

Development of an evidence-based patient information leaflet providing guidance about the use of lupus medications during pregnancy and breastfeeding

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Systemic lupus erythematosus (SLE) occurs most frequently in women of childbearing age and can be managed using a variety of anti-inflammatory and anti-rheumatic drugs. These drugs have varying safety profiles during conception, pregnancy and lactation (1). It is therefore vital that SLE patients have sufficient knowledge about their safety and risks before planning for a pregnancy or breastfeeding. The aim of this study was to identify the potential demand among female SLE patients for lay information on this topic and to develop, and evaluate patient responses to, an evidence-based information leaflet providing guidance about taking SLE medications during pregnancy and breastfeeding. Between February and April 2014, 19 female SLE patients of childbearing age (18-50 years), of which 10 were pregnant, were interviewed at the Lupus in Pregnancy (LiPs) and general SLE clinics at Central Manchester Foundation Trust (CMFT). Interviews were semi-structured, based around a questionnaire and carried out during both the planning and developmental stages of the leaflet. Patients' views were obtained regarding the perceived demand for the leaflet as well as its contents, readability, and structure. 18 (95%) patients believed there was not enough lay information available about taking SLE medications during pregnancy and breastfeeding. When patients were asked to subjectively rate their own knowledge of the safety and risks of taking SLE medications before conception, during pregnancy or during breastfeeding (0=very poor, 10=very good), they received mean scores of 4.2, 3.5 and 2.2, respectively. 19 (100%) patients believed that they would find an information leaflet on this subject useful. A literature review of the safety of SLE drugs during conception, pregnancy and lactation was carried out. The following keywords were used to search for publications in the ISI Web of Science and Cochrane databases: "[name of SLE drugs]", "anti-inflammatory", "antirheumatic", "immunosuppressive", "antithrombotic", or "anticoagulant", in combination with: "fertility", "pregnancy", "teratogen", "lactation", "breastfeeding" or "milk". An A5, six-page pilot leaflet was then developed and based on patient feedback the information was divided into two sections discussing pregnancy and breastfeeding separately. A traffic light rating system was used in both sections to stratify medications based on relative risk into 'unsafe', 'use with caution' or 'safe', accompanied by justifications. This concept was fully approved by 19 (100%) patients. The Gunning fog index (2) for the text (excluding drug names) was 8.8, confirming readability by a wider audience. Of the 14 patients who reviewed a final draft of the leaflet, 14 (100%) were satisfied by its readability and structure, 13 (93%) by its contents and depth of information, and 13 (93%) believed it was superior to any lay information already available. In summary, this study suggests that female SLE patients of childbearing age do not believe they have sufficient knowledge or enough access to lay information about the safety and risks of taking SLE medications before or during pregnancy and breastfeeding, and there is a high demand for more lay information on this topic. Following significant

input from a sample of the target audience, an evidence-based pilot information leaflet was developed and the majority of patients who reviewed a final draft were satisfied by its contents, readability and structure. As a result of positive patient feedback, the leaflet was submitted for publication by CMFT and will be made readily available for SLE patients attending clinics at CMFT.

1. Ostensen M *et al.* (2006) Anti-inflammatory and immunosuppressive drugs and reproduction. *Arthritis Res Ther* **8**: 209.
2. Gunning R (1952) In: *The Technique of Clear Writing*: McGraw-Hill: New York