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.

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:

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

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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 fors) 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, relatives of patients). Focus groups of RA patients, first-degree relatives of RA patients identified 5 key attributes of treatment (reduction in risk of RA, how treatment is taken, chance of side effects, certainty in estimates, 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, 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, relatives of patients).

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 [9,863, p<0.001]) was the most influential, followed in similar magnitude by increasing risk reduction (60 to 24 in 100) ([8,922, p<0.001], matching of patient and health care professional preferences ([8,900, p<0.001], and reducing risk of side effects ([8,839, p<0.001]). A risk reduction of 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 bio-logic 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.

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

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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, databases used, 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) methods of analysis, (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.

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