Concise Report

UK consultant rheumatologists’ access to biological agents and views on the BSR Biologics Register

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Objectives. The British Society for Rheumatology Biologics Register (BSRBR) is a prospective cohort study to determine the efficacy and toxicity of biological agents in rheumatoid arthritis (RA) patients compared with RA controls. Entry of patients to the register is a condition of use of anti-tumour necrosis factor (anti-TNF) therapy in the UK, but little is known of clinicians’ views of its usefulness. Data from the register suggest uneven provision of anti-TNF-α therapy.

Methods. A questionnaire was sent on behalf of the BSRBR to all UK consultant rheumatologists concerning provision and use of anti-TNF-α therapy and their experience of working with the BSRBR.

Results. Response rate was 49.5% representing 252 consultants. Forty-six per cent had some limitation of access to anti-TNF-α drugs, usually a financial cap (70%), even for RA patients meeting National Institute for Health and Clinical Excellence (NICE) criteria. Sixty-seven per cent could prescribe for ankylosing spondylitis (AS) or psoriatic arthritis (PsA) in some circumstances but only 25 and 35%, respectively, could prescribe according to BSR guidance. More than 50% found the workload involved in submitting data to the registry at least difficult, but most had favourable impressions of the BSRBR and thought similar registries desirable or essential for PsA, AS and rituximab.

Conclusions. Access to anti-TNF therapy for patients with inflammatory arthritis is variable in the UK, even for RA where it is NICE-approved. Access is more limited for conditions where NICE has not yet issued guidance. The BSRBR generates a significant workload for rheumatology staff but is generally well-regarded.

Key words: Rheumatoid arthritis, Anti-TNF therapy, Etanercept, Infliximab, Adalimumab, Cohort study, Survey.
tuberculosis and use of BSR guidance. Returned questionnaires were analysed using EPI INFO version 6.

Results
A total of 509 questionnaires were sent out. Of that, 136 responses were received on behalf of 252 consultants. A median of 1.9 consultants was covered per return, with a range of 1–7.

Limitations in prescribing anti-TNF-α therapy in RA
Fifty-six (42%) of the responses, representing 115 (46%) consultants, indicated that they had some form of limitation in their prescribing of anti-TNF-α agents for RA according to NICE guidance. These limitations were mainly in the form of capped funding or numbers of patients (40; 70%), staffing (12; 21%) or lack of other facilities (4; 9%). Free text responses included fixed numbers of patients to be treated per month, fixed financial caps, the presence of different limits for different Primary Care Trusts (funding bodies) and recent impositions of bans on treating any more patients until the next financial year.

Forty-eight (36%) of the responses indicated that the department had a waiting list of patients. The median waiting time for all patients was 4 weeks, with a maximum wait described of 156 weeks (interquartile range 2–12 weeks).

Additionally, 33 (25%) respondents described other restrictions in use of anti-TNF-α therapy in RA, including 14 (45%) who were not able to switch agents for patients where treatment was stopped because of toxicity and/or inefficacy, and 11 (36%) who were not able to prescribe adalimumab, which is not mentioned in the NICE guidance as it was not licensed at the time they were issued.

Prescribing of anti-TNF-α therapy for AS and PsA
Ninety (67%) of the respondents are able to prescribe anti-TNF-α therapy for AS and/or PsA in at least some circumstances, meaning that 44 (33%) have no access to these drugs for these conditions at all. Some respondents could be from Scotland where anti-TNF-α therapies for PsA [27] and AS [28] have been approved by the Scottish Medicines Consortium, but as the questionnaire was anonymous we are unable to identify them separately. Seventy-six consultants are completely unable to prescribe anti-TNF-α therapy for AS, PsA or both, despite the drugs being licensed in the UK. The ability to prescribe according to BSR guidance was limited to 61/252 (25%) consultants for AS and 76/252 (30%) consultants for PsA (Fig. 1). Again, in the free text responses some indicated that they could only prescribe where a patient who moved into the area had already received such treatment, named cases for compassionate reasons only could be treated, restrictions were increasing or that the drugs would not be available to them until NICE mandates their use.

Screening for tuberculosis
Over 99% of consultants (all except one) routinely check a chest X-ray to look for evidence of previous pulmonary tuberculosis. One hundred and twenty-five consultants (93%) take a specific history of tuberculosis infection or exposure, 60 (44%) examine for a BCG scar, 39 (29%) use a Heaf or Mantoux test and 12 (9%) use a serological immunological test.

Experience of the registry
Sixteen respondents (14%) described difficulty in submitting data to the BSRBR, most commonly through lack of time or difficulty in obtaining case notes at appropriate times. Fifty-one (39%) found the workload involved in submitting information to the BSRBR manageable, whereas 65 (49%) found it difficult, 12 (9%) found it very onerous and 3 found it impossible. Eighty-four per cent had assistance from a nurse at least partly funded by the National Health Service in completing the documentation.

Forty-four (38%) of the respondents had requested information from the registry. Twenty-five made free text comments representing a strongly positive experience, particularly referring to speed and helpfulness of the response, 5 had found the response fair or satisfactory and 5 reported a poor or unhelpful response, largely a lack of reply. Forty-two respondents had attended the BSRBR Open Meeting at the 2005 BSR Annual Meeting, where data from the BSRBR were presented, of whom 41 had found it useful or partly useful. One hundred and sixteen (87%) had received the annual report of their own data from BSRBR and 41 (35%) had requested a combined report for their department. Usefulness was rated at a median of 7/10 (interquartile range 5–8). The report had been used for internal audit purposes, appraisal, comparing oneself with others and in applications for funding. One unit discovered that patients had not been registered by the nurse as had been thought.

For the future, the majority of respondents felt that similar registries for AS, PsA and rituximab would be desirable (53, 56 and 36%) or essential (41, 38 and 60%, respectively) to answer questions about toxicity, particularly rare side effects, withdrawal rates and efficacy of these therapies.

Use of BSR guidelines concerning anti-TNF-α therapy
Levels of awareness and use of BSR guidance about the use of anti-TNF-α therapy in RA, AS and PsA were high. Only 1% were unaware of the guidance concerning RA (13% for AS and 16% for PsA), and the guidelines were used in routine practice by the majority (99% for RA, 73% AS and 71% PsA).

Conclusions
This survey describes UK consultant rheumatologists’ use of and access to anti-TNF-α therapy and their experience of and views about the BSRBR. The most striking findings are of the restrictions in access to anti-TNF-α agents, even in areas where their use has been mandated, such as for RA in England and Wales according to NICE guidance [14]. Over 40% of consultants are limited in their ability to prescribe anti-TNF-α for patients with RA who meet NICE criteria for treatment (although a minority of these consultants may practise in regions not covered by NICE). This limitation is most commonly in the form of...
a financial or numerical cap implemented by funding organizations, which is in direct contravention of government policy [29]. Long waiting times for patients to receive these drugs once a decision to prescribe has been made are not uncommon, which will add further to their deterioration and compromise their likely outcome. For indications for these therapies that have not yet received a decision from NICE; access to treatment is also limited. Only 67% of consultants have any access to anti-TNF-α therapy for their patients with PsA or AS, whilst ability to prescribe according to BSR guidance is limited to 25% for AS and 30% for PsA. Consultants are aware of and use the BSR guidance for use of anti-TNF therapy in these conditions [14, 19, 20], and there is evidence elsewhere that their use has increased the uniformity of assessment of patients’ suitability for treatment, amongst consultants [15]. The fact that different funding organizations set different restrictions has led to variation of access for equally affected patients to effective treatment, depending on where they live. As the survey was anonymous the disparity in provision cannot be mapped from our data.

The guidelines from the British Thoracic Society concerning assessment of risk of tuberculosis infection in patients being considered for anti-TNF-α therapy [21] are generally followed. Whilst use of a chest X-ray is almost universal, a small number of consultants indicated that they do not specifically take a history of previous tuberculosis infection or exposure, and the role of the tuberculin skin test remains difficult to define [22]. Consultant contributors generally view the BSRBR positively, although most regard the workload as difficult, and similar registries for other conditions and new drugs are viewed as important. Most have had little difficulty in submitting data, have met with a good response from the Register when making enquiries and have found the individual consultant annual report to be useful.

The BSRBR has the primary purpose of describing toxicity and efficacy of anti-TNF agents in their real-world use in RA, but this work has shown that it also has a role in monitoring provision of these agents and in clinical governance for rheumatologists.

### Key messages

- **UK use of anti-TNF therapy for rheumatoid arthritis is restricted by financial limits even though approved by NICE.**
- Access to anti-TNF therapy is restricted for psoriatic arthritis and ankylosing spondylitis.
- The BSR Biologics Register generates a difficult workload for members but is valued.

### References


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The authors are both practicing rheumatologists and members of the BSR and the BSRBR Management Committee. L.J.K. has received honoraria for speaking at meetings and workshops by Wyeth and Abbott.

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