



Measuring adherence of NHS boards to SMC advice for 'unique' treatments



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Scottish Medicines Consortium Evaluation Programme

Measuring adherence of NHS boards to SMC advice for 'unique' treatments

Full Report

Prepared by the SMC Evaluation Project Team

This work was undertaken by the National Medicines Utilisation Unit, Information Services Division, NHS National Services Scotland in collaboration with the Scottish Medicines Consortium

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Executive summary

Introduction

The Scottish Executive Health Department Letter (HDL) (2003) 60 advised that the Scottish Medicines Consortium (SMC) would designate certain medicines as 'unique'. Unique medicines, if approved by the SMC, would be introduced into NHSScotland according to an agreed national programme, normally within 3 months of the SMC advice being published.

Etanercept for psoriatic arthritis was classified by the SMC as 'unique' in June 2004. The SMC advice is summarised as follows:

Advice: following a full submission.

Etanercept (Enbrel[®]) is accepted for use within NHSScotland for the treatment of active and progressive psoriatic arthritis in adults. It is the first drug to be licensed for this indication and not only improves symptoms of arthritis and psoriasis, but may slow the progression of joint damage (at least over a period of one year).

Subsequently, the SMC established a group of specialists from within NHSScotland to develop a protocol for the use of etanercept. The SMC etanercept protocol included reference to the guideline produced by the British Society for Rheumatology (BSR).¹

This report provides a detailed case study of adherence of NHS boards in Scotland to the SMC etanercept protocol at August 2006, and examines the issues arising in measuring utilisation of etanercept in psoriatic arthritis. It forms part of a wider evaluation programme of SMC advice provided for the period of January 2002 to December 2005.

Method of study

The focus of this study was lead clinicians for rheumatology in each NHS board in Scotland, hospital pharmacy departments and the manufacturer of etanercept (Wyeth Pharmaceuticals). The review covered 15 NHS boards that existed during the time frame of the wider evaluation programme, prior to the integration of Argyll and Clyde NHS Board into Greater Glasgow and Highland NHS boards.

The study involved two separate strands of work.

- a) Questionnaire to survey implementation of the SMC etanercept protocol which included:
 - Engagement with clinicians and nurses to prepare and pilot questionnaire.
 - Postal survey in August 2006 to lead rheumatologists, liaising with lead dermatologists as appropriate.
 - Preparation of audit report.

¹ Kyle S, Chandler D, Griffiths CEM, Helliwell P, Lewis J, McInnes I, Oliver S, Symmons D and McHugh N on behalf of the British Society for Rheumatology Standards Guidelines Audit Working Group (SGAWG). Guideline for anti-TNF- α therapy in psoriatic arthritis. *Rheumatology* 2005; 44(3): 390-397.

b) Assessment of utilisation of etanercept in the period from January 2003 to December 2005, which included:

- Contacting the hospital pharmacy departments, lead clinicians and the manufacturer to quantify utilisation data (total quantity prescribed, number of patients treated and total spend).
- Analysing and interpreting the data provided.

Key findings

a) SMC etanercept protocol

Table 1 (page 7) outlines the findings from the questionnaire on adherence of NHS boards to criteria in the SMC etanercept protocol at August 2006. In summary:

Patient criteria

The majority (93%) of NHS boards met the criteria that etanercept should be aimed at seriously afflicted patients whose disease remains troublesome after treatment with at least two standard disease modifying anti-rheumatic drugs (DMARDs). In addition, all NHS boards met clinical exclusion criteria.

Local organisational structure

The majority (87%) of NHS boards had identified a named lead rheumatologist, in line with the SMC etanercept protocol, but few had identified a named lead dermatologist. The project team found it difficult to identify lead clinicians, as a central register had not been established.

All NHS boards provided clear and useful information for patients and had local arrangements in place regarding pharmacy supply. However, few NHS Boards (40%) established multidisciplinary implementation groups.

Stopping rules

All NHS boards assessed the clinical benefit of treatment after three months.

Clinical monitoring & audit

Despite SMC advice, a single Scottish centre has not been established to collate data on the clinical effectiveness of etanercept for psoriatic arthritis. The BSR guideline recommends specific data (19 separate items) that should be reported in a register. Only one NHS board recorded all 19 items, a further 10 NHS boards recorded 17 or 18 items, and one NHS board did not collect data locally.

The majority (87%) of NHS boards collected information on utilisation and effectiveness locally, but the information collected was not consistent across the NHS boards.

Safety monitoring

Some NHS boards (47%) enrolled patients in the British Society for Rheumatology Biologics Register (BSRBR)², which was established in response to a recommendation from the National Institute for Health and Clinical Excellence. The purpose of the register is to investigate the toxicity and efficacy of anti-tumour necrosis factor therapy compared to controlled cohorts, in patients with severe rheumatoid arthritis (RA). Although not within the core protocol for the register, approximately 600 patients with psoriatic arthritis across the UK were registered to May 2006, and will be followed up for 5 years. From 3 May 2006, new patients with psoriatic arthritis were no longer accepted on to this register.

b) Utilisation of etanercept

The evaluation team undertook to establish consistency of data, within individual NHS boards (where data were from different sources) and across NHS boards to support definition of a national picture.

In retrieving and analysing the data from the three sources chosen for the study, different and significant issues were identified with each source:

- Hospital pharmacy departments – differing models of service delivery exist across Scotland, ie secondary (hospital) care based service or homecare company services. This inhibited the ability to collect comprehensive volume and cost data on etanercept from the hospital pharmacy stock control systems. This dataset is also not patient specific and hence cannot differentiate between etanercept use for psoriatic arthritis and other clinical indications. Data provided were therefore not consistent across NHSScotland to enable appropriate interpretation.
- Lead clinicians – patient numbers were provided by NHS boards. These data did not differentiate between new starts and stops, and treatment durations were often unclear, inhibiting interpretation and comparison with other data sources.
- Manufacturer – data on patient numbers by NHS board were provided for the period July 2005 to July 2006 only. Data were compiled from sales teams interacting with specialist clinical teams in the hospitals. These data did not differentiate between new starts and stops, inhibiting accurate identification of patient numbers undergoing treatment.

In conclusion, at this point in time, there is not a clean and relevant dataset to perform a quantitative assessment of the utilisation of etanercept for psoriatic arthritis in NHSScotland.

² British Society for Rheumatology Biologics Register website. www.medicine.manchester.ac.uk/arc/BSRBR/

Good practice example

Elements of good practice were evident in several NHS boards. Of these, NHS Fife was of particular note and exhibited the following key characteristics:

- Full adherence to the BSR guideline and collection of all data recommended within this.
- Existence of a local multidisciplinary implementation group.
- Provision of written information to patients.
- Provision of information on utilisation and effectiveness to the NHS board and local clinicians, and feedback at half-day seminars, via newsletters, and to other healthcare professionals.
- Assessment of clinical benefit after 3 months of treatment, and blood monitoring.

Table 1: SMC etanercept protocol – Adherence of NHS boards in Scotland at August 2006

	Criteria	Number (%) of NHS boards meeting criterion	Percentage of Scottish population covered by net criterion	Comments
Patient Criteria	Previous failure with at least two standard disease modifying anti-rheumatic drugs (DMARDs).	14 (93%)	93%	
	Local protocols consistent with national guidance, or followed BSR guideline.	14 (93%)	93%	10 had a local protocol. Remaining 5 followed BSR guideline.
	Adherence to BSR published exclusion criteria.	15 (100%)	100%	
Local Organisational Structure	Knowledge of previous phototherapy treatment from phototherapy units obtained before etanercept commenced.	6 (40%)	32%	3 stated this hadn't been necessary while 3 received information from a different source.
	Local multidisciplinary implementation group established.	6 (40%)	51%	
	Named lead rheumatologist and a named lead dermatologist.	3 (20%)	25%	13 (87%) have a named lead rheumatologist although only 3 have both. There was no central register of these named lead clinicians.
	Clear and useful information available for patients embarking on treatment.	15 (100%)	100%	
	Local arrangements should apply regarding pharmacy supply issues.	15 (100%)	100%	13 (87%) used one specific homecare company.
Stopping Rules	Clinical benefit should be assessed after three months of treatment.	15 (100%)	100%	
	Single Scottish centre to collect data on clinical effectiveness.	0 (0%)	0%	A single Scottish centre has not been established.
Safety Monitoring & Audit	Information on utilisation and/or effectiveness available.	13 (87%)	90%	
	Adverse effects reported on Yellow Cards to CSM Scotland.	12 (80%)	89%	1 reported adverse effects to BSRBR.
Safety Monitoring	Patients enrolled in a central register of patients treated for this condition with this drug.	7 (47%)	44%	6 stated that it was either no longer possible or required to register patients with the BSRBR.

BSR – British Society for Rheumatology
BSRBR – British Society for Rheumatology Biologics Register
CSM Scotland – Now known as Yellow Card Centre (YCC) Scotland

Conclusions

The SMC etanercept protocol survey provides evidence that where patients are receiving etanercept for psoriatic arthritis, NHS boards follow a protocol for initiation, supply and monitoring of treatment.

Examination of medicines utilisation data from three separate sources was unable to provide a clean and relevant dataset on which to quantify the number of patients initiating treatment for etanercept for psoriatic arthritis in NHSScotland.

