structure and content to patients. The test version contained 79 items grouped into 7 sections measuring burden of fibromyalgia on patients' daily lives, developed simultaneously in French, German, Spanish and UK English. These sections evaluate Pain, Physical Impact, Impact on Daily Activities, Social Impact, Work Impact, Psychological Impact, Relationship to Doctors and Treatment, and One General Item.

Sixteen fibromyalgia patients were interviewed in France, Germany and Spain. UK comprehension tests are currently under way. Based on test results and deliberation with fibromyalgia experts, changes were made to the French, German, Spanish and UK English versions of the questionnaire during an international harmonisation meeting.

RESULTS: Patients' overall comprehension of the questionnaire was good. The comprehension tests identified problematic items, and suggestions for deletions or rewording. Seventeen items were deleted for reasons such as; lack of conceptual clarity eg 'I have pain that changes from one moment to the next' not clear between location and intensity; items considered conceptually too close eg 'I get tired for no reason' deleted because too close to 'I lack energy' and 'I get tired easily'; and wording too strong' eg 'I feel handicapped'. The answer choices were also modified to ensure cultural acceptance. The pilot version of the FMBA[®] contains 62 items divided into 7 sections.

CONCLUSIONS: The FMBA[®] is a questionnaire that assesses the functional impact and burden of fibromyalgia on patients' daily lives. The FMBA[®] will allow the consequences of FM on patients to be more widely recognised. A validation study is to be undertaken to validate psychometric properties and scoring of the questionnaire.

PMS74: Development Of A Tool To Help In The Early Detection Of Fibromyalgia In General Practice In Europe

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

Dias-Barbosa C¹, Guillemin I¹, Perrot S², Baron R³, Alegre C⁴, Choy E⁵, Cruccu G⁶, Desmeules J⁷, Margaux J⁸, Richards S⁹, Serra E¹⁰, Spaeth M¹¹, Arnould B¹

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OBJECTIVES: To develop a European screening tool to help primary care physicians (PCPs) identify fibromyalgia (FM) patients in general practice.

METHODS: A European multidisciplinary expert group was set up to provide clinical expertise and identify key issues around FM detection. A literature review and focus groups conducted with French (FR), German (DE) and English (UK) clinicians provided an overview of the knowledge in FM and of clinicians' awareness and experience. Psychologists then performed face-to-face exploratory interviews with FM patients (FR, DE and UK, n=29) to understand their attitudes and perceptions of the disease. Based on the findings, items were simultaneously generated in FR, UK and DE. The resulting tool was comprehension tested with FM-diagnosed or -suspected patients (n=3 and n=2 in each country, respectively), and modified based on results. Its acceptability and applicability was then assessed in real-life conditions in general practice.

RESULTS: The tool content defined using literature review, health professional and patient input had high consistency regardless of the source from which it was extracted. Factors found that may contribute to the early detection of FM included elements of FM definition, patient characteristics, personal and medical history, quality of life, attitude and personality, associated symptoms and influencing factors. The resulting pilot version of the FM screening tool includes 14 questions assessing patients' pain, fatigue, associated symptoms, impact on patients' everyday life, personal history, and attitudes towards their symptoms. Face validity and feasibility have been confirmed by PCPs and patients when administered in general practice.

CONCLUSIONS: In addition to the symptomatic picture, FM detection requires the assessment of multiple factors including patient past history and characteristics, impact of FM on patients' daily life, and situations/factors affecting patients' condition. By capturing each of these factors, the European FM screening tool will help PCPs identify potential FM patients. Quantitative validation of the tool is underway.

PIN39: Cost-Effectiveness Of Mass Varicella Vaccination In France: Economic Consequences Of An Intensive Vaccination Program

POSTER SESSION III, 27 October 2009 between 08:00 and 16:00

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OBJECTIVES: Varicella (chickenpox) affects most people and imposes an important burden on healthcare systems. It is, however, a preventable disease with childhood mass vaccination. The cost-effectiveness in France of replacing routine MMR with MMRV (Measles, Mumps, Rubella and Varicella) vaccine was explored.

METHODS: The epidemiology of varicella and consequences of implementing different vaccination programs were investigated using an age-structured dynamic model. The base case assumed one dose protects for 17 years and two doses for three times longer and no natural immunity boosting. MMRV vaccination was assumed to replace up to 80% of MMR over 5 years. An alternative scenario was analysed to assess the impact of an improved MMRV vaccination coverage (replacement of 100% of MMR over a 2-year period plus a catch up program for eight years in 5-year olds). A MMRV vaccine price of €54 per dose was assumed.

RESULTS: In the base case, varicella incidence decreased from 12,707 per million person-years before vaccination to 4,746 after 30 years of vaccination (steady state). With fewer varicella cases and associated complications, annual outpatient and hospital costs decrease by 32%. The cost per quality-adjusted life year (QALY) gained after 30 years was €3,347 (95%CI -1; 9,927)

With the scenario of improved vaccination coverage, varicella incidence decreased to 2,085 per million person-years and the cost per QALY was estimated at €3,284 (95%CI 15; 8,916) after 30 years of vaccination.

If a societal perspective is considered (including lost productivity costs), both the basecase and alternative vaccination scenario produced more QALYs and cost savings.

CONCLUSIONS: Gradual and partial replacement of MMR with MMRV vaccination is predicted to dramatically decrease varicella incidence, and, to be highly cost-effective from a payer perspective and cost-saving from a societal perspective. A more intensive MMRV coverage is predicted to further reduce varicella incidence while remaining a highly cost-effective vaccination strategy.

PMC33: Critical Review of Economic Models in Type 2 Diabetes

POSTER SESSION III, 27 October 2009 between 08.00 and 16.00

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OBJECTIVES: To identify and critically appraise cost-effectiveness models developed to evaluate type 2 diabetes (T2D) treatments and to assess which types of treatment effects they capture.

METHODS: A systematic search was performed in MEDLINE, EMBASE, Centre for Reviews and Dissemination databases at the University of York, and Health Economic Evaluation Database for the period up to September 2008. The websites of Health Technology Assessment (HTA) bodies in different countries were also screened for relevant models. For each of the identified original models, details of the structure, data in- and outputs and consistency were extracted and critically appraised using published criteria.

RESULTS: 78 articles and 41 HTAs reporting relevant economic evaluations were identified. There were ten models with multiple publications, and a further ten models with one associated publication. The critical review demonstrated that most of the existing models had the same fundamental structure, used similar microsimulation techniques and were based on the same key data sources. However, the process for identification of relevant data and their synthesis, as well as the selection of outcomes was, at times, inconsistent and lacked transparency. The models differed according to which diabetes complications and treatment-related adverse events were captured. For example, just one model incorporated changes in patient weight, despite the fact that weight gain can be a side effect of some treatments, and weight loss a potential benefit of others.

CONCLUSIONS: Whilst many economic models exist in T2D, most share common features such as the model type. Identified shortcomings are lack of transparency in data identification and evidence synthesis as well as the selection of the modelled outcomes. Future models should aim to include all relevant treatment outcomes, whether these relate to effects on underlying diabetes and its complications or to short- or long-term side effects of treatment.