FRI0604

TRENDS OF INFORMED CONSENT FORMS FOR INDUSTRY-SPONSORED CLINICAL TRIALS IN RHEUMATOLOGY OVER A 17-YEAR PERIOD: READABILITY, AND ASSESSMENT OF PATIENTS' HEALTH LITERACY AND PERCEPTIONS

A.S. Meza-Lopez¹, A. Gallardo-Castro¹, A. Villarreal-Castellanos¹, A. Barajas-Ochoa², J. Yanez³, L.P. Bustamante-Montes¹, C. Ramos-Remus¹. ¹Universidad Autonoma de Guadalajara; ²Unidad de Investigacion en Enfermedades Cronico-Degenerativas, Guadalajara; ³Campus Ciudad de Mexico, Universidad Iberoamericana, Mexico, Mexico

Background: The therapeutic arsenal in rheumatology has improved drastically during the last 20 years with the availability of biological and synthetic disease-modifying antirheumatic drugs. All these drugs required randomised controlled trials (RCTs) with thousands of rheumatic patients. All these patients went through the informed consent process and signed corresponding informed consent forms (ICFs).

Objectives: To assess trends in the length and readability of ICFs for industry-sponsored RCTs over a 17 year period. Additionally, to assess the health literacy (HL) and perceptions on ICFs among participants of current RCTs.

Methods: The grammatical readability (GR) of six pre-defined ICF sections (global, introduction, methods, risks/benefits, rights/responsibilities, and voluntary participation statement) of pivotal ICFs from industry-sponsored RCTs conducted at an outpatient rheumatology clinic during a 17 year period was assessed by using the INFLESZ instrument. Differences in GR were assessed by company, by disease and by study phase (95% CI of the mean and proportions; statistical significance assumed if no overlap), and by the years ICFs were written (1999—2005, 2006—2010, and 2011—2016; Kruskal-Wallis test). HL of patients was assessed with the SALHSA (inadequate, adequate) and S-TOFHLA (inadequate, marginal, adequate) instruments. Differences by age and schooling were determined by one-way ANOVA. Patient's perceptions and opinions on the ICF were assessed using a structured, self-reported, in-office questionnaire on an independent patient sample that had signed a pivotal ICF in the past 6 months.

Results: Thirty-nine ICFs about 22 drugs (18 biological or targeted synthetic DMARDs; 13 currently available on the market) from 13 pharmaceutical companies were analysed. The global mean readability was 57±3 (95% CI 56–58), and all ICFs were categorised as either "somewhat difficult to read" or "average". Readability remained at these levels without significant changes from 1999 to 2016. The "somewhat difficult" reading score was significantly more frequent in the "rights and responsibilities" and in the "informed consent statement" sections ($p<0.001$). The mean length of the ICFs written between 1999 and 2005 was 13±5 pages, with a significant increase thereafter (22±8 pages, $p<0.01$). Depending on the instrument, of 95 patients participating in the HL assessment, between 18% and 44% had limited HL. Of 90 patients participating in the perceptions questionnaire, 84% reported understanding the ICF well. However, 2%–57% misunderstood basic concepts, including the study drug name, randomization and placebo.

Conclusions: It seems that the considerable progress that has been made in medical research methods over time has not produced improvements in the process of informed consent in the industry-sponsored RCTs. The disparity between the readability of ICFs with patients' HL and their comprehension of ICFs continues, even after decades of attempts of regulatory agencies and numerous published suggestions.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.1565

FRI0605

THE DEVELOPMENT PROCESS OF MOBILE HEALTH APPLICATIONS FOR SELF-MANAGEMENT IN PATIENTS WITH RHEUMATIC AND MUSCULOSKELETAL DISEASES IS HETEROGENEOUS AND OFTEN INCOMPLETE: RESULTS OF A SYSTEMATIC LITERATURE REVIEW

A. Najm¹, E. Nikiforou², L. Gossec³, F. Berenbaum⁴. ¹Rheumatology department, Nantes University Hospital, Nantes, France; ²Academic Rheumatology Department, King's College London, London, UK; ³Rheumatology Department, Sorbonne Universités, UPMC University Paris; ⁴Department of Rheumatology, Inflammation-Immunopathology-Biotherapy Department, Pierre and Marie Curie University, Saint-Antoine hospital, Sorbonne University, Paris, France

Background: Mobile health (mHealth) is exponentially growing in the current era, providing new potential and transforming the face of healthcare delivery. While the increasing availability of applications (apps) may enable people with rheumatic and musculoskeletal diseases (RMDs) to better self-manage their health, there is a general lack of evidence on ways to ensure appropriate development and evaluation of apps.

Objectives: To obtain an overview of existing mHealth apps for self-management in patients with RMDs, regarding content and development methods in particular, through a systematic literature review.

Methods: A search was performed up to December 2017 using EMBASE, Pubmed, Cochrane library, Web of Science and Psychinfo databases, with relevant key words and MeSH terms addressing three key domains: RMDs, self-management and mHealth. Double screening was performed on 15% of all abstracts against agreed inclusion criteria. For each publication relevant to an app for RMDs, the content, the aims, the target population of the apps and their development strategies were noted. The analysis was descriptive.

Results: Of 562 abstracts, 57 full text were screened. 39 articles were included in the analysis. 13 articles referred to an app linked to a connected device. Most of the apps targeted rheumatoid arthritis patients ($n=11$), juvenile idiopathic arthritis ($n=7$) and osteoarthritis ($n=8$). The development process of the app was poorly described in 19/39 (48.7%) of the studies (figure 1). Only 6/39 (15.4%) included patients, and 14/39 (35.9%) included health professionals or physicians in the development of such apps. Moreover, a qualitative phase occurred in only 6/39 (15.4%) of the cases. The app was tested and evaluated by physicians in 6/39 (15.4%). Patients were more frequently involved in app evaluation (29/39, 74.4%) but mostly indirectly through their adherence to the app. Only few of the apps published on were commercially available (5/39, 12.8%), 4/5 are free. One app is currently under development.

Abstract FRI0605 – Figure 1. Description of the development process of the apps in the 39 articles.

Conclusions: The development process of most apps was poorly described and potentially not satisfying in many studies. Despite patient willingness to use mHealth apps for self-management of their RMDs, a strong effort needs to be made to provide a standard and ensure quality and safety of newly-developed apps. This work will further inform EULAR points to consider for development, evaluation and implementation of mobile health applications for self-management of RMDs by patients.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2129

FRI0606

THE LIFT STUDY'S DIRECT-TO-PATIENT DESIGN PROVIDES RELIABLE SELF-REPORTED DATA FROM LUPUS PATIENTS

A. Cheeks, L. Borisov, K. Warren, R. Terbruggen. DxTerity Diagnostics, Rancho Dominguez, USA

Background: Direct-to Patient (D2P) clinical studies that rely upon social media, mobile connectivity, wearables, self-collected patient samples, and patient reported outcome data have the potential to revolutionise health research by enabling population-scale studies without the cost and complexity of traditional multi-site trials. D2P studies are particularly interesting for longitudinal studies where the burden of participants travelling to a central site is high; however, the quality and reliability of patient reported outcome data is unclear¹.

Objectives: The study evaluated the accuracy of self-reported data from a subset of patients in a 1000+participant D2P lupus study (www.thelifstudy.com) by comparing patient-reported data to medical records as well as genomic testing of individuals using participant-collected fingerstick blood samples.

Methods: The study was reviewed and approved by a central IRB (WIRB; Puyallup, WA). Subjects were recruited online across the U.S using social media. Electronically consented participants with self-reported lupus were asked to complete online surveys about their disease and drug history as well as provide medical record review (MRR) consent. A third party firm was employed for MRR and an independent physician summarised the following information: 1) participant age 2) confirmation of lupus 3) current lupus medications and 4) current steroid medications.

Results: Of the 1043 participants enrolled over the first 6 weeks of the study, 327 had completed all aspects of the study. Thirty-seven participants (11%) were selected at random for MRR. Average age was 44±12 years with 35 females and 2 males. Self-reported (SR) age at time of enrollment was 100% confirmed by MRR. Lupus diagnosis was confirmed in 100% of the participants by the MRR directly or by conclusion of the independent physician based upon review of the medical record. SR and MRR drug information showed variable concordance upon review, with several patients reporting medications at the time of the survey that were not confirmed in their medical records (table 1). Percent agreement was determined by comparing the SR vs. the MRR for each participant (data not shown). Overall, there was an 88% agreement between SR and MRR for each of the medications where at least 1 participant reported prescription.

Abstract FRI0606 – Table 1. Common Lupus Medications and Steroids (n=36 unless otherwise noted)

Medications	SR		MR		% Agreement
	Yes	No	Yes	No	
cyclophosphamide	0	36	0	36	100%
methotrexate	4	32	2	34	94.4%
azathioprine	2	34	2	34	100%
cyclosporine	0	36	0	36	100%
belimumab	6	30	5	31	97.2%
chloroquine	0	36	0	36	100%
hydroxychloroquine (n=35)	26	10	21	14	77.1%
mycophenolate	6	30	4	32	94.4%
leflunomide	0	36	0	36	100%
steroids (n=37)	12	25	13	24	64.9%

Conclusions: Using a D2P study design, the resulting SR data corresponded well with the MRR for subject age, lupus diagnosis, and lupus medications. While there were some discrepancies in use of medications, many of these could be explained by the time-dependency of our questionnaire, where the date of prescription in the MRR was just outside of the 30 day window. The LIFT Study shows that a D2P study design is an effective method to rapidly enrol lupus patients and decrease study costs while collecting reliable self-reported data.

REFERENCE:

[1] Wallitt, et al. J Rheumatol. 2008 May;35(5):811–818.

Disclosure of Interest: A. Cheeks Employee of: DxTerity, L. Borisov Employee of: DxTerity, K. Warren Employee of: DxTerity, R. Terbrugge Shareholder of: DxTerity, Employee of: DxTerity

DOI: 10.1136/annrheumdis-2018-eular.3811

FRI0607 HOW TO DESIGN CLINICAL TRIALS TO BE MORE PATIENT ORIENTED: AN EXAMPLE FROM PREVENTATIVE TREATMENTS FOR RHEUMATOID ARTHRITIS

N. Bansback¹, M. Hudson², C. Koehn³, T.-L. Laba⁴, M. Harrison¹. ¹University of British Columbia, Vancouver; ²University of McGill, Montreal; ³Arthritis Consumer Experts, Vancouver, Canada; ⁴University of Sydney, Sydney, Australia

Background: It is widely acknowledged that many clinical trials do not always provide results that are meaningful to patients. We sought to utilise market research techniques, widely used in non-health consumer product development, to understand patient preferences that could improve the design of clinical trials. We use an example from preventative treatments in patients with preclinical asymptomatic RA where many trials are being designed or ongoing.

Objectives: To consider how to inform trial design for: i) which outcome/s should be primary? ii) what difference in the primary outcome between arms is important? iii) will patients want to use the intervention if it meets its primary endpoint/s?, and iv) does an alternative strategy exist that patients would prefer?

Methods: We developed a discrete choice experiment and surveyed first-degree relatives of patients. Focus groups of RA patients, first-degree relatives of RA patients and rheumatologists identified 5 key attributes of treatment (reduction in risk of RA, how treatment is taken, chance of side effects, certainty in estimates, health care providers opinion). DCE data was analysed using a conditional logit regression models to estimate the significance and relative importance of attributes in influencing preferences. We predicted uptake using estimates from the opt-out data analysed using a logit model.

Results: 288 first-degree relatives of people with RA started and completed all tasks in the survey. The majority of the sample were aged between 18 and 39 years (60%), and 60% female. All attributes levels significantly influenced preferences for treatments, but how treatment is taken (oral vs. infusion β 0.983, $p<0.001$) was the most influential, followed in similar magnitude by increasing risk

reduction (60 to 24 in 100) (β 0.922, $p<0.001$), matching of patient and health care professional preferences (β 0.900, $p<0.001$), and reducing risk of side effects (β 0.839, $p<0.001$). If a risk reduction of RA from 60 in 100 over 5 years to 44 in 100 is realised with only minor, reversible side-effects likely, then the uptake of hydroxychloroquine was predicted to be 86%. If all treatments currently under study in the pre-clinical phase of RA were assumed to be options for the asymptomatic phase and met hypothesised outcomes, the uptake of oral methotrexate was predicted to be 46% and hydroxychloroquine 20%. Predicted uptake of biologic drugs was 6% for abatacept and 4% for rituximab.

Conclusions: The study illustrates how market research can be used to design clinical trials that address patient centred priorities and outcomes. The results illustrate that a trial of preventative treatments for RA should: i) be powered to detect both a difference in preventing the development of RA, and the increase in minor side-effects, ii) require a significant reduction in risk of developing RA if any side-effects are possible. We calculate iii) that hydroxychloroquine would be likely to be used by pre-clinical asymptomatic patients, but biologics would likely not, iv) and that methotrexate should also be explored as an earlier option.

Acknowledgements: CIORA, BC SUPPORT Unit

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.5712

FRI0608 A SYSTEMATIC REVIEW AND CRITICAL APPRAISAL OF ECONOMIC EVALUATIONS IN SYSTEMIC LUPUS ERYTHEMATOSUS

S. P. Gavan¹, I. N. Bruce^{2,3}, K. Payne¹. ¹Manchester Centre for Health Economics, ²Arthritis Research UK Centre for Epidemiology, Centre for Musculoskeletal Research, The University of Manchester, ³NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, United Kingdom

Background: New strategies to manage systemic lupus erythematosus (SLE), including the use of biomarkers to target novel or existing therapies, will require evidence of relative cost-effectiveness before being recommended in routine clinical practice. Decision-analytic model-based economic evaluations can synthesise all available evidence to estimate the cost-effectiveness of health technologies. Complexities in the diagnosis, management, and progression of disease pose challenges when estimating the cost-effectiveness of care for SLE. No systematic appraisal of economic evaluations in SLE has been published to date.

Objectives: To identify and critically appraise all economic evaluations of treatments for SLE.

Methods: A systematic review of published economic evaluations in SLE was performed. Studies were included if they had reported a full economic evaluation of any pharmacological therapy for SLE. Medline and Embase were searched electronically from inception until November 2016. The search strategy comprised disease-specific terms for SLE and published filters to identify economic evaluations. Abstracts were screened independently by two reviewers and read in full by one reviewer. Key features (study characteristics, data sources, methods of analysis, and results) were extracted from each economic evaluation. The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement was used to appraise whether each economic evaluation had reported eighteen items with respect to its methods and results in full, partially, or not at all.

Results: The search strategy identified 2,001 abstracts and six published economic evaluations of treatments for SLE were included in the systematic review. These studies considered azathioprine (n=4), mycophenolate mofetil (n=3), cyclophosphamide (n=2), and belimumab (n=1) as relevant comparator therapies. The types of decision-analytic model included individual patient-level simulations (n=3), decision trees (n=2), and a cohort Markov model (n=1). Six elements of the CHEERS statement were reported incompletely across the sample: (1) target population, (2) choice of comparators, (3) measurement and valuation of preference-based outcomes, (4) estimation of resource use and costs, (5) choice and structure of the decision-analytic model, and (6) characterisation of heterogeneity.

Conclusions: The choice of treatments that are available currently for SLE are limited and this is reflected in the quantity of economic evaluations published to date. The incomplete reporting of methods within these economic evaluations highlighted notable gaps within the literature. Deficiencies in the evidence base manifest as parameter and structural uncertainties within decision-analytic model-based economic evaluations which, ultimately, affect the estimated expected cost-effectiveness of care. Greater use of existing datasets for SLE, including those from randomised controlled trials and observational cohort studies, can reduce these uncertainties in subsequent economic evaluations of strategies to manage SLE.

Acknowledgements: SPG is supported by two grants awarded to The University of Manchester for MASTERPLANS, funded by the Medical Research Council [grant number MR/M01665X/1] and Lupus UK.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.6460