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Rheumatologists' perceptions of the co-incidence of tuberculosis associated with TNF-a inhibitors used for the treatment of rheumatoid arthritis in South Africa.

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APPENDIX IV

SURVEY INSTRUMENT (INTERVEIW QUESTIONS):

TB is an on-going concern, especially with the high incidence of Tuberculosis (TB) in South Africa. Most studies on RA patients exposed toTumour necrosis factor (TNF) inhibitors have been conducted in countries with a low to intermediate burden of TB (USA, Sweden, United Kingdom, Korea, Portugal, and Spain). However, in South Africa, there is a lack of local robust data to analyze the incidence of TB co-incident with TNF-inhibitors. This limits the utilization of a quantitative approach to analyze the occurrence of TB infection in RA patients treated infliximab, etanercept and adalimumab in South Africa, a TB endemic country (TNF-inhibitor). A qualitative survey researching rheumatologists' perceptions, attitudes and concerns regarding the risk of TB associated with TNF-inhibitors would be more meaningful.

This survey will focus on three areas:

- TNF-inhibitor experience
- TB experience
- Vigilance in the clinical setting.

Main Question 1: Tell us about yourself?

Promoting Questions:

a) When did you qualify as a rheumatologist?
b) Where do you practice currently, and/or previously in which province?
c) Are you actively involved in Clinical Trials (specifically where biological DMARDs is the study drug)?
d) Do you practice Privately and/ or in State?
e) Are you an academic?

Main Question 2: Tell us about your clinical experience with biological DMARDs, specifically TNF-inhibitors in practice?

Prompting Questions:

a) Are you confidentin prescribing biological DMARDs (in particular TNF-inhibitors)?
b) What percentage of your RA patients are on TNF-inhibitors?
c) What percentage of your juvenile patients are on TNF-inhibitors?
d) What percentage of your patients on TNF-inhibitor therapy has co-morbid Diabetes Mellitus?
e) What percentage of your patients on TNF-inhibitor therapy has co-morbid COPD?
f) What percentage of your patients on TNF-inhibitor therapy has co-morbid asthma?
g) Do the patients' medical aids fund the TNF-inhibitors?
h) What percentage of your patients pays for their medication out of pocket?
i) What percentage of patients have their medication sponsored?
j) What is your opinion of the safety and efficacy of different TNF-inhibitor therapies that are currently available on the market?
k) What is your opinion of biological DMARDs being made available to State Hospitals?

Main Question 3: Tell us about your experience with LTBI in patients exposed to biological DMARDs?

Prompting Questions:

a) Do you prescreen your RA patients for LTBI prior to initiating TNF-inhibitor therapy?
b) Which TB test do you prefer?
c) Do you use the 2 step PPD test method?
d) Please provide a reason for the previous question (c)?
e) What approach do you take for patients that are currently on immunosuppressants (MTX, AZA, prednisone>10mg, Leflunomide and/or Cyclosporine) with respect to TB pre-screening?
f) What approach do you take for patients that have had a BCG vaccination?
g) What percentage of your patients was diagnosed with LTBI, whilst prescreened?
h) If LTBI is detected, what TB therapy is prescribed?
i) Once TB therapy for LTBI is initiated, after what period of time is TNF-inhibitor therapy initiated?
j) Do you rescreen patients for TB, whilst on TNF-inhibitor therapy?
k) What time intervals do you use, regarding the latter question?

Main Question 4: Tell us about your experience active TB infection in patients exposed to biological DMARDs?

Prompting Questions:

a) Please explain your approach in determining how active TB is diagnosed, prior to TNF-inhibitor therapy?
b) What percentage of your patients was diagnosed with active TB during prescreening?
c) If active TB is diagnosed during prescreening, what treatment do you advocate?
d) What period of time do you prescribe, before TNF-inhibitor therapy is administered?
e) Is there a specific TNF-inhibitor molecule that you prefer in these particular cases?
f) Have any of your patients developed active TB, whilst on TNF-inhibitor therapy?
g) What has been the period of time from the initiation of TB therapy to the diagnosis of TB?
h) What is your clinical approach in the latter clinical setting (See question 5f and 5g)?
i) What percentage of your patients that developed TB, whilst on TNF-inhibitor therapy, was diagnosed with extra pulmonary TB?
j) If a patient develops TB, is TNF-inhibitor therapy stopped?
k) Is TNF-inhibitor therapy restarted?
l) If yes, when?

Main Question5: Tell us about how you practice Pharmacovigilance in the clinical setting?

Prompting Questions:

a) Are patients educated regarding the need to be vigilant about the possible Adverse Drug Reactions (ADRs) related to TNF-inhibitor therapy?
b) In what form/ approach does this education take place?
c) Is TB alerted to immediately, or on routine follow-up patient visits?
d) What percentage of your patients that developed TB, whilst on TNF-inhibitor therapy, was initially diagnosed by his/her GP, prior to referral?
e) In the latter clinical settings, did the GP diagnose TB successfully and was TB therapy initiated promptly?
f) Are ADRs (specifically TB) reported to the National Adverse Drug Event Monitoring Centre(NADEMC)?

g) Do you feel that the public and general practitioners should be educated more intensively about the ADRs related to TNF-inhibitors?
h) If yes, what approach do you think should be taken, regarding the latter question?
i) If no, please provide a reason?
j) What is your opinion regarding the current safety data that is available locally, that is applicable to the South African setting?

Is there anything else that you would like to add?